108TH CONGRESS } HOUSE OF REPRESENTATIVES { REPT. 108–178
1st Session } { Part 2

MEDICARE PRESCRIPTION DRUG AND MODERNIZATION ACT OF 2003

JULY 15, 2003.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. THOMAS, from the Committee on Ways and Means, submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 2473]

The Committee on Ways and Means, to whom was referred the bill (H.R. 2473) to amend title XVIII of the Social Security Act to provide for a voluntary program for prescription drug coverage under the Medicare Program, to modernize the Medicare Program, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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19–006

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SECURITY ACT; REFERENCES TO BIPA AND SECRETARY; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Medicare Prescription Drug and Modernization Act of 2003".

(b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as otherwise specifically provided, whenever in this Act an amendment is expressed in terms of an amendment to or repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Social Security Act.

(c) BIPA; SECRETARY.—In this Act:

(1) BIPA.—The term "BIPA" means the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, as enacted into law by section 1(a)(6) of Public Law 106–554.

(2) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(d) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

SEC. 101. ESTABLISHMENT OF A MEDICARE PRESCRIPTION DRUG BENEFIT.

(a) IN GENERAL.—Title XVIII is amended—

(1) by redesignating part D as part F; and

(2) by inserting after part C the following new part:

"PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

"SEC. 1860D–1. BENEFITS; ELIGIBILITY; ENROLLMENT; AND COVERAGE PERIOD.

"(a) PROVISION OF QUALIFIED PRESCRIPTION DRUG COVERAGE THROUGH ENROLLMENT IN PLANS.—Subject to the succeeding provisions of this part, each individual who is entitled to benefits under part A or is enrolled under part B is entitled to obtain qualified prescription drug coverage (described in section 1860D–2(a)) as follows:

"(1) MEDICARE-RELATED PLANS.—

"(A) MEDICARE ADVANTAGE.—If the individual is eligible to enroll in a Medicare Advantage plan that provides qualified prescription drug coverage under section 1851(j), the individual may enroll in such plan and obtain coverage through such plan.

"(B) EFFS PLANS.—If the individual is eligible to enroll in an EFFS plan that provides qualified prescription drug coverage under part E under section 1860E–2(d), the individual may enroll in such plan and obtain coverage through such plan.

"(C) MA-EFFS PLAN; MA-EFFS RX PLAN.—For purposes of this part, the term 'MA-EFFS plan' means a Medicare Advantage plan under part C and an EFFS plan under part E and the term 'MA-EFFS Rx plan' means a MA-EFFS plan insofar as such plan provides qualified prescription drug coverage.

"(2) PRESCRIPTION DRUG PLAN.—If the individual is not enrolled in a MA-EFFS plan , the individual may enroll under this part in a prescription drug plan (as defined in section 1860D–10(a)(5)).

Such individuals shall have a choice of such plans under section 1860D–5(d).

"(b) GENERAL ELECTION PROCEDURES.—

"(1) IN GENERAL.—An individual eligible to make an election under subsection (a) may elect to enroll in a prescription drug plan under this part, or elect the option of qualified prescription drug coverage under a MA-EFFS Rx plan under part C or part E, and to change such election only in such manner and form as may be prescribed by regulations of the Administrator of the Medicare Benefits Administration (appointed under section 1809(b)) (in this part referred to as the 'Medicare Benefits Administrator') and only during an election period prescribed in or under this subsection.

"(2) ELECTION PERIODS.—

"(A) IN GENERAL.—Except as provided in this paragraph, the election periods under this subsection shall be the same as the coverage election periods under the Medicare Advantage and EFFS programs under section 1851(e), including—

"(i) annual coordinated election periods; and

"(ii) special election periods.

In applying the last sentence of section 1851(e)(4) (relating to discontinuance of an election during the first year of eligibility) under this subparagraph, in the case of an election described in such section in which the individual had elected or is provided qualified prescription drug coverage at the time of such first enrollment, the individual shall be permitted to enroll in a prescription drug plan under this part at the time of the election of coverage under the original fee-for-service plan.

"(B) INITIAL ELECTION PERIODS.—

"(i) INDIVIDUALS CURRENTLY COVERED.—In the case of an individual who is entitled to benefits under part A or enrolled under part B as of October 1, 2005, there shall be an initial election period of 6 months beginning on that date.

"(ii) INDIVIDUAL COVERED IN FUTURE.—In the case of an individual who is first entitled to benefits under part A or enrolled under part B after such date, there shall be an initial election period which is the same as the initial enrollment period under section 1837(d).

"(C) ADDITIONAL SPECIAL ELECTION PERIODS.—The Administrator shall establish special election periods—

"(i) in cases of individuals who have and involuntarily lose prescription drug coverage described in subsection (c)(2)(C);

"(ii) in cases described in section 1837(h) (relating to errors in enrollment), in the same manner as such section applies to part B;

"(iii) in the case of an individual who meets such exceptional conditions (including conditions provided under section 1851(e)(4)(D)) as the Administrator may provide; and

"(iv) in cases of individuals (as determined by the Administrator) who become eligible for prescription drug assistance under title XIX under section 1935(d).

"(3) INFORMATION ON PLANS.—Information described in section 1860D–3(b)(1) on prescription drug plans shall be made available during election periods.

"(c) GUARANTEED ISSUE; COMMUNITY RATING; AND NONDISCRIMINATION.—

"(1) GUARANTEED ISSUE.—

"(A) IN GENERAL.—An eligible individual who is eligible to elect qualified prescription drug coverage under a prescription drug plan or MA-EFFS Rx plan at a time during which elections are accepted under this part with respect to the plan shall not be denied enrollment based on any health status-related factor (described in section 2702(a)(1) of the Public Health Service Act) or any other factor.

"(B) MEDICARE ADVANTAGE LIMITATIONS PERMITTED.—The provisions of paragraphs (2) and (3) (other than subparagraph (C)(i), relating to default enrollment) of section 1851(g) (relating to priority and limitation on termination of election) shall apply to PDP sponsors under this subsection.

"(2) COMMUNITY-RATED PREMIUM.—

"(A) IN GENERAL.—In the case of an individual who enrolls under a prescription drug plan or in a MA-EFFS Rx plan during the individual's initial enrollment period under this part or maintains (as determined under subparagraph (C)) continuous prescription drug coverage since the date the individual first qualifies to elect prescription drug coverage under this part, a PDP sponsor or entity offering a prescription drug plan or MA-EFFS Rx plan and in which the individual is enrolled may not deny, limit, or condition the coverage or provision of covered prescription drug benefits or vary or increase the premium under the plan based on any health status-related factor described in section 2702(a)(1) of the Public Health Service Act or any other factor.

"(B) LATE ENROLLMENT PENALTY.—In the case of an individual who does not maintain such continuous prescription drug coverage (as described in subparagraph (C)), a PDP sponsor or an entity offering a MA-EFFS Rx plan may (notwithstanding any provision in this title) adjust the premium otherwise applicable or impose a pre-existing condition exclusion with respect to qualified prescription drug coverage in a manner that reflects additional actuarial risk involved. Such a risk shall be established through an appropriate actuarial opinion of the type described in subparagraphs (A) through (C) of section 2103(c)(4).

"(C) CONTINUOUS PRESCRIPTION DRUG COVERAGE.—An individual is considered for purposes of this part to be maintaining continuous prescription drug coverage on and after the date the individual first qualifies to elect prescription drug coverage under this part if the individual establishes that as of such date the individual is covered under any of the following prescription drug coverage and before the date that is the last day of the 63-day period that begins on the date of termination of the particular prescription drug coverage involved (regardless of whether the individual subsequently obtains any of the following prescription drug coverage):

"(i) COVERAGE UNDER PRESCRIPTION DRUG PLAN OR MA-EFFS RX PLAN.—Qualified prescription drug coverage under a prescription drug plan or under a MA-EFFS Rx plan.

"(ii) MEDICAID PRESCRIPTION DRUG COVERAGE.—Prescription drug coverage under a medicaid plan under title XIX, including through the Program of All-inclusive Care for the Elderly (PACE) under section 1934, through a social health maintenance organization (referred to in section 4104(c) of the Balanced Budget Act of 1997), or through a demonstration project under part C that demonstrates the application of capitation payment rates for frail elderly medicare beneficiaries through the use of an interdisciplinary team and through the provision of primary care services to such beneficiaries by means of such a team at the nursing facility involved.

"(iii) PRESCRIPTION DRUG COVERAGE UNDER GROUP HEALTH PLAN.—Any outpatient prescription drug coverage under a group health plan, including a health benefits plan under the Federal Employees Health Benefit Plan under chapter 89 of title 5, United States Code, and a qualified retiree prescription drug plan as defined in section 1860D–8(f)(1), but only if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

"(iv) PRESCRIPTION DRUG COVERAGE UNDER CERTAIN MEDIGAP POLICIES.—Coverage under a medicare supplemental policy under section 1882 that provides benefits for prescription drugs (whether or not such coverage conforms to the standards for packages of benefits under section 1882(p)(1)), but only if the policy was in effect on January 1, 2006, and if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

"(v) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—Coverage of prescription drugs under a State pharmaceutical assistance program, but only if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

"(vi) VETERANS' COVERAGE OF PRESCRIPTION DRUGS.—Coverage of prescription drugs for veterans under chapter 17 of title 38, United States Code, but only if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

"(D) CERTIFICATION.—For purposes of carrying out this paragraph, the certifications of the type described in sections 2701(e) of the Public Health Service Act and in section 9801(e) of the Internal Revenue Code shall also include a statement for the period of coverage of whether the individual involved had prescription drug coverage described in subparagraph (C).

"(E) DISCLOSURE.—

"(i) IN GENERAL.—Each entity that offers coverage of the type described in clause (iii), (iv), (v), or (vi) of subparagraph (C) shall provide for disclosure, consistent with standards established by the Administrator, of whether such coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

"(ii) WAIVER OF LIMITATIONS.—An individual may apply to the Administrator to waive the requirement that coverage of such type provide benefits at least equivalent to the benefits under a qualified prescription drug plan, if the individual establishes that the individual was not adequately informed that such coverage did not provide such level of benefits.

"(F) CONSTRUCTION.—Nothing in this section shall be construed as preventing the disenrollment of an individual from a prescription drug plan or a MA-EFFS Rx plan based on the termination of an election described in section 1851(g)(3), including for non-payment of premiums or for other reasons specified in subsection (d)(3), which takes into account a grace period described in section 1851(g)(3)(B)(i).

"(3) NONDISCRIMINATION.—A PDP sponsor that offers a prescription drug plan in an area designated under section 1860D–4(b)(5) shall make such plan available to all eligible individuals residing in the area without regard to their health or economic status or their place of residence within the area.

"(d) EFFECTIVE DATE OF ELECTIONS.—

"(1) IN GENERAL.—Except as provided in this section, the Administrator shall provide that elections under subsection (b) take effect at the same time as the Administrator provides that similar elections under section 1851(e) take effect under section 1851(f).

"(2) NO ELECTION EFFECTIVE BEFORE 2006.—In no case shall any election take effect before January 1, 2006.

"(3) TERMINATION.—The Administrator shall provide for the termination of an election in the case of—

"(A) termination of coverage under both part A and part B; and

"(B) termination of elections described in section 1851(g)(3) (including failure to pay required premiums).

"SEC. 1860D–2. REQUIREMENTS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.

"(a) REQUIREMENTS.—

"(1) IN GENERAL.—For purposes of this part and part C and part E, the term 'qualified prescription drug coverage' means either of the following:

"(A) STANDARD COVERAGE WITH ACCESS TO NEGOTIATED PRICES.—Standard coverage (as defined in subsection (b)) and access to negotiated prices under subsection (d).

"(B) ACTUARIALLY EQUIVALENT COVERAGE WITH ACCESS TO NEGOTIATED PRICES.—Coverage of covered outpatient drugs which meets the alternative coverage requirements of subsection (c) and access to negotiated prices

under subsection (d), but only if it is approved by the Administrator, as provided under subsection (c).

"(2) PERMITTING ADDITIONAL OUTPATIENT PRESCRIPTION DRUG COVERAGE.—

"(A) IN GENERAL.—Subject to subparagraph (B), nothing in this part shall be construed as preventing qualified prescription drug coverage from including coverage of covered outpatient drugs that exceeds the coverage required under paragraph (1), but any such additional coverage shall be limited to coverage of covered outpatient drugs.

"(B) DISAPPROVAL AUTHORITY.—The Administrator shall review the offering of qualified prescription drug coverage under this part or part C or E. If the Administrator finds, in the case of a qualified prescription drug coverage under a prescription drug plan or a MA-EFFS Rx plan, that the organization or sponsor offering the coverage is engaged in activities intended to discourage enrollment of classes of eligible medicare beneficiaries obtaining coverage through the plan on the basis of their higher likelihood of utilizing prescription drug coverage, the Administrator may terminate the contract with the sponsor or organization under this part or part C or E.

"(3) APPLICATION OF SECONDARY PAYOR PROVISIONS.—The provisions of section 1852(a)(4) shall apply under this part in the same manner as they apply under part C.

"(b) STANDARD COVERAGE.—For purposes of this part, the 'standard coverage' is coverage of covered outpatient drugs (as defined in subsection (f)) that meets the following requirements:

"(1) DEDUCTIBLE.—The coverage has an annual deductible—

"(A) for 2006, that is equal to $250; or

"(B) for a subsequent year, that is equal to the amount specified under this paragraph for the previous year increased by the percentage specified in paragraph (5) for the year involved.

Any amount determined under subparagraph (B) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

"(2) 80:20 BENEFIT STRUCTURE.—

"(A) 20 PERCENT COINSURANCE.—The coverage has cost-sharing (for costs above the annual deductible specified in paragraph (1) and up to the initial coverage limit under paragraph (3)) that is—

"(i) equal to 20 percent; or

"(ii) is actuarially equivalent (using processes established under subsection (e)) to an average expected payment of 20 percent of such costs.

"(B) USE OF TIERS.—Nothing in this part shall be construed as preventing a PDP sponsor from applying tiered copayments, so long as such tiered copayments are consistent with subparagraph (A).

"(3) INITIAL COVERAGE LIMIT.—Subject to paragraph (4), the coverage has an initial coverage limit on the maximum costs that may be recognized for payment purposes—

"(A) for 2006, that is equal to $2,000; or

"(B) for a subsequent year, that is equal to the amount specified in this paragraph for the previous year, increased by the annual percentage increase described in paragraph (5) for the year involved.

Any amount determined under subparagraph (B) that is not a multiple of $25 shall be rounded to the nearest multiple of $25.

"(4) CATASTROPHIC PROTECTION.—

"(A) IN GENERAL.—Notwithstanding paragraph (3), the coverage provides benefits with no cost-sharing after the individual has incurred costs (as described in subparagraph (C)) for covered outpatient drugs in a year equal to the annual out-of-pocket threshold specified in subparagraph (B).

"(B) ANNUAL OUT-OF-POCKET THRESHOLD.—

"(i) IN GENERAL.—For purposes of this part, the 'annual out-of-pocket threshold' specified in this subparagraph is equal to $3,500 (subject to adjustment under clause (ii) and subparagraph (D)).

"(ii) INFLATION INCREASE.—For a year after 2006, the dollar amount specified in clause (i) shall be increased by the annual percentage increase described in paragraph (5) for the year involved. Any amount determined under the previous sentence that is not a multiple of $100 shall be rounded to the nearest multiple of $100.

"(C) APPLICATION.—In applying subparagraph (A)—

"(i) incurred costs shall only include costs incurred for the annual deductible (described in paragraph (1)), cost-sharing (described in paragraph (2)), and amounts for which benefits are not provided because of the application of the initial coverage limit described in paragraph (3); and

"(ii) such costs shall be treated as incurred only if they are paid by the individual (or by another individual, such as a family member, on behalf of the individual), under section 1860D–7, under title XIX, or under a State pharmaceutical assistance program and the individual (or other individual) is not reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement (other than under such title or such program) for such costs.

"(D) ADJUSTMENT OF ANNUAL OUT-OF-POCKET THRESHOLDS.—

"(i) IN GENERAL.—For each enrollee in a prescription drug plan or in a MA-EFFS Rx plan whose adjusted gross income exceeds the income threshold as defined in clause (ii) for a year, the annual out-of-pocket threshold otherwise determined under subparagraph (B) for such year shall be increased by an amount equal to the percentage specified in clause (iii), multiplied by the lesser of—

"(I) the amount of such excess; or

"(II) the amount by which the income threshold limit exceeds the income threshold.

Any amount determined under the previous sentence that is not a multiple of $100 shall be rounded to the nearest multiple of $100.

"(ii) INCOME THRESHOLD.—For purposes of clause (i)—

"(I) IN GENERAL.—Subject to subclause (II), the term 'income threshold' means $60,000 and the term 'income threshold limit' means $200,000.

"(II) INCOME INFLATION ADJUSTMENT.—In the case of a year beginning after 2006, each of the dollar amounts in subclause (I) shall be increased by an amount equal to such dollar amount multiplied by the cost-of-living adjustment determined under section 1(f)(3) of the Internal Revenue Code of 1986 for such year, determined by substituting 'calendar year 2005' for 'calendar year 1992'. If any amount increased under the previous sentence is not a multiple of $100, such amount shall be rounded to the nearest multiple of $100.

"(iii) PERCENTAGE.—The percentage specified in this clause for a year is a fraction (expressed as a percentage) equal to—

"(I) the annual out-of-pocket threshold for a year under subparagraph (B) (determined without regard to this subparagraph), divided by

"(II) the income threshold under clause (ii) for that year.

If any percentage determined under the previous sentence that is not a multiple of 1/10th of 1 percentage point, such percentage shall be rounded to the nearest multiple of 1/10th of 1 percentage point.

"(iv) USE OF MOST RECENT RETURN INFORMATION.—For purposes of clause (i) for an enrollee for a year, except as provided in clause (v), the adjusted gross income of an individual shall be based on the most recent information disclosed to the Secretary under section 6109(l)(19) of the Internal Revenue Code of 1986 before the beginning of that year.

"(v) INDIVIDUAL ELECTION TO PRESENT MOST RECENT INFORMATION REGARDING INCOME.—The Secretary shall provide, in coordination with the Secretary of the Treasury, a procedure under which, for purposes of applying this subparagraph for a calendar year, instead of using the information described in clause (iv), an enrollee may elect to use more recent information, including information with respect to a taxable year ending in such calendar year. Such process shall—

"(I) require the enrollee to provide the Secretary with a copy of the relevant portion of the more recent return to be used under this clause;

"(II) provide for the Medicare Beneficiary Ombudsman (under section 1810) offering assistance to such enrollees in presenting such information and the toll-free number under such section being a point of contact for beneficiaries to inquire as to how to present such information;

"(III) provide for the verification of the information in such return by the Secretary of the Treasury under section 6103(l)(19) of the Internal Revenue Code of 1986; and

"(IV) provide for the payment by the Secretary (in a manner specified by the Secretary) to the enrollee of an amount equal to the excess of the benefit payments that would have been payable under the plan if the more recent return information were used, over the benefit payments that were made under the plan.

In the case of a payment under subclause (III) for an enrollee under a prescription drug plan, the PDP sponsor of the plan shall pay to the Secretary the amount so paid, less the applicable reinsurance amount that would have applied under section 1860D–8(c)(1)(B) if such payment had been treated as an allowable cost under such section. Such plan payment shall be deposited in the Treasury to the credit of the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund (under section 1841).

"(vi) DISSEMINATION OF INFORMATION ON PROCESS.—The Secretary shall provide, through the annual medicare handbook under section 1804(a), for a general description of the adjustment of annual out-of-pocket thresholds provided under this subparagraph, including the process for adjustment based upon more recent information and the confidentiality provisions of subparagraph (F), and shall provide for dissemination of a table for each year that sets forth the amount of the adjustment that is made under clause (i) based on the amount of an enrollee's adjusted gross income.

"(E) REQUESTING INFORMATION ON ENROLLEES.—

"(i) IN GENERAL.—The Secretary shall, periodically as required to carry out subparagraph (D), transmit to the Secretary of the Treasury a list of the names and TINs of enrollees in prescription drug plans (or in MA-EFFS Rx plans) and request that such Secretary disclose to the Secretary information under subparagraph (A) of section 6103(l)(19) of the Internal Revenue Code of 1986 with respect to those enrollees for a specified taxable year for application in a particular calendar year.

"(ii) DISCLOSURE TO PLAN SPONSORS.—In the case of a specified taxpayer (as defined in section 6103(l)(19)(B) of the Internal Revenue Code of 1986) who is enrolled in a prescription drug plan or in an MA-EFFS Rx plan, the Secretary shall disclose to the entity that offers the plan the annual out-of-pocket threshold applicable to such individual under subparagraph (D).

"(F) MAINTAINING CONFIDENTIALITY OF INFORMATION.—

"(i) IN GENERAL.—The amount of any increase in an annual out-of-pocket threshold under subparagraph (D) may not be disclosed by the Secretary except to a PDP sponsor or entity that offers a MA-EFFS Rx plan to the extent necessary to carry out this part.

"(ii) CRIMINAL AND CIVIL PENALTIES FOR UNAUTHORIZED DISCLOSURE.—A person who makes an unauthorized disclosure of information disclosed under section 6103(l)(19) of the Internal Revenue Code of 1986 (including disclosure of any increase in an annual out-of-pocket threshold under subparagraph (D)) shall be subject to penalty to the extent provided under—

"(I) section 7213 of such Code (relating to criminal penalty for unauthorized disclosure of information);

"(II) section 7213A of such Code (relating to criminal penalty for unauthorized inspection of returns or return information);

"(III) section 7431 of such Code (relating to civil damages for unauthorized inspection or disclosure of returns and return information);

"(IV) any other provision of the Internal Revenue Code of 1986; or

"(V) any other provision of law.

"(iii) APPLICATION OF ADDITIONAL CIVIL MONETARY PENALTY FOR UNAUTHORIZED DISCLOSURES.—In addition to any penalty otherwise provided under law, any person who makes an unauthorized disclosure of such information shall be subject to a civil monetary penalty of not to exceed $10,000 for each such unauthorized disclosure. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under section 1128A(a).

"(5) ANNUAL PERCENTAGE INCREASE.—For purposes of this part, the annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in average per capita aggregate expenditures for covered outpatient drugs in the United States for medicare beneficiaries, as determined by the Administrator for the 12-month period ending in July of the previous year.

"(c) ALTERNATIVE COVERAGE REQUIREMENTS.—A prescription drug plan or MA-EFFS Rx plan may provide a different prescription drug benefit design from the standard coverage described in subsection (b) so long as the Administrator deter-

mines (based on an actuarial analysis by the Administrator) that the following requirements are met and the plan applies for, and receives, the approval of the Administrator for such benefit design:

"(1) ASSURING AT LEAST ACTUARIALLY EQUIVALENT COVERAGE.—

"(A) ASSURING EQUIVALENT VALUE OF TOTAL COVERAGE.—The actuarial value of the total coverage (as determined under subsection (e)) is at least equal to the actuarial value (as so determined) of standard coverage.

"(B) ASSURING EQUIVALENT UNSUBSIDIZED VALUE OF COVERAGE.—The unsubsidized value of the coverage is at least equal to the unsubsidized value of standard coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage (as determined under subsection (e)) exceeds the actuarial value of the subsidy payments under section 1860D–8 with respect to such coverage.

"(C) ASSURING STANDARD PAYMENT FOR COSTS AT INITIAL COVERAGE LIMIT.—The coverage is designed, based upon an actuarially representative pattern of utilization (as determined under subsection (e)), to provide for the payment, with respect to costs incurred that are equal to the initial coverage limit under subsection (b)(3), of an amount equal to at least the product of—

"(i) the amount by which the initial coverage limit described in subsection (b)(3) exceeds the deductible described in subsection (b)(1); and

"(ii) 100 percent minus the cost-sharing percentage specified in subsection (b)(2)(A)(i).

"(2) CATASTROPHIC PROTECTION.—The coverage provides for beneficiaries the catastrophic protection described in subsection (b)(4).

"(d) ACCESS TO NEGOTIATED PRICES.—

"(1) IN GENERAL.—Under qualified prescription drug coverage offered by a PDP sponsor or an entity offering a MA-EFFS Rx plan, the sponsor or entity shall provide beneficiaries with access to negotiated prices (including applicable discounts) used for payment for covered outpatient drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of cost-sharing or an initial coverage limit (described in subsection (b)(3)). Insofar as a State elects to provide medical assistance under title XIX to a beneficiary enrolled under such title and under a prescription drug plan or MA-EFFS Rx plan for a drug based on the prices negotiated by a prescription drug plan or MA-EFFS Rx plan under this part, the requirements of section 1927 shall not apply to such drugs. The prices negotiated by a prescription drug plan under this part, by a MA-EFFS Rx plan with respect to covered outpatient drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D–8(f)(1)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B, shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).

"(2) DISCLOSURE.—The PDP sponsor or entity offering a MA-EFFS Rx plan shall disclose to the Administrator (in a manner specified by the Administrator) the extent to which discounts or rebates or other remuneration or price concessions made available to the sponsor or organization by a manufacturer are passed through to enrollees through pharmacies and other dispensers or otherwise. The provisions of section 1927(b)(3)(D) shall apply to information disclosed to the Administrator under this paragraph in the same manner as such provisions apply to information disclosed under such section.

"(3) AUDITS AND REPORTS.—To protect against fraud and abuse and to ensure proper disclosures and accounting under this part, in addition to any protections against fraud and abuse provided under section 1860D–4(b)(3)(C), the Administrator may periodically audit the financial statements and records of PDP sponsor or entities offering a MA-EFFS Rx plan.

"(e) ACTUARIAL VALUATION; DETERMINATION OF ANNUAL PERCENTAGE INCREASES.—

"(1) PROCESSES.—For purposes of this section, the Administrator shall establish processes and methods—

"(A) for determining the actuarial valuation of prescription drug coverage, including—

"(i) an actuarial valuation of standard coverage and of the reinsurance subsidy payments under section 1860D–8;

"(ii) the use of generally accepted actuarial principles and methodologies; and

"(iii) applying the same methodology for determinations of alternative coverage under subsection (c) as is used with respect to determinations of standard coverage under subsection (b); and

"(B) for determining annual percentage increases described in subsection (b)(5).

"(2) USE OF OUTSIDE ACTUARIES.—Under the processes under paragraph (1)(A), PDP sponsors and entities offering MA-EFFS Rx plans may use actuarial opinions certified by independent, qualified actuaries to establish actuarial values, but the Administrator shall determine whether such actuarial values meet the requirements under subsection (c)(1).

"(f) COVERED OUTPATIENT DRUGS DEFINED.—

"(1) IN GENERAL.—Except as provided in this subsection, for purposes of this part, the term 'covered outpatient drug' means—

"(A) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i) or (A)(ii) of section 1927(k)(2); or

"(B) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section,

and such term includes a vaccine licensed under section 351 of the Public Health Service Act and any use of a covered outpatient drug for a medically accepted indication (as defined in section 1927(k)(6)).

"(2) EXCLUSIONS.—

"(A) IN GENERAL.—Such term does not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2), other than subparagraph (E) thereof (relating to smoking cessation agents), or under section 1927(d)(3).

"(B) AVOIDANCE OF DUPLICATE COVERAGE.—A drug prescribed for an individual that would otherwise be a covered outpatient drug under this part shall not be so considered if payment for such drug is available under part A or B for an individual entitled to benefits under part A and enrolled under part B.

"(3) APPLICATION OF FORMULARY RESTRICTIONS.—A drug prescribed for an individual that would otherwise be a covered outpatient drug under this part shall not be so considered under a plan if the plan excludes the drug under a formulary and such exclusion is not successfully appealed under section 1860D–3(f)(2).

"(4) APPLICATION OF GENERAL EXCLUSION PROVISIONS.—A prescription drug plan or MA-EFFS Rx plan may exclude from qualified prescription drug coverage any covered outpatient drug—

"(A) for which payment would not be made if section 1862(a) applied to part D; or

"(B) which are not prescribed in accordance with the plan or this part.

Such exclusions are determinations subject to reconsideration and appeal pursuant to section 1860D–3(f).

"SEC. 1860D–3. BENEFICIARY PROTECTIONS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.

"(a) GUARANTEED ISSUE, COMMUNITY-RATED PREMIUMS, ACCESS TO NEGOTIATED PRICES, AND NONDISCRIMINATION.—For provisions requiring guaranteed issue, community-rated premiums, access to negotiated prices, and nondiscrimination, see sections 1860D–1(c)(1), 1860D–1(c)(2), 1860D–2(d), and 1860D–6(b), respectively.

"(b) DISSEMINATION OF INFORMATION.—

"(1) GENERAL INFORMATION.—A PDP sponsor shall disclose, in a clear, accurate, and standardized form to each enrollee with a prescription drug plan offered by the sponsor under this part at the time of enrollment and at least annually thereafter, the information described in section 1852(c)(1) relating to such plan. Such information includes the following:

"(A) Access to specific covered outpatient drugs, including access through pharmacy networks.

"(B) How any formulary used by the sponsor functions, including the drugs included in the formulary.

"(C) Co-payments and deductible requirements, including the identification of the tiered or other co-payment level applicable to each drug (or class of drugs).

"(D) Grievance and appeals procedures.

Such information shall also be made available upon request to prospective enrollees.

"(2) DISCLOSURE UPON REQUEST OF GENERAL COVERAGE, UTILIZATION, AND GRIEVANCE INFORMATION.—Upon request of an individual eligible to enroll under a prescription drug plan, the PDP sponsor shall provide the information described in section 1852(c)(2) (other than subparagraph (D)) to such individual.

"(3) RESPONSE TO BENEFICIARY QUESTIONS.—Each PDP sponsor offering a prescription drug plan shall have a mechanism for providing specific information

to enrollees upon request. The sponsor shall make available on a timely basis, through an Internet website and in writing upon request, information on specific changes in its formulary.

"(4) CLAIMS INFORMATION.—Each PDP sponsor offering a prescription drug plan must furnish to each enrollee in a form easily understandable to such enrollees an explanation of benefits (in accordance with section 1806(a) or in a comparable manner) and a notice of the benefits in relation to initial coverage limit and the annual out-of-pocket threshold applicable to such enrollee for the current year, whenever prescription drug benefits are provided under this part (except that such notice need not be provided more often than monthly).

"(c) ACCESS TO COVERED BENEFITS.—

"(1) ASSURING PHARMACY ACCESS.—

"(A) PARTICIPATION OF ANY WILLING PHARMACY.—A PDP sponsor and an entity offering a MA-EFFS Rx plan shall permit the participation of any pharmacy that meets terms and conditions that the plan has established.

"(B) DISCOUNTS ALLOWED FOR NETWORK PHARMACIES.—A prescription drug plan and a MA-EFFS Rx plan may, notwithstanding subparagraph (A), reduce coinsurance or copayments for its enrolled beneficiaries below the level otherwise provided for covered outpatient drugs dispensed through in-network pharmacies, but in no case shall such a reduction result in an increase in payments made by the Administrator under section 1860D–8 to a plan.

"(C) CONVENIENT ACCESS FOR NETWORK PHARMACIES.—The PDP sponsor of the prescription drug plan and the entity offering a MA-EFFS Rx plan shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules of the Administrator). The Administrator shall establish convenient access rules under this subparagraph that are no less favorable to enrollees than the rules for convenient access to pharmacies of the Secretary of Defense established as of June 1, 2003, for purposes of the TRICARE Retail Pharmacy (TRRx) program. Such rules shall include adequate emergency access for enrolled beneficiaries.

"(D) LEVEL PLAYING FIELD.—Such a sponsor shall permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a community pharmacy, rather than through mail order, with any differential in cost paid by such enrollees.

"(E) NOT REQUIRED TO ACCEPT INSURANCE RISK.—The terms and conditions under subparagraph (A) may not require participating pharmacies to accept insurance risk as a condition of participation.

"(2) USE OF STANDARDIZED TECHNOLOGY.—

"(A) IN GENERAL.—The PDP sponsor of a prescription drug plan and an entity offering a MA-EFFS Rx plan shall issue (and reissue, as appropriate) such a card (or other technology) that may be used by an enrollee to assure access to negotiated prices under section 1860D–2(d) for the purchase of prescription drugs for which coverage is not otherwise provided under the plan.

"(B) STANDARDS.—

"(i) DEVELOPMENT.—The Administrator shall provide for the development or utilization of uniform standards relating to a standardized format for the card or other technology referred to in subparagraph (A). Such standards shall be compatible with standards established under part C of title XI.

"(ii) APPLICATION OF ADVISORY TASK FORCE.—The advisory task force established under subsection (d)(3)(B)(ii) shall provide recommendations to the Administrator under such subsection regarding the standards developed under clause (i).

"(3) REQUIREMENTS ON DEVELOPMENT AND APPLICATION OF FORMULARIES.—If a PDP sponsor of a prescription drug plan or an entity offering a MA-EFFS Rx plan uses a formulary, the following requirements must be met:

"(A) PHARMACY AND THERAPEUTIC (P&T) COMMITTEE.—The sponsor or entity must establish a pharmacy and therapeutic committee that develops and reviews the formulary. Such committee shall include at least one practicing physician and at least one practicing pharmacist independent and free of conflict with respect to the committee both with expertise in the care of elderly or disabled persons and a majority of its members shall consist of individuals who are practicing physicians or practicing pharmacists (or both).

"(B) FORMULARY DEVELOPMENT.—In developing and reviewing the formulary, the committee shall—

"(i) base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and such other information as the committee determines to be appropriate; and

"(ii) shall take into account whether including in the formulary particular covered outpatient drugs has therapeutic advantages in terms of safety and efficacy.

"(C) INCLUSION OF DRUGS IN ALL THERAPEUTIC CATEGORIES.—The formulary must include drugs within each therapeutic category and class of covered outpatient drugs (although not necessarily for all drugs within such categories and classes). In establishing such classes, the committee shall take into account the standards published in the United States Pharmacopeia-Drug Information. The committee shall make available to the enrollees under the plan through the Internet or otherwise the bases for the exclusion of coverage of any drug from the formulary.

"(D) PROVIDER AND PATIENT EDUCATION.—The committee shall establish policies and procedures to educate and inform health care providers and enrollees concerning the formulary.

"(E) NOTICE BEFORE REMOVING DRUG FROM FORMULARY FOR CHANGING PREFERRED OR TIER STATUS OF DRUG.—Any removal of a covered outpatient drug from a formulary and any change in the preferred or tier cost-sharing status of such a drug shall take effect only after appropriate notice is made available to beneficiaries and physicians.

"(F) PERIODIC EVALUATION OF PROTOCOLS.—In connection with the formulary, a prescription drug plan shall provide for the periodic evaluation and analysis of treatment protocols and procedures.

"(G) GRIEVANCES AND APPEALS RELATING TO APPLICATION OF FORMULARIES.—For provisions relating to grievances and appeals of coverage, see subsections (e) and (f).

"(d) COST AND UTILIZATION MANAGEMENT; QUALITY ASSURANCE; MEDICATION THERAPY MANAGEMENT PROGRAM.—

"(1) IN GENERAL.—The PDP sponsor or entity offering a MA-EFFS Rx plan shall have in place, directly or through appropriate arrangements, with respect to covered outpatient drugs—

"(A) an effective cost and drug utilization management program, including medically appropriate incentives to use generic drugs and therapeutic interchange, when appropriate;

"(B) quality assurance measures and systems to reduce medical errors and adverse drug interactions, including side-effects, and improve medication use, including a medication therapy management program described in paragraph (2) and for years beginning with 2007, an electronic prescription program described in paragraph (3); and

"(C) a program to control fraud, abuse, and waste.

Nothing in this section shall be construed as impairing a PDP sponsor or entity from utilizing cost management tools (including differential payments) under all methods of operation.

"(2) MEDICATION THERAPY MANAGEMENT PROGRAM.—

"(A) IN GENERAL.—A medication therapy management program described in this paragraph is a program of drug therapy management and medication administration that may be furnished by a pharmacy provider and that is designed to assure, with respect to beneficiaries at risk for potential medication problems, such as beneficiaries with complex or chronic diseases (such as diabetes, asthma, hypertension, and congestive heart failure) or multiple prescriptions, that covered outpatient drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use and reduce the risk of adverse events, including adverse drug interactions. Such programs may distinguish between services in ambulatory and institutional settings.

"(B) ELEMENTS.—Such program may include—

"(i) enhanced beneficiary understanding to promote the appropriate use of medications by beneficiaries and to reduce the risk of potential adverse events associated with medications, through beneficiary education, counseling, case management, disease state management programs, and other appropriate means;

"(ii) increased beneficiary adherence with prescription medication regimens through medication refill reminders, special packaging, and other compliance programs and other appropriate means; and

"(iii) detection of patterns of overuse and underuse of prescription drugs.

"(C) DEVELOPMENT OF PROGRAM IN COOPERATION WITH LICENSED PHARMACISTS.—The program shall be developed in cooperation with licensed and practicing pharmacists and physicians.

"(D) CONSIDERATIONS IN PHARMACY FEES.—The PDP sponsor of a prescription drug program and an entity offering a MA-EFFS Rx plan shall take into account, in establishing fees for pharmacists and others providing services under the medication therapy management program, the resources and time used in implementing the program. Each such sponsor or entity shall disclose to the Administrator upon request the amount of any such management or dispensing fees.

"(3) ELECTRONIC PRESCRIPTION PROGRAM.—

"(A) IN GENERAL.—An electronic prescription drug program described in this paragraph is a program that includes at least the following components, consistent with uniform standards established under subparagraph (B):

"(i) ELECTRONIC TRANSMITTAL OF PRESCRIPTIONS.—Prescriptions must be written and transmitted electronically (other than by facsimile), except in emergency cases and other exceptional circumstances recognized by the Administrator.

"(ii) PROVISION OF INFORMATION TO PRESCRIBING HEALTH CARE PROFESSIONAL.—The program provides for the electronic transmittal to the prescribing health care professional of information that includes—

"(I) information (to the extent available and feasible) on the drug or drugs being prescribed for that patient and other information relating to the medical history or condition of the patient that may be relevant to the appropriate prescription for that patient;

"(II) cost-effective alternatives (if any) for the use of the drug prescribed; and

"(III) information on the drugs included in the applicable formulary.

To the extent feasible, such program shall permit the prescribing health care professional to provide (and be provided) related information on an interactive, real-time basis.

"(B) STANDARDS.—

"(i) DEVELOPMENT.—The Administrator shall provide for the development of uniform standards relating to the electronic prescription drug program described in subparagraph (A). Such standards shall be compatible with standards established under part C of title XI.

"(ii) ADVISORY TASK FORCE.—In developing such standards and the standards described in subsection (c)(2)(B)(i) the Administrator shall establish a task force that includes representatives of physicians, hospitals, pharmacies, beneficiaries, pharmacy benefit managers, individuals with expertise in information technology, and pharmacy benefit experts of the Departments of Veterans Affairs and Defense and other appropriate Federal agencies to provide recommendations to the Administrator on such standards, including recommendations relating to the following:

"(I) The range of available computerized prescribing software and hardware and their costs to develop and implement.

"(II) The extent to which such standards and systems reduce medication errors and can be readily implemented by physicians, pharmacies, and hospitals.

"(III) Efforts to develop uniform standards and a common software platform for the secure electronic communication of medication history, eligibility, benefit, and prescription information.

"(IV) Efforts to develop and promote universal connectivity and interoperability for the secure electronic exchange of such information.

"(V) The cost of implementing such systems in the range of hospital and physician office settings and pharmacies, including hardware, software, and training costs.

"(VI) Implementation issues as they relate to part C of title XI, and current Federal and State prescribing laws and regulations and their impact on implementation of computerized prescribing.

"(iii) DEADLINES.—

"(I) The Administrator shall constitute the task force under clause (ii) by not later than April 1, 2004.

"(II) Such task force shall submit recommendations to Administrator by not later than January 1, 2005.

"(III) The Administrator shall provide for the development and promulgation, by not later than January 1, 2006, of national standards relating to the electronic prescription drug program described in clause (ii). Such standards shall be issued by a standards organization accredited by the American National Standards Institute (ANSI) and shall be compatible with standards established under part C of title XI.

"(4) TREATMENT OF ACCREDITATION.—Section 1852(e)(4) (relating to treatment of accreditation) shall apply to prescription drug plans under this part with respect to the following requirements, in the same manner as they apply to plans under part C with respect to the requirements described in a clause of section 1852(e)(4)(B):

"(A) Paragraph (1) (including quality assurance), including medication therapy management program under paragraph (2).

"(B) Subsection (c)(1) (relating to access to covered benefits).

"(C) Subsection (g) (relating to confidentiality and accuracy of enrollee records).

"(5) PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS.—Each PDP sponsor and each entity offering a MA-EFFS Rx plan shall provide that each pharmacy or other dispenser that arranges for the dispensing of a covered outpatient drug shall inform the beneficiary at the time of purchase of the drug of any differential between the price of the prescribed drug to the enrollee and the price of the lowest cost available generic drug covered under the plan that is therapeutically equivalent and bioequivalent.

"(e) GRIEVANCE MECHANISM, COVERAGE DETERMINATIONS, AND RECONSIDERATIONS.—

"(1) IN GENERAL.—Each PDP sponsor shall provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the sponsor provides covered benefits) and enrollees with prescription drug plans of the sponsor under this part in accordance with section 1852(f).

"(2) APPLICATION OF COVERAGE DETERMINATION AND RECONSIDERATION PROVISIONS.—A PDP sponsor shall meet the requirements of paragraphs (1) through (3) of section 1852(g) with respect to covered benefits under the prescription drug plan it offers under this part in the same manner as such requirements apply to an organization with respect to benefits it offers under a plan under part C.

"(3) REQUEST FOR REVIEW OF TIERED FORMULARY DETERMINATIONS.—In the case of a prescription drug plan offered by a PDP sponsor or a MA-EFFS Rx plan that provides for tiered cost-sharing for drugs included within a formulary and provides lower cost-sharing for preferred drugs included within the formulary, an individual who is enrolled in the plan may request coverage of a nonpreferred drug under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both.

"(f) APPEALS.—

"(1) IN GENERAL.—Subject to paragraph (2), a PDP sponsor shall meet the requirements of paragraphs (4) and (5) of section 1852(g) with respect to drugs (including a determination related to the application of tiered cost-sharing described in subsection (e)(3)) in the same manner as such requirements apply to an organization with respect to benefits it offers under a plan under part C.

"(2) FORMULARY DETERMINATIONS.—An individual who is enrolled in a prescription drug plan offered by a PDP sponsor or in a MA-EFFS Rx plan may appeal to obtain coverage for a covered outpatient drug that is not on a formulary of the sponsor or entity offering the plan if the prescribing physician determines that the formulary drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both.

"(g) CONFIDENTIALITY AND ACCURACY OF ENROLLEE RECORDS.—A PDP sponsor that offers a prescription drug plan shall meet the requirements of section 1852(h) with respect to enrollees under the plan in the same manner as such requirements apply to an organization with respect to enrollees under part C. A PDP sponsor shall be treated as a business associate for purposes of the provisions of subpart E of part 164 of title 45, Code of Federal Regulations, adopted pursuant to the authority of the Secretary under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S. C. 1320d-2 note).

"SEC. 1860D–4. REQUIREMENTS FOR AND CONTRACTS WITH PRESCRIPTION DRUG PLAN (PDP) SPONSORS.

"(a) GENERAL REQUIREMENTS.—Each PDP sponsor of a prescription drug plan shall meet the following requirements:

"(1) LICENSURE.—Subject to subsection (c), the sponsor is organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan.

"(2) ASSUMPTION OF FINANCIAL RISK FOR UNSUBSIDIZED COVERAGE.—

"(A) IN GENERAL.—Subject to subparagraph (B) and section 1860D–5(d)(2), the entity assumes full financial risk on a prospective basis for qualified prescription drug coverage that it offers under a prescription drug plan and that is not covered under section 1860D–8.

"(B) REINSURANCE PERMITTED.—The entity may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee.

"(3) SOLVENCY FOR UNLICENSED SPONSORS.—In the case of a sponsor that is not described in paragraph (1), the sponsor shall meet solvency standards established by the Administrator under subsection (d).

"(b) CONTRACT REQUIREMENTS.—

"(1) IN GENERAL.—The Administrator shall not permit the election under section 1860D–1 of a prescription drug plan offered by a PDP sponsor under this part, and the sponsor shall not be eligible for payments under section 1860D–7 or 1860D–8, unless the Administrator has entered into a contract under this subsection with the sponsor with respect to the offering of such plan. Such a contract with a sponsor may cover more than one prescription drug plan. Such contract shall provide that the sponsor agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

"(2) NEGOTIATION REGARDING TERMS AND CONDITIONS.—The Administrator shall have the same authority to negotiate the terms and conditions of prescription drug plans under this part as the Director of the Office of Personnel Management has with respect to health benefits plans under chapter 89 of title 5, United States Code. In negotiating the terms and conditions regarding premiums for which information is submitted under section 1860D–6(a)(2), the Administrator shall take into account the subsidy payments under section 1860D–8.

"(3) INCORPORATION OF CERTAIN MEDICARE ADVANTAGE CONTRACT REQUIREMENTS.—The following provisions of section 1857 shall apply, subject to subsection (c)(5), to contracts under this section in the same manner as they apply to contracts under section 1857(a):

"(A) MINIMUM ENROLLMENT.—Paragraphs (1) and (3) of section 1857(b).

"(B) CONTRACT PERIOD AND EFFECTIVENESS.—Paragraphs (1) through (3) and (5) of section 1857(c).

"(C) PROTECTIONS AGAINST FRAUD AND BENEFICIARY PROTECTIONS.—Section 1857(d).

"(D) ADDITIONAL CONTRACT TERMS.—Section 1857(e); except that in applying section 1857(e)(2) under this part—

"(i) such section shall be applied separately to costs relating to this part (from costs under part C and part E);

"(ii) in no case shall the amount of the fee established under this subparagraph for a plan exceed 20 percent of the maximum amount of the fee that may be established under subparagraph (B) of such section; and

"(iii) no fees shall be applied under this subparagraph with respect to MA-EFFS Rx plans.

"(E) INTERMEDIATE SANCTIONS.—Section 1857(g).

"(F) PROCEDURES FOR TERMINATION.—Section 1857(h).

"(4) RULES OF APPLICATION FOR INTERMEDIATE SANCTIONS.—In applying paragraph (3)(E)—

"(A) the reference in section 1857(g)(1)(B) to section 1854 is deemed a reference to this part; and

"(B) the reference in section 1857(g)(1)(F) to section 1852(k)(2)(A)(ii) shall not be applied.

"(5) SERVICE AREA REQUIREMENT.—For purposes of this part, the Administrator shall designate at least 10 areas covering the entire United States and shall be consistent with EFFS regions established under section 1860E–1(a)(2).

"(c) WAIVER OF CERTAIN REQUIREMENTS TO EXPAND CHOICE.—

"(1) IN GENERAL.—In the case of an entity that seeks to offer a prescription drug plan in a State, the Administrator shall waive the requirement of sub-

section (a)(1) that the entity be licensed in that State if the Administrator determines, based on the application and other evidence presented to the Administrator, that any of the grounds for approval of the application described in paragraph (2) have been met.

"(2) GROUNDS FOR APPROVAL.—The grounds for approval under this paragraph are the grounds for approval described in subparagraph (B), (C), and (D) of section 1855(a)(2), and also include the application by a State of any grounds other than those required under Federal law.

"(3) APPLICATION OF WAIVER PROCEDURES.—With respect to an application for a waiver (or a waiver granted) under this subsection, the provisions of subparagraphs (E), (F), and (G) of section 1855(a)(2) shall apply.

"(4) LICENSURE DOES NOT SUBSTITUTE FOR OR CONSTITUTE CERTIFICATION.—The fact that an entity is licensed in accordance with subsection (a)(1) does not deem the entity to meet other requirements imposed under this part for a PDP sponsor.

"(5) REFERENCES TO CERTAIN PROVISIONS.—For purposes of this subsection, in applying provisions of section 1855(a)(2) under this subsection to prescription drug plans and PDP sponsors—

"(A) any reference to a waiver application under section 1855 shall be treated as a reference to a waiver application under paragraph (1); and

"(B) any reference to solvency standards shall be treated as a reference to solvency standards established under subsection (d).

"(d) SOLVENCY STANDARDS FOR NON-LICENSED SPONSORS.—

"(1) ESTABLISHMENT.—The Administrator shall establish, by not later than October 1, 2004, financial solvency and capital adequacy standards that an entity that does not meet the requirements of subsection (a)(1) must meet to qualify as a PDP sponsor under this part.

"(2) COMPLIANCE WITH STANDARDS.—Each PDP sponsor that is not licensed by a State under subsection (a)(1) and for which a waiver application has been approved under subsection (c) shall meet solvency and capital adequacy standards established under paragraph (1). The Administrator shall establish certification procedures for such PDP sponsors with respect to such solvency standards in the manner described in section 1855(c)(2).

"(e) RELATION TO STATE LAWS.—

"(1) IN GENERAL.—The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency, except as provided in subsection (d)) with respect to prescription drug plans which are offered by PDP sponsors under this part.

"(2) PROHIBITION OF STATE IMPOSITION OF PREMIUM TAXES.—No State may impose a premium tax or similar tax with respect to premiums paid to PDP sponsors for prescription drug plans under this part, or with respect to any payments made to such a sponsor by the Administrator under this part.

"SEC. 1860D–5. PROCESS FOR BENEFICIARIES TO SELECT QUALIFIED PRESCRIPTION DRUG COVERAGE.

"(a) IN GENERAL.—The Administrator shall establish a process for the selection of the prescription drug plan or MA-EFFS Rx plan through which eligible individuals elect qualified prescription drug coverage under this part.

"(b) ELEMENTS.—Such process shall include the following:

"(1) Annual, coordinated election periods, in which such individuals can change the qualifying plans through which they obtain coverage, in accordance with section 1860D–1(b)(2).

"(2) Active dissemination of information to promote an informed selection among qualifying plans based upon price, quality, and other features, in the manner described in (and in coordination with) section 1851(d), including the provision of annual comparative information, maintenance of a toll-free hotline, and the use of non-Federal entities.

"(3) Coordination of elections through filing with the entity offering a MA-EFFS Rx plan or a PDP sponsor, in the manner described in (and in coordination with) section 1851(c)(2).

"(4) Informing each enrollee before the beginning of each year of the annual out-of-pocket threshold applicable to the enrollee for that year under section 1860D–2(b)(4) at such time.

"(c) MA-EFFS RX ENROLLEE MAY ONLY OBTAIN BENEFITS THROUGH THE PLAN.—An individual who is enrolled under a MA-EFFS Rx plan may only elect to receive qualified prescription drug coverage under this part through such plan.

"(d) ASSURING ACCESS TO A CHOICE OF QUALIFIED PRESCRIPTION DRUG COVERAGE.—

"(1) CHOICE OF AT LEAST TWO PLANS IN EACH AREA.—

"(A) IN GENERAL.—The Administrator shall assure that each individual who is entitled to benefits under part A or enrolled under part B and who is residing in an area in the United States has available, consistent with subparagraph (B), a choice of enrollment in at least two qualifying plans (as defined in paragraph (5)) in the area in which the individual resides, at least one of which is a prescription drug plan.

"(B) REQUIREMENT FOR DIFFERENT PLAN SPONSORS.—The requirement in subparagraph (A) is not satisfied with respect to an area if only one PDP sponsor or one entity that offers a MA-EFFS Rx plan offers all the qualifying plans in the area.

"(2) GUARANTEEING ACCESS TO COVERAGE.—In order to assure access under paragraph (1) and consistent with paragraph (3), the Administrator may provide partial underwriting of risk for a PDP sponsor to expand the service area under an existing prescription drug plan to adjoining or additional areas or to establish such a plan (including offering such a plan on a regional or nationwide basis), but only so long as (and to the extent) necessary to assure the access guaranteed under paragraph (1).

"(3) LIMITATION ON AUTHORITY.—In exercising authority under this subsection, the Administrator—

"(A) shall not provide for the full underwriting of financial risk for any PDP sponsor; and

"(B) shall seek to maximize the assumption of financial risk by PDP sponsors or entities offering a MA-EFFS Rx plan.

"(4) REPORTS.—The Administrator shall, in each annual report to Congress under section 1809(f), include information on the exercise of authority under this subsection. The Administrator also shall include such recommendations as may be appropriate to minimize the exercise of such authority, including minimizing the assumption of financial risk.

"(5) QUALIFYING PLAN DEFINED.—For purposes of this subsection, the term 'qualifying plan' means a prescription drug plan or a MA-EFFS Rx plan.

"SEC. 1860D–6. SUBMISSION OF BIDS AND PREMIUMS.

"(a) SUBMISSION OF BIDS, PREMIUMS, AND RELATED INFORMATION.—

"(1) IN GENERAL.—Each PDP sponsor shall submit to the Administrator the information described in paragraph (2) in the same manner as information is submitted by an organization under section 1854(a)(1).

"(2) INFORMATION SUBMITTED.—The information described in this paragraph is the following:

"(A) COVERAGE PROVIDED.—Information on the qualified prescription drug coverage to be provided.

"(B) ACTUARIAL VALUE.—Information on the actuarial value of the coverage.

"(C) BID AND PREMIUM.—Information on the bid and the premium for the coverage, including an actuarial certification of—

"(i) the actuarial basis for such bid and premium;

"(ii) the portion of such bid and premium attributable to benefits in excess of standard coverage;

"(iii) the reduction in such bid resulting from the reinsurance subsidy payments provided under section 1860D–8(a)(2); and

"(iv) the reduction in such premium resulting from the direct and reinsurance subsidy payments provided under section 1860D–8.

"(D) ADDITIONAL INFORMATION.—Such other information as the Administrator may require to carry out this part.

"(3) REVIEW OF INFORMATION; NEGOTIATION AND APPROVAL OF PREMIUMS.—

"(A) IN GENERAL.—Subject to subparagraph (B), the Administrator shall review the information filed under paragraph (2) for the purpose of conducting negotiations under section 1860D–4(b)(2) (relating to using OPM-like authority under the FEHBP). The Administrator, using the information provided (including the actuarial certification under paragraph (2)(C)) shall approve the premium submitted under this subsection only if the premium accurately reflects both (i) the actuarial value of the benefits provided, and (ii) the 73 percent average subsidy provided under section 1860D–8 for the standard benefit. The Administrator shall apply actuarial principles to approval of a premium under this part in a manner similar to the manner in which those principles are applied in establishing the monthly part B premium under section 1839.

"(B) EXCEPTION.—In the case of a plan described in section 1851(a)(2)(C), the provisions of subparagraph (A) shall not apply and the provisions of paragraph (5)(B) of section 1854(a), prohibiting the review, approval, or dis-

approval of amounts described in such paragraph, shall apply to the negotiation and rejection of the monthly bid amounts and proportion referred to in subparagraph (A).

"(b) UNIFORM BID AND PREMIUM.—

"(1) IN GENERAL.—The bid and premium for a prescription drug plan under this section may not vary among enrollees in the plan in the same service area.

"(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed as preventing the imposition of a late enrollment penalty under section 1860D–1(c)(2)(B).

"(c) COLLECTION.—

"(1) BENEFICIARY'S OPTION OF PAYMENT THROUGH WITHHOLDING FROM SOCIAL SECURITY PAYMENT OR USE OF ELECTRONIC FUNDS TRANSFER MECHANISM.—In accordance with regulations, a PDP sponsor shall permit each enrollee, at the enrollee's option, to make payment of premiums under this part to the sponsor through withholding from benefit payments in the manner provided under section 1840 with respect to monthly premiums under section 1839 or through an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account) or otherwise. All premium payments that are withheld under this paragraph shall be credited to the Medicare Prescription Drug Trust Fund and shall be paid to the PDP sponsor involved.

"(2) OFFSETTING.—Reductions in premiums for coverage under parts A and B as a result of a selection of a MA-EFFS Rx plan may be used to reduce the premium otherwise imposed under paragraph (1).

"(d) ACCEPTANCE OF REFERENCE PREMIUM AMOUNT AS FULL PREMIUM FOR SUBSIDIZED LOW-INCOME INDIVIDUALS IF NO STANDARD (OR EQUIVALENT) COVERAGE IN AN AREA.—

"(1) IN GENERAL.—If there is no standard prescription drug coverage (as defined in paragraph (2)) offered in an area, in the case of an individual who is eligible for a premium subsidy under section 1860D–7 and resides in the area, the PDP sponsor of any prescription drug plan offered in the area (and any entity offering a MA-EFFS Rx plan in the area) shall accept the reference premium amount (under paragraph (3)) as payment in full for the premium charge for qualified prescription drug coverage.

"(2) STANDARD PRESCRIPTION DRUG COVERAGE DEFINED.—For purposes of this subsection, the term 'standard prescription drug coverage' means qualified prescription drug coverage that is standard coverage or that has an actuarial value equivalent to the actuarial value for standard coverage.

"(3) REFERENCE PREMIUM AMOUNT DEFINED.—For purposes of this subsection, the term 'reference premium amount' means, with respect to qualified prescription drug coverage offered under—

"(A) a prescription drug plan that—

"(i) provides standard coverage (or alternative prescription drug coverage the actuarial value is equivalent to that of standard coverage), the plan's PDP premium; or

"(ii) provides alternative prescription drug coverage the actuarial value of which is greater than that of standard coverage, the plan's PDP premium multiplied by the ratio of (I) the actuarial value of standard coverage, to (II) the actuarial value of the alternative coverage;

"(B) an EFFS plan, the EFFS monthly prescription drug beneficiary premium (as defined in section 1860E–4(a)(3)(B)); or

"(C) a Medicare Advantage, the Medicare Advantage monthly prescription drug beneficiary premium (as defined in section 1854(b)(2)(B)).

For purposes of subparagraph (A), the term 'PDP premium' means, with respect to a prescription drug plan, the premium amount for enrollment under the plan under this part (determined without regard to any low-income subsidy under section 1860D–7 or any late enrollment penalty under section 1860D–1(c)(2)(B)).

"SEC. 1860D–7. PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS.

"(a) INCOME-RELATED SUBSIDIES FOR INDIVIDUALS WITH INCOME BELOW 150 PERCENT OF FEDERAL POVERTY LEVEL.—

"(1) FULL PREMIUM SUBSIDY AND REDUCTION OF COST-SHARING FOR INDIVIDUALS WITH INCOME BELOW 135 PERCENT OF FEDERAL POVERTY LEVEL.—In the case of a subsidy eligible individual (as defined in paragraph (4)) who is determined to have income that does not exceed 135 percent of the Federal poverty level, the individual is entitled under this section—

"(A) to an income-related premium subsidy equal to 100 percent of the amount described in subsection (b)(1); and

"(B) subject to subsection (c), to the substitution for the beneficiary cost-sharing described in paragraphs (1) and (2) of section 1860D–2(b) (up to the initial coverage limit specified in paragraph (3) of such section) of amounts that do not exceed $2 for a multiple source or generic drug (as described in section 1927(k)(7)(A)) and $5 for a non-preferred drug.

"(2) SLIDING SCALE PREMIUM SUBSIDY FOR INDIVIDUALS WITH INCOME ABOVE 135, BUT BELOW 150 PERCENT, OF FEDERAL POVERTY LEVEL.—In the case of a subsidy eligible individual who is determined to have income that exceeds 135 percent, but does not exceed 150 percent, of the Federal poverty level, the individual is entitled under this section to an income-related premium subsidy determined on a linear sliding scale ranging from 100 percent of the amount described in subsection (b)(1) for individuals with incomes at 135 percent of such level to 0 percent of such amount for individuals with incomes at 150 percent of such level.

"(3) CONSTRUCTION.—Nothing in this section shall be construed as preventing a PDP sponsor or entity offering a MA-EFFS Rx plan from reducing to 0 the cost-sharing otherwise applicable to generic drugs.

"(4) DETERMINATION OF ELIGIBILITY.—

"(A) SUBSIDY ELIGIBLE INDIVIDUAL DEFINED.—For purposes of this section, subject to subparagraph (D), the term 'subsidy eligible individual' means an individual who—

"(i) is eligible to elect, and has elected, to obtain qualified prescription drug coverage under this part;

"(ii) has income below 150 percent of the Federal poverty line; and

"(iii) meets the resources requirement described in subparagraph (D)

.

"(B) DETERMINATIONS.—The determination of whether an individual residing in a State is a subsidy eligible individual and the amount of such individual's income shall be determined under the State medicaid plan for the State under section 1935(a) or by the Social Security Administration. In the case of a State that does not operate such a medicaid plan (either under title XIX or under a statewide waiver granted under section 1115), such determination shall be made under arrangements made by the Administrator. There are authorized to be appropriated to the Social Security Administration such sums as may be necessary for the determination of eligibility under this subparagraph.

"(C) INCOME DETERMINATIONS.—For purposes of applying this section—

"(i) income shall be determined in the manner described in section 1905(p)(1)(B); and

"(ii) the term 'Federal poverty line' means the official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved.

"(D) RESOURCE STANDARD APPLIED TO BE BASED ON TWICE SSI RESOURCE STANDARD.—The resource requirement of this subparagraph is that an individual's resources (as determined under section 1613 for purposes of the supplemental security income program) do not exceed—

"(i) for 2006 twice the maximum amount of resources that an individual may have and obtain benefits under that program; and

"(ii) for a subsequent year the resource limitation established under this clause for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any resource limitation established under clause (ii) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

"(E) TREATMENT OF TERRITORIAL RESIDENTS.—In the case of an individual who is not a resident of the 50 States or the District of Columbia, the individual is not eligible to be a subsidy eligible individual but may be eligible for financial assistance with prescription drug expenses under section 1935(e).

"(F) TREATMENT OF CONFORMING MEDIGAP POLICIES.—For purposes of this section, the term 'qualified prescription drug coverage' includes a medicare supplemental policy described in section 1860D–8(b)(4).

"(5) INDEXING DOLLAR AMOUNTS.—

"(A) FOR 2007.—The dollar amounts applied under paragraphs (1)(B) for 2007 shall be the dollar amounts specified in such paragraph increased by the annual percentage increase described in section 1860D–2(b)(5) for 2007.

"(B) FOR SUBSEQUENT YEARS.—The dollar amounts applied under paragraph (1)(B) for a year after 2007 shall be the amounts (under this para-

graph) applied under paragraph (1)(B) for the preceding year increased by the annual percentage increase described in section 1860D–2(b)(5) (relating to growth in medicare prescription drug costs per beneficiary) for the year involved.

"(b) PREMIUM SUBSIDY AMOUNT.—

"(1) IN GENERAL.—The premium subsidy amount described in this subsection for an individual residing in an area is the benchmark premium amount (as defined in paragraph (2)) for qualified prescription drug coverage offered by the prescription drug plan or the MA-EFFS Rx plan in which the individual is enrolled.

"(2) BENCHMARK PREMIUM AMOUNT DEFINED.—For purposes of this subsection, the term 'benchmark premium amount' means, with respect to qualified prescription drug coverage offered under—

"(A) a prescription drug plan that—

"(i) provides standard coverage (or alternative prescription drug coverage the actuarial value of which is equivalent to that of standard coverage), the premium amount for enrollment under the plan under this part (determined without regard to any subsidy under this section or any late enrollment penalty under section 1860D–1(c)(2)(B)); or

"(ii) provides alternative prescription drug coverage the actuarial value of which is greater than that of standard coverage, the premium amount described in clause (i) multiplied by the ratio of (I) the actuarial value of standard coverage, to (II) the actuarial value of the alternative coverage; or

"(B) a MA-EFFS Rx plan, the portion of the premium amount that is attributable to statutory drug benefits (described in section 1853(a)(1)(A)(ii)(II)).

"(c) RULES IN APPLYING COST-SHARING SUBSIDIES.—

"(1) IN GENERAL.—In applying subsection (a)(1)(B), nothing in this part shall be construed as preventing a plan or provider from waiving or reducing the amount of cost-sharing otherwise applicable.

"(2) LIMITATION ON CHARGES.—In the case of an individual receiving cost-sharing subsidies under subsection (a)(1)(B), the PDP sponsor or entity offering a MA-EFFS Rx plan may not charge more than $5 per prescription.

"(3) APPLICATION OF INDEXING RULES.—The provisions of subsection (a)(5) shall apply to the dollar amount specified in paragraph (2) in the same manner as they apply to the dollar amounts specified in subsections (a)(1)(B).

"(d) ADMINISTRATION OF SUBSIDY PROGRAM.—The Administrator shall provide a process whereby, in the case of an individual who is determined to be a subsidy eligible individual and who is enrolled in prescription drug plan or is enrolled in a MA-EFFS Rx plan—

"(1) the Administrator provides for a notification of the PDP sponsor or the entity offering the MA-EFFS Rx plan involved that the individual is eligible for a subsidy and the amount of the subsidy under subsection (a);

"(2) the sponsor or entity involved reduces the premiums or cost-sharing otherwise imposed by the amount of the applicable subsidy and submits to the Administrator information on the amount of such reduction; and

"(3) the Administrator periodically and on a timely basis reimburses the sponsor or entity for the amount of such reductions.

The reimbursement under paragraph (3) with respect to cost-sharing subsidies may be computed on a capitated basis, taking into account the actuarial value of the subsidies and with appropriate adjustments to reflect differences in the risks actually involved.

"(e) RELATION TO MEDICAID PROGRAM.—

"(1) IN GENERAL.—For provisions providing for eligibility determinations, and additional financing, under the medicaid program, see section 1935.

"(2) MEDICAID PROVIDING WRAP AROUND BENEFITS.—The coverage provided under this part is primary payor to benefits for prescribed drugs provided under the medicaid program under title XIX consistent with section 1935(d)(1).

"(3) COORDINATION.—The Administrator shall develop and implement a plan for the coordination of prescription drug benefits under this part with the benefits provided under the medicaid program under title XIX, with particular attention to insuring coordination of payments and prevention of fraud and abuse. In developing and implementing such plan, the Administrator shall involve the Secretary, the States, the data processing industry, pharmacists, and pharmaceutical manufacturers, and other experts.

"SEC. 1860D–8. SUBSIDIES FOR ALL MEDICARE BENEFICIARIES FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.

"(a) SUBSIDY PAYMENT.—In order to reduce premium levels applicable to qualified prescription drug coverage for all medicare beneficiaries consistent with an overall subsidy level of 73 percent, to reduce adverse selection among prescription drug plans and MA-EFFS Rx plans, and to promote the participation of PDP sponsors under this part, the Administrator shall provide in accordance with this section for payment to a qualifying entity (as defined in subsection (b)) of the following subsidies:

"(1) DIRECT SUBSIDY.—In the case of an enrollee enrolled for a month in a prescription drug plan or a MA-EFFS Rx plan, a direct subsidy equal to 43 percent of the national average monthly bid amount (computed under subsection (g)) for that month.

"(2) SUBSIDY THROUGH REINSURANCE.—In the case of an enrollee enrolled for a month in a prescription drug plan or a MA-EFFS Rx plan, the reinsurance payment amount (as defined in subsection (c)), which in the aggregate is 30 percent of the total payments made by qualifying entities for standard coverage under the respective plan, for excess costs incurred in providing qualified prescription drug coverage—

"(A) for enrollees with a prescription drug plan under this part; and

"(B) for enrollees with a MA-EFFS Rx plan.

"(3) EMPLOYER AND UNION FLEXIBILITY.—In the case of an individual who is a participant or beneficiary in a qualified retiree prescription drug plan (as defined in subsection (f)(1)) and who is not enrolled in a prescription drug plan or in a MA-EFFS Rx plan, the special subsidy payments under subsection (f)(3).

This section constitutes budget authority in advance of appropriations Acts and represents the obligation of the Administrator to provide for the payment of amounts provided under this section. In applying the percentages under paragraphs (1) and (2), there shall be taken into account under the respective paragraphs the portion of the employer and union special subsidy payments under subsection (f)(3) that reflect payments that would have been made under the respective paragraphs if such paragraphs had applied to qualified retiree prescription drug plans instead of paragraph (3).

"(b) QUALIFYING ENTITY DEFINED.—For purposes of this section, the term 'qualifying entity' means any of the following that has entered into an agreement with the Administrator to provide the Administrator with such information as may be required to carry out this section:

"(1) A PDP sponsor offering a prescription drug plan under this part.

"(2) An entity that offers a MA-EFFS Rx plan.

"(3) The sponsor of a qualified retiree prescription drug plan (as defined in subsection (f)).

"(c) REINSURANCE PAYMENT AMOUNT.—

"(1) IN GENERAL.—Subject to subsection (d)(1)(B) and paragraph (4), the reinsurance payment amount under this subsection for a qualifying covered individual (as defined in paragraph (5)) for a coverage year (as defined in subsection (h)(2)) is equal to the sum of the following:

"(A) REINSURANCE BETWEEN INITIAL REINSURANCE THRESHOLD AND THE INITIAL COVERAGE LIMIT.—For the portion of the individual's gross covered prescription drug costs (as defined in paragraph (3)) for the year that exceeds the initial reinsurance threshold specified in paragraph (4), but does not exceed the initial coverage limit specified in section 1860D–2(b)(3), an amount equal to 20 percent of the allowable costs (as defined in paragraph (2)) attributable to such gross covered prescription drug costs.

"(B) REINSURANCE ABOVE ANNUAL OUT-OF-POCKET THRESHOLD.—For the portion of the individual's gross covered prescription drug costs for the year that exceeds the annual out-of-pocket threshold specified in 1860D–2(b)(4)(B), an amount equal to 80 percent of the allowable costs attributable to such gross covered prescription drug costs.

"(2) ALLOWABLE COSTS.—For purposes of this section, the term 'allowable costs' means, with respect to gross covered prescription drug costs under a plan described in subsection (b) offered by a qualifying entity, the part of such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were standard coverage.

"(3) GROSS COVERED PRESCRIPTION DRUG COSTS.—For purposes of this section, the term 'gross covered prescription drug costs' means, with respect to an enrollee with a qualifying entity under a plan described in subsection (b) during a coverage year, the costs incurred under the plan (including costs attributable

to administrative costs) for covered prescription drugs dispensed during the year, including costs relating to the deductible, whether paid by the enrollee or under the plan, regardless of whether the coverage under the plan exceeds standard coverage and regardless of when the payment for such drugs is made.

"(4) INITIAL REINSURANCE THRESHOLD.—The initial reinsurance threshold specified in this paragraph—

"(A) for 2006, is equal to $1,000; or

"(B) for a subsequent year, is equal to the payment threshold specified in this paragraph for the previous year, increased by the annual percentage increase described in section 1860D–2(b)(5) for the year involved.

Any amount determined under subparagraph (B) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

"(5) QUALIFYING COVERED INDIVIDUAL DEFINED.—For purposes of this subsection, the term 'qualifying covered individual' means an individual who—

"(A) is enrolled with a prescription drug plan under this part; or

"(B) is enrolled with a MA-EFFS Rx plan.

"(d) ADJUSTMENT OF PAYMENTS.—

"(1) ADJUSTMENT OF REINSURANCE PAYMENTS TO ASSURE 30 PERCENT LEVEL OF SUBSIDY THROUGH REINSURANCE.—

"(A) ESTIMATION OF PAYMENTS.—The Administrator shall estimate—

"(i) the total payments to be made (without regard to this subsection) during a year under subsections (a)(2) and (c); and

"(ii) the total payments to be made by qualifying entities for standard coverage under plans described in subsection (b) during the year.

"(B) ADJUSTMENT.—The Administrator shall proportionally adjust the payments made under subsections (a)(2) and (c) for a coverage year in such manner so that the total of the payments made under such subsections (and under subsection (f)(3) insofar as such payments reflect payments that would have been made under such subsections if such subsections had applied to qualified retiree prescription drug plans instead of subsections (a)(3) and (f)(3)) for the year is equal to 30 percent of the total payments described in subparagraph (A)(ii).

"(2) RISK ADJUSTMENT FOR DIRECT SUBSIDIES.—To the extent the Administrator determines it appropriate to avoid risk selection, the payments made for direct subsidies under subsection (a)(1) are subject to adjustment based upon risk factors specified by the Administrator. Any such risk adjustment shall be designed in a manner as to not result in a change in the aggregate payments made under such subsection.

"(e) PAYMENT METHODS.—

"(1) IN GENERAL.—Payments under this section shall be based on such a method as the Administrator determines. The Administrator may establish a payment method by which interim payments of amounts under this section are made during a year based on the Administrator's best estimate of amounts that will be payable after obtaining all of the information.

"(2) SOURCE OF PAYMENTS.—Payments under this section shall be made from the Medicare Prescription Drug Trust Fund.

"(f) RULES RELATING TO QUALIFIED RETIREE PRESCRIPTION DRUG PLAN.—

"(1) DEFINITION.—For purposes of this section, the term 'qualified retiree prescription drug plan' means employment-based retiree health coverage (as defined in paragraph (4)(A)) if, with respect to an individual who is a participant or beneficiary under such coverage and is eligible to be enrolled in a prescription drug plan or a MA-EFFS Rx plan under this part, the following requirements are met:

"(A) ACTUARIAL EQUIVALENCE TO STANDARD COVERAGE.—The Administrator determines (based on an actuarial analysis by the Administrator) that coverage provides at least the same actuarial value as standard coverage. Such determination may be made on an annual basis.

"(B) AUDITS.—The sponsor (and the plan) shall maintain, and afford the Administrator access to, such records as the Administrator may require for purposes of audits and other oversight activities necessary to ensure the adequacy of prescription drug coverage and the accuracy of payments made.

"(C) PROVISION OF CERTIFICATION OF PRESCRIPTION DRUG COVERAGE.—The sponsor of the plan shall provide for issuance of certifications of the type described in section 1860D–1(c)(2)(D).

"(2) LIMITATION ON BENEFIT ELIGIBILITY.—No payment shall be provided under this section with respect to a participant or beneficiary in a qualified retiree prescription drug plan unless the individual is—

"(A) is covered under the plan; and

"(B) is eligible to obtain qualified prescription drug coverage under section 1860D–1 but did not elect such coverage under this part (either through a prescription drug plan or through a MA-EFFS Rx plan).

"(3) EMPLOYER AND UNION SPECIAL SUBSIDY AMOUNTS.—

"(A) IN GENERAL.—For purposes of subsection (a), the special subsidy payment amount under this paragraph for a qualifying covered retiree(as defined in paragraph (6)) for a coverage year (as defined in subsection (h)) enrolled in a qualifying entity described in subsection (b)(3) under a qualified retiree prescription drug plan is, for the portion of the individual's gross covered prescription drug costs for the year that exceeds the deductible amount specified in subparagraph (B), an amount equal to, subject to subparagraph (D), 28 percent of the allowable costs attributable to such gross covered prescription drug costs, but only to the extent such costs exceed the deductible under subparagraph (B) and do not exceed the cost limit under such subparagraph in the case of any such individual for the plan year.

"(B) DEDUCTIBLE AND COST LIMIT APPLICABLE.—Subject to subparagraph (C)—

"(i) the deductible under this subparagraph is equal to $250 for plan years that end in 2006; and

"(ii) the cost limit under this subparagraph is equal to $5,000 for plan years that end in 2006.

"(C) INDEXING.—The deductible and cost limit amounts specified in subparagraphs (B) for a plan year that ends after 2006 shall be adjusted in the same manner as the annual deductible under section 1860D–2(b)(1) is annually adjusted under such section.

"(D) ADJUSTMENT CONTINGENCY.—The Secretary may adjust the percentage specified in subparagraph (A) with respect to plan years that end in a year in a manner so that the aggregate expenditures in the year under this section are the same as the aggregate expenditures that would have been made under this section (taking into account the effect of any adjustment under subsection (d)(1)(B)) if paragraphs (1) and (2) of subsection (a) had applied to qualified prescription drug coverage instead of this paragraph and subsection (a)(3).

"(4) RELATED DEFINITIONS.—As used in this section:

"(A) EMPLOYMENT-BASED RETIREE HEALTH COVERAGE.—The term 'employment-based retiree health coverage' means health insurance or other coverage of health care costs for individuals eligible to enroll in a prescription drug plan or MA-EFFS Rx plan under this part (or for such individuals and their spouses and dependents) under a group health plan (including such a plan that is established or maintained under or pursuant to one or more collective bargaining agreements) based on their status as retired participants in such plan.

"(B) QUALIFYING COVERED RETIREE.—The term 'qualifying covered retiree' means an individual who is eligible to obtain qualified prescription drug coverage under section 1860D–1 but did not elect such coverage under this part (either through a prescription drug plan or through a MA-EFFS Rx plan) but is covered under a qualified retiree prescription drug plan.

"(C) SPONSOR.—The term 'sponsor' means a plan sponsor, as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974, except that, in the case of a single-employer plan (as defined in section 3(41) of such Act), such term means the employer of the plan participants if such employer has been designated as the plan sponsor in all prior summary plan descriptions and annual reports issued with respect to the plan under part 1 of subtitle B of title I of such Act.

"(5) CONSTRUCTION.—Nothing in this subsection shall be construed as—

"(A) precluding an individual who is covered under employment-based retiree health coverage from enrolling in a prescription drug plan or in a MA-EFFS plan;

"(B) precluding such employment-based retiree health coverage or an employer or other person from paying all or any portion of any premium required for coverage under such a prescription drug plan or MA-EFFS plan on behalf of such an individual; or

"(C) preventing such employment-based retiree health coverage from providing coverage for retirees—

"(i) who are covered under a qualified retiree prescription plan that is better than standard coverage; or

"(ii) who are not covered under a qualified retiree prescription plan but who are enrolled in a prescription drug plan or a MA-EFFS Rx plan, that is supplemental to the benefits provided under such prescrip-

tion drug plan or MA-EFFS Rx plan, except that any such supplemental coverage (not including payment of any premium referred to in subparagraph (B)) shall be treated as primary coverage to which section 1862(b)(2)(A)(i) is deemed to apply.

"(g) COMPUTATION OF NATIONAL AVERAGE MONTHLY BID AMOUNT.—

"(1) IN GENERAL.—For each year (beginning with 2006) the Administrator shall compute a national average monthly bid amount equal to the average of the benchmark bid amounts for each prescription drug plan and for each MA-EFFS Rx plan (as computed under paragraph (2), but excluding plans described in section 1851(a)(2)(C))) adjusted under paragraph (4) to take into account reinsurance payments.

"(2) BENCHMARK BID AMOUNT DEFINED.—For purposes of this subsection, the term 'benchmark bid amount' means, with respect to qualified prescription drug coverage offered under—

"(A) a prescription drug plan that—

"(i) provides standard coverage (or alternative prescription drug coverage the actuarial value of which is equivalent to that of standard coverage), the PDP bid; or

"(ii) provides alternative prescription drug coverage the actuarial value of which is greater than that of standard coverage, the PDP bid multiplied by the ratio of (I) the actuarial value of standard coverage, to (II) the actuarial value of the alternative coverage; or

"(B) a MA-EFFS Rx plan, the portion of the bid amount that is attributable to statutory drug benefits (described in section 1853(a)(1)(A)(ii)(II)).

For purposes of subparagraph (A), the term 'PDP bid' means, with respect to a prescription drug plan, the bid amount for enrollment under the plan under this part (determined without regard to any low-income subsidy under section 1860D–7 or any late enrollment penalty under section 1860D–1(c)(2)(B)).

"(3) WEIGHTED AVERAGE.—

"(A) IN GENERAL.—The monthly national average monthly bid amount computed under paragraph (1) shall be a weighted average, with the weight for each plan being equal to the average number of beneficiaries enrolled under such plan in the previous year.

"(B) SPECIAL RULE FOR 2006.—For purposes of applying this subsection for 2006, the Administrator shall establish procedures for determining the weighted average under subparagraph (A) for 2005.

"(4) ADJUSTMENT TO ADD BACK IN VALUE OF REINSURANCE SUBSIDIES.—The adjustment under this paragraph, to take into account reinsurance payments under subsection (c) making up 30 percent of total payments, is such an adjustment as will make the national average monthly bid amount represent represent 100 percent, instead of representing 70 percent, of average payments under this part.

"(h) COVERAGE YEAR DEFINED.—For purposes of this section, the term 'coverage year' means a calendar year in which covered outpatient drugs are dispensed if a claim for payment is made under the plan for such drugs, regardless of when the claim is paid.

"SEC. 1860D–9. MEDICARE PRESCRIPTION DRUG TRUST FUND.

"(a) IN GENERAL.—There is created on the books of the Treasury of the United States a trust fund to be known as the 'Medicare Prescription Drug Trust Fund' (in this section referred to as the 'Trust Fund'). The Trust Fund shall consist of such gifts and bequests as may be made as provided in section 201(i)(1), and such amounts as may be deposited in, or appropriated to, such fund as provided in this part. Except as otherwise provided in this section, the provisions of subsections (b) through (i) of section 1841 shall apply to the Trust Fund in the same manner as they apply to the Federal Supplementary Medical Insurance Trust Fund under such section.

"(b) PAYMENTS FROM TRUST FUND.—

"(1) IN GENERAL.—The Managing Trustee shall pay from time to time from the Trust Fund such amounts as the Administrator certifies are necessary to make—

"(A) payments under section 1860D–7 (relating to low-income subsidy payments);

"(B) payments under section 1860D–8 (relating to subsidy payments); and

"(C) payments with respect to administrative expenses under this part in accordance with section 201(g).

"(2) TRANSFERS TO MEDICAID ACCOUNT FOR INCREASED ADMINISTRATIVE COSTS.—The Managing Trustee shall transfer from time to time from the Trust Fund to the Grants to States for Medicaid account amounts the Administrator

certifies are attributable to increases in payment resulting from the application of a higher Federal matching percentage under section 1935(b).

"(c) DEPOSITS INTO TRUST FUND.—

"(1) LOW-INCOME TRANSFER.—There is hereby transferred to the Trust Fund, from amounts appropriated for Grants to States for Medicaid, amounts equivalent to the aggregate amount of the reductions in payments under section 1903(a)(1) attributable to the application of section 1935(c).

"(2) APPROPRIATIONS TO COVER GOVERNMENT CONTRIBUTIONS.—There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, to the Trust Fund, an amount equivalent to the amount of payments made from the Trust Fund under subsection (b), reduced by the amount transferred to the Trust Fund under paragraph (1).

"(d) RELATION TO SOLVENCY REQUIREMENTS.—Any provision of law that relates to the solvency of the Trust Fund under this part shall take into account the Trust Fund and amounts receivable by, or payable from, the Trust Fund.

"SEC. 1860D–10. DEFINITIONS; APPLICATION TO MEDICARE ADVANTAGE AND EFFS PROGRAMS; TREATMENT OF REFERENCES TO PROVISIONS IN PART C.

"(a) DEFINITIONS.—For purposes of this part:

"(1) COVERED OUTPATIENT DRUGS.—The term 'covered outpatient drugs' is defined in section 1860D–2(f).

"(2) INITIAL COVERAGE LIMIT.—The term 'initial coverage limit' means such limit as established under section 1860D–2(b)(3), or, in the case of coverage that is not standard coverage, the comparable limit (if any) established under the coverage.

"(3) MEDICARE PRESCRIPTION DRUG TRUST FUND.—The term 'Medicare Prescription Drug Trust Fund' means the Trust Fund created under section 1860D–9(a).

"(4) PDP SPONSOR.—The term 'PDP sponsor' means an entity that is certified under this part as meeting the requirements and standards of this part for such a sponsor.

"(5) PRESCRIPTION DRUG PLAN.—The term 'prescription drug plan' means health benefits coverage that—

"(A) is offered under a policy, contract, or plan by a PDP sponsor pursuant to, and in accordance with, a contract between the Administrator and the sponsor under section 1860D–4(b);

"(B) provides qualified prescription drug coverage; and

"(C) meets the applicable requirements of the section 1860D–3 for a prescription drug plan.

"(6) QUALIFIED PRESCRIPTION DRUG COVERAGE.—The term 'qualified prescription drug coverage' is defined in section 1860D–2(a).

"(7) STANDARD COVERAGE.—The term 'standard coverage' is defined in section 1860D–2(b).

"(b) OFFER OF QUALIFIED PRESCRIPTION DRUG COVERAGE UNDER MEDICARE ADVANTAGE AND EFFS PROGRAMS.—

"(1) AS PART OF MEDICARE ADVANTAGE PLAN.—Medicare Advantage organizations are required to offer Medicare Advantage plans that include qualified prescription drug coverage under part C pursuant to section 1851(j).

"(2) AS PART OF EFFS PLAN.—EFFS organizations are required to offer EFFS plans that include qualified prescription drug coverage under part E pursuant to section 1860E–2(d).

"(c) APPLICATION OF PART C PROVISIONS UNDER THIS PART.—For purposes of applying provisions of part C under this part with respect to a prescription drug plan and a PDP sponsor, unless otherwise provided in this part such provisions shall be applied as if—

"(1) any reference to a Medicare Advantage or other plan included a reference to a prescription drug plan;

"(2) any reference to a provider-sponsored organization included a reference to a PDP sponsor;

"(3) any reference to a contract under section 1857 included a reference to a contract under section 1860D–4(b); and

"(4) any reference to part C included a reference to this part.

"(d) REPORT ON PHARMACY SERVICES PROVIDED TO NURSING FACILITY PATIENTS.—

"(1) REVIEW.—Within 6 months after the date of the enactment of this section, the Secretary shall review the current standards of practice for pharmacy services provided to patients in nursing facilities.

"(2) EVALUATIONS AND RECOMMENDATIONS.—Specifically in the review under paragraph (1), the Secretary shall—

"(A) assess the current standards of practice, clinical services, and other service requirements generally utilized for pharmacy services in the long-term care setting;

"(B) evaluate the impact of those standards with respect to patient safety, reduction of medication errors and quality of care; and

"(C) recommend (in the Secretary's report under paragraph (3)) necessary actions and appropriate reimbursement to ensure the provision of prescription drugs to medicare beneficiaries residing in nursing facilities in a manner consistent with existing patient safety and quality of care standards under applicable State and Federal laws.

"(3) REPORT.—The Secretary shall submit a report to the Congress on the Secretary's findings and recommendations under this subsection, including a detailed description of the Secretary's plans to implement this part in a manner consistent with applicable State and Federal laws designed to protect the safety and quality of care of nursing facility patients.".

(b) ADDITIONAL CONFORMING CHANGES.—

(1) CONFORMING REFERENCES TO PREVIOUS PART D.—Any reference in law (in effect before the date of the enactment of this Act) to part D of title XVIII of the Social Security Act is deemed a reference to part F of such title (as in effect after such date).

(2) CONFORMING AMENDMENT PERMITTING WAIVER OF COST-SHARING.—Section 1128B(b)(3) (42 U.S.C. 1320a–7b(b)(3)) is amended—

(A) by striking "and" at the end of subparagraph (E);

(B) by striking the period at the end of subparagraph (F) and inserting "; and"; and

(C) by adding at the end the following new subparagraph:

"(G) the waiver or reduction of any cost-sharing imposed under part D of title XVIII.".

(3) SUBMISSION OF LEGISLATIVE PROPOSAL.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress a legislative proposal providing for such technical and conforming amendments in the law as are required by the provisions of this subtitle.

(c) STUDY ON TRANSITIONING PART B PRESCRIPTION DRUG COVERAGE.—Not later than January 1, 2005, the Medicare Benefits Administrator shall submit a report to Congress that makes recommendations regarding methods for providing benefits under part D of title XVIII of the Social Security Act for outpatient prescription drugs for which benefits are provided under part B of such title.

SEC. 102. OFFERING OF QUALIFIED PRESCRIPTION DRUG COVERAGE UNDER MEDICARE ADVANTAGE AND ENHANCED FEE-FOR-SERVICE (EFFS) PROGRAM.

(a) MEDICARE ADVANTAGE.—Section 1851 (42 U.S.C. 1395w–21) is amended by adding at the end the following new subsection:

"(j) AVAILABILITY OF PRESCRIPTION DRUG BENEFITS AND SUBSIDIES.—

"(1) OFFERING OF QUALIFIED PRESCRIPTION DRUG COVERAGE.—A Medicare Advantage organization on and after January 1, 2006—

"(A) may not offer a Medicare Advantage plan described in section 1851(a)(2)(A) in an area unless either that plan (or another Medicare Advantage plan offered by the organization in that area) includes qualified prescription drug coverage; and

"(B) may not offer the prescription drug coverage (other than that required under parts A and B) to an enrollee under a Medicare Advantage plan, unless such drug coverage is at least qualified prescription drug coverage and unless the requirements of this subsection with respect to such coverage are met.

"(2) REQUIREMENT FOR ELECTION OF PART D COVERAGE TO OBTAIN QUALIFIED PRESCRIPTION DRUG COVERAGE.—For purposes of this part, an individual who has not elected qualified prescription drug coverage under section 1860D–1(b) shall be treated as being ineligible to enroll in a Medicare Advantage plan under this part that offers such coverage.

"(3) COMPLIANCE WITH CERTAIN ADDITIONAL BENEFICIARY PROTECTIONS FOR PRESCRIPTION DRUG COVERAGE.—With respect to the offering of qualified prescription drug coverage by a Medicare Advantage organization under this part on and after January 1, 2006, the organization and plan shall meet the requirements of subsections (a) through (d) of section 1860D–3 in the same manner as they apply to a PDP sponsor and a prescription drug plan under part D and shall submit to the Administrator the information described in section 1860D–6(a)(2). The Administrator shall waive such requirements to the extent the Administrator determines that such requirements duplicate requirements otherwise applicable to the organization or plan under this part.

"(4) AVAILABILITY OF PREMIUM AND COST-SHARING SUBSIDIES.—In the case of low-income individuals who are enrolled in a Medicare Advantage plan that provides qualified prescription drug coverage, premium and cost-sharing subsidies are provided for such coverage under section 1860D–7.

"(5) AVAILABILITY OF DIRECT AND REINSURANCE SUBSIDIES TO REDUCE BIDS AND PREMIUMS.—Medicare Advantage organizations are provided direct and reinsurance subsidy payments for providing qualified prescription drug coverage under this part under section 1860D–8.

"(6) CONSOLIDATION OF DRUG AND NON-DRUG PREMIUMS.—In the case of a Medicare Advantage plan that includes qualified prescription drug coverage, with respect to an enrollee in such plan there shall be a single premium for both drug and non-drug coverage provided under the plan.

"(7) TRANSITION IN INITIAL ENROLLMENT PERIOD.—Notwithstanding any other provision of this part, the annual, coordinated election period under subsection (e)(3)(B) for 2006 shall be the 6-month period beginning with November 2005.

"(8) QUALIFIED PRESCRIPTION DRUG COVERAGE; STANDARD COVERAGE.—For purposes of this part, the terms 'qualified prescription drug coverage' and 'standard coverage' have the meanings given such terms in section 1860D–2.

"(9) SPECIAL RULES FOR PRIVATE FEE-FOR-SERVICE PLANS.— With respect to a Medicare Advantage plan described in section 1851(a)(2)(C) that offers qualified prescription drug coverage—

"(A) REQUIREMENTS REGARDING NEGOTIATED PRICES.—Subsections (a)(1) and (d)(1) of section 1860D–2 shall not be construed to require the plan to negotiate prices or discounts but shall apply to the extent the plan does so.

"(B) MODIFICATION OF PHARMACY PARTICIPATION REQUIREMENT.—If the plan provides access, without charging additional copayments, to all pharmacies without regard to whether they are participating pharmacies in a network, section 1860D-3(c)(1)(A)(iii) shall not apply to the plan.

"(C) DRUG UTILIZATION MANAGEMENT PROGRAM NOT REQUIRED.—The requirements of section 1860D-3(d)(1)(A) shall not apply to the plan.

"(D) NON-PARTICIPATING PHARMACY DISCLOSURE EXCEPTION.—If the plan provides coverage for drugs purchased from all pharmacies, without entering into contracts or agreements with pharmacies to provide drugs to enrollees covered by the plan, section 1860D-3(d)(5) shall not apply to the plan.".

(b) APPLICATION TO EFFS PLANS.—Subsection (d) of section 1860E–2, as added by section 201(a), is amended to read as follows:

"(d) AVAILABILITY OF PRESCRIPTION DRUG BENEFITS AND SUBSIDIES.—

"(1) OFFERING OF QUALIFIED PRESCRIPTION DRUG COVERAGE.—An EFFS organization—

"(A) may not offer an EFFS plan in an area unless either that plan (or another EFFS plan offered by the organization in that area) includes qualified prescription drug coverage; and

"(B) may not offer the prescription drug coverage (other than that required under parts A and B) to an enrollee under an EFFS plan, unless such drug coverage is at least qualified prescription drug coverage and unless the requirements of this subsection with respect to such coverage are met.

"(2) REQUIREMENT FOR ELECTION OF PART D COVERAGE TO OBTAIN QUALIFIED PRESCRIPTION DRUG COVERAGE.—For purposes of this part, an individual who has not elected qualified prescription drug coverage under section 1860D–1(b) shall be treated as being ineligible to enroll in an EFFS plan under this part that offers such coverage.

"(3) COMPLIANCE WITH CERTAIN ADDITIONAL BENEFICIARY PROTECTIONS FOR PRESCRIPTION DRUG COVERAGE.—With respect to the offering of qualified prescription drug coverage by an EFFS organization under this part, the organization and plan shall meet the requirements of subsections (a) through (d) of section 1860D–3 in the same manner as they apply to a PDP sponsor and a prescription drug plan under part D and shall submit to the Administrator the information described in section 1860D–6(a)(2). The Administrator shall waive such requirements to the extent the Administrator determines that such requirements duplicate requirements otherwise applicable to the organization or plan under this part.

"(4) AVAILABILITY OF PREMIUM AND COST-SHARING SUBSIDIES.—In the case of low-income individuals who are enrolled in an EFFS plan that provides qualified prescription drug coverage, premium and cost-sharing subsidies are provided for such coverage under section 1860D–7.

"(5) AVAILABILITY OF DIRECT AND REINSURANCE SUBSIDIES TO REDUCE BIDS AND PREMIUMS.—EFFS organizations are provided direct and reinsurance sub-

sidy payments for providing qualified prescription drug coverage under this part under section 1860D–8.

"(6) CONSOLIDATION OF DRUG AND NON-DRUG PREMIUMS.—In the case of an EFFS plan that includes qualified prescription drug coverage, with respect to an enrollee in such plan there shall be a single premium for both drug and non-drug coverage provided under the plan.

"(7) QUALIFIED PRESCRIPTION DRUG COVERAGE; STANDARD COVERAGE.—For purposes of this part, the terms 'qualified prescription drug coverage' and 'standard coverage' have the meanings given such terms in section 1860D–2.".

(c) CONFORMING AMENDMENTS.—Section 1851 (42 U.S.C. 1395w–21) is amended—

(1) in subsection (a)(1)—

(A) by inserting "(other than qualified prescription drug benefits)" after "benefits";

(B) by striking the period at the end of subparagraph (B) and inserting a comma; and

(C) by adding after and below subparagraph (B) the following:

"and may elect qualified prescription drug coverage in accordance with section 1860D–1."; and

(2) in subsection (g)(1), by inserting "and section 1860D–1(c)(2)(B)" after "in this subsection".

(d) EFFECTIVE DATE.—The amendments made by this section apply to coverage provided on or after January 1, 2006.

SEC. 103. MEDICAID AMENDMENTS.

(a) DETERMINATIONS OF ELIGIBILITY FOR LOW-INCOME SUBSIDIES.—

(1) REQUIREMENT.—Section 1902(a) (42 U.S.C. 1396a(a)) is amended—

(A) by striking "and" at the end of paragraph (64);

(B) by striking the period at the end of paragraph (65) and inserting "; and"; and

(C) by inserting after paragraph (65) the following new paragraph:

"(66) provide for making eligibility determinations under section 1935(a).".

(2) NEW SECTION.—Title XIX is further amended—

(A) by redesignating section 1935 as section 1936; and

(B) by inserting after section 1934 the following new section:

"SPECIAL PROVISIONS RELATING TO MEDICARE PRESCRIPTION DRUG BENEFIT

"SEC. 1935. (a) REQUIREMENT FOR MAKING ELIGIBILITY DETERMINATIONS FOR LOW-INCOME SUBSIDIES.—As a condition of its State plan under this title under section 1902(a)(66) and receipt of any Federal financial assistance under section 1903(a), a State shall—

"(1) make determinations of eligibility for premium and cost-sharing subsidies under (and in accordance with) section 1860D–7;

"(2) inform the Administrator of the Medicare Benefits Administration of such determinations in cases in which such eligibility is established; and

"(3) otherwise provide such Administrator with such information as may be required to carry out part D of title XVIII (including section 1860D–7).

"(b) PAYMENTS FOR ADDITIONAL ADMINISTRATIVE COSTS.—

"(1) IN GENERAL.—The amounts expended by a State in carrying out subsection (a) are, subject to paragraph (2), expenditures reimbursable under the appropriate paragraph of section 1903(a); except that, notwithstanding any other provision of such section, the applicable Federal matching rates with respect to such expenditures under such section shall be increased as follows (but in no case shall the rate as so increased exceed 100 percent):

"(A) For expenditures attributable to costs incurred during 2005, the otherwise applicable Federal matching rate shall be increased by 10 percent of the percentage otherwise payable (but for this subsection) by the State.

"(B)(i) For expenditures attributable to costs incurred during 2006 and each subsequent year through 2013, the otherwise applicable Federal matching rate shall be increased by the applicable percent (as defined in clause (ii)) of the percentage otherwise payable (but for this subsection) by the State.

"(ii) For purposes of clause (i), the 'applicable percent' for—

"(I) 2006 is 20 percent; or

"(II) a subsequent year is the applicable percent under this clause for the previous year increased by 10 percentage points.

"(C) For expenditures attributable to costs incurred after 2013, the otherwise applicable Federal matching rate shall be increased to 100 percent.

"(2) COORDINATION.—The State shall provide the Administrator with such information as may be necessary to properly allocate administrative expenditures

described in paragraph (1) that may otherwise be made for similar eligibility determinations.".

(b) PHASED-IN FEDERAL ASSUMPTION OF MEDICAID RESPONSIBILITY FOR PREMIUM AND COST-SHARING SUBSIDIES FOR DUALLY ELIGIBLE INDIVIDUALS.—

(1) IN GENERAL.—Section 1903(a)(1) (42 U.S.C. 1396b(a)(1)) is amended by inserting before the semicolon the following: ", reduced by the amount computed under section 1935(c)(1) for the State and the quarter".

(2) AMOUNT DESCRIBED.—Section 1935, as inserted by subsection (a)(2), is amended by adding at the end the following new subsection:

"(c) FEDERAL ASSUMPTION OF MEDICAID PRESCRIPTION DRUG COSTS FOR DUALLY-ELIGIBLE BENEFICIARIES.—

"(1) IN GENERAL.—For purposes of section 1903(a)(1), for a State that is one of the 50 States or the District of Columbia for a calendar quarter in a year (beginning with 2005) the amount computed under this subsection is equal to the product of the following:

"(A) MEDICARE SUBSIDIES.—The total amount of payments made in the quarter under section 1860D–7 (relating to premium and cost-sharing prescription drug subsidies for low-income medicare beneficiaries) that are attributable to individuals who are residents of the State and are entitled to benefits with respect to prescribed drugs under the State plan under this title (including such a plan operating under a waiver under section 1115).

"(B) STATE MATCHING RATE.—A proportion computed by subtracting from 100 percent the Federal medical assistance percentage (as defined in section 1905(b)) applicable to the State and the quarter.

"(C) PHASE-OUT PROPORTION.—The phase-out proportion (as defined in paragraph (2)) for the quarter.

"(2) PHASE-OUT PROPORTION.—For purposes of paragraph (1)(C), the 'phase-out proportion' for a calendar quarter in—

"(A) 2006 is 93-⅓ percent;

"(B) a subsequent year before 2021, is the phase-out proportion for calendar quarters in the previous year decreased by 6-⅔ percentage points; or

"(C) a year after 2020 is 0 percent.".

(c) MEDICAID PROVIDING WRAP-AROUND BENEFITS.—Section 1935, as so inserted and amended, is further amended by adding at the end the following new subsection:

"(d) ADDITIONAL PROVISIONS.—

"(1) MEDICAID AS SECONDARY PAYOR.—In the case of an individual who is entitled to qualified prescription drug coverage under a prescription drug plan under part D of title XVIII (or under a MA-EFFS Rx plan under part C or E of such title) and medical assistance for prescribed drugs under this title, medical assistance shall continue to be provided under this title (other than for copayment amounts specified in section 1860D–7(a)(1)(B), notwithstanding section 1916) for prescribed drugs to the extent payment is not made under the prescription drug plan or MA-EFFS Rx plan selected by the individual.

"(2) CONDITION.—A State may require, as a condition for the receipt of medical assistance under this title with respect to prescription drug benefits for an individual eligible to obtain qualified prescription drug coverage described in paragraph (1), that the individual elect qualified prescription drug coverage under section 1860D–1.".

(d) TREATMENT OF TERRITORIES.—

(1) IN GENERAL.—Section 1935, as so inserted and amended, is further amended—

(A) in subsection (a) in the matter preceding paragraph (1), by inserting "subject to subsection (e)" after "section 1903(a)";

(B) in subsection (c)(1), by inserting "subject to subsection (e)" after "1903(a)(1)"; and

(C) by adding at the end the following new subsection:

"(e) TREATMENT OF TERRITORIES.—

"(1) IN GENERAL.—In the case of a State, other than the 50 States and the District of Columbia—

"(A) the previous provisions of this section shall not apply to residents of such State; and

"(B) if the State establishes a plan described in paragraph (2) (for providing medical assistance with respect to the provision of prescription drugs to medicare beneficiaries), the amount otherwise determined under section 1108(f) (as increased under section 1108(g)) for the State shall be increased by the amount specified in paragraph (3).

"(2) PLAN.—The plan described in this paragraph is a plan that—

"(A) provides medical assistance with respect to the provision of covered outpatient drugs (as defined in section 1860D–2(f)) to low-income medicare beneficiaries; and

"(B) assures that additional amounts received by the State that are attributable to the operation of this subsection are used only for such assistance.

"(3) INCREASED AMOUNT.—

"(A) IN GENERAL.—The amount specified in this paragraph for a State for a year is equal to the product of—

"(i) the aggregate amount specified in subparagraph (B); and

"(ii) the amount specified in section 1108(g)(1) for that State, divided by the sum of the amounts specified in such section for all such States.

"(B) AGGREGATE AMOUNT.—The aggregate amount specified in this subparagraph for—

"(i) 2006, is equal to $25,000,000; or

"(ii) a subsequent year, is equal to the aggregate amount specified in this subparagraph for the previous year increased by annual percentage increase specified in section 1860D–2(b)(5) for the year involved.

"(4) REPORT.—The Administrator shall submit to Congress a report on the application of this subsection and may include in the report such recommendations as the Administrator deems appropriate.".

(2) CONFORMING AMENDMENT.—Section 1108(f) (42 U.S.C. 1308(f)) is amended by inserting "and section 1935(e)(1)(B)" after "Subject to subsection (g)".

(e) AMENDMENT TO BEST PRICE.—Section 1927(c)(1)(C)(i) (42 U.S.C. 1396r–8(c)(1)(C)(i)) is amended—

(1) by striking "and" at the end of subclause (III);

(2) by striking the period at the end of subclause (IV) and inserting "; and"; and

(3) by adding at the end the following new subclause:

"(V) any prices charged which are negotiated by a prescription drug plan under part D of title XVIII, by a MA-EFFS Rx plan under part C or E of such title with respect to covered outpatient drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D–8(f)(1)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title.".

SEC. 104. MEDIGAP TRANSITION.

(a) IN GENERAL.—Section 1882 (42 U.S.C. 1395ss) is amended by adding at the end the following new subsection:

"(v) COVERAGE OF PRESCRIPTION DRUGS.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, except as provided in paragraph (3) no new medicare supplemental policy that provides coverage of expenses for prescription drugs may be issued under this section on or after January 1, 2006, to an individual unless it replaces a medicare supplemental policy that was issued to that individual and that provided some coverage of expenses for prescription drugs. Nothing in this subsection shall be construed as preventing the policy holder of a medicare supplemental policy issued before January 1, 2006, from continuing to receive benefits under such policy on and after such date.

"(2) ISSUANCE OF SUBSTITUTE POLICIES FOR BENEFICIARIES ENROLLED WITH A PLAN UNDER PART D.—

"(A) IN GENERAL.—The issuer of a medicare supplemental policy—

"(i) may not deny or condition the issuance or effectiveness of a medicare supplemental policy that has a benefit package classified as 'A', 'B', 'C', 'D', 'E', 'F', or 'G' (under the standards established under subsection (p)(2)) and that is offered and is available for issuance to new enrollees by such issuer;

"(ii) may not discriminate in the pricing of such policy, because of health status, claims experience, receipt of health care, or medical condition; and

"(iii) may not impose an exclusion of benefits based on a pre-existing condition under such policy,

in the case of an individual described in subparagraph (B) who seeks to enroll under the policy not later than 63 days after the date of the termination of enrollment described in such paragraph and who submits evidence of the date of termination or disenrollment along with the application for such medicare supplemental policy.

"(B) INDIVIDUAL COVERED.—An individual described in this subparagraph is an individual who—

"(i) enrolls in a prescription drug plan under part D; and

"(ii) at the time of such enrollment was enrolled and terminates enrollment in a medicare supplemental policy which has a benefit package classified as 'H', 'I', or 'J' under the standards referred to in subparagraph (A)(i) or terminates enrollment in a policy to which such standards do not apply but which provides benefits for prescription drugs.

"(C) ENFORCEMENT.—The provisions of paragraph (4) of subsection (s) shall apply with respect to the requirements of this paragraph in the same manner as they apply to the requirements of such subsection.

"(3) NEW STANDARDS.—In applying subsection (p)(1)(E) (including permitting the NAIC to revise its model regulations in response to changes in law) with respect to the change in benefits resulting from title I of the Medicare Prescription Drug and Modernization Act of 2003, with respect to policies issued to individuals who are enrolled in a plan under part D, the changes in standards shall only provide for substituting (for the benefit packages described in paragraph (2)(B)(ii) that included coverage for prescription drugs) two benefit packages that may provide for coverage of cost-sharing (other than the prescription drug deductible) with respect to qualified prescription drug coverage under such part. The two benefit packages shall be consistent with the following:

"(A) FIRST NEW POLICY.—The policy described in this subparagraph has the following benefits, notwithstanding any other provision of this section relating to a core benefit package:

"(i) Coverage of 50 percent of the cost-sharing otherwise applicable under parts A and B, except coverage of 100 percent of any cost-sharing otherwise applicable for preventive benefits.

"(ii) No coverage of the part B deductible.

"(iii) Coverage for all hospital coinsurance for long stays (as in the current core benefit package).

"(iv) A limitation on annual out-of-pocket expenditures under parts A and B to $4,000 in 2005 (or, in a subsequent year, to such limitation for the previous year increased by an appropriate inflation adjustment specified by the Secretary).

"(B) SECOND NEW POLICY.—The policy described in this subparagraph has the same benefits as the policy described in subparagraph (A), except as follows:

"(i) Substitute '75 percent' for '50 percent' in clause (i) of such subparagraph.

"(ii) Substitute '$2,000' for '$4,000' in clause (iv) of such subparagraph.

"(4) CONSTRUCTION.—Any provision in this section or in a medicare supplemental policy relating to guaranteed renewability of coverage shall be deemed to have been met through the offering of other coverage under this subsection.".

(b) NAIC REPORT TO CONGRESS ON MEDIGAP MODERNIZATION.—The Secretary shall request the National Association of Insurance Commissioners to submit to Congress, not later than 18 months after the date of the enactment of this Act, a report that includes recommendations on the modernization of coverage under the medigap program under section 1882 of the Social Security Act (42 U.S.C. 1395ss).

SEC. 105. MEDICARE PRESCRIPTION DRUG DISCOUNT CARD ENDORSEMENT PROGRAM.

(a) IN GENERAL.—Title XVIII is amended by inserting after section 1806 the following new sections:

"MEDICARE PRESCRIPTION DRUG DISCOUNT CARD ENDORSEMENT PROGRAM

"SEC. 1807. (a) ESTABLISHMENT OF PROGRAM.—

"(1) IN GENERAL.—The Secretary (or the Medicare Benefits Administrator pursuant to section 1809(c)(3)(C)) shall establish a program to endorse prescription drug discount card programs (each such program referred to as an 'endorsed program') that meet the requirements of this section in order to provide access to prescription drug discounts for medicare beneficiaries throughout the United States. The Secretary shall make available to medicare beneficiaries information regarding endorsed programs under this section.

"(2) LIMITED PERIOD OF OPERATION.—The Secretary shall begin the program under this section as soon as possible, but in no case later than 90 days after the date of the enactment of this section. The Secretary shall provide for an appropriate transition and discontinuation of such program at the time medicare prescription drug benefits first become available under part D.

"(b) REQUIREMENTS FOR CARD ENDORSEMENT PROGRAM.—The Secretary may not endorse a prescription drug discount card program under this section unless the program meets the following requirements:

"(1) SAVINGS TO MEDICARE BENEFICIARIES.—The program passes on to medicare beneficiaries who enroll in the program discounts, rebates, and other price concessions on prescription drugs, including discounts negotiated with pharmacies and manufacturers.

"(2) PROHIBITION ON APPLICATION ONLY TO MAIL ORDER.—The program applies to drugs that are available other than solely through mail order.

"(3) BENEFICIARY SERVICES.—The program provides pharmaceutical support services, such as education and counseling, and services to prevent adverse drug interactions.

"(4) INFORMATION.—The program makes available to medicare beneficiaries through the Internet and otherwise information, including information on enrollment fees, prices charged to beneficiaries, and services offered under the program, that the Secretary identifies as being necessary to provide for informed choice by beneficiaries among endorsed programs.

"(5) DEMONSTRATED EXPERIENCE.—The program is operated directly, or through arrangements with affiliated organization, by an entity that has demonstrated experience and expertise in operating such a program or a similar program.

"(6) QUALITY ASSURANCE.—Such operating entity has in place adequate procedures for assuring quality service under the program.

"(7) ENROLLMENT FEES.—The program may charge an annual enrollment fee, but the amount of such annual fee may not exceed $30. A State may pay some or all of the fee for individuals residing in the State.

"(8) CONFIDENTIALITY PROTECTIONS.—The program implements policies and procedures to safeguard the use and disclosure of program beneficiaries' individually identifiable health information in a manner consistent with the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

"(9) PERIODIC REPORTS TO SECRETARY.—The entity operating the program shall submit to the Secretary periodic reports on performance, utilization, finances, and such other matters as the Secretary may specify.

"(10) ADDITIONAL BENEFICIARY PROTECTIONS.—The program meets such additional requirements as the Secretary identifies to protect and promote the interest of medicare beneficiaries, including requirements that ensure that beneficiaries are not charged more than the lower of the negotiated retail price or the usual and customary price.

The prices negotiated by a prescription drug discount card program endorsed under this section shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).

"(c) PROGRAM OPERATION.—The Secretary shall operate the program under this section consistent with the following:

"(1) PROMOTION OF INFORMED CHOICE.—In order to promote informed choice among endorsed prescription drug discount card programs, the Secretary shall provide for the dissemination of information which compares the prices and services of such programs in a manner coordinated with the dissemination of educational information on Medicare Advantage plans under part C.

"(2) OVERSIGHT.—The Secretary shall provide appropriate oversight to ensure compliance of endorsed programs with the requirements of this section, including verification and disclosure (upon request) of the discounts and services provided, the amount of dispensing fees recognized, and audits under section 1860D–2(d)(3).

"(3) USE OF MEDICARE TOLL-FREE NUMBER.—The Secretary shall provide through the 1-800-medicare toll free telephone number for the receipt and response to inquiries and complaints concerning the program and programs endorsed under this section.

"(4) SANCTIONS FOR ABUSIVE PRACTICES.—The Secretary may implement intermediate sanctions or may revoke the endorsement of a program in the case of a program that the Secretary determines no longer meets the requirements of this section or that has engaged in false or misleading marketing practices.

"(5) ENROLLMENT PRACTICES.—A medicare beneficiary may not be enrolled in more than one endorsed program at any time. A medicare beneficiary may change the endorsed program in which the beneficiary is enrolled, but may not make such change until the beneficiary has been enrolled in a program for a minimum period of time specified by the Secretary.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

"(e) INTERIM, FINAL REGULATORY AUTHORITY.—In order to carry out this section in a timely manner, the Secretary may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment.

"TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE PROGRAM FOR LOW-INCOME BENEFICIARIES

"SEC. 1807A. (a) PURPOSE.—The purpose of this section is to provide low-income medicare beneficiaries with incomes below 150 percent of the Federal poverty level immediate assistance in the purchase of covered outpatient prescription drugs during the period before the program under part D becomes effective.

"(b) APPROPRIATIONS.—For the purpose of carrying out this section, there is appropriated, out of any money in the Treasury not otherwise appropriated—

"(1) for fiscal year 2004, $2,000,000,000; and

"(2) for fiscal year 2005, $3,000,000,000.

"(c) ELIGIBILITY.—

"(1) IN GENERAL.—The Secretary shall establish eligibility standards consistent with this subsection.

"(2) SPECIFICS.—In no case shall an individual be eligible for assistance under this section unless the individual—

"(A) is entitled to benefits under part A or enrolled under part B;

"(B) has income that is at or below 150 percent of the Federal poverty line;

"(C) meets the resources requirement described in section 1905(p)(1)(C);

"(D) is enrolled under a prescription drug discount card program under section 1807 (or under an alternative program authorized under subsection (d)(2)); and

"(E) is not eligible for coverage of, or assistance for, outpatient prescription drugs under any of the following:

"(i) A medicaid plan under title XIX (including under any waiver approved under section 1115).

"(ii) Enrollment under a group health plan or health insurance coverage.

"(iii) Enrollment under a medicare supplemental insurance policy.

"(iv) Chapter 55 of title 10, United States Code (relating to medical and dental care for members of the uniformed services).

"(v) Chapter 17 of title 38, United States Code (relating to Veterans' medical care).

"(vi) Enrollment under a plan under chapter 89 of title 5, United States Code (relating to the Federal employees' health benefits program).

"(vii) The Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.).

"(d) FORM OF ASSISTANCE.—

"(1) IN GENERAL.—Subject to paragraph (2), the assistance under this section to an eligible individual shall be in such form as the Secretary shall specify, including the use of a debit card mechanism to pay for drugs purchased through the use of the prescription drug discount card program to eligible individuals who are enrolled in such program.

"(2) THROUGH ALTERNATIVE STATE PROGRAM.—A State may apply to the Secretary for authorization to provide the assistance under this section to an eligible individual through a State pharmaceutical assistance program or private program of pharmaceutical assistance. The Secretary shall not authorize the use of such a program unless the Secretary finds that the program—

"(A) was in existence before the date of the enactment of this section; and

"(B) is reasonably designed to provide for pharmaceutical assistance for a number of individuals, and in a scope, that is not less than the number of individuals, and minimum required amount, that would occur if the provisions of this paragraph had not applied in the State.

"(3) RELATIONSHIP TO DISCOUNTS.—The assistance provided under this section is in addition to the discount otherwise available to individuals enrolled in prescription drug discount card programs who are not eligible individuals.

"(4) LIMITATION ON ASSISTANCE.—

"(A) IN GENERAL.—The assistance under this section for an eligible individual shall be limited to assistance—

"(i) for covered outpatient drugs (as defined for purposes of part D) and for enrollment fees imposed under prescription drug discount card programs; and

"(ii) for expenses incurred—

"(I) on and after the date the individual is both enrolled in the prescription drug discount card program and determined to be an eligible individual under this section; and

"(II) before the date benefits are first available under the program under part D.

"(B) AUTHORITY.—The Secretary shall take such steps as may be necessary to assure compliance with the expenditure limitations described in subsection (b).

"(e) PAYMENT OF FEDERAL SUBSIDY TO SPONSORS.—

"(1) IN GENERAL.—Insofar as assistance is provided under this section through programs under section 1807, the Secretary shall make payment (within the amounts under subsection (b), less the administrative costs relating to determinations of eligibility) to the sponsor of the prescription drug discount card program (or to a State or other entity operating an alternative program under subsection (d)(2)) in which an eligible individual is enrolled of the amount of the assistance provided by the sponsor pursuant to this section.

"(2) PERIODIC PAYMENTS.—Payments under this subsection shall be made on a monthly or other periodic installment basis, based upon estimates of the Secretary and shall be reduced or increased to the extent of any overpayment or underpayment which the Secretary determines was made under this section for any prior period and with respect to which adjustment has not already been made under this paragraph.

"(f) DEFINITIONS.—For purposes of this section:

"(1) ELIGIBLE INDIVIDUAL.—The term 'eligible individual' means an individual who is determined by a State to be eligible for assistance under this section.

"(2) PRESCRIPTION DRUG DISCOUNT CARD PROGRAM.—The term 'prescription drug discount card program' means such a program that is endorsed under section 1807.

"(3) SPONSOR.—The term 'sponsor' means the sponsor of a prescription drug discount card program, or, in the case of an alternative program authorized under subsection (d)(2), the State or other entity operating the program.".

(b) CONFORMING AMENDMENT.—Section 1927(c)(1)(C)(i)(V) (42 U.S.C. 1396r–8(c)(1)(C)(i)(V)), as added by section 103(e), is amended by striking "or by a qualified retiree prescription drug plan (as defined in section 1860D–8(f)(1))" and inserting "by a qualified retiree prescription drug plan (as defined in section 1860D–8(f)(1)), or by a prescription drug discount card program endorsed under section 1807".

SEC. 106. DISCLOSURE OF RETURN INFORMATION FOR PURPOSES OF CARRYING OUT MEDICARE CATASTROPHIC PRESCRIPTION DRUG PROGRAM.

(a) IN GENERAL.—Subsection (l) of section 6103 of the Internal Revenue Code of 1986 (relating to disclosure of returns and return information for purposes other than tax administration) is amended by adding at the end the following new paragraph:

"(19) DISCLOSURE OF RETURN INFORMATION FOR PURPOSES OF CARRYING OUT MEDICARE CATASTROPHIC PRESCRIPTION DRUG PROGRAM.—

"(A) IN GENERAL.—The Secretary may, upon written request from the Secretary of Health and Human Services under section 1860D–2(b)(4)(E)(i) of the Social Security Act, disclose to officers and employees of the Department of Health and Human Services with respect to a specified taxpayer for the taxable year specified by the Secretary of Health and Human Services in such request—

"(i) the taxpayer identity information with respect to such taxpayer, and

"(ii) the adjusted gross income of such taxpayer for the taxable year (or, if less, the income threshold limit specified in section 1860D–2(b)(4)(D)(ii) for the calendar year specified by such Secretary in such request).

"(B) SPECIFIED TAXPAYER.—For purposes of this paragraph, the term 'specified taxpayer' means any taxpayer who—

"(i) is identified by the Secretary of Health and Human Services in the request referred to in subparagraph (A), and

"(ii) either—

"(I) has an adjusted gross income for the taxable year referred to in subparagraph (A) in excess of the income threshold specified in section 1860D–2(b)(4)(D)(ii) of such Act for the calendar year referred to in such subparagraph, or

"(II) is identified by such Secretary under subparagraph (A) as being an individual who elected to use more recent information under section 1860D–2(b)(4)(D)(v) of such Act.

"(C) JOINT RETURNS.—In the case of a joint return, the Secretary shall, for purposes of applying this paragraph, treat each spouse as a separate taxpayer having an adjusted gross income equal to one-half of the adjusted gross income determined with respect to such return.

"(D) RESTRICTION ON USE OF DISCLOSED INFORMATION.—Return information disclosed under subparagraph (A) may be used by officers and employees of the Department of Health and Human Services only for the purpose of administering the prescription drug benefit under title XVIII of the Social Security Act. Such officers and employees may disclose the annual out-of-pocket threshold which applies to an individual under such part to the entity that offers the plan referred to in section 1860D–2(b)(4)(E)(ii) of such Act in which such individual is enrolled. Such sponsor may use such information only for purposes of administering such benefit.".

(b) CONFIDENTIALITY.—Paragraph (3) of section 6103(a) of such Code is amended by striking "or (16)" and inserting "(16), or (19)".

(c) PROCEDURES AND RECORDKEEPING RELATED TO DISCLOSURES.—Subsection (p)(4) of section 6103 of such Code is amended by striking "any other person described in subsection (l)(16) or (17)" each place it appears and inserting "any other person described in subsection (l)(16), (17), or (19)".

(d) UNAUTHORIZED DISCLOSURE.—Paragraph (2) of section 7213(a) of such Code is amended by striking "or (16)" and inserting "(16), or (19)".

(e) UNAUTHORIZED INSPECTION.—Subparagraph (B) of section 7213A(a)(1) of such Code is amended by inserting "or (19)" after "subsection (l)(18)".

SEC. 107. STATE PHARMACEUTICAL ASSISTANCE TRANSITION COMMISSION.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—There is established, as of the first day of the third month beginning after the date of the enactment of this Act, a State Pharmaceutical Assistance Transition Commission (in this section referred to as the "Commission") to develop a proposal for addressing the unique transitional issues facing State pharmaceutical assistance programs, and program participants, due to the implementation of the medicare prescription drug program under part D of title XVIII of the Social Security Act.

(2) DEFINITIONS.—For purposes of this section:

(A) STATE PHARMACEUTICAL ASSISTANCE PROGRAM DEFINED.—The term "State pharmaceutical assistance program" means a program (other than the medicaid program) operated by a State (or under contract with a State) that provides as of the date of the enactment of this Act assistance to low-income medicare beneficiaries for the purchase of prescription drugs.

(B) PROGRAM PARTICIPANT.—The term "program participant" means a low-income medicare beneficiary who is a participant in a State pharmaceutical assistance program.

(b) COMPOSITION.—The Commission shall include the following:

(1) A representative of each governor of each State that the Secretary identifies as operating on a statewide basis a State pharmaceutical assistance program that provides for eligibility and benefits that are comparable or more generous than the low-income assistance eligibility and benefits offered under part D of title XVIII of the Social Security Act.

(2) Representatives from other States that the Secretary identifies have in operation other State pharmaceutical assistance programs, as appointed by the Secretary.

(3) Representatives of organizations that have an inherent interest in program participants or the program itself, as appointed by the Secretary but not to exceed the number of representatives under paragraphs (1) and (2).

(4) Representatives of Medicare Advantage organizations and other private health insurance plans, as appointed by the Secretary.

(5) The Secretary (or the Secretary's designee) and such other members as the Secretary may specify

The Secretary shall designate a member to serve as chair of the Commission and the Commission shall meet at the call of the chair.

(c) DEVELOPMENT OF PROPOSAL.—The Commission shall develop the proposal described in subsection (a) in a manner consistent with the following principles:

(1) Protection of the interests of program participants in a manner that is the least disruptive to such participants and that includes a single point of contact for enrollment and processing of benefits.

(2) Protection of the financial and flexibility interests of States so that States are not financially worse off as a result of the enactment of this title.

(3) Principles of medicare modernization provided under title II of this Act.

(d) REPORT.—By not later than January 1, 2005, the Commission shall submit to the President and the Congress a report that contains a detailed proposal (including specific legislative or administrative recommendations, if any) and such other recommendations as the Commission deems appropriate.

(e) SUPPORT.—The Secretary shall provide the Commission with the administrative support services necessary for the Commission to carry out its responsibilities under this section.

(f) TERMINATION.—The Commission shall terminate 30 days after the date of submission of the report under subsection (d).

TITLE II—MEDICARE ENHANCED FEE-FOR-SERVICE AND MEDICARE ADVANTAGE PROGRAMS; MEDICARE COMPETITION

SEC. 200. MEDICARE MODERNIZATION AND REVITALIZATION.

This title provides for—

(1) establishment of the medicare enhanced fee-for-service (EFFS) program under which medicare beneficiaries are provided access to a range of enhanced fee-for-service (EFFS) plans that may use preferred provider networks to offer an enhanced range of benefits;

(2) establishment of a Medicare Advantage program that offers improved managed care plans with coordinated care; and

(3) competitive bidding, in the style of the Federal Employees Health Benefits program (FEHBP), among enhanced fee-for-service plans and Medicare Advantage plans in order to promote greater efficiency and responsiveness to medicare beneficiaries.

Subtitle A—Medicare Enhanced Fee-for-Service Program

SEC. 201. ESTABLISHMENT OF ENHANCED FEE-FOR-SERVICE (EFFS) PROGRAM UNDER MEDICARE.

(a) IN GENERAL.—Title XVIII, as amended by section 101(a), is amended—

(1) by redesignating part E as part F; and

(2) by inserting after part D the following new part:

"PART E—ENHANCED FEE-FOR-SERVICE PROGRAM

"OFFERING OF ENHANCED FEE-FOR-SERVICE PLANS THROUGHOUT THE UNITED STATES

"SEC. 1860E–1. (a) ESTABLISHMENT OF PROGRAM.—

"(1) IN GENERAL.—The Administrator shall establish under this part beginning January 1, 2006, an enhanced fee-for-service program under which enhanced fee-for-service plans (as defined in subsection (b)) are offered to EFFS-eligible individuals (as so defined) in EFFS regions throughout the United States.

"(2) EFFS REGIONS.—For purposes of this part the Administrator shall establish EFFS regions throughout the United States by dividing the entire United States into at least 10 such regions. Before establishing such regions, the Administrator shall conduct a market survey and analysis, including an examination of current insurance markets, to determine how the regions should be established. The regions shall be established in a manner to take into consideration maximizing full access for all EFFS-eligible individuals, especially those residing in rural areas.

"(b) DEFINITIONS.—For purposes of this part:

"(1) EFFS ORGANIZATION.—The 'EFFS organization' means an entity that the Administrator certifies as meeting the requirements and standards applicable to such organization under this part.

"(2) ENHANCED FEE-FOR-SERVICE PLAN; EFFS PLAN.—The terms 'enhanced fee-for-service plan' and 'EFFS plan' mean health benefits coverage offered under a policy, contract, or plan by an EFFS organization pursuant to and in accordance with a contract pursuant to section 1860E–4(c), but only if the plan provides either fee-for-service coverage described in the following subparagraph (A) or preferred provider coverage described in the following subparagraph (B):

"(A) FEE-FOR-SERVICE COVERAGE.—The plan—

"(i) reimburses hospitals, physicians, and other providers at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk;

"(ii) does not vary such rates for such a provider based on utilization relating to such provider; and

"(iii) does not restrict the selection of providers among those who are lawfully authorized to provide the covered services and agree to accept the terms and conditions of payment established by the plan.

"(B) PREFERRED PROVIDER COVERAGE.—The plan—

"(i) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; and

"(ii) provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers.

"(3) EFFS ELIGIBLE INDIVIDUAL.—The term 'EFFS eligible individual' means an eligible individual described in section 1851(a)(3).

"(4) EFFS REGION.—The term 'EFFS region' means a region established under subsection (a)(2).

"(c) APPLICATION OF CERTAIN ELIGIBILITY, ENROLLMENT, ETC. REQUIREMENTS.—The provisions of section 1851 (other than subsection (h)(4)(A)) shall apply to EFFS plans offered by an EFFS organization in an EFFS region, including subsection (g) (relating to guaranteed issue and renewal).

"OFFERING OF ENHANCED FEE-FOR-SERVICE (EFFS) PLANS

"SEC. 1860E–2. (a) PLAN REQUIREMENTS.—No EFFS plan may be offered under this part in an EFFS region unless the requirements of this part are met with respect to the plan and EFFS organization offering the plan.

"(b) AVAILABLE TO ALL EFFS BENEFICIARIES IN THE ENTIRE REGION.—With respect to an EFFS plan offered in an EFFS region—

"(1) IN GENERAL.—The plan must be offered to all EFFS-eligible individuals residing in the region.

"(2) ASSURING ACCESS TO SERVICES.—The plan shall comply with the requirements of section 1852(d)(4).

"(c) BENEFITS.—

"(1) IN GENERAL.—Each EFFS plan shall provide to members enrolled in the plan under this part benefits, through providers and other persons that meet the applicable requirements of this title and part A of title XI—

"(A) for the items and services described in section 1852(a)(1);

"(B) that are uniform for the plan for all EFFS eligible individuals residing in the same EFFS region;

"(C) that include a single deductible applicable to benefits under parts A and B and include a catastrophic limit on out-of-pocket expenditures for such covered benefits; and

"(D) that include benefits for prescription drug coverage for each enrollee who elects under part D to be provided qualified prescription drug coverage through the plan.

"(2) DISAPPROVAL AUTHORITY.—The Administrator shall not approve a plan of an EFFS organization if the Administrator determines (pursuant to the last sentence of section 1852(b)(1)(A)) that the benefits are designed to substantially discourage enrollment by certain EFFS eligible individuals with the organization.

"(d) OUTPATIENT PRESCRIPTION DRUG COVERAGE.—For rules concerning the offering of prescription drug coverage under EFFS plans, see the amendment made by section 102(b) of the Medicare Prescription Drug and Modernization Act of 2003.

"(e) OTHER ADDITIONAL PROVISIONS.—The provisions of section 1852 (other than subsection (a)(1)) shall apply under this part to EFFS plans. For the application of chronic care improvement provisions, see the amendment made by section 722(b).

"SUBMISSION OF BIDS; BENEFICIARY SAVINGS; PAYMENT OF PLANS

"SEC. 1860E–3. (a) SUBMISSION OF BIDS.—

"(1) REQUIREMENT.—

"(A) EFFS MONTHLY BID AMOUNT.—For each year (beginning with 2006), an EFFS organization shall submit to the Administrator an EFFS monthly bid amount for each EFFS plan offered in each region. Each such bid is referred to in this section as the 'EFFS monthly bid amount'.

"(B) FORM.—Such bid amounts shall be submitted for each such plan and region in a form and manner and time specified by the Administrator, and shall include information described in paragraph (3)(A).

"(2) UNIFORM BID AMOUNTS.—Each EFFS monthly bid amount submitted under paragraph (1) by an EFFS organization under this part for an EFFS plan in an EFFS region may not vary among EFFS eligible individuals residing in the EFFS region involved.

"(3) SUBMISSION OF BID AMOUNT INFORMATION BY EFFS ORGANIZATIONS.—

"(A) INFORMATION TO BE SUBMITTED.—The information described in this subparagraph is as follows:

"(i) The EFFS monthly bid amount for provision of all items and services under this part, which amount shall be based on average costs for a typical beneficiary residing in the region, and the actuarial basis for determining such amount.

"(ii) The proportions of such bid amount that are attributable to—

"(I) the provision of statutory non-drug benefits (such portion referred to in this part as the 'unadjusted EFFS statutory non-drug monthly bid amount');

"(II) the provision of statutory prescription drug benefits; and

"(III) the provision of non-statutory benefits;

and the actuarial basis for determining such proportions.

"(iii) Such additional information as the Administrator may require to verify the actuarial bases described in clauses (i) and (ii).

"(B) STATUTORY BENEFITS DEFINED.—For purposes of this part:

"(i) The term 'statutory non-drug benefits' means benefits under section 1852(a)(1).

"(ii) The term 'statutory prescription drug benefits' means benefits under part D.

"(iii) The term 'statutory benefits' means statutory prescription drug benefits and statutory non-drug benefits.

"(C) ACCEPTANCE AND NEGOTIATION OF BID AMOUNTS.—The Administrator has the authority to negotiate regarding monthly bid amounts submitted under subparagraph (A) (and the proportion described in subparagraph (A)(ii)), and for such purpose, the Administrator has negotiation authority that the Director of the Office of Personnel Management has with respect to health benefits plans under chapter 89 of title 5, United States Code. The Administrator may reject such a bid amount or proportion if the Administrator determines that such amount or proportion is not supported by the actuarial bases provided under subparagraph (A).

"(D) CONTRACT AUTHORITY.—The Administrator may, taking into account the unadjusted EFFS statutory non-drug monthly bid amounts accepted under subparagraph (C), enter into contracts for the offering of up to 3 EFFS plans in any region.

"(b) PROVISION OF BENEFICIARY SAVINGS FOR CERTAIN PLANS.—

"(1) BENEFICIARY REBATE RULE.—

"(A) REQUIREMENT.—The EFFS plan shall provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings (if any) described in paragraph (2) applicable to the plan and year involved.

"(B) FORM OF REBATE.—A rebate required under this paragraph shall be provided—

"(i) through the crediting of the amount of the rebate towards the EFFS monthly prescription drug beneficiary premium (as defined in section 1860E–4(a)(3)(B)) and the EFFS monthly supplemental beneficiary premium (as defined in section 1860E–4(a)(3)(C));

"(ii) through a direct monthly payment (through electronic funds transfer or otherwise); or

"(iii) through other means approved by the Medicare Benefits Administrator,

or any combination thereof.

"(2) COMPUTATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—For purposes of paragraph (1)(A), the average per capita monthly savings referred to in such paragraph for an EFFS plan and year is computed as follows:

"(A) DETERMINATION OF REGION-WIDE AVERAGE RISK ADJUSTMENT.—

"(i) IN GENERAL.—The Medicare Benefits Administrator shall determine, at the same time rates are promulgated under section 1853(b)(1) (beginning with 2006), for each EFFS region the average of the risk adjustment factors described in subsection (c)(3) to be applied to enrollees under this part in that region. In the case of an EFFS region in which an EFFS plan was offered in the previous year, the Administrator may compute such average based upon risk adjustment factors applied under subsection (c)(3) in that region in a previous year.

"(ii) TREATMENT OF NEW REGIONS.—In the case of a region in which no EFFS plan was offered in the previous year, the Administrator shall estimate such average. In making such estimate, the Administrator may use average risk adjustment factors applied to comparable EFFS regions or applied on a national basis.

"(B) DETERMINATION OF RISK ADJUSTED BENCHMARK AND RISK-ADJUSTED BID.—For each EFFS plan offered in an EFFS region, the Administrator shall—

"(i) adjust the EFFS region-specific non-drug monthly benchmark amount (as defined in paragraph (3)) by the applicable average risk adjustment factor computed under subparagraph (A); and

"(ii) adjust the unadjusted EFFS statutory non-drug monthly bid amount by such applicable average risk adjustment factor.

"(C) DETERMINATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—The average per capita monthly savings described in this subparagraph is equal to the amount (if any) by which—

"(i) the risk-adjusted benchmark amount computed under subparagraph (B)(i), exceeds

"(ii) the risk-adjusted bid computed under subparagraph (B)(ii).

"(3) COMPUTATION OF EFFS REGION-SPECIFIC NON-DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of this part, the term 'EFFS region-specific non-drug monthly benchmark amount' means, with respect to an EFFS region for a month in a year, an amount equal to 1/12 of the average (weighted by number of EFFS eligible individuals in each payment area described in section 1853(d)) of the annual capitation rate as calculated under section 1853(c)(1) for that area.

"(c) PAYMENT OF PLANS BASED ON BID AMOUNTS.—

"(1) NON-DRUG BENEFITS.—Under a contract under section 1860E–4(c) and subject to section 1853(g) (as made applicable under subsection (d)), the Administrator shall make monthly payments under this subsection in advance to each EFFS organization, with respect to coverage of an individual under this part in an EFFS region for a month, in an amount determined as follows:

"(A) PLANS WITH BIDS BELOW BENCHMARK.—In the case of a plan for which there are average per capita monthly savings described in subsection (b)(2)(C), the payment under this subsection is equal to the unadjusted EFFS statutory non-drug monthly bid amount, adjusted under paragraphs (3) and (4), plus the amount of the monthly rebate computed under subsection (b)(1)(A) for that plan and year.

"(B) PLANS WITH BIDS AT OR ABOVE BENCHMARK.—In the case of a plan for which there are no average per capita monthly savings described in subsection (b)(2)(C), the payment amount under this subsection is equal to the EFFS region-specific non-drug monthly benchmark amount, adjusted under paragraphs (3) and (4).

"(2) FOR FEDERAL DRUG SUBSIDIES.—In the case in which an enrollee who elects under part D to be provided qualified prescription drug coverage through the plan, the EFFS organization offering such plan also is entitled—

"(A) to direct subsidy payment under section 1860D–8(a)(1);

"(B) to reinsurance subsidy payments under section 1860D–8(a)(2); and

"(C) to reimbursement for premium and cost-sharing reductions for low-income individuals under section 1860D–7(c)(3).

"(3) DEMOGRAPHIC RISK ADJUSTMENT, INCLUDING ADJUSTMENT FOR HEALTH STATUS.—The Administrator shall adjust under paragraph (1)(A) the unadjusted EFFS statutory non-drug monthly bid amount and under paragraph (1)(B) the EFFS region-specific non-drug monthly benchmark amount for such risk factors as age, disability status, gender, institutional status, and such other factors as the Administrator determines to be appropriate, including adjustment for health status under section 1853(a)(3) (as applied under subsection (d)), so as to ensure actuarial equivalence. The Administrator may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.

"(4) ADJUSTMENT FOR INTRA-REGIONAL GEOGRAPHIC VARIATIONS.—The Administrator shall also adjust such amounts in a manner to take into account variations in payments rates under part C among the different payment areas under such part included in each EFFS region.

"(d) APPLICATION OF ADDITIONAL PAYMENT RULES.—The provisions of section 1853 (other than subsections (a)(1)(A), (d), and (e)) shall apply to an EFFS plan under this part, except as otherwise provided in this section.

"PREMIUMS; ORGANIZATIONAL AND FINANCIAL REQUIREMENTS; ESTABLISHMENT OF STANDARDS; CONTRACTS WITH EFFS ORGANIZATIONS

"SEC. 1860E–4. (a) PREMIUMS.—

"(1) IN GENERAL.—The provisions of section 1854 (other than subsections (a)(6)(C) and (h)), including subsection (b)(5) relating to the consolidation of drug and non-drug beneficiary premiums and subsection (c) relating to uniform bids and premiums, shall apply to an EFFS plan under this part, subject to paragraph (2).

"(2) CROSS-WALK.—In applying paragraph (1), any reference in section 1854(b)(1)(A) or 1854(d) to—

"(A) a Medicare Advantage monthly basic beneficiary premium is deemed a reference to the EFFS monthly basic beneficiary premium (as defined in paragraph (3)(A));

"(B) a Medicare Advantage monthly prescription drug beneficiary premium is deemed a reference to the EFFS monthly prescription drug beneficiary premium (as defined in paragraph (3)(B)); and

"(C) a Medicare Advantage monthly supplemental beneficiary premium is deemed a reference to the EFFS monthly supplemental beneficiary premium (as defined in paragraph (3)(C)).

"(3) DEFINITIONS.—For purposes of this part:

"(A) EFFS MONTHLY BASIC BENEFICIARY PREMIUM.—The term 'EFFS monthly basic beneficiary premium' means, with respect to an EFFS plan—

"(i) described in section 1860E–3(c)(1)(A) (relating to plans providing rebates), zero; or

"(ii) described in section 1860E–3(c)(1)(B), the amount (if any) by which the unadjusted EFFS statutory non-drug monthly bid amount exceeds the EFFS region-specific non-drug monthly benchmark amount (as defined in section 1860E–3(b)(3)).

"(B) EFFS MONTHLY PRESCRIPTION DRUG BENEFICIARY PREMIUM.—The term 'EFFS monthly prescription drug beneficiary premium' means, with respect to an EFFS plan, the portion of the aggregate monthly bid amount submitted under clause (i) of section 1860E–3(a)(3)(A) for the year that is attributable under such section to the provision of statutory prescription drug benefits.

"(C) EFFS MONTHLY SUPPLEMENTAL BENEFICIARY PREMIUM.—The term 'EFFS monthly supplemental beneficiary premium' means, with respect to an EFFS plan, the portion of the aggregate monthly bid amount submitted under clause (i) of section 1860E–3(a)(3)(A) for the year that is attributable under such section to the provision of nonstatutory benefits.

"(b) ORGANIZATIONAL AND FINANCIAL REQUIREMENTS.—The provisions of section 1855 shall apply to an EFFS plan offered by an EFFS organization under this part.

"(c) CONTRACTS WITH EFFS ORGANIZATIONS.—The provisions of section 1857 shall apply to an EFFS plan offered by an EFFS organization under this part, except that any reference in such section to part C is deemed a reference to this part.".

(b) PROHIBITION ON COVERAGE UNDER MEDIGAP PLANS OF DEDUCTIBLE IMPOSED UNDER EFFS PLANS.—Section 1882 (42 U.S.C. 1395ss), as amended by section 104(a), is amended by adding at the end the following new subsection:

"(w) PROHIBITION ON COVERAGE OF DEDUCTIBLE AND CERTAIN COST-SHARING IMPOSED UNDER EFFS PLANS.—Notwithstanding any other provision of law, no medicare supplemental policy (other than the 2 benefit packages described in subsection (v)(3)) may provide for coverage of the single deductible or more than 50 percent of other cost-sharing imposed under an EFFS plan under part E.".

(c) CONFORMING PROVISIONS.—Section 1882 of the Social Security Act (42 U.S.C. 1395ss) shall be administered as if any reference to a Medicare+Choice organization offering a Medicare+Choice plan under part C of title XVIII of such Act were a reference both to a Medicare Advantage organization offering a Medicare Advantage plan under such part and an EFFS organization offering an EFFS plan under part E of such title.

Subtitle B—Medicare Advantage Program

CHAPTER 1—IMPLEMENTATION OF PROGRAM

SEC. 211. IMPLEMENTATION OF MEDICARE ADVANTAGE PROGRAM.

(a) IN GENERAL.—There is hereby established the Medicare Advantage program. The Medicare Advantage program shall consist of the program under part C of title XVIII of the Social Security Act, as amended by this title.

(b) REFERENCES.—Any reference to the program under part C of title XVIII of the Social Security Act shall be deemed a reference to the Medicare Advantage program and, with respect to such part, any reference to "Medicare+Choice" is deemed a reference to "Medicare Advantage".

SEC. 212. MEDICARE ADVANTAGE IMPROVEMENTS.

(a) EQUALIZING PAYMENTS WITH FEE-FOR-SERVICE.—

(1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C. 1395w–23(c)(1)) is amended by adding at the end the following:

"(D) BASED ON 100 PERCENT OF FEE-FOR-SERVICE COSTS.—

"(i) IN GENERAL.—For 2004, the adjusted average per capita cost for the year involved, determined under section 1876(a)(4) for the Medicare Advantage payment area for services covered under parts A and B for individuals entitled to benefits under part A and enrolled under part B who are not enrolled in a Medicare Advantage under this part for the year, but adjusted to exclude costs attributable to payments under section 1886(h).

"(ii) INCLUSION OF COSTS OF VA AND DOD MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the adjusted average per capita cost under clause (i) for a year, such cost shall be adjusted to include the Secretary's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Veterans Affairs or the Department of Defense.".

(2) CONFORMING AMENDMENT.—Such section is further amended, in the matter before subparagraph (A), by striking "or (C)" and inserting "(C), or (D)".

(b) CHANGE IN BUDGET NEUTRALITY FOR BLEND.—Section 1853(c) (42 U.S.C. 1395w–23(c)) is amended—

(1) in paragraph (1)(A), by inserting "(for a year other than 2004)" after "multiplied"; and

(2) in paragraph (5), by inserting "(other than 2004)" after "for each year".

(c) INCREASING MINIMUM PERCENTAGE INCREASE TO NATIONAL GROWTH RATE.—

(1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C. 1395w–23(c)(1)) is amended—

(A) in subparagraph (B)(iv), by striking "and each succeeding year" and inserting ", 2003, and 2004";

(B) in subparagraph (C)(iv), by striking "and each succeeding year" and inserting "and 2003"; and

(C) by adding at the end of subparagraph (C) the following new clause:

"(v) For 2004 and each succeeding year, the greater of—

"(I) 102 percent of the annual Medicare Advantage capitation rate under this paragraph for the area for the previous year; or

"(II) the annual Medicare Advantage capitation rate under this paragraph for the area for the previous year increased by the national per capita Medicare Advantage growth percentage, described in paragraph (6) for that succeeding year, but not taking into account any adjustment under paragraph (6)(C) for a year before 2004.".

(2) CONFORMING AMENDMENT.—Section 1853(c)(6)(C) (42 U.S.C. 1395w–23(c)(6)(C)) is amended by inserting before the period at the end the following: ", except that for purposes of paragraph (1)(C)(v)(II), no such adjustment shall be made for a year before 2004".

(d) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES IN CALCULATION OF MEDICARE+CHOICE PAYMENT RATES.—Section 1853(c)(3) (42 U.S.C. 1395w–23(c)(3)) is amended—

(1) in subparagraph (A), by striking "subparagraph (B)" and inserting "subparagraphs (B) and (E)", and

(2) by adding at the end the following new subparagraph:

"(E) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the area-specific Medicare+Choice capitation rate under subparagraph (A) for a year (beginning with 2004), the annual per capita rate of payment for 1997 determined under section 1876(a)(1)(C) shall be adjusted to include in the rate the Secretary's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs.".

(e) EXTENDING SPECIAL RULE FOR CERTAIN INPATIENT HOSPITAL STAYS TO REHABILITATION HOSPITALS.—

(1) IN GENERAL.—Section 1853(g) (42 U.S.C. 1395w–23(g)) is amended—

(A) by inserting "or from a rehabilitation facility (as defined in section 1886(j)(1)(A))" after "1886(d)(1)(B))"; and

(B) in paragraph (2)(B), by inserting "or section 1886(j), as the case may be," after "1886(d)".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to contract years beginning on or after January 1, 2004.

(f) MEDPAC STUDY OF AAPCC.—

(1) STUDY.—The Medicare Payment Advisory Commission shall conduct a study that assesses the method used for determining the adjusted average per capita cost (AAPCC) under section 1876(a)(4) of the Social Security Act (42 U.S.C. 1395mm(a)(4)) as applied under section 1853(c)(1)(A) of such Act (as amended by subsection (a)). Such study shall include an examination of—

(A) the bases for variation in such costs between different areas, including differences in input prices, utilization, and practice patterns;

(B) the appropriate geographic area for payment under the Medicare Advantage program under part C of title XVIII of such Act; and

(C) the accuracy of risk adjustment methods in reflecting differences in costs of providing care to different groups of beneficiaries served under such program.

(2) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study conducted under paragraph (1).

(g) REPORT ON IMPACT OF INCREASED FINANCIAL ASSISTANCE TO MEDICARE ADVANTAGE PLANS.—Not later than July 1, 2006, the Medicare Benefits Administrator shall submit to Congress a report that describes the impact of additional financing provided under this Act and other Acts (including the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and BIPA) on the availability of Medicare Advantage plans in different areas and its impact on lowering premiums and increasing benefits under such plans.

CHAPTER 2—IMPLEMENTATION OF COMPETITION PROGRAM

SEC. 221. COMPETITION PROGRAM BEGINNING IN 2006.

(a) SUBMISSION OF EFFS-LIKE BIDDING INFORMATION BEGINNING IN 2006.—Section 1854 (42 U.S.C. 1395w–24) is amended—

(1) by amending the section heading to read as follows:

"PREMIUMS AND BID AMOUNT";

(2) in subsection (a)(1)(A)—

(A) by striking "(A)" and inserting "(A)(i) if the following year is before 2006,"; and

(B) by inserting before the semicolon at the end the following: "or (ii) if the following year is 2006 or later, the information described in paragraph (3) or (6)(A) for the type of plan involved"; and

(3) by adding at the end of subsection (a) the following:

"(6) SUBMISSION OF BID AMOUNTS BY MEDICARE ADVANTAGE ORGANIZATIONS.—

"(A) INFORMATION TO BE SUBMITTED.—The information described in this subparagraph is as follows:

"(i) The monthly aggregate bid amount for provision of all items and services under this part, which amount shall be based on average costs for a typical beneficiary residing in the area, and the actuarial basis for determining such amount.

"(ii) The proportions of such bid amount that are attributable to—

"(I) the provision of statutory non-drug benefits (such portion referred to in this part as the 'unadjusted Medicare Advantage statutory non-drug monthly bid amount');

"(II) the provision of statutory prescription drug benefits; and

"(III) the provision of non-statutory benefits;

and the actuarial basis for determining such proportions.

"(iii) Such additional information as the Administrator may require to verify the actuarial bases described in clauses (i) and (ii).

"(B) STATUTORY BENEFITS DEFINED.—For purposes of this part:

"(i) The term 'statutory non-drug benefits' means benefits under section 1852(a)(1).

"(ii) The term 'statutory prescription drug benefits' means benefits under part D.

"(iii) The term 'statutory benefits' means statutory prescription drug benefits and statutory non-drug benefits.

"(C) ACCEPTANCE AND NEGOTIATION OF BID AMOUNTS.—

"(i) IN GENERAL.—Subject to clause (ii)—

"(I) the Administrator has the authority to negotiate regarding monthly bid amounts submitted under subparagraph (A) (and the proportion described in subparagraph (A)(ii)), and for such purpose and subject to such clause, the Administrator has negotiation authority that the Director of the Office of Personnel Management has with respect to health benefits plans under chapter 89 of title 5, United States Code; and

"(II) the Administrator may reject such a bid amount or proportion if the Administrator determines that such amount or proportion is not supported by the actuarial bases provided under subparagraph (A).

"(ii) EXCEPTION.—In the case of a plan described in section 1851(a)(2)(C), the provisions of clause (i) shall not apply and the provisions of paragraph (5)(B), prohibiting the review, approval, or disapproval of amounts described in such paragraph, shall apply to the negotiation and rejection of the monthly bid amounts and proportion referred to in subparagraph (A).".

(b) PROVIDING FOR BENEFICIARY SAVINGS FOR CERTAIN PLANS.—

(1) IN GENERAL.—Section 1854(b) (42 U.S.C. 1395w–24(b)) is amended—

(A) by adding at the end of paragraph (1) the following new subparagraph:

"(C) BENEFICIARY REBATE RULE.—

"(i) REQUIREMENT.—The Medicare Advantage plan shall provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings (if any) described in paragraph (3) applicable to the plan and year involved.

"(iii) FORM OF REBATE.—A rebate required under this subparagraph shall be provided—

"(I) through the crediting of the amount of the rebate towards the Medicare Advantage monthly supplementary beneficiary premium or the premium imposed for prescription drug coverage under part D;

"(II) through a direct monthly payment (through electronic funds transfer or otherwise); or

"(III) through other means approved by the Medicare Benefits Administrator,

or any combination thereof."; and

(B) by adding at the end the following new paragraphs:

"(3) COMPUTATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—For purposes of paragraph (1)(C)(i), the average per capita monthly savings referred to in such paragraph for a Medicare Advantage plan and year is computed as follows:

"(A) DETERMINATION OF STATE-WIDE AVERAGE RISK ADJUSTMENT.—

"(i) IN GENERAL.—The Medicare Benefits Administrator shall determine, at the same time rates are promulgated under section 1853(b)(1) (beginning with 2006), for each State the average of the risk adjustment factors to be applied under section 1853(a)(1)(A) to payment for enrollees in that State. In the case of a State in which a Medicare Advantage plan was offered in the previous year, the Administrator may compute such average based upon risk adjustment factors applied in that State in a previous year.

"(ii) TREATMENT OF NEW STATES.—In the case of a State in which no Medicare Advantage plan was offered in the previous year, the Administrator shall estimate such average. In making such estimate, the Administrator may use average risk adjustment factors applied to comparable States or applied on a national basis.

"(B) DETERMINATION OF RISK ADJUSTED BENCHMARK AND RISK-ADJUSTED BID.—For each Medicare Advantage plan offered in a State, the Administrator shall—

"(i) adjust the Medicare Advantage area-specific non-drug monthly benchmark amount (as defined in subsection (j)) by the applicable average risk adjustment factor computed under subparagraph (A); and

"(ii) adjust the unadjusted Medicare Advantage statutory non-drug monthly bid amount by such applicable average risk adjustment factor.

"(C) DETERMINATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—The average per capita monthly savings described in this subparagraph is equal to the amount (if any) by which—

"(i) the risk-adjusted benchmark amount computed under subparagraph (B)(i), exceeds

"(ii) the risk-adjusted bid computed under subparagraph (B)(ii).

"(D) AUTHORITY TO DETERMINE RISK ADJUSTMENT FOR AREAS OTHER THAN STATES.—The Administrator may provide for the determination and application of risk adjustment factors under this paragraph on the basis of areas other than States.

"(4) BENEFICIARY'S OPTION OF PAYMENT THROUGH WITHHOLDING FROM SOCIAL SECURITY PAYMENT OR USE OF ELECTRONIC FUNDS TRANSFER MECHANISM.—In accordance with regulations, a Medicare Advantage organization shall permit each enrollee, at the enrollee's option, to make payment of premiums under this part to the organization indirectly through withholding from benefit payments in the manner provided under section 1840 with respect to monthly premiums under section 1839 or through an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account) or otherwise. All premium payments that are withheld under this paragraph that are credited to the Federal Supplementary Medical Insurance Drug Trust Fund shall be paid to the Medicare Advantage organization involved.".

(2) PROVISION OF SINGLE CONSOLIDATED PREMIUM.—Section 1854(b) (42 U.S.C. 1395w–24(b)), as amended by paragraph (1), is further amended by adding at the end the following new paragraph:

"(5) SINGLE CONSOLIDATED PREMIUM.—In the case of an enrollee in a Medicare Advantage plan who elects under part D to be provided qualified prescription drug coverage through the plan, the Administrator shall provide a mechanism for the consolidation of the beneficiary premium amount for non-drug benefits under this part with the premium amount for prescription drug coverage under part D provided through the plan.".

(3) COMPUTATION OF MEDICARE ADVANTAGE AREA-SPECIFIC NON-DRUG BENCHMARK.—Section 1853 (42 U.S.C. 1395w–23) is amended by adding at the end the following new subsection:

"(j) COMPUTATION OF MEDICARE ADVANTAGE AREA-SPECIFIC NON-DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of this part, the term 'Medicare Advantage area-specific non-drug monthly benchmark amount' means, with respect to a Medicare Advantage payment area for a month in a year, an amount equal to 1/12 of the annual Medicare Advantage capitation rate under section 1853(c)(1) for the area for the year.".

(c) PAYMENT OF PLANS BASED ON BID AMOUNTS.—

(1) IN GENERAL.—Section 1853(a)(1)(A) (42 U.S.C. 1395w–23) is amended by striking "in an amount" and all that follows and inserting the following: "in an amount determined as follows:

"(i) PAYMENT BEFORE 2006.—For years before 2006, the payment amount shall be equal to 1/12 of the annual Medicare Advantage capitation rate (as calculated under subsection (c)(1)) with respect to that individual for that area, reduced by the amount of any reduction elected under section 1854(f)(1)(E) and adjusted under clause (iv).

"(ii) PAYMENT FOR STATUTORY NON-DRUG BENEFITS BEGINNING WITH 2006.—For years beginning with 2006—

"(I) PLANS WITH BIDS BELOW BENCHMARK.—In the case of a plan for which there are average per capita monthly savings described in section 1854(b)(3)(C), the payment under this subsection is equal to the unadjusted Medicare Advantage statutory non-drug monthly bid amount, adjusted under clause (iv), plus the amount of the monthly rebate computed under section 1854(b)(1)(C)(i) for that plan and year.

"(II) PLANS WITH BIDS AT OR ABOVE BENCHMARK.—In the case of a plan for which there are no average per capita monthly savings described in section 1854(b)(3)(C), the payment amount under this subsection is equal to the Medicare Advantage area-specific non-drug monthly benchmark amount, adjusted under clause (iv).

"(iii) FOR FEDERAL DRUG SUBSIDIES.—In the case in which an enrollee who elects under part D to be provided qualified prescription drug coverage through the plan, the Medicare Advantage organization offering such plan also is entitled—

"(I) to direct subsidy payment under section 1860D–8(a)(1);

"(II) to reinsurance subsidy payments under section 1860D–8(a)(2); and

"(III) to reimbursement for premium and cost-sharing reductions for low-income individuals under section 1860D–7(c)(3).

"(iv) DEMOGRAPHIC ADJUSTMENT, INCLUDING ADJUSTMENT FOR HEALTH STATUS.—The Administrator shall adjust the payment amount under clause (i), the unadjusted Medicare Advantage statutory non-drug monthly bid amount under clause (ii)(I), and the Medicare Advantage area-specific non-drug monthly benchmark amount under clause (ii)(II) for such risk factors as age, disability status, gender, institutional status, and such other factors as the Administrator determines to be appropriate, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence. The Administrator may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.".

(d) CONFORMING AMENDMENTS.—

(1) PROTECTION AGAINST BENEFICIARY SELECTION.—Section 1852(b)(1)(A) (42 U.S.C. 1395w–22(b)(1)(A)) is amended by adding at the end the following: "The Administrator shall not approve a plan of an organization if the Administrator determines that the benefits are designed to substantially discourage enrollment by certain Medicare Advantage eligible individuals with the organization.".

(2) CONFORMING AMENDMENT TO PREMIUM TERMINOLOGY.—Section 1854(b)(2) (42 U.S.C. 1395w–24(b)(2)) is amended by redesignating subparagraph (C) as subparagraph (D) and by striking subparagraphs (A) and (B) and inserting the following:

"(A) MEDICARE ADVANTAGE MONTHLY BASIC BENEFICIARY PREMIUM.—The term 'Medicare Advantage monthly basic beneficiary premium' means, with respect to a Medicare Advantage plan—

"(i) described in section 1853(a)(1)(A)(ii)(I) (relating to plans providing rebates), zero; or

"(ii) described in section 1853(a)(1)(A)(ii)(II), the amount (if any) by which the unadjusted Medicare Advantage statutory non-drug monthly bid amount exceeds the Medicare Advantage area-specific non-drug monthly benchmark amount.

"(B) MEDICARE ADVANTAGE MONTHLY PRESCRIPTION DRUG BENEFICIARY PREMIUM.—The term 'Medicare Advantage monthly prescription drug beneficiary premium' means, with respect to a Medicare Advantage plan, that portion of the bid amount submitted under clause (i) of subsection (a)(6)(A) for the year that is attributable under such section to the provision of statutory prescription drug benefits.

"(C) MEDICARE ADVANTAGE MONTHLY SUPPLEMENTAL BENEFICIARY PREMIUM.—The term 'Medicare Advantage monthly supplemental beneficiary premium' means, with respect to a Medicare Advantage plan, the portion of the aggregate monthly bid amount submitted under clause (i) of subsection (a)(6)(A) for the year that is attributable under such section to the provision of nonstatutory benefits.".

(3) REQUIREMENT FOR UNIFORM PREMIUM AND BID AMOUNTS.—Section 1854(c) (42 U.S.C. 1395w–24(c)) is amended to read as follows:

"(c) UNIFORM PREMIUM AND BID AMOUNTS.—The Medicare Advantage monthly bid amount submitted under subsection (a)(6), the Medicare Advantage monthly basic, prescription drug, and supplemental beneficiary premiums, and the Medicare Advantage monthly MSA premium charged under subsection (b) of a Medicare Advantage organization under this part may not vary among individuals enrolled in the plan.".

(4) PERMITTING BENEFICIARY REBATES.—

(A) Section 1851(h)(4)(A) (42 U.S.C. 1395w–21(h)(4)(A)) is amended by inserting "except as provided under section 1854(b)(1)(C)" after "or otherwise".

(B) Section 1854(d) (42 U.S.C. 1395w–24(d)) is amended by inserting ", except as provided under subsection (b)(1)(C)," after "and may not provide".

(5) OTHER CONFORMING AMENDMENTS RELATING TO BIDS.—Section 1854 (42 U.S.C. 1395w–24) is amended—

(A) in the heading of subsection (a), by inserting "AND BID AMOUNTS" after "PREMIUMS"; and

(B) in subsection (a)(5)(A), by inserting "paragraphs (2), (3), and (4) of" after "filed under".

(e) ADDITIONAL CONFORMING AMENDMENTS.—

(1) ANNUAL DETERMINATION AND ANNOUNCEMENT OF CERTAIN FACTORS.—Section 1853(b)(1) (42 U.S.C. 1395w–23(b)(1)) is amended by striking "the respective calendar year" and all that follows and inserting the following: "the calendar year concerned with respect to each Medicare Advantage payment area, the following:

"(A) PRE-COMPETITION INFORMATION.—For years before 2006, the following:

"(i) MEDICARE ADVANTAGE CAPITATION RATES.—The annual Medicare Advantage capitation rate for each Medicare Advantage payment area for the year.

"(ii) ADJUSTMENT FACTORS.—The risk and other factors to be used in adjusting such rates under subsection (a)(1)(A) for payments for months in that year.

"(B) COMPETITION INFORMATION.—For years beginning with 2006, the following:

"(i) BENCHMARK.—The Medicare Advantage area-specific non-drug benchmark under section 1853(j).

"(ii) ADJUSTMENT FACTORS.—The adjustment factors applied under section 1853(a)(1)(A)(iv) (relating to demographic adjustment), section 1853(a)(1)(B) (relating to adjustment for end-stage renal disease), and section 1853(a)(3) (relating to health status adjustment).".

(2) REPEAL OF PROVISIONS RELATING TO ADJUSTED COMMUNITY RATE (ACR).—

(A) IN GENERAL.—Subsections (e) and (f) of section 1854 (42 U.S.C. 1395w–24) are repealed.

(B) CONFORMING AMENDMENTS.—(i) Section 1839(a)(2) (42 U.S.C. 1395r(a)(2)) is amended by striking ", and to reflect" and all that follows and inserting a period.

(ii) Section 1852(a)(1) (42 U.S.C. 1395w–22(a)(1)) is amended by striking "title XI" and all that follows and inserting the following: "title XI those items and services (other than hospice care) for which benefits are available under parts A and B to individuals residing in the area served by the plan.".

(iii) Section 1857(d)(1) (42 U.S.C. 1395w–27(d)(1)) is amended by striking ", costs, and computation of the adjusted community rate" and inserting "and costs".

(f) REFERENCES UNDER PART E.—Section 1859 (42 U.S.C. 1395w–29) is amended by adding at the end the following new subsection:

"(f) APPLICATION UNDER PART E.—In the case of any reference under part E to a requirement or provision of this part in the relation to an EFFS plan or organization under such part, except as otherwise specified any such requirement or provision shall be applied to such organization or plan in the same manner as such requirement or provision applies to a Medicare Advantage private fee-for-service plan (and the Medicare Advantage organization that offers such plan) under this part.".

(g) EFFECTIVE DATE.—The amendments made by this section shall apply to payments and premiums for months beginning with January 2006.

CHAPTER 3—ADDITIONAL REFORMS

SEC. 231. MAKING PERMANENT CHANGE IN MEDICARE ADVANTAGE REPORTING DEADLINES AND ANNUAL, COORDINATED ELECTION PERIOD.

(a) CHANGE IN REPORTING DEADLINE.—Section 1854(a)(1) (42 U.S.C. 1395w–24(a)(1)), as amended by section 532(b)(1) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, is amended by striking "2002, 2003, and 2004 (or July 1 of each other year)" and inserting "2002 and each subsequent year".

(b) DELAY IN ANNUAL, COORDINATED ELECTION PERIOD.—Section 1851(e)(3)(B) (42 U.S.C. 1395w–21(e)(3)(B)), as amended by section 532(c)(1)(A) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, is amended—

(1) by striking "and after 2005"; and

(2) by striking ", 2004, and 2005" and inserting "and any subsequent year".

(c) ANNUAL ANNOUNCEMENT OF PAYMENT RATES.—Section 1853(b)(1) (42 U.S.C. 1395w–23(b)(1)), as amended by section 532(d)(1) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, is amended—

(1) by striking "and after 2005"; and

(2) by striking "and 2005" and inserting "and each subsequent year".

(d) REQUIRING PROVISION OF AVAILABLE INFORMATION COMPARING PLAN OPTIONS.—The first sentence of section 1851(d)(2)(A)(ii) (42 U.S.C. 1395w–21(d)(2)(A)(ii)) is amended by inserting before the period the following: "to the extent

such information is available at the time of preparation of materials for the mailing".

SEC. 232. AVOIDING DUPLICATIVE STATE REGULATION.

(a) IN GENERAL.—Section 1856(b)(3) (42 U.S.C. 1395w–26(b)(3)) is amended to read as follows:

"(3) RELATION TO STATE LAWS.—The standards established under this subsection shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to Medicare Advantage plans which are offered by Medicare Advantage organizations under this part.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act.

SEC. 233. SPECIALIZED MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS BENEFICIARIES.

(a) TREATMENT AS COORDINATED CARE PLAN.—Section 1851(a)(2)(A) (42 U.S.C. 1395w–21(a)(2)(A)) is amended by adding at the end the following new sentence: "Specialized Medicare Advantage plans for special needs beneficiaries (as defined in section 1859(b)(4)) may be any type of coordinated care plan.".

(b) SPECIALIZED MEDICARE ADVANTAGE PLAN FOR SPECIAL NEEDS BENEFICIARIES DEFINED.—Section 1859(b) (42 U.S.C. 1395w–29(b)) is amended by adding at the end the following new paragraph:

"(4) SPECIALIZED MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—

"(A) IN GENERAL.—The term 'specialized Medicare Advantage plan for special needs beneficiaries' means a Medicare Advantage plan that exclusively serves special needs beneficiaries (as defined in subparagraph (B)).

"(B) SPECIAL NEEDS BENEFICIARY.—The term 'special needs beneficiary' means a Medicare Advantage eligible individual who—

"(i) is institutionalized (as defined by the Secretary);

"(ii) is entitled to medical assistance under a State plan under title XIX; or

"(iii) meets such requirements as the Secretary may determine would benefit from enrollment in such a specialized Medicare Advantage plan described in subparagraph (A) for individuals with severe or disabling chronic conditions.".

(c) RESTRICTION ON ENROLLMENT PERMITTED.—Section 1859 (42 U.S.C. 1395w–29) is amended by adding at the end the following new subsection:

"(f) RESTRICTION ON ENROLLMENT FOR SPECIALIZED MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—In the case of a specialized Medicare Advantage plan (as defined in subsection (b)(4)), notwithstanding any other provision of this part and in accordance with regulations of the Secretary and for periods before January 1, 2007, the plan may restrict the enrollment of individuals under the plan to individuals who are within one or more classes of special needs beneficiaries.".

(d) REPORT TO CONGRESS.—Not later than December 31, 2005, the Medicare Benefits Administrator shall submit to Congress a report that assesses the impact of specialized Medicare Advantage plans for special needs beneficiaries on the cost and quality of services provided to enrollees. Such report shall include an assessment of the costs and savings to the medicare program as a result of amendments made by subsections (a), (b), and (c).

(e) EFFECTIVE DATES.—

(1) IN GENERAL.—The amendments made by subsections (a), (b), and (c) shall take effect upon the date of the enactment of this Act.

(2) DEADLINE FOR ISSUANCE OF REQUIREMENTS FOR SPECIAL NEEDS BENEFICIARIES; TRANSITION.—No later than 6 months after the date of the enactment of this Act, the Secretary shall issue interim final regulations to establish requirements for special needs beneficiaries under section 1859(b)(4)(B)(iii) of the Social Security Act, as added by subsection (b).

SEC. 234. MEDICARE MSAS.

(a) EXEMPTION FROM REPORTING ENROLLEE ENCOUNTER DATA.—

(1) IN GENERAL.—Section 1852(e)(1) (42 U.S.C. 1395w–22(e)(1)) is amended by inserting "(other than MSA plans)" after "plans".

(2) CONFORMING AMENDMENTS.—Section 1852 (42 U.S.C. 1395w–22) is amended—

(A) in subsection (c)(1)(I), by inserting before the period at the end the following: "if required under such section"; and

(B) in subparagraphs (A) and (B) of subsection (e)(2), by striking ", a non-network MSA plan," and ", NON-NETWORK MSA PLANS," each place it appears.

(b) MAKING PROGRAM PERMANENT AND ELIMINATING CAP.—Section 1851(b)(4) (42 U.S.C. 1395w–21(b)(4)) is amended—

(1) in the heading, by striking "ON A DEMONSTRATION BASIS";

(2) by striking the first sentence of subparagraph (A); and

(3) by striking the second sentence of subparagraph (C).

(c) APPLYING LIMITATIONS ON BALANCE BILLING.—Section 1852(k)(1) (42 U.S.C. 1395w–22(k)(1)) is amended by inserting "or with an organization offering a MSA plan" after "section 1851(a)(2)(A)".

(d) ADDITIONAL AMENDMENT.—Section 1851(e)(5)(A) (42 U.S.C. 1395w–21(e)(5)(A)) is amended—

(1) by adding "or" at the end of clause (i);

(2) by striking ", or" at the end of clause (ii) and inserting a semicolon; and

(3) by striking clause (iii).

SEC. 235. EXTENSION OF REASONABLE COST CONTRACTS.

Subparagraph (C) of section 1876(h)(5) (42 U.S.C. 1395mm(h)(5)) is amended to read as follows:

"(C)(i) Subject to clause (ii), may be extended or renewed under this subsection indefinitely.

"(ii) For any period beginning on or after January 1, 2008, a reasonable cost reimbursement contract under this subsection may not be extended or renewed for a service area insofar as such area, during the entire previous year, was within the service area of 2 or more plans which were coordinated care Medicare Advantage plans under part C or 2 or more enhanced fee-for-service plans under part E and each of which plan for that previous year for the area involved meets the following minimum enrollment requirements:

"(I) With respect to any portion of the area involved that is within a Metropolitan Statistical Area with a population of more than 250,000 and counties contiguous to such Metropolitan Statistical Area, 5,000 individuals.

"(II) With respect to any other portion of such area, 1,500 individuals.".

SEC. 236. EXTENSION OF MUNICIPAL HEALTH SERVICE DEMONSTRATION PROJECTS.

Section 9215(a) of the Consolidated Omnibus Budget Reconciliation Act of 1985 (42 U.S.C. 1395b–1 note), as amended by section 6135 of the Omnibus Budget Reconciliation Act of 1989, section 13557 of the Omnibus Budget Reconciliation Act of 1993, section 4017 of BBA, section 534 of BBRA (113 Stat. 1501A–390), and section 633 of BIPA, is amended by striking "December 31, 2004" and inserting "December 31, 2009".

Subtitle C—Application of FEHBP-Style Competitive Reforms

SEC. 241. APPLICATION OF FEHBP-STYLE COMPETITIVE REFORM BEGINNING IN 2010.

(a) IDENTIFICATION OF COMPETITIVE EFFS REGIONS; COMPUTATION OF COMPETITIVE EFFS NON-DRUG BENCHMARKS UNDER EFFS PROGRAM.—

(1) IN GENERAL.—Section 1860E–3, as added by section 201(a), is amended by adding at the end the following new subsection:

"(e) APPLICATION OF COMPETITION.—

"(1) DETERMINATION OF COMPETITIVE EFFS REGIONS.—

"(A) IN GENERAL.—For purposes of this part, the term 'competitive EFFS region' means, for a year beginning with 2010, an EFFS region that the Administrator finds—

"(i) there will be offered in the region during the annual, coordinated election period under section 1851(e)(3)(B) (as applied under section 1860E–1(c)) before the beginning of the year at least 2 EFFS plans (in addition to the fee-for-service program under parts A and B), each offered by a different EFFS organization and each of which met the minimum enrollment requirements of paragraph (1) of section 1857(b) (as applied without regard to paragraph (3) thereof) as of March of the previous year; and

"(ii) during March of the previous year at least the percentage specified in subparagraph (C) of the number of EFFS eligible individuals who reside in the region were enrolled in an EFFS plan.

"(B) PERCENTAGE SPECIFIED.—

"(i) IN GENERAL.—For purposes of subparagraph (A), subject to clause (ii), the percentage specified in this subparagraph for a year is equal the lesser of 20 percent or to the sum of—

"(I) the percentage, as estimated by the Administrator, of EFFS eligible individuals in the United States who are enrolled in EFFS plans during March of the previous year; and

"(II) the percentage, as estimated by the Administrator, of Medicare Advantage eligible individuals in the United States who are enrolled in Medicare Advantage plans during March of the previous year.

"(ii) EXCEPTION.—In the case of an EFFS region that was a competitive EFFS region for the previous year, the Medicare Benefits Administrator may continue to treat the region as meeting the requirement of subparagraph (A)(ii) if the region would meet such requirement but for a de minimis reduction below the percentage specified in clause (i).

"(2) COMPETITIVE EFFS NON-DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of this part, the term 'competitive EFFS non-drug monthly benchmark amount' means, with respect to an EFFS region for a month in a year and subject to paragraph (8), the sum of the 2 components described in paragraph (3) for the region and year. The Administrator shall compute such benchmark amount for each competitive EFFS region before the beginning of each annual, coordinated election period under section 1851(e)(3)(B) for each year (beginning with 2010) in which it is designated as such a region.

"(3) 2 COMPONENTS.—For purposes of paragraph (2), the 2 components described in this paragraph for an EFFS region and a year are the following:

"(A) EFFS COMPONENT.—The product of the following:

"(i) WEIGHTED AVERAGE OF PLAN BIDS IN REGION.—The weighted average of the EFFS plan bids for the region and year (as determined under paragraph (4)(A)).

"(ii) NON-FFS MARKET SHARE.—1 minus the fee-for-service market share percentage determined under paragraph (5) for the region and the year.

"(B) FEE-FOR-SERVICE COMPONENT.—The product of the following:

"(i) FEE-FOR-SERVICE REGION-SPECIFIC NON-DRUG AMOUNT.—The fee-for-service region-specific non-drug amount (as defined in paragraph (6)) for the region and year.

"(ii) FEE-FOR-SERVICE MARKET SHARE.—The fee-for-service market share percentage (determined under paragraph (5)) for the region and the year.

"(4) DETERMINATION OF WEIGHTED AVERAGE EFFS PLAN BIDS FOR A REGION.—

"(A) IN GENERAL.—For purposes of paragraph (3)(A)(i), the weighted average of EFFS plan bids for an EFFS region and a year is the sum of the following products for EFFS plans described in subparagraph (C) in the region and year:

"(i) UNADJUSTED EFFS STATUTORY NON-DRUG MONTHLY BID AMOUNT.—The unadjusted EFFS statutory non-drug monthly bid amount (as defined in subsection (a)(3)(A)(ii)(I)) for the region and year.

"(ii) PLAN'S SHARE OF EFFS ENROLLMENT IN REGION.—The number of individuals described in subparagraph (B), divided by the total number of such individuals for all EFFS plans described in subparagraph (C) for that region and year.

"(B) COUNTING OF INDIVIDUALS.—The Administrator shall count, for each EFFS plan described in subparagraph (C) for an EFFS region and year, the number of individuals who reside in the region and who were enrolled under such plan under this part during March of the previous year.

"(C) EXCLUSION OF PLANS NOT OFFERED IN PREVIOUS YEAR.—For an EFFS region and year, the EFFS plans described in this subparagraph are plans that are offered in the region and year and were offered in the region in March of the previous year.

"(5) COMPUTATION OF FEE-FOR-SERVICE MARKET SHARE PERCENTAGE.—The Administrator shall determine, for a year and an EFFS region, the proportion (in this subsection referred to as the 'fee-for-service market share percentage') of the EFFS eligible individuals who are residents of the region during March of the previous year, of such individuals who were not enrolled in an EFFS plan or in a Medicare Advantage plan (or, if greater, such proportion determined for individuals nationally).

"(6) FEE-FOR-SERVICE REGION-SPECIFIC NON-DRUG AMOUNT.—

"(A) IN GENERAL.—For purposes of paragraph (3)(B)(i) and section 1839(h)(2)(A), subject to subparagraph (B), the term 'fee-for-service region-specific non-drug amount' means, for a competitive EFFS region and a year, the adjusted average per capita cost for the year involved, determined under section 1876(a)(4) for such region for services covered under parts A

and B for individuals entitled to benefits under part A and enrolled under this part who are not enrolled in an EFFS plan under part E or a Medicare Advantage plan under part C for the year, but adjusted to exclude costs attributable to payments under section 1886(h).

"(B) INCLUSION OF COSTS OF VA AND DOD MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the adjusted average per capita cost under subparagraph (A) for a year, such cost shall be adjusted to include the Administrator's estimate, on a per capita basis, of the amount of additional payments that would have been made in the region involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Veterans Affairs or the Department of Defense.

"(7) APPLICATION OF COMPETITION.—In the case of an EFFS region that is a competitive EFFS region for a year, for purposes of applying subsections (b) and (c)(1) and section 1860E–4(a), any reference to an EFFS region-specific non-drug monthly benchmark amount shall be treated as a reference to the competitive EFFS non-drug monthly benchmark amount under paragraph (2) for the region and year.

"(8) PHASE-IN OF BENCHMARK FOR EACH REGION.—

"(A) USE OF BLENDED BENCHMARK.—In the case of a region that has not been a competitive EFFS region for each of the previous 4 years, the competitive EFFS non-drug monthly benchmark amount shall be equal to the sum of the following:

"(i) NEW COMPETITIVE COMPONENT.—The product of—

"(I) the weighted average phase-in proportion for that area and year, as specified in subparagraph (B); and

"(II) the competitive EFFS non-drug monthly benchmark amount for the region and year, determined under paragraph (2) without regard to this paragraph.

"(ii) OLD COMPETITIVE COMPONENT.—The product of—

"(I) 1 minus the weighted average phase-in proportion for that region and year; and

"(II) the EFFS region-specific non-drug benchmark amount for the region and the year.

"(B) COMPUTATION OF WEIGHTED AVERAGE PHASE-IN PROPORTION.—For purposes of this paragraph, the 'weighted average phase-in proportion' for an EFFS region for a year shall be determined as follows:

"(i) FIRST YEAR (AND REGION NOT COMPETITIVE REGION IN PREVIOUS YEAR).—If the area was not a competitive EFFS region in the previous year, the weighted average phase-in proportion for the region for the year is equal to ⅕.

"(ii) COMPETITIVE REGION IN PREVIOUS YEAR.—If the region was a competitive EFFS region in the previous year, the weighted average phase-in proportion for the region for the year is equal to the weighted average phase-in proportion determined under this subparagraph for the region for the previous year plus ⅕, but in no case more than 1.".

(2) CONFORMING AMENDMENTS.—

(A) Such section 1860E–3 is further amended—

(i) in subsection (b), by adding at the end the following new paragraph:

"(4) APPLICATION IN COMPETITIVE REGIONS.—For special rules applying this subsection in competitive EFFS regions, see subsection (e)(7).";

(ii) in subsection (c)(1), by inserting "and subsection (e)(7)" after "(as made applicable under subsection (d))"; and

(iii) in subsection (d) , by striking "and (e)" and inserting "(e), and (k) ".

(B) Section 1860E–4(a)(1), as inserted by section 201(a)(2), is amended by inserting ", except as provided in section 1860E–3(e)(7)" after "paragraph (2)".

(b) IDENTIFICATION OF COMPETITIVE MEDICARE ADVANTAGE AREAS; APPLICATION OF COMPETITIVE MEDICARE ADVANTAGE NON-DRUG BENCHMARKS UNDER MEDICARE ADVANTAGE PROGRAM.—

(1) IN GENERAL.—Section 1853, as amended by section 221(b)(3), is amended by adding at the end the following new subsection:

"(k) APPLICATION OF COMPETITION.—

"(1) DETERMINATION OF COMPETITIVE MEDICARE ADVANTAGE AREAS.—

"(A) IN GENERAL.—For purposes of this part, the terms 'competitive Medicare Advantage area' and 'CMA area' mean, for a year beginning with 2010, an area (which is a metropolitan statistical area or other area with a sub-

stantial number of Medicare Advantage enrollees) that the Administrator finds—

"(i) there will be offered during the annual, coordinated election period under section 1851(e)(3)(B) under this part before the beginning of the year at least 2 Medicare Advantage plans (in addition to the fee-for-service program under parts A and B), each offered by a different Medicare Advantage organization and each of which met the minimum enrollment requirements of paragraph (1) of section 1857(b) (as applied without regard to paragraph (3) thereof) as of March of the previous year with respect to the area; and

"(ii) during March of the previous year at least the percentage specified in subparagraph (B) of the number of Medicare Advantage eligible individuals who reside in the area were enrolled in a Medicare Advantage plan.

"(B) PERCENTAGE SPECIFIED.—

"(i) IN GENERAL.—For purposes of subparagraph (A), subject to clause (ii), the percentage specified in this subparagraph for a year is equal the lesser of 20 percent or to the sum of—

"(I) the percentage, as estimated by the Administrator, of EFFS eligible individuals in the United States who are enrolled in EFFS plans during March of the previous year; and

"(II) the percentage, as estimated by the Administrator, of Medicare Advantage eligible individuals in the United States who are enrolled in Medicare Advantage plans during March of the previous year.

"(ii) EXCEPTION.—In the case of an area that was a competitive area for the previous year, the Medicare Benefits Administrator may continue to treat the area as meeting the requirement of subparagraph (A)(ii) if the area would meet such requirement but for a de minimis reduction below the percentage specified in clause (i).

"(2) COMPETITIVE MEDICARE ADVANTAGE NON-DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of this part, the term 'competitive Medicare Advantage non-drug monthly benchmark amount' means, with respect to a competitive Medicare Advantage area for a month in a year subject to paragraph (8), the sum of the 2 components described in paragraph (3) for the area and year. The Administrator shall compute such benchmark amount for each competitive Medicare Advantage area before the beginning of each annual, coordinated election period under section 1851(e)(3)(B) for each year (beginning with 2010) in which it is designated as such an area.

"(3) 2 COMPONENTS.—For purposes of paragraph (2), the 2 components described in this paragraph for a competitive Medicare Advantage area and a year are the following:

"(A) MEDICARE ADVANTAGE COMPONENT.—The product of the following:

"(i) WEIGHTED AVERAGE OF MEDICARE ADVANTAGE PLAN BIDS IN AREA.—The weighted average of the plan bids for the area and year (as determined under paragraph (4)(A)).

"(ii) NON-FFS MARKET SHARE.—1 minus the fee-for-service market share percentage, determined under paragraph (5) for the area and year.

"(B) FEE-FOR-SERVICE COMPONENT.—The product of the following:

"(i) FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG AMOUNT.—The fee-for-service area-specific non-drug amount (as defined in paragraph (6)) for the area and year.

"(ii) FEE-FOR-SERVICE MARKET SHARE.—The fee-for-service market share percentage, determined under paragraph (5) for the area and year.

"(4) DETERMINATION OF WEIGHTED AVERAGE MEDICARE ADVANTAGE BIDS FOR AN AREA.—

"(A) IN GENERAL.—For purposes of paragraph (3)(A)(i), the weighted average of plan bids for an area and a year is the sum of the following products for Medicare Advantage plans described in subparagraph (C) in the area and year:

"(i) MONTHLY MEDICARE ADVANTAGE STATUTORY NON-DRUG BID AMOUNT.—The unadjusted Medicare Advantage statutory non-drug monthly bid amount.

"(ii) PLAN'S SHARE OF MEDICARE ADVANTAGE ENROLLMENT IN AREA.—The number of individuals described in subparagraph (B), divided by the total number of such individuals for all Medicare Advantage plans described in subparagraph (C) for that area and year.

"(B) COUNTING OF INDIVIDUALS.—The Administrator shall count, for each Medicare Advantage plan described in subparagraph (C) for an area and year, the number of individuals who reside in the area and who were enrolled under such plan under this part during March of the previous year.

"(C) EXCLUSION OF PLANS NOT OFFERED IN PREVIOUS YEAR.—For an area and year, the Medicare Advantage plans described in this subparagraph are plans described in the first sentence of section 1851(a)(2)(A) that are offered in the area and year and were offered in the area in March of the previous year.

"(5) COMPUTATION OF FEE-FOR-SERVICE MARKET SHARE PERCENTAGE.—The Administrator shall determine, for a year and a competitive Medicare Advantage area, the proportion (in this subsection referred to as the 'fee-for-service market share percentage') of Medicare Advantage eligible individuals residing in the area who during March of the previous year were not enrolled in a Medicare Advantage plan or in an EFFS plan (or, if greater, such proportion determined for individuals nationally).

"(6) FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG AMOUNT.—

"(A) IN GENERAL.—For purposes of paragraph (3)(B)(i) and section 1839(h)(1)(A), subject to subparagraph (B), the term 'fee-for-service area-specific non-drug amount' means, for a competitive Medicare Advantage area and a year, the adjusted average per capita cost for the year involved, determined under section 1876(a)(4) for such area for services covered under parts A and B for individuals entitled to benefits under part A and enrolled under this part who are not enrolled in a Medicare Advantage plan under part C or an EFFS plan under part E for the year, but adjusted to exclude costs attributable to payments under section 1886(h).

"(B) INCLUSION OF COSTS OF VA AND DOD MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the adjusted average per capita cost under subparagraph (A) for a year, such cost shall be adjusted to include the Administrator's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Veterans Affairs or the Department of Defense.

"(7) APPLICATION OF COMPETITION.—In the case of an area that is a competitive Medicare Advantage area for a year, for purposes of applying subsection (a)(1)(A)(ii) and sections 1854(b)(2)(A)(ii) and 1854(b)(3)(B)(i), any reference to a Medicare Advantage area-specific non-drug monthly benchmark amount shall be treated as a reference to the competitive Medicare Advantage non-drug monthly benchmark amount under paragraph (2) for the area and year.

"(8) PHASE-IN OF BENCHMARK FOR EACH AREA.—

"(A) USE OF BLENDED BENCHMARK.—In the case of an area that has not been a competitive Medicare Advantage area for each of the previous 4 years, the competitive Medicare Advantage non-drug monthly benchmark amount shall be equal to the sum of the following:

"(i) NEW COMPETITIVE COMPONENT.—The product of—

"(I) the weighted average phase-in proportion for that area and year, as specified in subparagraph (B); and

"(II) the competitive Medicare Advantage non-drug monthly benchmark amount for the area and year, determined under paragraph (2) without regard to this paragraph.

"(ii) OLD COMPETITIVE COMPONENT.—The product of—

"(I) 1 minus the weighted average phase-in proportion for that area and year; and

"(II) the Medicare Advantage area-wide non-drug benchmark amount for the area and the year.

"(B) COMPUTATION OF WEIGHTED AVERAGE PHASE-IN PROPORTION.—For purposes of this paragraph, the 'weighted average phase-in proportion' for a Medicare Advantage payment area for a year shall be determined as follows:

"(i) FIRST YEAR (AND AREA NOT COMPETITIVE AREA IN PREVIOUS YEAR).—If the area was not a Medicare Advantage competitive area in the previous year, the weighted average phase-in proportion for the area for the year is equal to ⅕.

"(ii) COMPETITIVE AREA IN PREVIOUS YEAR.—If the area was a competitive Medicare Advantage area in the previous year, the weighted average phase-in proportion for the area for the year is equal to the weighted average phase-in proportion determined under this subpara-

graph for the area for the previous year plus ⅕, but in no case more than 1.

"(C) MEDICARE ADVANTAGE AREA-WIDE NON-DRUG BENCHMARK AMOUNT.—For purposes of subparagraph (A)(ii)(II), the term 'Medicare Advantage area-wide non-drug benchmark amount' means, for an area and year, the weighted average of the amounts described in section 1853(j) for Medicare Advantage payment area or areas included in the area (based on the number of traditional fee-for-service enrollees in such payment area or areas) and year.".

(2) APPLICATION.—Section 1854 (42 U.S.C. 1395w–24) is amended—

(A) in subsection (b)(1)(C)(i), as added by section 221(b)(1)(A), by striking "(i) REQUIREMENT.—The" and inserting "(i) REQUIREMENT FOR NON-COMPETITIVE AREAS.—In the case of a Medicare Advantage payment area that is not a competitive Medicare Advantage area designated under section 1853(k)(1), the";

(B) in subsection (b)(1)(C), as so added, by inserting after clause (i) the following new clause:

"(ii) REQUIREMENT FOR COMPETITIVE MEDICARE ADVANTAGE AREAS.—In the case of a Medicare Advantage payment area that is designated as a competitive Medicare Advantage area under section 1853(k)(1), if there are average per capita monthly savings described in paragraph (6) for a Medicare Advantage plan and year, the Medicare Advantage plan shall provide to the enrollee a monthly rebate equal to 75 percent of such savings."; and

(C) by adding at the end of subsection (b), as amended by sections 221(b)(1)(B) and 221(b)(2), the following new paragraph:

"(6) COMPUTATION OF AVERAGE PER CAPITA MONTHLY SAVINGS FOR COMPETITIVE MEDICARE ADVANTAGE AREAS.—For purposes of paragraph (1)(C)(ii), the average per capita monthly savings referred to in such paragraph for a Medicare Advantage plan and year shall be computed in the same manner as the average per capita monthly savings is computed under paragraph (3) except that the reference to the Medicare Advantage area-specific non-drug monthly benchmark amount in paragraph (3)(B)(i) (or to the benchmark amount as adjusted under paragraph (3)(C)(i)) is deemed to be a reference to the competitive Medicare Advantage non-drug monthly benchmark amount (or such amount as adjusted in the manner described in paragraph (3)(B)(i)).".

(3) ADDITIONAL CONFORMING AMENDMENTS.—

(A) PAYMENT OF PLANS.—Section 1853(a)(1)(A)(ii), as amended by section 221(c)(1), is amended—

(i) in subclauses (I) and (II), by inserting "(or, insofar as such payment area is a competitive Medicare Advantage area, described in section 1854(b)(6))" after "section 1854(b)(3)(C)"; and

(ii) in subclause (II), by inserting "(or, insofar as such payment area is a competitive Medicare Advantage area, the competitive Medicare Advantage non-drug monthly benchmark amount)" after "Medicare Advantage area-specific non-drug monthly benchmark amount"; and

(B) DISCLOSURE OF INFORMATION.—Section 1853(b)(1)(B), as amended by section 221(e)(1), is amended to read as follows:

"(B) COMPETITION INFORMATION.—For years beginning with 2006, the following:

"(i) BENCHMARKS.—The Medicare Advantage area-specific non-drug benchmark under section 1853(j) and, if applicable, the competitive Medicare Advantage non-drug benchmark under section 1853(k)(2), for the year and competitive Medicare Advantage area involved and the national fee-for-service market share percentage for the area and year.

"(ii) ADJUSTMENT FACTORS.—The adjustment factors applied under section 1853(a)(1)(A)(iv) (relating to demographic adjustment), section 1853(a)(1)(B) (relating to adjustment for end-stage renal disease), and section 1853(a)(3) (relating to health status adjustment).

"(iii) CERTAIN BENCHMARKS AND AMOUNTS.—In the case of a competitive Medicare Advantage area, the Medicare Advantage area-wide non-drug benchmark amount (as defined in subsection (k)(8)(C)) and the fee-for-service area-specific non-drug amount (as defined in section 1853(k)(6)) for the area.

"(iv) INDIVIDUALS.—The number of individuals counted under subsection (k)(4)(B) and enrolled in each Medicare Advantage plan in the area.".

(C) DEFINITION OF MONTHLY BASIC PREMIUM.—Section 1854(b)(2)(A)(ii), as amended by section 221(d)(2), is amended by inserting "(or, in the case of

a competitive Medicare Advantage area, the competitive Medicare Advantage non-drug monthly benchmark amount or, in applying this paragraph under part E in the case of a competitive EFFS region, the competitive EFFS non-drug monthly benchmark amount)" after "benchmark amount".

(c) PREMIUM ADJUSTMENT.—

(1) IN GENERAL.—Section 1839 (42 U.S.C. 1395r) is amended by adding at the end the following new subsection:

"(h)(1)(A) In the case of an individual who resides in a competitive Medicare Advantage area under section 1853(k)(1) (regardless of whether such area is in a competitive EFFS region under section 1860E–3(e)) and who is not enrolled in a Medicare Advantage plan under part C or in an EFFS plan under part E, the monthly premium otherwise applied under this part (determined without regard to subsections (b) and (f) or any adjustment under this subsection) shall be adjusted as follows: If the fee-for-service area-specific non-drug amount (as defined in section 1853(k)(6)) for the competitive Medicare Advantage area in which the individual resides for a month—

"(i) does not exceed the competitive Medicare Advantage non-drug benchmark (as determined under paragraph (2) of section 1853(k), without regard to paragraph (8) thereof) for such area, the amount of the premium for the individual for the month shall be reduced by an amount equal to the product of the adjustment factor under subparagraph (C) and 75 percent of the amount by which such competitive benchmark exceeds such fee-for-service area-specific non-drug amount; or

"(ii) exceeds such competitive Medicare Advantage non-drug benchmark, the amount of the premium for the individual for the month shall be adjusted to ensure, subject to subparagraph (B), that—

"(I) the sum of the amount of the adjusted premium and the competitive Medicare Advantage non-drug benchmark for the area, is equal to

"(II) the sum of the unadjusted premium plus amount of the fee-for-service area-specific non-drug amount for the area.

"(B) In no case shall the actual amount of an adjustment under subparagraph (A)(ii) exceed the product of the adjustment factor under subparagraph (C) and the amount of the adjustment otherwise computed under subparagraph (A)(ii) without regard to this subparagraph.

"(C) The adjustment factor under this subparagraph for an area for a year is equal to—

"(i) the number of consecutive years (in the 5-year period ending with the year involved) in which such area was a competitive Medicare Advantage area; divided by

"(ii) 5.

"(2)(A) In the case of an individual who resides in an area that is within a competitive EFFS region under section 1860E–3(e) but is not within a competitive Medicare Advantage area under section 1853(k)(1) and who is not enrolled in a Medicare Advantage plan under part C or in an EFFS plan under part E, the monthly premium otherwise applied under this part (determined without regard to subsections (b) and (f) or any adjustment under this subsection) shall be adjusted as follows: If the fee-for-service region-specific non-drug amount (as defined in section 1860E–3(e)(6)) for a region for a month—

"(i) does not exceed the competitive EFFS non-drug monthly benchmark amount (as determined under paragraph (2) of section 1860E–3(e), without regard to paragraph (8) thereof) for such region, the amount of the premium for the individual for the month shall be reduced by an amount equal to the product of the adjustment factor under subparagraph (C) and 75 percent of the amount by which such competitive benchmark amount exceeds such fee-for-service region-specific non-drug benchmark amount; or

"(ii) exceeds such competitive EFFS non-drug monthly benchmark amount, the amount of the premium for the individual for the month shall be adjusted to ensure, subject to subparagraph (B), that—

"(I) the sum of the amount of the adjusted premium and the competitive EFFS non-drug monthly benchmark amount for the region, is equal to

"(II) the sum of the unadjusted premium plus the amount of the EFFS region-specific non-drug monthly bidfor the region.

"(B) In no case shall the actual amount of an adjustment under subparagraph (A)(ii) exceed the product of the adjustment factor under subparagraph (C) and the amount of the adjustment otherwise computed under subparagraph (A)(ii) without regard to this subparagraph.

"(C) The adjustment factor under this subparagraph for an EFFS region for a year is equal to—

"(i) the number of consecutive years (in the 5-year period ending with the year involved) in which such region was a competitive EFFS region; divided by

"(ii) 5.

"(3) Nothing in this subsection shall be construed as preventing a reduction under paragraph (1)(A) or paragraph (2)(A) in the premium otherwise applicable under this part to zero or from requiring the provision of a rebate to the extent such premium would otherwise be required to be less than zero.

"(4) The adjustment in the premium under this subsection shall be effected in such manner as the Medicare Benefits Administrator determines appropriate.

"(5) In order to carry out this subsection (insofar as it is effected through the manner of collection of premiums under 1840(a)), the Medicare Benefits Administrator shall transmit to the Commissioner of Social Security—

"(A) at the beginning of each year, the name, social security account number, and the amount of the adjustment (if any) under this subsection for each individual enrolled under this part for each month during the year; and

"(B) periodically throughout the year, information to update the information previously transmitted under this paragraph for the year.".

(2) CONFORMING AMENDMENT.—Section 1844(c) (42 U.S.C. 1395w(c)) is amended by inserting "and without regard to any premium adjustment effected under section 1839(h)" before the period at the end.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect on January 1, 2010.

TITLE III—COMBATTING WASTE, FRAUD, AND ABUSE

SEC. 301. MEDICARE SECONDARY PAYOR (MSP) PROVISIONS.

(a) TECHNICAL AMENDMENT CONCERNING SECRETARY'S AUTHORITY TO MAKE CONDITIONAL PAYMENT WHEN CERTAIN PRIMARY PLANS DO NOT PAY PROMPTLY.—

(1) IN GENERAL.—Section 1862(b)(2) (42 U.S.C. 1395y(b)(2)) is amended—

(A) in subparagraph (A)(ii), by striking "promptly (as determined in accordance with regulations)";

(B) in subparagraph (B)—

(i) by redesignating clauses (i) through (iii) as clauses (ii) through (iv), respectively; and

(ii) by inserting before clause (ii), as so redesignated, the following new clause:

"(i) AUTHORITY TO MAKE CONDITIONAL PAYMENT.—The Secretary may make payment under this title with respect to an item or service if a primary plan described in subparagraph (A)(ii) has not made or cannot reasonably be expected to make payment with respect to such item or service promptly (as determined in accordance with regulations). Any such payment by the Secretary shall be conditioned on reimbursement to the appropriate Trust Fund in accordance with the succeeding provisions of this subsection.".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall be effective as if included in the enactment of title III of the Medicare and Medicaid Budget Reconciliation Amendments of 1984 (Public Law 98-369).

(b) CLARIFYING AMENDMENTS TO CONDITIONAL PAYMENT PROVISIONS.—Section 1862(b)(2) (42 U.S.C. 1395y(b)(2)) is further amended—

(1) in subparagraph (A), in the matter following clause (ii), by inserting the following sentence at the end: "An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.";

(2) in subparagraph (B)(ii), as redesignated by subsection (a)(2)(B)—

(A) by striking the first sentence and inserting the following: "A primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment made by the Secretary under this title with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service. A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means."; and

(B) in the final sentence, by striking "on the date such notice or other information is received" and inserting "on the date notice of, or information related to, a primary plan's responsibility for such payment or other information is received"; and

(3) in subparagraph (B)(iii), , as redesignated by subsection (a)(2)(B), by striking the first sentence and inserting the following: "In order to recover payment made under this title for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity.".

(c) CLERICAL AMENDMENTS.—Section 1862(b) (42 U.S.C. 1395y(b)) is amended—

(1) in paragraph (1)(A), by moving the indentation of clauses (ii) through (v) 2 ems to the left; and

(2) in paragraph (3)(A), by striking "such" before "paragraphs".

SEC. 302. COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES.

(a) IN GENERAL.—Section 1847 (42 U.S.C. 1395w–3) is amended to read as follows:

"COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES

"SEC. 1847. (a) ESTABLISHMENT OF COMPETITIVE ACQUISITION PROGRAMS.—

"(1) IMPLEMENTATION OF PROGRAMS.—

"(A) IN GENERAL.—The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.

"(B) PHASED-IN IMPLEMENTATION.—The programs shall be phased-in—

"(i) among competitive acquisition areas over a period of not longer than 3 years in a manner so that the competition under the programs occurs in—

"(I) at least ⅓ of such areas in 2005; and

"(II) at least ⅔ of such areas in 2006; and

"(ii) among items and services in a manner such that the programs apply to the highest cost and highest volume items and services first.

"(C) WAIVER OF CERTAIN PROVISIONS.—In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

"(2) ITEMS AND SERVICES DESCRIBED.—The items and services referred to in paragraph (1) are the following:

"(A) DURABLE MEDICAL EQUIPMENT AND MEDICAL SUPPLIES.—Covered items (as defined in section 1834(a)(13)) for which payment is otherwise made under section 1834(a), including items used in infusion and drugs and supplies used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act.

"(B) OTHER EQUIPMENT AND SUPPLIES.—Items, equipment, and supplies (as described in section 1842(s)(2)(D) other than enteral nutrients).

"(C) OFF-THE-SHELF ORTHOTICS.—Orthotics (described in section 1861(s)(9)) for which payment is otherwise made under section 1834(h) which require minimal self-adjustment for appropriate use and does not require expertise in trimming, bending, molding, assembling, or customizing to fit to the patient.

"(3) EXCEPTION AUTHORITY.—In carrying out the programs under this section, the Secretary may exempt—

"(A) rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service; and

"(B) items and services for which the application of competitive acquisition is not likely to result in significant savings.

"(4) SPECIAL RULE FOR CERTAIN RENTED ITEMS OF DURABLE MEDICAL EQUIPMENT.—In the case of a covered item for which payment is made on a rental

basis under section 1834(a), the Secretary shall establish a process by which rental agreements for the covered items entered into before the application of the competitive acquisition program under this section for the item may be continued notwithstanding this section. In the case of any such continuation, the supplier involved shall provide for appropriate servicing and replacement, as required under section 1834(a).

"(5) PHYSICIAN AUTHORIZATION.—The Secretary may establish a process under which a physician may prescribe a particular brand or mode of delivery of an item or service if the item or service involved is clinically more appropriate than other similar items or services.

"(6) APPLICATION.—For each competitive acquisition area in which the program is implemented under this subsection with respect to items and services, the payment basis determined under the competition conducted under subsection (b) shall be substituted for the payment basis otherwise applied under section 1834(a).

"(b) PROGRAM REQUIREMENTS.—

"(1) IN GENERAL.—The Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services.

"(2) CONDITIONS FOR AWARDING CONTRACT.—

"(A) IN GENERAL.—The Secretary may not award a contract to any entity under the competition conducted in an competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

"(i) The entity meets quality and financial standards specified by the Secretary or developed by the Program Advisory and Oversight Committee established under subsection (c).

"(ii) The total amounts to be paid under the contract (including costs associated with the administration of the contract) are expected to be less than the total amounts that would otherwise be paid.

"(iii) Beneficiary access to a choice of multiple suppliers in the area is maintained.

"(iv) Beneficiary liability is limited to 20 percent of the applicable contract award price, except in such cases where a supplier has furnished an upgraded item and has executed an advanced beneficiary notice.

"(B) DEVELOPMENT OF QUALITY STANDARDS FOR DME PRODUCTS.—

"(i) IN GENERAL.—The quality standards specified under subparagraph (A)(i) shall not be less than the quality standards that would otherwise apply if this section did not apply and shall include consumer services standards. Not later than July 1, 2004, the Secretary shall establish new quality standards for products subject to competitive acquisition under this section. Such standards shall be applied prospectively and shall be published on the website of the Department of Health and Human Services.

"(ii) CONSULTATION WITH PROGRAM ADVISORY AND OVERSIGHT COMMITTEE.—The Secretary shall consult with the Program Advisory and Oversight Committee (established under subsection (c)) to review (and advise the Secretary concerning) the quality standards referred to in clause (i).

"(3) CONTENTS OF CONTRACT.—

"(A) IN GENERAL.—A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify.

"(B) TERM OF CONTRACTS.—The Secretary shall recompete contracts under this section not less often than once every 3 years.

"(4) LIMIT ON NUMBER OF CONTRACTORS.—

"(A) IN GENERAL.—The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts. In awarding contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of beneficiaries for such items or services in the geographic area covered under the contract on a timely basis.

"(B) MULTIPLE WINNERS.—The Secretary shall award contracts to multiple entities submitting bids in each area for an item or service.

"(5) PAYMENT.—Payment under this part for competitively priced items and services described in subsection (a)(2) shall be based on the bids submitted and accepted under this section for such items and services.

"(6) PARTICIPATING CONTRACTORS.—Payment shall not be made for items and services described in subsection (a)(2) furnished by a contractor and for which competition is conducted under this section unless—

"(A) the contractor has submitted a bid for such items and services under this section; and

"(B) the Secretary has awarded a contract to the contractor for such items and services under this section.

In this section, the term 'bid' means a request for a proposal for an item or service that includes the cost of the item or service, and where appropriate, any services that are attendant to the provision of the item or service.

"(7) CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary shall consider the similarity of the clinical efficiency and value of specific codes and products, including products that may provide a therapeutic advantage to beneficiaries, before delineating the categories and products that will be subject to bidding.

"(8) AUTHORITY TO CONTRACT FOR EDUCATION, MONITORING, OUTREACH AND COMPLAINT SERVICES.—The Secretary may enter into a contract with an appropriate entity to address complaints from beneficiaries who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such beneficiaries and monitoring quality of services with respect to the program.

"(c) PROGRAM ADVISORY AND OVERSIGHT COMMITTEE.—

"(1) ESTABLISHMENT.—There is established a Program Advisory and Oversight Committee (hereinafter in this section referred to as the 'Committee').

"(2) MEMBERSHIP; TERMS.—The Committee shall consist of such members as the Secretary may appoint who shall serve for such term as the Secretary may specify.

"(3) DUTIES.—

"(A) TECHNICAL ASSISTANCE.—The Committee shall provide advice and technical assistance to the Secretary with respect to the following functions:

"(i) The implementation of the program under this section.

"(ii) The establishment of requirements for collection of data.

"(iii) The development of proposals for efficient interaction among manufacturers and distributors of the items and services and providers and beneficiaries.

"(B) ADDITIONAL DUTIES.—The Committee shall perform such additional functions to assist the Secretary in carrying out this section as the Secretary may specify.

"(4) INAPPLICABILITY OF FACA.—The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply.

"(d) ANNUAL REPORTS.—The Secretary shall submit to Congress an annual management report on the programs under this section. Each such report shall include information on savings, reductions in beneficiary cost-sharing, access to and quality of items and services, and beneficiary satisfaction.

"(e) DEMONSTRATION PROJECT FOR CLINICAL LABORATORY SERVICES.—

"(1) IN GENERAL.—The Secretary shall conduct a demonstration project on the application of competitive acquisition under this section to clinical diagnostic laboratory tests—

"(A) for which payment is otherwise made under section 1833(h) or 1834(d)(1) (relating to colorectal cancer screening tests); and

"(B) which are furnished by entities that did not have a face-to-face encounter with the individual.

"(2) TERMS AND CONDITIONS.—Such project shall be under the same conditions as are applicable to items and services described in subsection (a)(2).

"(3) REPORT.—The Secretary shall submit to Congress—

"(A) an initial report on the project not later than December 31, 2005; and

"(B) such progress and final reports on the project after such date as the Secretary determines appropriate.".

(b) CONFORMING AMENDMENTS.—

(1) DURABLE MEDICAL EQUIPMENT; ELIMINATION OF INHERENT REASONABLENESS AUTHORITY.—Section 1834(a) (42 U.S.C. 1395m(a)) is amended—

(A) in paragraph (1)(B), by striking "The payment basis" and inserting "Subject to subparagraph (E)(i), the payment basis";

(B) in paragraph (1)(C), by striking "This subsection" and inserting "Subject to subparagraph (E)(ii), this subsection";

(C) by adding at the end of paragraph (1) the following new subparagraph:

"(E) APPLICATION OF COMPETITIVE ACQUISITION; ELIMINATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of covered items and services that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)—

"(i) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and

"(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847 and in the case of such adjustment, paragraph (10)(B) shall not be applied."; and

(D) in paragraph (10)(B), by inserting "in an area and with respect to covered items and services for which the Secretary does not make a payment amount adjustment under paragraph (1)(E)" after "under this subsection".

(2) OFF-THE-SHELF ORTHOTICS; ELIMINATION OF INHERENT REASONABLENESS AUTHORITY.—Section 1834(h) (42 U.S.C. 1395m(h)) is amended—

(A) in paragraph (1)(B), by striking "and (E)" and inserting ", (E) , and (H)(i)";

(B) in paragraph (1)(D), by striking "This subsection" and inserting "Subject to subparagraph (H)(ii), this subsection";

(C) by adding at the end of paragraph (1) the following new subparagraph:

"(H) APPLICATION OF COMPETITIVE ACQUISITION TO ORTHOTICS; ELIMINATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of orthotics described in paragraph (2)(B) of section 1847(a) that are included in a competitive acquisition program in a competitive acquisition area under such section—

"(i) the payment basis under this subsection for such orthotics furnished in such area shall be the payment basis determined under such competitive acquisition program; and

"(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.".

(c) REPORT ON ACTIVITIES OF SUPPLIERS.—The Secretary shall conduct a study to determine the extent to which (if any) suppliers of covered items of durable medical equipment that are subject to the competitive acquisition program under section 1847 of the Social Security Act, as amended by subsection (a), are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability.

SEC. 303. COMPETITIVE ACQUISITION OF COVERED OUTPATIENT DRUGS AND BIOLOGICALS.

(a) ADJUSTMENT TO PHYSICIAN FEE SCHEDULE.—

(1) ADJUSTMENT IN PRACTICE EXPENSE RELATIVE VALUE UNITS.—Section 1848(c)(2) (42 U.S.C. 1395w–4(c)(2)) is amended—

(A) in subparagraph (B)—

(i) in clause (ii)(II), by striking "The adjustments" and inserting "Subject to clause (iv), the adjustments"; and

(ii) by adding at the end of subparagraph (B), the following new clause:

"(iv) EXCEPTION TO BUDGET NEUTRALITY.—The additional expenditures attributable to clauses (ii) and (iii) of subparagraph (H) shall not be taken into account in applying clause (ii)(II) for 2005."; and

(B) by adding at the end the following new subparagraph:

"(H) ADJUSTMENTS IN PRACTICE EXPENSE RELATIVE VALUE UNITS FOR 2004.—

"(i) IN GENERAL.—As part of the annual process of establishing the physician fee schedule under subsection (b) for 2004, the Secretary shall increase the practice expense relative value units for 2004 consistent with clauses (ii) and (iii).

"(ii) USE OF SUPPLEMENTAL SURVEY DATA.—For 2004 for any specialty that submitted survey data that included expenses for the administration of drugs and biologicals for which payment is made under section 1842(o) (or section 1847A), the Secretary shall use such supplemental

survey data in carrying out this subparagraph insofar as they are collected and provided by entities and organizations consistent with the criteria established by the Secretary pursuant to section 212(a) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and insofar as such data are submitted to the Secretary by the date of the enactment of this subparagraph.

"(iii) EXPEDITING CONSIDERATION OF CPT CODES FOR AFFECTED PHYSICIAN SPECIALTIES.—The Secretary shall, in cooperation with representatives of physician specialities affected by section 1847A, take such actions as are necessary to expedite considerations of CPT codes, or expand the ability to appropriately bill for physicians' services under existing CPT codes, for costs associated with the administration of covered outpatient drugs. The Secretary shall consult with representatives of advisory physician groups in expediting such considerations.

"(iv) SUBSEQUENT, BUDGET NEUTRAL ADJUSTMENTS PERMITTED.—Nothing in this subparagraph shall be construed as preventing the Secretary from providing for adjustments in practice expense relative value units under (and consistent with) subparagraph (B) for years after 2004.

"(v) CONSULTATION.—Before publishing the notice of proposed rulemaking to carry out this subparagraph, the Secretary shall consult with the Comptroller General of the United States and with groups representing the physician specialties involved.

"(vi) TREATMENT AS CHANGE IN LAW AND REGULATION IN SUSTAINABLE GROWTH RATE DETERMINATION.—The enactment of subparagraph (B)(iv) and this subparagraph shall be treated as a change in law for purposes of applying subsection (f)(2)(D).".

(2) PROHIBITION OF ADMINISTRATIVE AND JUDICIAL REVIEW.—Section 1848(i)(1) (42 U.S.C. 1395w–4(i)(1)) is amended—

(A) by striking "and" at the end of subparagraph (D);

(B) by striking the period at the end of subparagraph (E) and inserting ", and"; and

(C) by adding at the end the following new subparagraph:

"(F) adjustments in practice expense relative value units for 2005 under subsection (c)(2)(H).".

(3) TREATMENT OF OTHER SERVICES CURRENTLY IN THE NON-PHYSICIAN WORK POOL.—The Secretary shall make adjustments to the non-physician work pool methodology (as such term is used in the regulations promulgated by the Secretary in the Federal Register as of December 31, 2002) for determination of practice expense relative value units under the physician fee schedule described in section 1848(c)(2)(C)(ii) of the Social Security Act so that the practice expense relative value units for services determined under such methodology are not disproportionately reduced relative to the practice expense relative value units of other services not determined under such non-physician work pool methodology, as the result of amendments made by paragraph (1).

(4) SUBMISSION OF PRACTICE EXPENSE SURVEY DATA.—Any physician specialty may submit survey data related to practice expenses to the Secretary through Decmeber 31, 2004. Nothing in this paragraph shall be construed as waiving the application of budget neutrality under section 1848 of the Social Security Act.

(b) PAYMENT BASED ON COMPETITION.—Title XVIII is amended by inserting after section 1847 (42 U.S.C. 1395w–3), as amended by section 302, the following new sections:

"COMPETITIVE ACQUISITION OF COVERED OUTPATIENT DRUGS AND BIOLOGICALS

"SEC. 1847A. (a) IMPLEMENTATION OF COMPETITIVE ACQUISITION.—

"(1) IMPLEMENTATION OF PROGRAM.—

"(A) IN GENERAL.—The Secretary shall establish and implement a competitive acquisition program under which—

"(i) competitive acquisition areas are established throughout the United States for contract award purposes for acquisition of and payment for categories of covered outpatient drugs and biologicals (as defined in paragraph (2)) under this part; and

"(ii) each physician who does not elect section 1847B to apply makes an annual selection, under paragraph (5) of the contractor through which drugs and biologicals within a category of drugs and biologicals will be acquired and delivered to the physician under this part.

"(B) IMPLEMENTATION.—The Secretary shall implement the program so that the program applies to—

"(i) the oncology category beginning in 2005; and

"(ii) the non-oncology category beginning in 2006.

This section shall not apply in the case of a physician who elects section 1847B to apply.

"(C) WAIVER OF CERTAIN PROVISIONS.—In order to promote competition, efficient service, and product quality, in carrying out the program the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

"(D) EXCLUSION AUTHORITY.—The Secretary may exclude covered outpatient drugs and biologicals (including a class of such drugs and biologicals) from the competitive bidding system under this section if the drugs or biologicals (or class) are not appropriate for competitive bidding due to low volume of utilization by beneficiaries under this part or a unique mode or method of delivery or similar reasons.

"(2) COVERED OUTPATIENT DRUGS AND BIOLOGICALS, CATEGORIES, PROGRAM DEFINED.—For purposes of this section—

"(A) COVERED OUTPATIENT DRUGS AND BIOLOGICALS DEFINED.—The term 'covered outpatient drugs and biologicals' means drugs and biologicals to which section 1842(o) applies and which are not covered under section 1847 (relating to competitive acquisition for items of durable medical equipment). Such term does not include the following:

"(i) Blood clotting factors.

"(ii) Drugs and biologicals furnished to individuals in connection with the treatment of end stage renal disease.

"(iii) Radiopharmaceuticals.

"(B) 2 CATEGORIES.—Each of the following shall be a separate category of covered outpatient drugs and biologicals, as identified by the Secretary:

"(i) ONCOLOGY CATEGORY.—A category (in this section referred to as the 'oncology category') consisting of those covered outpatient drugs and biologicals that, as determined by the Secretary, are typically primarily billed by oncologists or are otherwise used to treat cancer.

"(ii) NON-ONCOLOGY CATEGORIES.—Such numbers of categories (in this section referred to as the 'non-oncology categories') consisting of covered outpatient drugs and biologicals not described in clause (i), and appropriate subcategories of such drugs and biologicals as the Secretary may specify.

"(C) PROGRAM.—The term 'program' means the competitive acquisition program under this section.

"(D) COMPETITIVE ACQUISITION AREA; AREA.—The terms 'competitive acquisition area' and 'area' mean an appropriate geographic region established by the Secretary under the program.

"(E) CONTRACTOR.—The term 'contractor' means an entity that has entered into a contract with the Secretary under this section.

"(3) APPLICATION OF PROGRAM PAYMENT METHODOLOGY.—With respect to covered outpatient drugs and biologicals which are supplied under the program in an area and which are prescribed by a physician who has not elected section 1847B to apply—

"(A) the claim for such drugs and biologicals shall be submitted by the contractor that supplied the drugs and biologicals;

"(B) collection of amounts of any deductible and coinsurance applicable with respect to such drugs and biologicals shall be the responsibility of such contractor and shall not be collected unless the drug or biological is administered to the beneficiary involved; and

"(C) the payment under this section (and related coinsurance amounts) for such drugs and biologicals—

"(i) shall be made only to such contractor;

"(ii) shall be conditioned upon the administration of such drugs and biologicals; and

"(iii) shall be based on the average of the bid prices for such drugs and biologicals in the area, as computed under subsection (d).

The Secretary shall provide a process for recoupment in the case in which payment is made for drugs and biologicals which were billed at the time of dispensing but which were not actually administered.

"(4) CONTRACT REQUIRED.—

"(A) IN GENERAL.—Payment may not be made under this part for covered outpatient drugs and biologicals prescribed by a physician who has not

elected section 1847B to apply within a category and a competitive acquisition area with respect to which the program applies unless—

"(i) the drugs or biologicals are supplied by a contractor with a contract under this section for such category of drugs and biologicals and area; and

"(ii) the physician has elected such contractor under paragraph (5) for such category and area.

"(B) PHYSICIAN CHOICE.—Subparagraph (A) shall not apply for a category of drugs for an area if the physician prescribing the covered outpatient drug in such category and area has elected to apply section 1847B instead of this section.

"(5) CONTRACTOR SELECTION PROCESS.—

"(A) IN GENERAL.—The Secretary shall provide a process for the selection of a contractor, on an annual basis and in such exigent circumstances as the Secretary may provide and with respect to each category of covered outpatient drugs and biologicals for an area, by physicians prescribing such drugs and biologicals in the area of the contractor under this section that will supply the drugs and biologicals within that category and area. Such selection shall also include the election described in section 1847B(a).

"(B) INFORMATION ON CONTRACTORS.—The Secretary shall make available to physicians on an ongoing basis, through a directory posted on the Department's Internet website or otherwise and upon request, a list of the contractors under this section in the different competitive acquisition areas.

"(C) SELECTING PHYSICIAN DEFINED.—For purposes of this section, the term 'selecting physician' means, with respect to a contractor and category and competitive acquisition area, a physician who has not elected section 1847B to apply and has selected to apply under this section such contractor for such category and area.

"(b) PROGRAM REQUIREMENTS.—

"(1) CONTRACT FOR COVERED OUTPATIENT DRUGS AND BIOLOGICALS.—The Secretary shall conduct a competition among entities for the acquisition of a covered outpatient drug or biological within each HCPCS code within each category for each competitive acquisition area.

"(2) CONDITIONS FOR AWARDING CONTRACT.—

"(A) IN GENERAL.—The Secretary may not award a contract to any entity under the competition conducted in a competitive acquisition area pursuant to paragraph (1) with respect to the acquisition of covered outpatient drugs and biologicals within a category unless the Secretary finds that the entity meets all of the following with respect to the contract period involved:

"(i) CAPACITY TO SUPPLY COVERED OUTPATIENT DRUG OR BIOLOGICAL WITHIN CATEGORY.—

"(I) IN GENERAL.—The entity has sufficient arrangements to acquire and to deliver covered outpatient drugs and biologicals within such category in the area specified in the contract at the bid price specified in the contract for all physicians that may elect such entity.

"(II) SHIPMENT METHODOLOGY.—The entity has arrangements in effect for the shipment at least 5 days each week of covered outpatient drugs and biologicals under the contract and for the timely delivery (including for emergency situations) of such drugs and biologicals in the area under the contract.

"(ii) QUALITY, SERVICE, FINANCIAL PERFORMANCE AND SOLVENCY STANDARDS.—The entity meets quality, service, financial performance, and solvency standards specified by the Secretary, including—

"(I) the establishment of procedures for the prompt response and resolution of physician and beneficiary complaints and inquiries regarding the shipment of covered outpatient drugs and biologicals; and

"(II) a grievance process for the resolution of disputes.

"(B) ADDITIONAL CONSIDERATIONS.—The Secretary may refuse to award a contract under this section, and may terminate such a contract, with an entity based upon—

"(i) the suspension or revocation, by the Federal Government or a State government, of the entity's license for the distribution of drugs or biologicals (including controlled substances); or

"(ii) the exclusion of the entity under section 1128 from participation under this title.

"(C) APPLICATION OF MEDICARE PROVIDER OMBUDSMAN.—For provision providing for a program-wide Medicare Provider Ombudsman to review

complaints, see section 1868(b), as added by section 923 of the Medicare Prescription Drug and Modernization Act of 2003.

"(3) AWARDING MULTIPLE CONTRACTS FOR A CATEGORY AND AREA.—In order to provide a choice of at least 2 contractors in each competitive acquisition area for a category of drugs and biologicals, the Secretary may limit (but not below 2) the number of qualified entities that are awarded such contracts for any category and area. The Secretary shall select among qualified entities based on the following:

"(A) The bid prices for covered outpatient drugs and biologicals within the category and area.

"(B) Bid price for distribution of such drugs and biologicals.

"(C) Ability to ensure product integrity.

"(D) Customer service.

"(E) Past experience in the distribution of drugs and biologicals, including controlled substances.

"(F) Such other factors as the Secretary may specify.

"(4) TERMS OF CONTRACTS.—

"(A) IN GENERAL.—A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify consistent with this section.

"(B) PERIOD OF CONTRACTS.—A contract under this section shall be for a term of 2 years, but may be terminated by the Secretary or the entity with appropriate, advance notice.

"(C) INTEGRITY OF DRUG AND BIOLOGICAL DISTRIBUTION SYSTEM.—The Secretary—

"(i) shall require that for all drug and biological products distributed by a contractor under this section be acquired directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer; and

"(ii) may require, in the case of such products that are particularly susceptible to counterfeit or diversion, that the contractor comply with such additional product integrity safeguards as may be determined to be necessary.

"(D) IMPLEMENTATION OF ANTI-COUNTERFEITING, QUALITY, SAFETY, AND RECORD KEEPING REQUIREMENTS.—The Secretary shall require each contractor to implement (through its officers, agents, representatives, and employees) requirements relating to the storage and handling of covered outpatient drugs and biologicals and for the establishment and maintenance of distribution records for such drugs and biologicals. A contract under this section may include requirements relating to the following:

"(i) Secure facilities.

"(ii) Safe and appropriate storage of drugs and biologicals.

"(iii) Examination of drugs and biologicals received and dispensed.

"(iv) Disposition of damaged and outdated drugs and biologicals.

"(v) Record keeping and written policies and procedures.

"(vi) Compliance personnel.

"(E) COMPLIANCE WITH CODE OF CONDUCT AND FRAUD AND ABUSE RULES.—Under the contract—

"(i) the contractor shall comply with a code of conduct, specified or recognized by the Secretary, that includes standards relating to conflicts of interest; and

"(ii) the contractor shall comply with all applicable provisions relating to prevention of fraud and abuse, including compliance with applicable guidelines of the Department of Justice and the Inspector General of the Department of Health and Human Services.

"(F) DIRECT DELIVERY OF DRUGS AND BIOLOGICALS TO PHYSICIANS.—Under the contract the contractor shall only supply covered outpatient drugs and biologicals directly to the selecting physicians and not directly to beneficiaries, except under circumstances and settings where a beneficiary currently receives a drug or biological in the beneficiary's home or other nonphysician office setting as the Secretary may provide. The contractor shall not deliver drugs and biologicals to a selecting physician except upon receipt of a prescription for such drugs and biologicals, and such necessary data as may be required by the Secretary to carry out this section. This section does not require a physician to submit a prescription for each individual treatment and does not change the physician's flexibility in terms of writing a prescription for drugs for a single treatment or a course of treatment.

"(5) PERMITTING ACCESS TO DRUGS AND BIOLOGICALS.—The Secretary shall establish rules under this section under which drugs and biologicals which are acquired through a contractor under this section may be used to resupply inventories of such drugs and biologicals which are administered consistent with safe drug practices and with adequate safeguards against fraud and abuse. The previous sentence shall apply—

"(A) in cases in which the drugs or biologicals are immediately required;

"(B) in cases in which the physician could not have reasonably anticipated the immediate requirement for the drugs or biologicals;

"(C) in cases in which the contractor could not deliver to the physician the drugs or biologicals in a timely manner; and

"(D) in emergency situations.

"(6) CONSTRUCTION.—Nothing in this section shall be construed as waiving applicable State requirements relating to licensing of pharmacies.

"(c) BIDDING PROCESS.—

"(1) IN GENERAL.—In awarding a contract for a category of drugs and biologicals in an area under the program, the Secretary shall consider with respect to each entity seeking to be awarded a contract the prices bid to acquire and supply the covered outpatient drugs and biologicals for that category and area and the other factors referred to in subsection (b)(3).

"(2) PRICES BID.—The prices bid by an entity under paragraph (1) shall be the prices in effect and available for the supply of contracted drugs and biologicals in the area through the entity for the contract period.

"(3) REJECTION OF CONTRACT OFFER.—The Secretary shall reject the contract offer of an entity with respect to a category of drugs and biologicals for an area if the Secretary estimates that the prices bid, in the aggregate on average, would exceed 120 percent of the average sales price (as determined under section 1847B).

"(4) BIDDING ON A NATIONAL OR REGIONAL BASIS.—Nothing in this section shall be construed as precluding a bidder from bidding for contracts in all areas of the United States or as requiring a bidder to submit a bid for all areas of the United States.

"(5) UNIFORMITY OF BIDS WITHIN AREA.—The amount of the bid submitted under a contract offer for any covered outpatient drug or biological for an area shall be the same for that drug or biological for all portions of that area.

"(6) CONFIDENTIALITY OF BIDS.—The provisions of subparagraph (D) of section 1927(b)(3) shall apply to a bid submitted in a contract offer for a covered outpatient drug or biological under this section in the same manner as it applies to information disclosed under such section, except that any reference—

"(A) in that subparagraph to a 'manufacturer or wholesaler' is deemed a reference to a 'bidder' under this section;

"(B) in that section to 'prices charged for drugs' is deemed a reference to a 'bid' submitted under this section; and

"(C) in clause (i) of that section to 'this section', is deemed a reference to 'part B of title XVIII'.

"(7) INCLUSION OF COSTS.—The bid price submitted in a contract offer for a covered outpatient drug or biological shall—

"(A) include all costs related to the delivery of the drug or biological to the selecting physician (or other point of delivery); and

"(B) include the costs of dispensing (including shipping) of such drug or biological and management fees, but shall not include any costs related to the administration of the drug or biological, or wastage, spillage, or spoilage.

"(8) PRICE ADJUSTMENTS DURING CONTRACT PERIOD; DISCLOSURE OF COSTS.—Each contract awarded shall provide for—

"(A) disclosure to the Secretary the contractor's reasonable, net acquisition costs for periods specified by the Secretary, not more often than quarterly, of the contract; and

"(B) appropriate price adjustments over the period of the contract to reflect significant increases or decreases in a contractor's reasonable, net acquisition costs, as so disclosed.

"(d) COMPUTATION OF AVERAGE BID PRICES FOR A CATEGORY AND AREA.—

"(1) IN GENERAL.—For each year or other contract period for each covered outpatient drug or biological and area with respect to which a competition is conducted under the program, the Secretary shall compute an area average of the bid prices submitted, in contract offers accepted for the category and area, for that year or other contract period.

"(2) SPECIAL RULES.—The Secretary shall establish rules regarding the use under this section of the alternative payment amount provided under section

1847B to the use of a price for specific covered outpatient drugs and biologicals in the following cases:

"(A) NEW DRUGS AND BIOLOGICALS.—A covered outpatient drug or biological for which an average bid price has not been previously determined.

"(B) OTHER CASES.—Such other exceptional cases as the Secretary may specify in regulations.

Such alternative payment amount shall be based upon actual market price information and in no case shall it exceed the average sales price (as determined under section 1847B).

"(e) COINSURANCE.—

"(1) IN GENERAL.—Coinsurance under this part with respect to a covered outpatient drug or biological for which payment is payable under this section shall be based on 20 percent of the payment basis under this section.

"(2) COLLECTION.—Such coinsurance shall be collected by the contractor that supplies the drug or biological involved and, subject to subsection (a)(3)(B), in the same manner as coinsurance is collected for durable medical equipment under this part.

"(f) SPECIAL PAYMENT RULES.—

"(1) IN GENERAL.—The Secretary may not provide for an adjustment to reimbursement for covered outpatient drugs and biologicals unless adjustments to the practice expense payment adjustment are made on the basis of supplemental surveys under section 1848(c)(2)(H)(ii) of the Social Security Act, as added by subsection (a)(1)(B).

"(B) USE IN EXCLUSION CASES.—If the Secretary excludes a drug or biological (or class of drugs or biologicals) under subsection (a)(1)(D), the Secretary may provide for reimbursement to be made under this part for such drugs and biologicals (or class) using the payment methodology under section 1847B or other market based pricing system.

"(2) COORDINATION RULES.—The provisions of section 1842(h)(3) shall apply to a contractor with respect to covered outpatients drugs and biologicals supplied by that contractor in the same manner as they apply to a participating supplier. In order to administer this section, the Secretary may condition payment under this part to a person for the administration of a drug or biological supplied under this section upon person's provision of information on such administration.

"(3) APPLICATION OF REQUIREMENT FOR ASSIGNMENT.—For provision requiring assignment of claims for covered outpatient drugs and biologicals, see section 1842(o)(3).

"(4) PROTECTION FOR BENEFICIARY IN CASE OF MEDICAL NECESSITY DENIAL.—For protection of beneficiaries against liability in the case of medical necessity determinations, see section 1842(b)(3)(B)(ii)(III).

"(5) PHYSICIAN ROLE IN APPEALS PROCESS.—The Secretary shall establish a procedure under which a physician who prescribes a drug or biological for which payment is made under this section has appeal rights that are similar to those provided to a physician who prescribes durable medical equipment or a laboratory test.

"(g) ADVISORY COMMITTEE.—The Secretary shall establish an advisory committee that includes representatives of parties affected by the program under this section, including physicians, specialty pharmacies, distributors, manufacturers, and beneficiaries. The committee shall advise the Secretary on issues relating to the effective implementation of this section.

"(h) ANNUAL REPORTS.—The Secretary shall submit to Congress an annual report in each of 2004, 2005, and 2006, on the program. Each such report shall include information on savings, reductions in cost-sharing, access to covered outpatient drugs and biologicals, the range of choices of contractors available to providers, and beneficiary and provider satisfaction.

"OPTIONAL USE OF AVERAGE SALES PRICE PAYMENT METHODOLOGY

"SEC. 1847B. (a) IN GENERAL.—In connection with the election made by a physician under section 1847A(a)(5), the physician may elect to apply this section to the payment for covered outpatient drugs instead of the payment methodology under section 1847A. For purposes of this section, the term 'covered outpatient drug' has the meaning given such term in section 1847A(a)(2)(A).

"(b) COMPUTATION OF PAYMENT AMOUNT.—

"(1) IN GENERAL.—If this section applies with respect to a covered outpatient drug, the amount payable for the drug (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance—

"(A) in the case of a multiple source drug (as defined in subsection (c)(6)(C)), the amount determined under paragraph (3); or

"(B) in the case of a single source drug (as defined in subsection (c)(6)(D)), the amount determined under paragraph (4).

"(2) SPECIFICATION OF UNIT.—

"(A) SPECIFICATION BY MANUFACTURER.—The manufacturer of a covered outpatient drug shall specify the unit associated with each National Drug Code as part of the submission of data under section 1927(b)(3)(A)(iii).

"(B) UNIT DEFINED.—In this section, the term 'unit' means, with respect to a covered outpatient drug, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids.

"(3) MULTIPLE SOURCE DRUG.—For all drug products included within the same multiple source drug, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1927(b)(3)(A)(iii) computed as follows:

"(A) Compute the sum of the products (for each national drug code assigned to such drug products) of—

"(i) the manufacturer's average sales price (as defined in subsection (c)); and

"(ii) the total number of units specified under paragraph (2) sold, as reported under section 1927(b)(3)(A)(iii).

"(B) Divide the sum computed under subparagraph (A) by the sum of the total number of units under subparagraph (A)(ii) for all national drug codes assigned to such drug products.

"(4) SINGLE SOURCE DRUG.—The amount specified in this paragraph for a single source drug is the lesser of the following:

"(A) MANUFACTURER'S AVERAGE SALES PRICE.—The manufacturer's average sales price for a national drug code, as computed using the methodology applied under paragraph (3).

"(B) WHOLESALE ACQUISITION COST (WAC).—The wholesale acquisition cost (as defined in subsection (c)(6)(B)) reported for the single source drug.

"(5) BASIS FOR DETERMINATION.—The payment amount shall be determined under this subsection based on information reported under subsection (e) and without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

"(c) MANUFACTURER'S AVERAGE SALES PRICE.—

"(1) IN GENERAL.—For purposes of this subsection, subject to paragraphs (2) and (3), the manufacturer's 'average sales price' means, of a covered outpatient drug for a NDC code for a calendar quarter for a manufacturer for a unit—

"(A) the manufacturer's total sales (as defined by the Secretary in regulations for purposes of section 1927(c)(1)) in the United States for such drug in the calendar quarter; divided by

"(B) the total number of such units of such drug sold by the manufacturer in such quarter.

"(2) CERTAIN SALES EXEMPTED FROM COMPUTATION.—In calculating the manufacturer's average sales price under this subsection, the following sales shall be excluded:

"(A) SALES EXEMPT FROM BEST PRICE.—Sales exempt from the inclusion in the determination of 'best price' under section 1927(c)(1)(C)(i).

"(B) SALES AT NOMINAL CHARGE.—Such other sales as the Secretary identifies by regulation as sales to an entity that are nominal in price or do not reflect a market price paid by an entity to which payment is made under this section.

"(3) SALE PRICE NET OF DISCOUNTS.—In calculating the manufacturer's average sales price under this subsection, such price shall be determined taking into account volume discounts, prompt pay discounts, cash discounts, the free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927), that result in a reduction of the cost to the purchaser. A rebate to a payor or other entity that does not take title to a covered outpatient drug shall not be taken into account in determining such price unless the manufacturer has an agreement with the payor or other entity under which the purchaser's price for the drug is reduced as a consequence of such rebate.

"(4) AUTHORITY TO DISREGARD AVERAGE SALES PRICE DURING FIRST QUARTER OF SALES.—In the case of a covered outpatient drug during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug is not sufficiently available from the manufacturer to compute an average sales price for the drug, the Secretary may determine the amount payable

under this section for the drug without considering the manufacturer's average sales price of that manufacturer for that drug.

"(5) FREQUENCY OF DETERMINATIONS.—

"(A) IN GENERAL ON A QUARTERLY BASIS.—The manufacturer's average sales price, for a covered outpatient drug of a manufacturer, shall be determined by such manufacturer under this subsection on a quarterly basis. In making such determination insofar as there is a lag in the reporting of the information on rebates and chargebacks under paragraph (3) so that adequate data are not available on a timely basis, the manufacturer shall apply a methodology established by the Secretary based on a 12-month rolling average for the manufacturer to estimate costs attributable to rebates and chargebacks.

"(B) UPDATES IN RATES.—The payment rates under subsection (b)(1) and (b)(2)(A) shall be updated by the Secretary on a quarterly basis and shall be applied based upon the manufacturer's average sales price determined for the most recent calendar quarter.

"(C) USE OF CONTRACTORS; IMPLEMENTATION.—The Secretary may use a carrier, fiscal intermediary, or other contractor to determine the payment amount under subsection (b). Notwithstanding any other provision of law, the Secretary may implement, by program memorandum or otherwise, any of the provisions of this section.

"(6) DEFINITIONS AND OTHER RULES.—In this section:

"(A) MANUFACTURER.—The term 'manufacturer' means, with respect to a covered outpatient drug, the manufacturer (as defined in section 1927(k)(5)) whose national drug code appears on such drug.

"(ii) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' means, with respect to a covered outpatient drug, the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug pricing data.

"(C) MULTIPLE SOURCE DRUG.—The term 'multiple source drug' means, for a calendar quarter, a covered outpatient drug for which there are 2 or more drug products which—

"(i) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations'),

"(ii) except as provided in subparagraph (E), are pharmaceutically equivalent and bioequivalent, as determined under subparagraph (F) and as determined by the Food and Drug Administration, and

"(iii) are sold or marketed in the United States during the quarter.

"(D) SINGLE SOURCE DRUG.—The term 'single source drug' means a covered outpatient drug which is not a multiple source drug and which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application, or which is a biological.

"(E) EXCEPTION FROM PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVALENCE REQUIREMENT.—Subparagraph (C)(ii) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (C)(i), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (F).

"(F) DETERMINATION OF PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVALENCE.—For purposes of this paragraph—

"(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; and

"(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence.

"(G) INCLUSION OF VACCINES.—In applying provisions of section 1927 under this section, 'other than a vaccine' is deemed deleted from section 1927(k)(2)(B).

"(d) MONITORING PRICE INFORMATION.—

"(1) IN GENERAL.—The Secretary shall monitor available pricing information, including information on average sales price and average manufacturer price.

"(2) RESPONSE TO SIGNIFICANT DISCREPANCIES.—

"(A) REPORT TO CONGRESS.—If the Secretary finds that there are significant discrepancies among such prices and that the manufacturer's average sales price does not reflect a broad-based market price or a reasonable approximation of the acquisition cost of the covered outpatient drug involved to purchasers reimbursed under this section, the Secretary shall submit to Congress a report.

"(B) CONFIDENTIALITY OF INFORMATION REPORTED.—Consistent with requirements relating to maintaining the confidentiality of information reported on manufacturer's average prices under section 1927(b)(3)(D), such report shall include details regarding such discrepancies and recommendations on how to best address such discrepancies. Such report shall not disclose average manufacturer prices or average sales prices.

"(C) RECOMMENDATIONS.—Such recommendations may include other changes in payment methodology.

"(D) AUTHORITY TO MODIFY PAYMENT METHODOLOGY BY RULE.—Upon submission of such report, the Secretary may commence a rulemaking to change such percent or payment methodologies under paragraph (1)(D) and (2) as applied to the covered outpatient drug involved under this section.

"(3) RESPONSE TO PUBLIC HEALTH EMERGENCY.—In the case of a public health emergency under section 319 of the Public Health Service Act in which there is a documented inability to access covered outpatient drugs, and a concomitant increase in the price, of a drug which is not reflected in the manufacturer's average sales price for one or more quarters, the Secretary may use the wholesale acquisition cost (or other reasonable measure of drug price) instead of the manufacturer's average sales price for such quarters and for subsequent quarters until the price and availability of the drug has stabilized and is substantially reflected in the applicable manufacturer's average sales price.

"(4) ANNUAL REPORT TO CONGRESS.—The Secretary shall submit to the Committees on Energy and Commerce and Ways and Means of the House of Representatives and the Committee on Finance of the Senate an annual report on the operation of this section. Such report shall be submitted in coordination with the submission of reports under section 1927(i). Such report shall include information on the following:

"(A) Trends in average sales price under subsection (b).

"(B) Administrative costs associated with compliance with this section.

"(C) Total value of payments made under this section.

"(D) Comparison of the average manufacturer price as applied under section 1927 for a covered outpatient drug with the manufacturer's average sales price for the drug under this section.

"(e) REPORTS ON PRICING INFORMATION.—

"(1) REFERENCE TO REPORTING REQUIREMENT ON AVERAGE SALES PRICE.—For requirements for reporting the manufacturer's average sales price (and, if required to make payment, the manufacturer's wholesale acquisition cost) for the covered outpatient drug, see section 1927(b)(3).

"(2) MEDPAC REVIEW.—The Medicare Payment Advisory Commission shall periodically review the payment methodology established under this section and submit to Congress such recommendations on such methodology as it deems appropriate as part of its annual reports to Congress.

"(3) CONSTRUCTION.—Nothing in this subsection shall be construed as authorizing the Secretary to review for purposes of this section information reported only under section 1927(b)(3).

"(f) RESTRICTION ON ADMINISTRATIVE AND JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations of manufacturer's average sales price under subsection (c).".

(c) CONTINUATION OF PAYMENT METHODOLOGY FOR RADIOPHARMACEUTICALS.—Nothing in the amendments made by this section shall be construed as changing the payment methodology under part B of title XVIII of the Social Security Act for radiopharmaceuticals, including the use by carriers of invoice pricing methodology.

(d) CONFORMING AMENDMENTS.—

(1) IN GENERAL.—Section 1842(o) (42 U.S.C. 1395u(o)) is amended—

(A) in paragraph (1), by inserting ", subject to section 1847A and 1847B," before "the amount payable for the drug or biological"; and

(B) by adding at the end of paragraph (2) the following: "This paragraph shall not apply in the case of payment under section 1847A or 1847B.".

(2) NO CHANGE IN COVERAGE BASIS.—Section 1861(s)(2)(A) (42 U.S.C. 1395x(s)(2)(A)) is amended by inserting "(or would have been so included but for the application of section 1847A or 1847B)" after "included in the physicians' bills".

(3) PAYMENT.—Section 1833(a)(1)(S) (42 U.S.C. 1395l(a)(1)(S)) is amended by inserting "(or, if applicable, under section 1847A or 1847B)" after "1842(o)".

(4) CONSOLIDATED REPORTING OF PRICING INFORMATION.—Section 1927 (42 U.S.C. 1396r–8) is amended—

(A) in subsection (a)(1), by inserting "or under part B of title XVIII" after "section 1903(a)";

(B) in subsection (b)(3)(A)—

(i) in clause (i), by striking "and" at the end;

(ii) in clause (ii), by striking the period and inserting "; and"; and

(iii) by adding at the end the following new clause:

"(iii) for calendar quarters beginning on or after April 1, 2004, in conjunction with reporting required under clause (i) and by national drug code (NDC)—

"(I) the manufacturer's average sales price (as defined in section 1847B(c)) and the total number of units specified under section 1847B(b)(2)(A);

"(II) if required to make payment under section 1847B, the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section; and

"(III) information on those sales that were made at a nominal price or otherwise described in section 1847B(c)(2)(B), which information is subject to audit by the Inspector General of the Department of Health and Human Services;

for a covered outpatient drug for which payment is made under section 1847B.";

(C) in subsection (b)(3)(B)—

(i) in the heading, by inserting "AND MANUFACTURER'S AVERAGE SALES PRICE" after "PRICE"; and

(ii) by inserting "and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment" after "manufacturer prices"; and

(D) in subsection (b)(3)(D)(i), by inserting "and section 1847B" after "this section".

(e) GAO STUDY.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to assess the impact of the amendments made by this section on the delivery of services, including their impact on—

(A) beneficiary access to drugs and biologicals for which payment is made under part B of title XVIII of the Social Security Act; and

(B) the site of delivery of such services.

(2) REPORT.—Not later than 2 years after the year in which the amendment made by subsection (a)(1) first takes effect, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).

(f) MEDPAC RECOMMENDATIONS ON BLOOD CLOTTING FACTORS.—The Medicare Payment Advisory Commission shall submit to Congress, in its annual report in 2004, specific recommendations regarding a payment amount (or amounts) for blood clotting factors and its administration under the medicare program.

(g) ESTABLISHMENT OF PHARMACEUTICAL MANAGEMENT FEE WHERE DRUGS PROVIDED THROUGH A CONTRACTOR.—Section 1848(a) (42 U.S.C. 1395w–4(a)) is amended by adding at the end the following new paragraph:

"(5) RECOGNITION OF PHARMACEUTICAL MANAGEMENT FEE IN CERTAIN CASES.—In establishing the fee schedule under this section, the Secretary shall provide for a separate payment with respect to physicians' services consisting of the unique administrative and management costs associated with covered drugs and biologicals which are furnished to physicians through a contractor under section 1847A (compared with such costs if such drugs and biologicals were acquired directly by such physicians).".

SEC. 304. DEMONSTRATION PROJECT FOR USE OF RECOVERY AUDIT CONTRACTORS.

(a) IN GENERAL.—The Secretary of Health and Human Services shall conduct a demonstration project under this section (in this section referred to as the "project") to demonstrate the use of recovery audit contractors under the Medicare Integrity Program in identifying underpayments and overpayments and recouping overpayments under the medicare program for services for which payment is made under part A or part B of title XVIII of the Social Security Act. Under the project—

(1) payment may be made to such a contractor on a contingent basis;

(2) a percentage of the amount recovered may be retained by the Secretary and shall be available to the program management account of the Centers for Medicare & Medicaid Services; and

(3) the Secretary shall examine the efficacy of such use with respect to duplicative payments, accuracy of coding, and other payment policies in which inaccurate payments arise.

(b) SCOPE AND DURATION.—

(1) SCOPE.—The project shall cover at least 2 States that are among the States with—

(A) the highest per capita utilization rates of medicare services, and

(B) at least 3 contractors.

(2) DURATION.—The project shall last for not longer than 3 years.

(c) WAIVER.—The Secretary of Health and Human Services shall waive such provisions of title XVIII of the Social Security Act as may be necessary to provide for payment for services under the project in accordance with subsection (a).

(d) QUALIFICATIONS OF CONTRACTORS.—

(1) IN GENERAL.—The Secretary shall enter into a recovery audit contract under this section with an entity only if the entity has staff that has the appropriate clinical knowledge of and experience with the payment rules and regulations under the medicare program or the entity has or will contract with another entity that has such knowledgeable and experienced staff.

(2) INELIGIBILITY OF CERTAIN CONTRACTORS.—The Secretary may not enter into a recovery audit contract under this section with an entity to the extent that the entity is a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h), a carrier under section 1842 of such Act (42 U.S.C. 1395u), or a Medicare Administrative Contractor under section 1874A of such Act.

(3) PREFERENCE FOR ENTITIES WITH DEMONSTRATED PROFICIENCY WITH PRIVATE INSURERS.—In awarding contracts to recovery audit contractors under this section, the Secretary shall give preference to those risk entities that the Secretary determines have demonstrated more than 3 years direct management experience and a proficiency in recovery audits with private insurers or under the medicaid program under title XIX of such Act.

(e) CONSTRUCTION RELATING TO CONDUCT OF INVESTIGATION OF FRAUD.—A recovery of an overpayment to a provider by a recovery audit contractor shall not be construed to prohibit the Secretary or the Attorney General from investigating and prosecuting, if appropriate, allegations of fraud or abuse arising from such overpayment.

(f) REPORT.—The Secretary of Health and Human Services shall submit to Congress a report on the project not later than 6 months after the date of its completion. Such reports shall include information on the impact of the project on savings to the medicare program and recommendations on the cost-effectiveness of extending or expanding the project.

TITLE IV—RURAL HEALTH CARE IMPROVEMENTS

SEC. 401. ENHANCED DISPROPORTIONATE SHARE HOSPITAL (DSH) TREATMENT FOR RURAL HOSPITALS AND URBAN HOSPITALS WITH FEWER THAN 100 BEDS.

(a) DOUBLING THE CAP.—

(1) IN GENERAL.—Section 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is amended by adding at the end the following new clause:

"(xiv)(I) In the case of discharges in a fiscal year beginning on or after October 1, 2003, subject to subclause (II), there shall be substituted for the disproportionate share adjustment percentage otherwise determined under clause (iv) (other than subclause (I)) or under clause (viii), (x), (xi), (xii), or (xiii), the disproportionate share adjustment percentage determined under clause (vii) (relating to large, urban hospitals).

"(II) Under subclause (I), the disproportionate share adjustment percentage shall not exceed 10 percent for a hospital that is not classified as a rural referral center under subparagraph (C).".

(2) CONFORMING AMENDMENTS.—Section 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is amended—

(A) in each of subclauses (II), (III), (IV), (V), and (VI) of clause (iv), by inserting "subject to clause (xiv) and" before "for discharges occurring";

(B) in clause (viii), by striking "The formula" and inserting "Subject to clause (xiv), the formula"; and

(C) in each of clauses (x), (xi), (xii), and (xiii), by striking "For purposes" and inserting "Subject to clause (xiv), for purposes".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to discharges occurring on or after October 1, 2003.

SEC. 402. IMMEDIATE ESTABLISHMENT OF UNIFORM STANDARDIZED AMOUNT IN RURAL AND SMALL URBAN AREAS.

(a) IN GENERAL.—Section 1886(d)(3)(A) (42 U.S.C. 1395ww(d)(3)(A)) is amended—

(1) in clause (iv), by inserting "and ending on or before September 30, 2003," after "October 1, 1995,"; and

(2) by redesignating clauses (v) and (vi) as clauses (vii) and (viii), respectively, and inserting after clause (iv) the following new clauses:

"(v) For discharges occurring in the fiscal year beginning on October 1, 2003, the average standardized amount for hospitals located in areas other than a large urban area shall be equal to the average standardized amount for hospitals located in a large urban area.".

(b) CONFORMING AMENDMENTS.—

(1) COMPUTING DRG-SPECIFIC RATES.—Section 1886(d)(3)(D) (42 U.S.C. 1395ww(d)(3)(D)) is amended—

(A) in the heading, by striking "IN DIFFERENT AREAS";

(B) in the matter preceding clause (i), by striking ", each of";

(C) in clause (i)—

(i) in the matter preceding subclause (I), by inserting "for fiscal years before fiscal year 2004," before "for hospitals"; and

(ii) in subclause (II), by striking "and" after the semicolon at the end;

(D) in clause (ii)—

(i) in the matter preceding subclause (I), by inserting "for fiscal years before fiscal year 2004," before "for hospitals"; and

(ii) in subclause (II), by striking the period at the end and inserting "; and"; and

(E) by adding at the end the following new clause:

"(iii) for a fiscal year beginning after fiscal year 2003, for hospitals located in all areas, to the product of—

"(I) the applicable standardized amount (computed under subparagraph (A)), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C) for the fiscal year; and

"(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.".

(2) TECHNICAL CONFORMING SUNSET.—Section 1886(d)(3) (42 U.S.C. 1395ww(d)(3)) is amended—

(A) in the matter preceding subparagraph (A), by inserting ", for fiscal years before fiscal year 1997," before "a regional adjusted DRG prospective payment rate"; and

(B) in subparagraph (D), in the matter preceding clause (i), by inserting ", for fiscal years before fiscal year 1997," before "a regional DRG prospective payment rate for each region,".

SEC. 403. ESTABLISHMENT OF ESSENTIAL RURAL HOSPITAL CLASSIFICATION.

(a) CLASSIFICATION.—Section 1861(mm) (42 U.S.C. 1395x(mm)) is amended—

(1) in the heading by adding "ESSENTIAL RURAL HOSPITALS" at the end; and

(2) by adding at the end the following new paragraphs:

"(4)(A) The term 'essential rural hospital' means a subsection (d) hospital (as defined in section 1886(d)(1)(B)) that is located in a rural area (as defined for purposes of section 1886(d)), has more than 25 licensed acute care inpatient beds, has applied to the Secretary for classification as such a hospital, and with respect to which the Secretary has determined that the closure of the hospital would significantly diminish the ability of medicare beneficiaries to obtain essential health care services.

"(B) The determination under subparagraph (A) shall be based on the following criteria:

"(i) HIGH PROPORTION OF MEDICARE BENEFICIARIES RECEIVING CARE FROM HOSPITAL.—(I) A high percentage of such beneficiaries residing in the area of the hospital who are hospitalized (during the most recent year for which complete data are available) receive basic inpatient medical care at the hospital.

"(II) For a hospital with more than 200 licensed beds, a high percentage of such beneficiaries residing in such area who are hospitalized (during such recent year) receive specialized surgical inpatient care at the hospital.

"(III) Almost all physicians described in section 1861(r)(1) in such area have privileges at the hospital and provide their inpatient services primarily at the hospital.

"(ii) SIGNIFICANT ADVERSE IMPACT IN ABSENCE OF HOSPITAL.—If the hospital were to close—

"(I) there would be a significant amount of time needed for residents to reach emergency treatment, resulting in a potential significant harm to beneficiaries with critical illnesses or injuries;

"(II) there would be an inability in the community to stablize emergency cases for transfers to another acute care setting, resulting in a potential for significant harm to medicare beneficiaries; and

"(III) any other nearby hospital lacks the physical and clinical capacity to take over the hospital's typical admissions.

"(C) In making such determination, the Secretary may also consider the following:

"(i) Free-standing ambulatory surgery centers, office-based oncology care, and imaging center services are insufficient in the hospital's area to handle the outpatient care of the hospital.

"(ii) Beneficiaries in nearby areas would be adversely affected if the hospital were to close as the hospital provides specialized knowledge and services to a network of smaller hospitals and critical access hospitals.

"(iii) Medicare beneficiaries would have difficulty in accessing care if the hospital were to close as the hospital provides significant subsidies to support ambulatory care in local clinics, including mental health clinics and to support post acute care.

"(iv) The hospital has a committment to provide graduate medical education in a rural area.

"(C) QUALITY CARE.—The hospital inpatient score for quality of care is not less than the median hospital score for qualify of care for hospitals in the State, as established under standards of the utilization and quality control peer review organization under part B of title XI or other quality standards recognized by the Secretary.

A hospital classified as an essential rural hospital may not change such classification and a hospital so classified shall not be treated as a sole community hospital, medicare dependent hospital, or rural referral center for purposes of section 1886.".

(b) PAYMENT BASED ON 102 PERCENT OF ALLOWED COSTS.—

(1) INPATIENT HOSPITAL SERVICES.—Section 1886(d) (42 U.S.C. 1395ww(d)) is amended by adding at the end the following:

"(11) In the case of a hospital classified as an essential rural hospital under section 1861(mm)(4) for a cost reporting period, the payment under this subsection for inpatient hospital services for discharges occurring during the period shall be based on 102 percent of the reasonable costs for such services. Nothing in this paragraph shall be construed as affecting the application or amount of deductibles or copayments otherwise applicable to such services under part A or as waiving any requirement for billing for such services.".

(2) HOSPITAL OUTPATIENT SERVICES.—Section 1833(t)(13) (42 U.S.C. 1395l(t)(13)) is amended by adding at the end the following new subparagraph:

"(B) SPECIAL RULE FOR ESSENTIAL RURAL HOSPITALS.—In the case of a hospital classified as an essential rural hospital under section 1861(mm)(4) for a cost reporting period, the payment under this subsection for covered OPD services during the period shall be based on 102 percent of the reasonable costs for such services. Nothing in this subparagraph shall be construed as affecting the application or amount of deductibles or copayments otherwise applicable to such services under this part or as waiving any requirement for billing for such services.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to cost reporting periods beginning on or after October 1, 2004.

SEC. 404. MORE FREQUENT UPDATE IN WEIGHTS USED IN HOSPITAL MARKET BASKET.

(a) MORE FREQUENT UPDATES IN WEIGHTS.—After revising the weights used in the hospital market basket under section 1886(b)(3)(B)(iii) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(iii)) to reflect the most current data available, the Secretary shall establish a frequency for revising such weights, including the labor share, in such market basket to reflect the most current data available more frequently than once every 5 years.

(b) REPORT.—Not later than October 1, 2004, the Secretary shall submit a report to Congress on the frequency established under subsection (a), including an explanation of the reasons for, and options considered, in determining such frequency.

SEC. 405. IMPROVEMENTS TO CRITICAL ACCESS HOSPITAL PROGRAM.

(a) INCREASE IN PAYMENT AMOUNTS.—

(1) IN GENERAL.—Sections 1814(l), 1834(g)(1), and 1883(a)(3) (42 U.S.C. 1395f(l); 1395m(g)(1); 42 U.S.C. 1395tt(a)(3)) are each amended by inserting "equal to 102 percent of" before "the reasonable costs".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to payments for services furnished during cost reporting periods beginning on or after October 1, 2003.

(b) COVERAGE OF COSTS FOR CERTAIN EMERGENCY ROOM ON-CALL PROVIDERS.—

(1) IN GENERAL.—Section 1834(g)(5) (42 U.S.C. 1395m(g)(5)) is amended—

(A) in the heading—

(i) by inserting "CERTAIN" before "EMERGENCY"; and

(ii) by striking "PHYSICIANS" and inserting "PROVIDERS";

(B) by striking "emergency room physicians who are on-call (as defined by the Secretary)" and inserting "physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on-call (as defined by the Secretary) to provide emergency services"; and

(C) by striking "physicians' services" and inserting "services covered under this title".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply with respect to costs incurred for services provided on or after January 1, 2004.

(c) MODIFICATION OF THE ISOLATION TEST FOR COST-BASED CAH AMBULANCE SERVICES.—

(1) IN GENERAL.—Section 1834(l)(8) (42 U.S.C. 1395m(l)), as added by section 205(a) of BIPA (114 Stat. 2763A–482), is amended by adding at the end the following: "The limitation described in the matter following subparagraph (B) in the previous sentence shall not apply if the ambulance services are furnished by such a provider or supplier of ambulance services who is a first responder to emergencies (as determined by the Secretary).".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to ambulances services furnished on or after the first cost reporting period that begins after the date of the enactment of this Act.

(d) REINSTATEMENT OF PERIODIC INTERIM PAYMENT (PIP).—

(1) IN GENERAL.—Section 1815(e)(2) (42 U.S.C. 1395g(e)(2)) is amended—

(A) in the matter before subparagraph (A), by inserting ", in the cases described in subparagraphs (A) through (D)" after "1986"; and

(B) by striking "and" at the end of subparagraph (C);

(C) by adding "and" at the end of subparagraph (D); and

(D) by inserting after subparagraph (D) the following new subparagraph:

"(E) inpatient critical access hospital services;".

(2) DEVELOPMENT OF ALTERNATIVE METHODS OF PERIODIC INTERIM PAYMENTS.—With respect to periodic interim payments to critical access hospitals for inpatient critical access hospital services under section 1815(e)(2)(E) of the Social Security Act, as added by paragraph (1), the Secretary shall develop alternative methods for such payments that are based on expenditures of the hospital.

(3) REINSTATEMENT OF PIP.—The amendments made by paragraph (1) shall apply to payments made on or after January 1, 2004.

(e) CONDITION FOR APPLICATION OF SPECIAL PHYSICIAN PAYMENT ADJUSTMENT.—

(1) IN GENERAL.—Section 1834(g)(2) (42 U.S.C. 1395m(g)(2)) is amended by adding after and below subparagraph (B) the following:

"The Secretary may not require, as a condition for applying subparagraph (B) with respect to a critical access hospital, that each physician providing professional services in the hospital must assign billing rights with respect to such services, except that such subparagraph shall not apply to those physicians who have not assigned such billing rights.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall be effective as if included in the enactment of section 403(d) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (113 Stat. 1501A–371).

(f) FLEXIBILITY IN BED LIMITATION FOR HOSPITALS.—Section 1820 (42 U.S.C. 1395i–4) is amended—

(1) in subsection (c)(2)(B)(iii), by inserting "subject to paragraph (3)" after "(iii) provides";

(2) by adding at the end of subsection (c) the following new paragraph:

"(3) INCREASE IN MAXIMUM NUMBER OF BEDS FOR HOSPITALS WITH STRONG SEASONAL CENSUS FLUCTUATIONS.—

"(A) IN GENERAL.—Subject to subparagraph (C), in the case of a hospital that demonstrates that it meets the standards established under subparagraph (B) and has not made the election described in subsection (f)(2)(A), the bed limitations otherwise applicable under paragraph (2)(B)(iii) and subsection (f) shall be increased by 5 beds.

"(B) STANDARDS.—The Secretary shall specify standards for determining whether a critical access hospital has sufficiently strong seasonal variations

in patient admissions to justify the increase in bed limitation provided under subparagraph (A).''; and

(3) in subsection (f)—

(A) by inserting ''(1)'' after ''(f)''; and

(B) by adding at the end the following new paragraph:

''(2)(A) A hospital may elect to treat the reference in paragraph (1) to '15 beds' as a reference to '25 beds', but only if no more than 10 beds in the hospital are at any time used for non-acute care services. A hospital that makes such an election is not eligible for the increase provided under subsection (c)(3)(A).

''(B) The limitations in numbers of beds under the first sentence of paragraph (1) are subject to adjustment under subsection (c)(3).''.

(4) EFFECTIVE DATE.—The amendments made by this subsection shall apply to designations made before, on, or after January 1, 2004.

(g) ADDITIONAL 5-YEAR PERIOD OF FUNDING FOR GRANT PROGRAM.—

(1) IN GENERAL.—Section 1820(g) (42 U.S.C. 1395i–4(g)) is amended by adding at the end the following new paragraph:

''(4) FUNDING.—

''(A) IN GENERAL.—Subject to subparagraph (B), payment for grants made under this subsection during fiscal years 2004 through 2008 shall be made from the Federal Hospital Insurance Trust Fund.

''(B) ANNUAL AGGREGATE LIMITATION.—In no case may the amount of payment provided for under subparagraph (A) for a fiscal year exceed $25,000,000.''.

(2) CONFORMING AMENDMENT.—Section 1820 (42 U.S.C. 1395i–4) is amended by striking subsection (j).

SEC. 406. REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.

(a) IN GENERAL.—Section 1886(h)(4) (42 U.S.C. 1395ww(h)(4)) is amended—

(1) in subparagraph (F)(i), by inserting ''subject to subparagraph (I),'' after ''October 1, 1997,'';

(2) in subparagraph (H)(i), by inserting ''subject to subparagraph (I),'' after ''subparagraphs (F) and (G),''; and

(3) by adding at the end the following new subparagraph:

''(I) REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.—

''(i) REDUCTION IN LIMIT BASED ON UNUSED POSITIONS.—

''(I) IN GENERAL.—If a hospital's resident level (as defined in clause (iii)(I)) is less than the otherwise applicable resident limit (as defined in clause (iii)(II)) for each of the reference periods (as defined in subclause (II)), effective for cost reporting periods beginning on or after January 1, 2004, the otherwise applicable resident limit shall be reduced by 75 percent of the difference between such limit and the reference resident level specified in subclause (III) (or subclause (IV) if applicable).

''(II) REFERENCE PERIODS DEFINED.—In this clause, the term 'reference periods' means, for a hospital, the 3 most recent consecutive cost reporting periods of the hospital for which cost reports have been settled (or, if not, submitted) on or before September 30, 2002.

''(III) REFERENCE RESIDENT LEVEL.—Subject to subclause (IV), the reference resident level specified in this subclause for a hospital is the highest resident level for the hospital during any of the reference periods.

''(IV) ADJUSTMENT PROCESS.—Upon the timely request of a hospital, the Secretary may adjust the reference resident level for a hospital to be the resident level for the hospital for the cost reporting period that includes July 1, 2003.

''(V) AFFILIATION.—With respect to hospitals which are members of the same affiliated group (as defined by the Secretary under subparagraph (H)(ii)), the provisions of this section shall be applied with respect to such an affiliated group by deeming the affiliated group to be a single hospital.

''(ii) REDISTRIBUTION.—

''(I) IN GENERAL.—The Secretary is authorized to increase the otherwise applicable resident limits for hospitals by an aggregate number estimated by the Secretary that does not exceed the aggregate reduction in such limits attributable to clause (i) (without taking into account any adjustment under subclause (IV) of such clause).

''(II) EFFECTIVE DATE.—No increase under subclause (I) shall be permitted or taken into account for a hospital for any portion of a

cost reporting period that occurs before July 1, 2004, or before the date of the hospital's application for an increase under this clause. No such increase shall be permitted for a hospital unless the hospital has applied to the Secretary for such increase by December 31, 2005.

"(III) CONSIDERATIONS IN REDISTRIBUTION.—In determining for which hospitals the increase in the otherwise applicable resident limit is provided under subclause (I), the Secretary shall take into account the need for such an increase by specialty and location involved, consistent with subclause (IV).

"(IV) PRIORITY FOR RURAL AND SMALL URBAN AREAS.—In determining for which hospitals and residency training programs an increase in the otherwise applicable resident limit is provided under subclause (I), the Secretary shall first distribute the increase to programs of hospitals located in rural areas or in urban areas that are not large urban areas (as defined for purposes of subsection (d)) on a first-come-first-served basis (as determined by the Secretary) based on a demonstration that the hospital will fill the positions made available under this clause and not to exceed an increase of 25 full-time equivalent positions with respect to any hospital.

"(V) APPLICATION OF LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—With respect to additional residency positions in a hospital attributable to the increase provided under this clause, notwithstanding any other provision of this subsection, the approved FTE resident amount is deemed to be equal to the locality adjusted national average per resident amount computed under subparagraph (E) for that hospital.

"(VI) CONSTRUCTION.—Nothing in this clause shall be construed as permitting the redistribution of reductions in residency positions attributable to voluntary reduction programs under paragraph (6) or as affecting the ability of a hospital to establish new medical residency training programs under subparagraph (H).

"(iii) RESIDENT LEVEL AND LIMIT DEFINED.—In this subparagraph:

"(I) RESIDENT LEVEL.—The term 'resident level' means, with respect to a hospital, the total number of full-time equivalent residents, before the application of weighting factors (as determined under this paragraph), in the fields of allopathic and osteopathic medicine for the hospital.

"(II) OTHERWISE APPLICABLE RESIDENT LIMIT.—The term 'otherwise applicable resident limit' means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) on the resident level for the hospital determined without regard to this subparagraph.".

(b) CONFORMING AMENDMENT TO IME.—Section 1886(d)(5)(B)(v) (42 U.S.C. 1395ww(d)(5)(B)(v)) is amended by adding at the end the following: "The provisions of subparagraph (I) of subsection (h)(4) shall apply with respect to the first sentece of this clause in the same manner as it applies with respect to subparagraph (F) of such subsection.".

(c) REPORT ON EXTENSION OF APPLICATIONS UNDER REDISTRIBUTION PROGRAM.—Not later than July 1, 2005, the Secretary shall submit to Congress a report containing recommendations regarding whether to extend the deadline for applications for an increase in resident limits under section 1886(h)(4)(I)(ii)(II) of the Social Security Act (as added by subsection (a)).

SEC. 407. TWO-YEAR EXTENSION OF HOLD HARMLESS PROVISIONS FOR SMALL RURAL HOSPITALS AND SOLE COMMUNITY HOSPITALS UNDER PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES.

(a) HOLD HARMLESS PROVISIONS.—

(1) IN GENERAL.—Section 1833(t)(7)(D)(i) (42 U.S.C. 1395l(t)(7)(D)(i)) is amended—

(A) in the heading, by striking "SMALL" and inserting "CERTAIN";

(B) by inserting "or a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) located in a rural area" after "100 beds"; and

(C) by striking "2004" and inserting "2006".

(2) EFFECTIVE DATE.—The amendment made by subsection (a)(2) shall apply with respect to payment for OPD services furnished on and after January 1, 2004.

(b) STUDY; ADJUSTMENT.—

(1) STUDY.—The Secretary shall conduct a study to determine if, under the prospective payment system for hospital outpatient department services under

section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)), costs incurred by rural providers of services by ambulatory payment classification groups (APCs) exceed those costs incurred by urban providers of services.

(2) ADJUSTMENT.—Insofar as the Secretary determines under paragraph (1) that costs incurred by rural providers exceed those costs incurred by urban providers of services, the Secretary shall provide for an appropriate adjustment under such section 1833(t) to reflect those higher costs by January 1, 2005.

SEC. 408. EXCLUSION OF CERTAIN RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES FROM THE PROSPECTIVE PAYMENT SYSTEM FOR SKILLED NURSING FACILITIES.

(a) IN GENERAL.—Section 1888(e)(2)(A) (42 U.S.C. 1395yy(e)(2)(A)) is amended—

(1) in clause (i)(II), by striking "clauses (ii) and (iii)" and inserting "clauses (ii), (iii), and (iv)"; and

(2) by adding at the end the following new clause:

"(iv) EXCLUSION OF CERTAIN RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES.—Services described in this clause are—

"(I) rural health clinic services (as defined in paragraph (1) of section 1861(aa)); and

"(II) Federally qualified health center services (as defined in paragraph (3) of such section);

that would be described in clause (ii) if such services were not furnished by an individual affiliated with a rural health clinic or a Federally qualified health center.".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to services furnished on or after January 1, 2004.

SEC. 409. RECOGNITION OF ATTENDING NURSE PRACTITIONERS AS ATTENDING PHYSICIANS TO SERVE HOSPICE PATIENTS.

(a) IN GENERAL.—Section 1861(dd)(3)(B) (42 U.S.C. 1395x(dd)(3)(B)) is amended by inserting "or nurse practitioner (as defined in subsection (aa)(5))" after "the physician (as defined in subsection (r)(1))".

(b) PROHIBITION ON NURSE PRACTITIONER CERTIFYING NEED FOR HOSPICE.—Section 1814(a)(7)(A)(i)(I) (42 U.S.C. 1395f(a)(7)(A)(i)(I)) is amended by inserting "(which for purposes of this subparagraph does not include a nurse practitioner)" after "attending physician (as defined in section 1861(dd)(3)(B))".

SEC. 410. IMPROVEMENT IN PAYMENTS TO RETAIN EMERGENCY CAPACITY FOR AMBULANCE SERVICES IN RURAL AREAS.

Section 1834(l) (42 U.S.C. 1395m(l)) is amended—

(1) by redesignating paragraph (8), as added by section 221(a) of BIPA (114 Stat. 2763A–486), as paragraph (9); and

(2) by adding at the end the following new paragraph:

"(10) ASSISTANCE FOR RURAL PROVIDERS FURNISHING SERVICES IN LOW MEDICARE POPULATION DENSITY AREAS.—

"(A) IN GENERAL.—In the case of ground ambulance services furnished on or after January 1, 2004, for which the transportation originates in a qualified rural area (as defined in subparagraph (B)), the Secretary shall provide for an increase in the base rate of the fee schedule for mileage for a trip established under this subsection. In establishing such increase, the Secretary shall, based on the relationship of cost and volume, estimate the average increase in cost per trip for such services as compared with the cost per trip for the average ambulance service.

"(B) QUALIFIED RURAL AREA DEFINED.—For purposes of subparagraph (A), the term 'qualified rural area' is a rural area (as defined in section 1886(d)(2)(D)) with a population density of medicare beneficiaries residing in the area that is in the lowest quartile of all rural county populations.".

SEC. 411. TWO-YEAR INCREASE FOR HOME HEALTH SERVICES FURNISHED IN A RURAL AREA.

(a) IN GENERAL.—In the case of home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act (42 U.S.C. 1395ww(d)(2)(D))) during 2004 and 2005, the Secretary shall increase the payment amount otherwise made under section 1895 of such Act (42 U.S.C. 1395fff) for such services by 5 percent.

(b) WAIVING BUDGET NEUTRALITY.—The Secretary shall not reduce the standard prospective payment amount (or amounts) under section 1895 of the Social Security Act (42 U.S.C. 1395fff) applicable to home health services furnished during a period to offset the increase in payments resulting from the application of subsection (a).

SEC. 412. PROVIDING SAFE HARBOR FOR CERTAIN COLLABORATIVE EFFORTS THAT BENEFIT MEDICALLY UNDERSERVED POPULATIONS.

(a) IN GENERAL.—Section 1128B(b)(3) (42 U.S.C. 1320a–7(b)(3)), as amended by section 101(b)(2), is amended—

(1) in subparagraph (F), by striking "and" after the semicolon at the end;

(2) in subparagraph (G), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following new subparagraph:

"(H) any remuneration between a public or nonprofit private health center entity described under clause (i) or (ii) of section 1905(l)(2)(B) and any individual or entity providing goods, items, services, donations or loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity.".

(b) RULEMAKING FOR EXCEPTION FOR HEALTH CENTER ENTITY ARRANGEMENTS.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the "Secretary") shall establish, on an expedited basis, standards relating to the exception described in section 1128B(b)(3)(H) of the Social Security Act, as added by subsection (a), for health center entity arrangements to the antikickback penalties.

(B) FACTORS TO CONSIDER.—The Secretary shall consider the following factors, among others, in establishing standards relating to the exception for health center entity arrangements under subparagraph (A):

(i) Whether the arrangement between the health center entity and the other party results in savings of Federal grant funds or increased revenues to the health center entity.

(ii) Whether the arrangement between the health center entity and the other party restricts or limits a patient's freedom of choice.

(iii) Whether the arrangement between the health center entity and the other party protects a health care professional's independent medical judgment regarding medically appropriate treatment.

The Secretary may also include other standards and criteria that are consistent with the intent of Congress in enacting the exception established under this section.

(2) INTERIM FINAL EFFECT.—No later than 180 days after the date of enactment of this Act, the Secretary shall publish a rule in the Federal Register consistent with the factors under paragraph (1)(B). Such rule shall be effective and final immediately on an interim basis, subject to such change and revision, after public notice and opportunity (for a period of not more than 60 days) for public comment, as is consistent with this subsection.

SEC. 413. GAO STUDY OF GEOGRAPHIC DIFFERENCES IN PAYMENTS FOR PHYSICIANS' SERVICES.

(a) STUDY.—The Comptroller General of the United States shall conduct a study of differences in payment amounts under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for physicians' services in different geographic areas. Such study shall include—

(1) an assessment of the validity of the geographic adjustment factors used for each component of the fee schedule;

(2) an evaluation of the measures used for such adjustment, including the frequency of revisions; and

(3) an evaluation of the methods used to determine professional liability insurance costs used in computing the malpractice component, including a review of increases in professional liability insurance premiums and variation in such increases by State and physician specialty and methods used to update the geographic cost of practice index and relative weights for the malpractice component.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subsection (a). The report shall include recommendations regarding the use of more current data in computing geographic cost of practice indices as well as the use of data directly representative of physicians' costs (rather than proxy measures of such costs).

SEC. 414. TREATMENT OF MISSING COST REPORTING PERIODS FOR SOLE COMMUNITY HOSPITALS.

(a) IN GENERAL.—Section 1886(b)(3)(I) (42 U.S.C. 1395ww(b)(3)(I)) is amended by adding at the end the following new clause:

"(iii) In no case shall a hospital be denied treatment as a sole community hospital or payment (on the basis of a target rate as such as a hospital) because data are unavailable for any cost reporting period due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances, so long as data for at least one applicable base cost reporting period is available.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to cost reporting periods beginning on or after January 1, 2004.

SEC. 415. EXTENSION OF TELEMEDICINE DEMONSTRATION PROJECT.

Section 4207 of Balanced Budget Act of 1997 (Public Law 105–33) is amended—

(1) in subsection (a)(4), by striking "4-year" and inserting "8-year"; and

(2) in subsection (d)(3), by striking "$30,000,000" and inserting "$60,000,000".

SEC. 416. ADJUSTMENT TO THE MEDICARE INPATIENT HOSPITAL PPS WAGE INDEX TO REVISE THE LABOR-RELATED SHARE OF SUCH INDEX.

(a) IN GENERAL.—Section 1886(d)(3)(E) (42 U.S.C. 1395ww(d)(3)(E)) is amended—

(1) by striking "WAGE LEVELS.—The Secretary" and inserting "WAGE LEVELS.—

"(i) IN GENERAL.—Except as provided in clause (ii), the Secretary"; and

(2) by adding at the end the following new clause:

"(ii) ALTERNATIVE PROPORTION TO BE ADJUSTED BEGINNING IN FISCAL YEAR 2004.—

"(I) IN GENERAL.—Except as provided in subclause (II), for discharges occurring on or after October 1, 2003, the Secretary shall substitute the '62 percent' for the proportion described in the first sentence of clause (i).

"(II) HOLD HARMLESS FOR CERTAIN HOSPITALS.—If the application of subclause (I) would result in lower payments to a hospital than would otherwise be made, then this subparagraph shall be applied as if this clause had not been enacted.".

(b) WAIVING BUDGET NEUTRALITY.—Section 1886(d)(3)(E) (42 U.S.C. 1395ww(d)(3)(E)), as amended by subsection (a), is amended by adding at the end of clause (i) the following new sentence: "The Secretary shall apply the previous sentence for any period as if the amendments made by section 402(a) of the Medicare Prescription Drug and Modernization Act of 2003 had not been enacted.".

SEC. 417. MEDICARE INCENTIVE PAYMENT PROGRAM IMPROVEMENTS FOR PHYSICIAN SCARCITY.

(a) ADDITIONAL BONUS PAYMENT FOR CERTAIN PHYSICIAN SCARCITY AREAS.—

(1) IN GENERAL.—Section 1833 (42 U.S.C. 1395*l*) is amended by adding at the end the following new subsection:

"(u) INCENTIVE PAYMENTS FOR PHYSICIAN SCARCITY AREAS.—

"(1) IN GENERAL.—In the case of physicians' services furnished in a year—

"(A) by a primary care physician in a primary care scarcity county (identified under paragraph (4)); or

"(B) by a physician who is not a primary care physician in a specialist care scarcity county (as so identified),

in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid an amount equal to 5 percent of the payment amount for the service under this part.

"(2) DETERMINATION OF RATIOS OF PHYSICIANS TO MEDICARE BENEFICIARIES IN AREA.—Based upon available data, the Secretary shall periodically determine, for each county or equivalent area in the United States, the following:

"(A) NUMBER OF PHYSICIANS PRACTICING IN THE AREA.—The number of physicians who furnish physicians' services in the active practice of medicine or osteopathy in that county or area, other than physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services. Of such number, the number of such physicians who are—

"(i) primary care physicians; or

"(ii) physicians who are not primary care physicians.

"(B) NUMBER OF MEDICARE BENEFICIARIES RESIDING IN THE AREA.—The number of individuals who are residing in the county and are entitled to benefits under part A or enrolled under this part, or both.

"(C) DETERMINATION OF RATIOS.—

"(i) PRIMARY CARE RATIO.—The ratio (in this paragraph referred to as the 'primary care ratio') of the number of primary care physicians (de-

termined under subparagraph (A)(i)), to number of medicare beneficiaries determined under subparagraph (B).

"(ii) SPECIALIST CARE RATIO.—The ratio (in this paragraph referred to as the 'specialist care ratio') of the number of other physicians (determined under subparagraph (A)(ii)), to number of medicare beneficiaries determined under subparagraph (B).

"(3) RANKING OF COUNTIES.—The Secretary shall rank each such county or area based separately on its primary care ratio and its specialist care ratio.

"(4) IDENTIFICATION OF COUNTIES.—The Secretary shall identify—

"(A) those counties and areas (in this paragraph referred to as 'primary care scarcity counties') with the lowest primary care ratios that represent, if each such county or area were weighted by the number of medicare beneficiaries determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the medicare beneficiaries determined under such paragraph; and

"(B) those counties and areas (in this subsection referred to as 'specialist care scarcity counties') with the lowest specialist care ratios that represent, if each such county or area were weighted by the number of medicare beneficiaries determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the medicare beneficiaries determined under such paragraph.

There is no administrative or judicial review respecting the identification of a county or area or the assignment of a specialty of any physician under this paragraph.

"(5) RURAL CENSUS TRACKS.—To the extent feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725) as an equivalent area for purposes of qualifying as a primary care scarcity county or specialist care scarcity county under this subsection.

"(6) PHYSICIAN DEFINED.—For purposes of this paragraph, the term 'physician' means a physician described in section 1861(r)(1) and the term 'primary care physician' means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

"(7) PUBLICATION OF LIST OF COUNTIES.—In carrying out this subsection for a year, the Secretary shall include, as part of the proposed and final rule to implement the physician fee schedule under section 1848 for the year, a list of all areas which will qualify as a primary care scarcity county or specialist care scarcity county under this subsection for the year involved.".

(2) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to physicians' services furnished or after January 1, 2004.

(b) IMPROVEMENT TO MEDICARE INCENTIVE PAYMENT PROGRAM.—

(1) IN GENERAL.—Section 1833(m) (42 U.S.C. 1395*l*(m)) is amended—

(A) by inserting "(1)" after "(m)"; and

(B) by adding at the end the following new paragraphs:

"(2) The Secretary shall establish procedures under which the Secretary, and not the physician furnishing the service, is responsible for determining when a payment is required to be made under paragraph (1).

"(3) In carrying out paragraph (1) for a year, the Secretary shall include, as part of the proposed and final rule to implement the physician fee schedule under section 1848 for the year, a list of all areas which will qualify as a health professional shortage area under paragraph (1) for the year involved.".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to physicians' services furnished or after January 1, 2004.

TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

SEC. 501. REVISION OF ACUTE CARE HOSPITAL PAYMENT UPDATES.

Section 1886(b)(3)(B)(i) (42 U.S.C. 1395ww(b)(3)(B)(i)) is amended—

(1) by striking "and" at the end of subclause (XVIII);

(2) by striking subclause (XIX); and

(3) by inserting after subclause (XVIII) the following new subclauses:

"(XIX) for each of fiscal years 2004 through 2006, the market basket percentage increase minus 0.4 percentage points for hospitals in all areas; and

"(XX) for fiscal year 2007 and each subsequent fiscal year, the market basket percentage increase for hospitals in all areas.".

SEC. 502. RECOGNITION OF NEW MEDICAL TECHNOLOGIES UNDER INPATIENT HOSPITAL PPS.

(a) IMPROVING TIMELINESS OF DATA COLLECTION.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is amended by adding at the end the following new clause:

"(vii) Under the mechanism under this subparagraph, the Secretary shall provide for the addition of new diagnosis and procedure codes in April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) under this subsection until the fiscal year that begins after such date.".

(b) ELIGIBILITY STANDARD FOR TECHNOLOGY OUTLIERS.—

(1) MINIMUM PERIOD FOR RECOGNITION OF NEW TECHNOLOGIES.—Section 1886(d)(5)(K)(vi) (42 U.S.C. 1395ww(d)(5)(K)(vi)) is amended—

(A) by inserting "(I)" after "(vi)"; and

(B) by adding at the end the following new subclause:

"(II) Under such criteria, a service or technology shall not be denied treatment as a new service or technology on the basis of the period of time in which the service or technology has been in use if such period ends before the end of the 2-to-3-year period that begins on the effective date of implementation of a code under ICD–9–CM (or a successor coding methodology) that enables the identification of specific discharges in which the service or technology has been used.".

(2) ADJUSTMENT OF THRESHOLD.—Section 1886(d)(5)(K)(ii)(I) (42 U.S.C. 1395ww(d)(5)(K)(ii)(I)) is amended by inserting "(applying a threshold specified by the Secretary that is 75 percent of one standard deviation for the diagnosis-related group involved)" after "is inadequate".

(3) CRITERION FOR SUBSTANTIAL IMPROVEMENT.—Section 1886(d)(5)(K)(vi) (42 U.S.C. 1395ww(d)(5)(K)(vi)), as amended by paragraph (1), is further amended by adding at the end the following subclause:

"(III) The Secretary shall by regulation provide for further clarification of the criteria applied to determine whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of beneficiaries. Under such criteria, in determining whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of beneficiaries, the Secretary shall deem a service or technology as meeting such requirement if the service or technology is a drug or biological that is designated under section 506 of the Federal Food, Drug, and Cosmetic Act, approved under section 314.510 or 601.41 of title 21, Code of Federal Regulations, or designated for priority review when the marketing application for such drug or biological was filed or is a medical device for which an exemption has been granted under section 520(m) of such Act, or for which priority review has been provided under section 515(d)(5) of such Act. Nothing in this subclause shall be construed as effecting the authority of the Secretary to determine whether items and services are medically necessary and appropriate under section 1862(a)(1).".

(4) PROCESS FOR PUBLIC INPUT.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)), as amended by paragraph (1), is amended—

(A) in clause (i), by adding at the end the following: "Such mechanism shall be modified to meet the requirements of clause (viii).."; and

(B) by adding at the end the following new clause:

"(viii) The mechanism established pursuant to clause (i) shall be adjusted to provide, before publication of a proposed rule, for public input regarding whether a new service or technology not described in the second sentence of clause (vi)(III) represents an advance in medical technology that substantially improves the diagnosis or treatment of beneficiaries as follows:

"(I) The Secretary shall make public and periodically update a list of all the services and technologies for which an application for additional payment under this subparagraph is pending.

"(II) The Secretary shall accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial improvement.

"(III) The Secretary shall provide for a meeting at which organizations representing hospitals, physicians, medicare beneficiaries, manufacturers, and any other interested party may present comments, recommendations, and data to the clinical staff of the Centers for Medicare & Medicaid Services before publication of a notice of proposed rulemaking regarding whether service or technology represents a substantial improvement.".

(c) PREFERENCE FOR USE OF DRG ADJUSTMENT.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is further amended by adding at the end the following new clause:

"(ix) Before establishing any add-on payment under this subparagraph with respect to a new technology, the Secretary shall seek to identify one or more diagnosis-related groups associated with such technology, based on similar clinical or anatomical characteristics and the cost of the technology. Within such groups the Secretary shall assign an eligible new technology into a diagnosis-related group where the average costs of care most closely approximate the costs of care of using the new technology. In such case, the new technology would no longer meet the threshold of exceeding 75 percent of the standard deviation for the diagnosis-related group involved under clause (ii)(I). No add-on payment under this subparagraph shall be made with respect to such new technology and this clause shall not affect the application of paragraph (4)(C)(iii).".

(d) IMPROVEMENT IN PAYMENT FOR NEW TECHNOLOGY.—Section 1886(d)(5)(K)(ii)(III) (42 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by inserting after "the estimated average cost of such service or technology" the following: "(based on the marginal rate applied to costs under subparagraph (A))".

(e) ESTABLISHMENT OF NEW FUNDING FOR HOSPITAL INPATIENT TECHNOLOGY.—Section 1886(d)(5)(K)(ii)(III) (42 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by striking "subject to paragraph (4)(C)(iii),".

(f) EFFECTIVE DATE.—

(1) IN GENERAL.—The Secretary shall implement the amendments made by this section so that they apply to classification for fiscal years beginning with fiscal year 2005.

(2) RECONSIDERATIONS OF APPLICATIONS FOR FISCAL YEAR 2003 THAT ARE DENIED.—In the case of an application for a classification of a medical service or technology as a new medical service or technology under section 1886(d)(5)(K) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)) that was filed for fiscal year 2004 and that is denied—

(A) the Secretary shall automatically reconsider the application as an application for fiscal year 2005 under the amendments made by this section; and

(B) the maximum time period otherwise permitted for such classification of the service or technology shall be extended by 12 months.

SEC. 503. INCREASE IN FEDERAL RATE FOR HOSPITALS IN PUERTO RICO.

Section 1886(d)(9) (42 U.S.C. 1395ww(d)(9)) is amended—

(1) in subparagraph (A)—

(A) in clause (i), by striking "for discharges beginning on or after October 1, 1997, 50 percent (and for discharges between October 1, 1987, and September 30, 1997, 75 percent)" and inserting "the applicable Puerto Rico percentage (specified in subparagraph (E))"; and

(B) in clause (ii), by striking "for discharges beginning in a fiscal year beginning on or after October 1, 1997, 50 percent (and for discharges between October 1, 1987, and September 30, 1997, 25 percent)" and inserting "the applicable Federal percentage (specified in subparagraph (E))"; and

(2) by adding at the end the following new subparagraph:

"(E) For purposes of subparagraph (A), for discharges occurring—

"(i) on or after October 1, 1987, and before October 1, 1997, the applicable Puerto Rico percentage is 75 percent and the applicable Federal percentage is 25 percent;

"(ii) on or after October 1, 1997, and before October 1, 2003, the applicable Puerto Rico percentage is 50 percent and the applicable Federal percentage is 50 percent;

"(iii) during fiscal year 2004, the applicable Puerto Rico percentage is 41 percent and the applicable Federal percentage is 59 percent;

"(iv) during fiscal year 2005, the applicable Puerto Rico percentage is 33 percent and the applicable Federal percentage is 67 percent; and

"(v) on or after October 1, 2005, the applicable Puerto Rico percentage is 25 percent and the applicable Federal percentage is 75 percent.".

SEC. 504. WAGE INDEX ADJUSTMENT RECLASSIFICATION REFORM .

(a) IN GENERAL.—Section 1886(d) (42 U.S.C. 1395ww(d)) is amended by adding at the end the following:

"(11)(A) In order to recognize commuting patterns among Metropolitan Statistical Areas and between such Areas and rural areas, the Secretary shall establish a process, upon application of a subsection (d) hospital that establishes that it is a qualifying hospital described in subparagraph (B), for an increase of the wage index applied under paragraph (3)(E) for the hospital in the amount computed under subparagraph (D).

"(B) A qualifying hospital described in this subparagraph is a subsection (d) hospital—

"(i) the average wages of which exceed the average wages for the area in which the hospital is located; and

"(ii) which has at least 10 percent of its employees who reside in one or more higher wage index areas.

"(C) For purposes of this paragraph, the term 'higher wage index area' means, with respect to a hospital, an area with a wage index that exceeds that of the area in which the hospital is located.

"(D) The increase in the wage index under subparagraph (A) for a hospital shall be equal to the percentage of the employees of the hospital that resides in any higher wage index area multiplied by the sum of the products, for each higher wage index area of—

"(i) the difference between (I) the wage index for such area, and (II) the wage index of the area in which the hospital is located (before the application of this paragraph); and

"(ii) the number of employees of the hospital that reside in such higher wage index area divided by the total number of such employees that reside in all high wage index areas.

"(E) The process under this paragraph shall be based upon the process used by the Medicare Geographic Classification Review Board under paragraph (10) with respect to data submitted by hospitals to the Board on the location of residence of hospital employees and wages under the applicable schedule established for geographic reclassification.

"(F) A reclassification under this paragraph shall be effective for a period of 3 fiscal years, except that the Secretary shall establish procedures under which a subsection (d) hospital may elect to terminate such reclassification before the end of such period.

"(G) A hospital that is reclassified under this paragraph for a period is not eligible for reclassification under paragraphs (8) or (10) during that period.

"(H) Any increase in a wage index under this paragraph for a hospital shall not be taken into account for purposes of—

"(i) computing the wage index for the area in which the hospital is located or any other area; or

"(ii) applying any budget neutrality adjustment with respect to such index under paragraph (8)(D).".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall first apply to the wage index for cost reporting period beginning on or after October 1, 2004.

SEC. 505. MEDPAC REPORT ON SPECIALTY HOSPITALS.

(a) MEDPAC STUDY.—The Medicare Payment Advisory Commission shall conduct a study of specialty hospitals compared with other similar general acute care hospitals under the medicare program. Such study shall examine—

(1) whether there are excessive self-referrals;

(2) quality of care furnished;

(3) the impact of specialty hospitals on such general acute care hospitals; and

(4) differences in the scope of services, medicaid utilization, and uncompensated care furnished.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under subsection (a), and shall include any recommendations for legislation or administrative change as the Secretary determines appropriate.

Subtitle B—Other Provisions

SEC. 511. PAYMENT FOR COVERED SKILLED NURSING FACILITY SERVICES.

(a) ADJUSTMENT TO RUGS FOR AIDS RESIDENTS.—Paragraph (12) of section 1888(e) (42 U.S.C. 1395yy(e)) is amended to read as follows:

"(12) ADJUSTMENT FOR RESIDENTS WITH AIDS.—

"(A) IN GENERAL.—Subject to subparagraph (B), in the case of a resident of a skilled nursing facility who is afflicted with acquired immune deficiency syndrome (AIDS), the per diem amount of payment otherwise applicable shall be increased by 128 percent to reflect increased costs associated with such residents.

"(B) SUNSET.—Subparagraph (A) shall not apply on and after such date as the Secretary certifies that there is an appropriate adjustment in the case mix under paragraph (4)(G)(i) to compensate for the increased costs associated with residents described in such subparagraph.".

(b) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to services furnished on or after October 1, 2003.

SEC. 512. COVERAGE OF HOSPICE CONSULTATION SERVICES.

(a) COVERAGE OF HOSPICE CONSULTATION SERVICES.—Section 1812(a) (42 U.S.C. 1395d(a)) is amended—

(1) by striking "and" at the end of paragraph (3);

(2) by striking the period at the end of paragraph (4) and inserting "; and"; and

(3) by inserting after paragraph (4) the following new paragraph:

"(5) for individuals who are terminally ill, have not made an election under subsection (d)(1), and have not previously received services under this paragraph, services that are furnished by a physician who is either the medical director or an employee of a hospice program and that consist of—

"(A) an evaluation of the individual's need for pain and symptom management;

"(B) counseling the individual with respect to end-of-life issues and care options; and

"(C) advising the individual regarding advanced care planning.".

(b) PAYMENT.—Section 1814(i) (42 U.S.C. l395f(i)) is amended by adding at the end the following new paragraph:

"(4) The amount paid to a hospice program with respect to the services under section 1812(a)(5) for which payment may be made under this part shall be equal to an amount equivalent to the amount established for an office or other outpatient visit for evaluation and management associated with presenting problems of moderate severity under the fee schedule established under section 1848(b), other than the portion of such amount attributable to the practice expense component.".

(c) CONFORMING AMENDMENT.—Section 1861(dd)(2)(A)(i) (42 U.S.C. 1395x(dd)(2)(A)(i)) is amended by inserting before the comma at the end the following: "and services described in section 1812(a)(5)".

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to services provided by a hospice program on or after January 1, 2004.

TITLE VI—PROVISIONS RELATING TO PART B

Subtitle A—Physicians' Services

SEC. 601. REVISION OF UPDATES FOR PHYSICIANS' SERVICES.

(a) UPDATE FOR 2004 AND 2005.—

(1) IN GENERAL.—Section 1848(d) (42 U.S.C. 1395w–4(d)) is amended by adding at the end the following new paragraph:

"(5) UPDATE FOR 2004 AND 2005.—The update to the single conversion factor established in paragraph (1)(C) for each of 2004 and 2005 shall be not less than 1.5 percent.".

(2) CONFORMING AMENDMENT.—Paragraph (4)(B) of such section is amended, in the matter before clause (i), by inserting "and paragraph (5)" after "subparagraph (D)".

(3) NOT TREATED AS CHANGE IN LAW AND REGULATION IN SUSTAINABLE GROWTH RATE DETERMINATION.—The amendments made by this subsection shall not be treated as a change in law for purposes of applying section 1848(f)(2)(D) of the Social Security Act (42 U.S.C. 1395w–4(f)(2)(D)).

(b) USE OF 10-YEAR ROLLING AVERAGE IN COMPUTING GROSS DOMESTIC PRODUCT.—

(1) IN GENERAL.—Section 1848(f)(2)(C) (42 U.S.C. 1395w–4(f)(2)(C)) is amended—

(A) by striking "projected" and inserting "annual average"; and

(B) by striking "from the previous applicable period to the applicable period involved" and inserting "during the 10-year period ending with the applicable period involved".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to computations of the sustainable growth rate for years beginning with 2003.

SEC. 602. STUDIES ON ACCESS TO PHYSICIANS' SERVICES.

(a) GAO STUDY ON BENEFICIARY ACCESS TO PHYSICIANS' SERVICES.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on access of medicare beneficiaries to physicians' services under the medicare program. The study shall include—

(A) an assessment of the use by beneficiaries of such services through an analysis of claims submitted by physicians for such services under part B of the medicare program;

(B) an examination of changes in the use by beneficiaries of physicians' services over time;

(C) an examination of the extent to which physicians are not accepting new medicare beneficiaries as patients.

(2) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1). The report shall include a determination whether—

(A) data from claims submitted by physicians under part B of the medicare program indicate potential access problems for medicare beneficiaries in certain geographic areas; and

(B) access by medicare beneficiaries to physicians' services may have improved, remained constant, or deteriorated over time.

(b) STUDY AND REPORT ON SUPPLY OF PHYSICIANS.—

(1) STUDY.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct a study on the adequacy of the supply of physicians (including specialists) in the United States and the factors that affect such supply.

(2) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of this section, the Secretary shall submit to Congress a report on the results of the study described in paragraph (1), including any recommendations for legislation.

(c) GAO STUDY OF MEDICARE PAYMENT FOR INHALATION THERAPY.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to examine the adequacy of current reimbursements for inhalation therapy under the medicare program.

(2) REPORT.—Not later than May 1, 2004, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).

SEC. 603. MEDPAC REPORT ON PAYMENT FOR PHYSICIANS' SERVICES.

(a) PRACTICE EXPENSE COMPONENT.—Not later than 1 year after the date of the enactment of this Act, the Medicare Payment Advisory Commission shall submit to Congress a report on the effect of refinements to the practice expense component of payments for physicians' services, after the transition to a full resource-based payment system in 2002, under section 1848 of the Social Security Act (42 U.S.C. 1395w–4). Such report shall examine the following matters by physician specialty:

(1) The effect of such refinements on payment for physicians' services.

(2) The interaction of the practice expense component with other components of and adjustments to payment for physicians' services under such section.

(3) The appropriateness of the amount of compensation by reason of such refinements.

(4) The effect of such refinements on access to care by medicare beneficiaries to physicians' services.

(5) The effect of such refinements on physician participation under the medicare program.

(b) VOLUME OF PHYSICIAN SERVICES.—The Medicare Payment Advisory Commission shall submit to Congress a report on the extent to which increases in the volume of physicians' services under part B of the medicare program are a result of care that improves the health and well-being of medicare beneficiaries. The study shall include the following:

(1) An analysis of recent and historic growth in the components that the Secretary includes under the sustainable growth rate (under section 1848(f) of the Social Security Act).

(2) An examination of the relative growth of volume in physician services between medicare beneficiaries and other populations.

(3) An analysis of the degree to which new technology, including coverage determinations of the Centers for Medicare & Medicaid Services, has affected the volume of physicians' services.

(4) An examination of the impact on volume of demographic changes.

(5) An examination of shifts in the site of service of services that influence the number and intensity of services furnished in physicians' offices and the extent to which changes in reimbursement rates to other providers have affected these changes.

(6) An evaluation of the extent to which the Centers for Medicare & Medicaid Services takes into account the impact of law and regulations on the sustainable growth rate.

Subtitle B—Preventive Services

SEC. 611. COVERAGE OF AN INITIAL PREVENTIVE PHYSICAL EXAMINATION.

(a) COVERAGE.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)) is amended—

(1) in subparagraph (U), by striking "and" at the end;

(2) in subparagraph (V), by inserting "and" at the end; and

(3) by adding at the end the following new subparagraph:

"(W) an initial preventive physical examination (as defined in subsection (ww));".

(b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

"Initial Preventive Physical Examination

"(ww) The term 'initial preventive physical examination' means physicians' services consisting of a physical examination with the goal of health promotion and disease detection and includes items and services (excluding clinical laboratory tests), as determined by the Secretary, consistent with the recommendations of the United States Preventive Services Task Force.".

(c) WAIVER OF DEDUCTIBLE AND COINSURANCE.—

(1) DEDUCTIBLE.—The first sentence of section 1833(b) (42 U.S.C. 1395l(b)) is amended—

(A) by striking "and" before "(6)", and

(B) by inserting before the period at the end the following: ", and (7) such deductible shall not apply with respect to an initial preventive physical examination (as defined in section 1861(ww))".

(2) COINSURANCE.—Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)) is amended—

(A) in clause (N), by inserting "(or 100 percent in the case of an initial preventive physical examination, as defined in section 1861(ww))" after "80 percent"; and

(B) in clause (O), by inserting "(or 100 percent in the case of an initial preventive physical examination, as defined in section 1861(ww))" after "80 percent".

(d) PAYMENT AS PHYSICIANS' SERVICES.—Section 1848(j)(3) (42 U.S.C. 1395w–4(j)(3)) is amended by inserting "(2)(W)," after "(2)(S),".

(e) OTHER CONFORMING AMENDMENTS.—Section 1862(a) (42 U.S.C. 1395y(a)) is amended—

(1) in paragraph (1)—

(A) by striking "and" at the end of subparagraph (H);

(B) by striking the semicolon at the end of subparagraph (I) and inserting ", and"; and

(C) by adding at the end the following new subparagraph:

"(J) in the case of an initial preventive physical examination, which is performed not later than 6 months after the date the individual's first coverage period begins under part B;"; and

(2) in paragraph (7), by striking "or (H)" and inserting "(H), or (J)".

(f) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2004, but only for individuals whose coverage period begins on or after such date.

SEC. 612. COVERAGE OF CHOLESTEROL AND BLOOD LIPID SCREENING.

(a) COVERAGE.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)), as amended by section 611(a), is amended—

(1) in subparagraph (V), by striking "and" at the end;

(2) in subparagraph (W), by inserting "and" at the end; and

(3) by adding at the end the following new subparagraph:

"(X) cholesterol and other blood lipid screening tests (as defined in subsection (XX));".

(b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C. 1395x), as amended by section 611(b), is amended by adding at the end the following new subsection:

"Cholesterol and Other Blood Lipid Screening Test

"(xx)(1) The term 'cholesterol and other blood lipid screening test' means diagnostic testing of cholesterol and other lipid levels of the blood for the purpose of early detection of abnormal cholesterol and other lipid levels.

"(2) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency and type of cholesterol and other blood lipid

screening tests, except that such frequency may not be more often than once every 2 years.".

(c) FREQUENCY.—Section 1862(a)(1) (42 U.S.C. 1395y(a)(1)), as amended by section 611(e), is amended—

(1) by striking "and" at the end of subparagraph (I);

(2) by striking the semicolon at the end of subparagraph (J) and inserting "; and"; and

(3) by adding at the end the following new subparagraph:

"(K) in the case of a cholesterol and other blood lipid screening test (as defined in section 1861(xx)(1)), which is performed more frequently than is covered under section 1861(xx)(2).".

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to tests furnished on or after January 1, 2005.

SEC. 613. WAIVER OF DEDUCTIBLE FOR COLORECTAL CANCER SCREENING TESTS.

(a) IN GENERAL.—The first sentence of section 1833(b) (42 U.S.C. 1395*l*(b)), as amended by section 611(c)(1), is amended—

(1) by striking "and" before "(7)"; and

(2) by inserting before the period at the end the following: ", and (8) such deductible shall not apply with respect to colorectal cancer screening tests (as described in section 1861(pp)(1))".

(b) CONFORMING AMENDMENTS.—Paragraphs (2)(C)(ii) and (3)(C)(ii) of section 1834(d) (42 U.S.C. 1395m(d)) are each amended—

(1) by striking "DEDUCTIBLE AND" in the heading; and

(2) in subclause (I), by striking "deductible or" each place it appears.

(c) EFFECTIVE DATE.—The amendment made by this section shall apply to items and services furnished on or after Janaury 1, 2004.

SEC. 614. IMPROVED PAYMENT FOR CERTAIN MAMMOGRAPHY SERVICES.

(a) EXCLUSION FROM OPD FEE SCHEDULE.—Section 1833(t)(1)(B)(iv) (42 U.S.C. 1395l(t)(1)(B)(iv)) is amended by inserting before the period at the end the following: "and does not include screening mammography (as defined in section 1861(jj)) and unilateral and bilateral diagnostic mammography".

(b) ADJUSTMENT TO TECHNICAL COMPONENT.—For diagnostic mammography performed on or after January 1, 2004, for which payment is made under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4), the Secretary, based on the most recent cost data available, shall provide for an appropriate adjustment in the payment amount for the technical component of the diagnostic mammography.

(c) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to mammography performed on or after January 1, 2004.

Subtitle C—Other Services

SEC. 621. HOSPITAL OUTPATIENT DEPARTMENT (HOPD) PAYMENT REFORM.

(a) PAYMENT FOR DRUGS.—

(1) MODIFICATION OF AMBULATORY PAYMENT CLASSIFICATION (APC) GROUPS.—Section 1833(t) (42 U.S.C. 1395l(t)) is amended—

(A) by redesignating paragraph (13) as paragraph (14); and

(B) by inserting after paragraph (12) the following new paragraph:

"(13) DRUG APC PAYMENT RATES.—

"(A) IN GENERAL.—With respect to payment for covered OPD services that includes a specified covered outpatient drug (defined in subparagraph (B)), the amount provided for payment for such drug under the payment system under this subsection for services furnished in—

"(i) 2004, 2005, or 2006, shall in no case—

"(I) exceed 95 percent of the average wholesale price for the drug; or

"(II) be less than the transition percentage (under subparagraph (C)) of the average wholesale price for the drug; or

"(ii) a subsequent year, shall be equal to the average price for the drug for that area and year established under the competitive acquisition program under section 1847A as calculated and applied by the Secretary for purposes of this paragraph.

"(B) SPECIFIED COVERED OUTPATIENT DRUG DEFINED.—

"(i) IN GENERAL.—In this paragraph, the term 'specified covered outpatient drug' means, subject to clause (ii), a covered outpatient drug (as defined in 1927(k)(2), that is—

"(I) a radiopharmaceutical; or

"(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

"(ii) EXCEPTION.—Such term does not include—

"(I) a drug for which payment is first made on or after January 1, 2003, under paragraph (6); or

"(II) a drug for a which a temporary HCPCS code has not been assigned.

"(C) TRANSITION TOWARDS HISTORICAL AVERAGE ACQUISITION COST.—The transition percentage under this subparagraph for drugs furnished in a year is determined in accordance with the following table:

For the year—	The transition percentage for— Single source drugs are—	Innovator multiple source drugs are—	Generic drugs are—
2004	83%	81.5%	46%
2005	77%	75%	46%
2006	71%	68%	46%

"(D) PAYMENT FOR NEW DRUGS UNTIL TEMPORARY HCPCS CODE ASSIGNED.—With respect to payment for covered OPD services that includes a covered outpatient drug (as defined in 1927(k)) for a which a temporary HCPCS code has not been assigned, the amount provided for payment for such drug under the payment system under this subsection shall be equal to 95 percent of the average wholesale price for the drug.

"(E) CLASSES OF DRUGS.—For purposes of this paragraph, each of the following shall be treated as a separate class of drugs:

"(i) SOLE SOURCE DRUGS.—A sole source drug which for purposes of this paragraph means a drug or biological that is not a multiple source drug (as defined in subclauses (I) and (II) of section 1927(k)(7)(A)(i)) and is not a drug approved under an abbreviated new drug application under section 355(j) of the Federal Food, Drug, and Cosmetic Act.

"(ii) INNOVATOR MULTIPLE SOURCE DRUGS.—Innovator multiple source drugs (as defined in section 1927(k)(7)(A)(ii)).

"(iii) NONINNOVATOR MULTIPLE SOURCE DRUGS.—Noninnovator multiple source drugs (as defined in section 1927(k)(7)(A)(iii)).

"(F) INAPPLICABILITY OF EXPENDITURES IN DETERMINING CONVERSION FACTORS.—Additional expenditures resulting from this paragraph and paragraph (14)(C) in a year shall not be taken into account in establishing the conversion factor for that year.".

(2) REDUCTION IN THRESHOLD FOR SEPARATE APCS FOR DRUGS.—Section 1833(t)(14), as redesignated by paragraph (1)(A), is amended by adding at the end the following new subparagraph:

"(B) THRESHOLD FOR ESTABLISHMENT OF SEPARATE APCS FOR DRUGS.—The Secretary shall reduce the threshold for the establishment of separate ambulatory procedure classification groups (APCs) with respect to drugs to $50 per administration.".

(3) EXCLUSION OF SEPARATE DRUG APCS FROM OUTLIER PAYMENTS.—Section 1833(t)(5) is amended by adding at the end the following new subparagraph:

"(E) EXCLUSION OF SEPARATE DRUG APCS FROM OUTLIER PAYMENTS.—No additional payment shall be made under subparagraph (A) in the case of ambulatory procedure codes established separately for drugs.".

(4) PAYMENT FOR PASS THROUGH DRUGS.—Clause (i) of section 1833(t)(6)(D) (42 U.S.C. 1395l(t)(6)(D)) is amended by inserting after "under section 1842(o)" the following: "(or if the drug is covered under a competitive acquisition contract under section 1847A for an area, an amount determined by the Secretary equal to the average price for the drug for that area and year established under such section as calculated and applied by the Secretary for purposes of this paragraph)".

(5) EFFECTIVE DATE.—The amendments made by this subsection shall apply to services furnished on or after January 1, 2004.

(b) SPECIAL PAYMENT FOR BRACHYTHERAPY.—

(1) IN GENERAL.—Section 1833(t)(14), as so redesignated and amended by subsection (a)(2), is amended by adding at the end the following new subparagraph:

"(C) PAYMENT FOR DEVICES OF BRACHYTHERAPY AT CHARGES ADJUSTED TO COST.—Notwithstanding the preceding provisions of this subsection, for a device of brachytherapy furnished on or after January 1, 2004, and before January 1, 2007, the payment basis for the device under this subsection shall be equal to the hospital's charges for each device furnished, adjusted to cost.".

(2) SPECIFICATION OF GROUPS FOR BRACHYTHERAPY DEVICES.—Section 1833(t)(2) (42 U.S.C. 1395l(t)(2) is amended—

(A) in subparagraph (F), by striking "and" at the end;

(B) in subparagraph (G), by striking the period at the end and inserting "; and"; and

(C) by adding at the end the following new subparagraph:

"(H) with respect to devices of brachytherapy, the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices.".

(3) GAO REPORT.—The Comptroller General of the United States shall conduct a study to determine appropriate payment amounts under section 1833(t)(13)(B) of the Social Security Act, as added by paragraph (1), for devices of brachytherapy. Not later than January 1, 2005, the Comptroller General shall submit to Congress and the Secretary a report on the study conducted under this paragraph, and shall include specific recommendations for appropriate payments for such devices.

(c) APPLICATION OF FUNCTIONAL EQUIVALENCE TEST.—

(1) IN GENERAL.—Section 1833(t)(6) (42 U.S.C. 1395l(t)(6)) is amended by adding at the end the following new subparagraph:

"(F) LIMITATION ON APPLICATION OF FUNCTIONAL EQUIVALENCE STANDARD.—The Secretary may not apply a 'functional equivalence' payment standard (including such standard promulgated on November 1, 2002) or any other similar standard in order to deem a particular drug or biological to be identical to or similar to another drug or biological with respect to its mechanism of action or clinical effect to deny pass-through status to new drugs or biologics or to remove such status of an existing eligible drug or biologic under this paragraph unless—

"(i) the Secretary develops by regulation (after providing notice and a period for public comment) criteria for the application of such standard; and

"(ii) such criteria provide for coordination with the Federal Food and Drug Administration and require scientific studies that show the clinical relationship between the drugs or biologicals treated as functionally equivalent.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to the application of a functional equivalence standard to a drug or biological on or after the date of the enactment of this Act, unless such application was being made to such drug or biological prior to June 13, 2003.

(d) HOSPITAL ACQUISITION COST STUDY.—

(1) IN GENERAL.—The Secretary shall conduct a study on the costs incurred by hospitals in acquiring covered outpatient drugs for which payment is made under section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)).

(2) DRUGS COVERED.—The study in paragraph (1) shall not include those drugs for which the acquisition costs is less than $50 per administration.

(3) REPRESENTATIVE SAMPLE OF HOSPITALS.—In conducting the study under paragraph (1), the Secretary shall collect data from a statistically valid sample of hospitals with an urban/rural stratification.

(4) REPORT.—Not later than January 1, 2006, the Secretary shall submit to Congress a report on the study conducted under paragraph (1), and shall include recommendations with respect to the following:

(A) Whether the study should be repeated, and if so, how frequently.

(B) Whether the study produced useful data on hospital acquisition cost.

(C) Whether data produced in the study is appropriate for use in making adjustments to payments for drugs and biologicals under section 1847A of the Social Security Act.

(D) Whether separate estimates can made of overhead costs, including handing and administering costs for drugs.

SEC. 622. PAYMENT FOR AMBULANCE SERVICES.

(a) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—Section 1834(l) (42 U.S.C. 1395m(l)), as amended by section 410(a), is amended—

(1) in paragraph (2)(E), by inserting "consistent with paragraph (11)" after "in an efficient and fair manner"; and

(2) by adding at the end the following new paragraph:

"(11) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—In carrying out the phase-in under paragraph (2)(E) for each level of service furnished in a year, the portion of the payment amount that is based on the fee schedule shall not be less than the following blended rate of the fee schedule under paragraph (1) and of a regional fee schedule for the region involved:

"(A) For 2004, the blended rate shall be based 20 percent on the fee schedule under paragraph (1) and 80 percent on the regional fee schedule.

"(B) For 2005, the blended rate shall be based 40 percent on the fee schedule under paragraph (1) and 60 percent on the regional fee schedule.

"(C) For 2006, the blended rate shall be based 60 percent on the fee schedule under paragraph (1) and 40 percent on the regional fee schedule.

"(D) For 2007, 2008, and 2009, the blended rate shall be based 80 percent on the fee schedule under paragraph (1) and 20 percent on the regional fee schedule.

"(E) For 2010 and each succeeding year, the blended rate shall be based 100 percent on the fee schedule under paragraph (1).

For purposes of this paragraph, the Secretary shall establish a regional fee schedule for each of the 9 Census divisions using the methodology (used in establishing the fee schedule under paragraph (1)) to calculate a regional conversion factor and a regional mileage payment rate and using the same payment adjustments and the same relative value units as used in the fee schedule under such paragraph.".

(b) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG TRIPS.—Section 1834(l), as amended by subsection (a), is further amended by adding at the end the following new paragraph:

"(12) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG TRIPS.—In the case of ground ambulance services furnished on or after January 1, 2004, and before January 1, 2009, regardless of where the transportation originates, the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 50 miles the per mile rate otherwise established shall be increased by ¼ of the payment per mile otherwise applicable to such miles.".

(c) GAO REPORT ON COSTS AND ACCESS.—Not later than December 31, 2005, the Comptroller General of the United States shall submit to Congress an initial report on how costs differ among the types of ambulance providers and on access, supply, and quality of ambulance services in those regions and States that have a reduction in payment under the medicare ambulance fee schedule (under section 1834(l) of the Social Security Act, as amended by this section). Not later than December 31, 2007, the Comptroller General shall submit to Congress a final report on such access and supply.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to ambulance services furnished on or after January 1, 2004.

SEC. 623. RENAL DIALYSIS SERVICES.

(a) DEMONSTRATION OF ALTERNATIVE DELIVERY MODELS.—

(1) USE OF ADVISORY BOARD.—In carrying out the demonstration project relating to improving care for people with end-stage renal disease through alternative delivery models (as published in the Federal Register of June 4, 2003), the Secretary shall establish an advisory board comprised of representatives described in paragraph (2) to provide advice and recommendations with respect to the establishment and operation of such demonstration project.

(2) REPRESENTATIVES.—Representatives referred to in paragraph (1) include representatives of the following:

(A) Patient organizations.

(B) Clinicians.

(C) The medicare payment advisory commission, established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6).

(D) The National Kidney Foundation.

(E) The National Institute of Diabetes and Digestive and Kidney Diseases of National Institutes of Health.

(F) End-stage renal disease networks.

(G) Medicare contractors to monitor quality of care.

(I) providers of services and renal dialysis facilities furnishing end-stage renal disease services.

(J) Economists.

(K) Researchers.

(b) RESTORING COMPOSITE RATE EXCEPTIONS FOR PEDIATRIC FACILITIES.—

(1) IN GENERAL.—Section 422(a)(2) of BIPA is amended—

(A) in subparagraph (A), by striking "and (C)" and inserting ", (C), and (D)";

(B) in subparagraph (B), by striking "In the case" and inserting "Subject to subparagraph (D), in the case"; and

(C) by adding at the end the following new subparagraph:

"(D) INAPPLICABILITY TO PEDIATRIC FACILITIES.—Subparagraphs (A) and (B) shall not apply, as of October 1, 2002, to pediatric facilities that do not have an exception rate described in subparagraph (C) in effect on such date. For purposes of this subparagraph, the term 'pediatric facility' means a renal facility at least 50 percent of whose patients are individuals under 18 years of age.".

(2) CONFORMING AMENDMENT.—The fourth sentence of section 1881(b)(7) (42 U.S.C. 1395rr(b)(7)), as amended by subsection (b), is further amended by striking "Until" and inserting "Subject to section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, and until".

(c) INCREASE IN RENAL DIALYSIS COMPOSITE RATE FOR SERVICES FURNISHED IN 2004.—Notwithstanding any other provision of law, with respect to payment under part B of title XVIII of the Social Security Act for renal dialysis services furnished in 2004, the composite payment rate otherwise established under section 1881(b)(7) of such Act (42 U.S.C. 1395rr(b)(7)) shall be increased by 1.6 percent.

SEC. 624. ONE-YEAR MORATORIUM ON THERAPY CAPS; PROVISIONS RELATING TO REPORTS.

(a) 1-YEAR MORATORIUM ON THERAPY CAPS.—Section 1833(g)(4) (42 U.S.C. 1395l(g)(4)) is amended by striking "and 2002" and inserting "2002, and 2004".

(b) PROMPT SUBMISSION OF OVERDUE REPORTS ON PAYMENT AND UTILIZATION OF OUTPATIENT THERAPY SERVICES.—Not later than December 31, 2003, the Secretary shall submit to Congress the reports required under section 4541(d)(2) of the Balanced Budget Act of 1997 (relating to alternatives to a single annual dollar cap on outpatient therapy) and under section 221(d) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (relating to utilization patterns for outpatient therapy).

(c) IDENTIFICATION OF CONDITIONS AND DISEASES JUSTIFYING WAIVER OF THERAPY CAP.—

(1) STUDY.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to identify conditions or diseases that should justify conducting an assessment of the need to waive the therapy caps under section 1833(g)(4) of the Social Security Act (42 U.S.C. 1395l(g)(4)).

(2) REPORTS TO CONGRESS.—

(A) PRELIMINARY REPORT.—Not later than July 1, 2004, the Secretary shall submit to Congress a preliminary report on the conditions and diseases identified under paragraph (1).

(B) FINAL REPORT.—Not later than September 1, 2004, the Secretary shall submit to Congress a final report on such conditions and diseases.

(C) RECOMMENDATIONS.—Not later than October 1, 2004, the Secretary shall submit to Congress a recommendation of criteria, with respect to such conditions and disease, under which a waiver of the therapy caps would apply.

(d) GAO STUDY OF PATIENT ACCESS TO PHYSICAL THERAPIST SERVICES.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on access to physical therapist services in States authorizing such services without a physician referral and in States that require such a physician referral. The study shall—

(A) examine the use of and referral patterns for physical therapist services for patients age 50 and older in States that authorize such services without a physician referral and in States that require such a physician referral;

(B) examine the use of and referral patterns for physical therapist services for patients who are medicare beneficiaries;

(C) examine the potential effect of prohibiting a physician from referring patients to physical therapy services owned by the physician and provided in the physician's office;

(D) examine the delivery of physical therapists' services within the facilities of Department of Defense; and

(E) analyze the potential impact on medicare beneficiaries and on expenditures under the medicare program of eliminating the need for a physician referral and physician certification for physical therapist services under the medicare program.

(2) REPORT.—The Comptroller General shall submit to Congress a report on the study conducted under paragraph (1) by not later than 1 year after the date of the enactment of this Act.

SEC. 625. ADJUSTMENT TO PAYMENTS FOR SERVICES FURNISHED IN AMBULATORY SURGICAL CENTERS.

Section 1833(i)(2)(C) (42 U.S.C. 1395l(i)(2)(C)) is amended in the last sentence by inserting "and each of fiscal years 2004 through 2008" after "In each of the fiscal years 1998 through 2002".

SEC. 626. PAYMENT FOR CERTAIN SHOES AND INSERTS UNDER THE FEE SCHEDULE FOR ORTHOTICS AND PROSTHETICS.

(a) IN GENERAL.—Section 1833(o) (42 U.S.C. 1395l(o)) is amended—

(1) in paragraph (1), by striking "no more than the limits established under paragraph (2)" and inserting "no more than the amount of payment applicable under paragraph (2)"; and

(2) in paragraph (2), to read as follows:

"(2)(A) Except as provided by the Secretary under subparagraphs (B) and (C), the amount of payment under this paragraph for custom molded shoes, extra depth shoes, and inserts shall be the amount determined for such items by the Secretary under section 1834(h).

"(B) The Secretary or a carrier may establish payment amounts for shoes and inserts that are lower than the amount established under section 1834(h) if the Secretary finds that shoes and inserts of an appropriate quality are readily available at or below the amount established under such section.

"(C) In accordance with procedures established by the Secretary, an individual entitled to benefits with respect to shoes described in section 1861(s)(12) may substitute modification of such shoes instead of obtaining one (or more, as specified by the Secretary) pair of inserts (other than the original pair of inserts with respect to such shoes). In such case, the Secretary shall substitute, for the payment amount established under section 1834(h), a payment amount that the Secretary estimates will assure that there is no net increase in expenditures under this subsection as a result of this subparagraph.".

(b) CONFORMING AMENDMENTS.—(1) Section 1834(h)(4)(C) (42 U.S.C. 1395m(h)(4)(C)) is amended by inserting "(and includes shoes described in section 1861(s)(12))" after "in section 1861(s)(9)".

(2) Section 1842(s)(2) (42 U.S.C. 1395u(s)(2)) is amended by striking subparagraph (C).

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to items furnished on or after January 1, 2004.

SEC. 627. WAIVER OF PART B LATE ENROLLMENT PENALTY FOR CERTAIN MILITARY RETIREES; SPECIAL ENROLLMENT PERIOD.

(a) WAIVER OF PENALTY.—

(1) IN GENERAL.—Section 1839(b) (42 U.S.C. 1395r(b)) is amended by adding at the end the following new sentence: "No increase in the premium shall be effected for a month in the case of an individual who is 65 years of age or older, who enrolls under this part during 2001, 2002, 2003, or 2004 and who demonstrates to the Secretary before December 31, 2004, that the individual is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code). The Secretary of Health and Human Services shall consult with the Secretary of Defense in identifying individuals described in the previous sentence.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to premiums for months beginning with January 2004. The Secretary of Health and Human Services shall establish a method for providing rebates of premium penalties paid for months on or after January 2004 for which a penalty does not apply under such amendment but for which a penalty was previously collected.

(b) MEDICARE PART B SPECIAL ENROLLMENT PERIOD.—

(1) IN GENERAL.—In the case of any individual who, as of the date of the enactment of this Act, is 65 years of age or older, is eligible to enroll but is not enrolled under part B of title XVIII of the Social Security Act, and is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code), the Secretary of Health and Human Services shall provide for a special enrollment period during which the individual may enroll under such part. Such period

shall begin as soon as possible after the date of the enactment of this Act and shall end on December 31, 2004.

(2) COVERAGE PERIOD.—In the case of an individual who enrolls during the special enrollment period provided under paragraph (1), the coverage period under part B of title XVIII of the Social Security Act shall begin on the first day of the month following the month in which the individual enrolls.

SEC. 628. PART B DEDUCTIBLE.

Section 1833(b) (42 U.S.C. 1395l(b)) is amended—

(1) by striking "1991 and" and inserting "1991,"; and

(2) by striking "and subsequent years" and inserting "and each subsequent year through 2003, and for a subsequent year after 2003 the amount of such deductible for the previous year increased by the annual percentage increase in the monthly actuarial rate under section 1839(a)(1) ending with such subsequent year (rounded to the nearest $1)".

SEC. 629. EXTENSION OF COVERAGE OF INTRAVENOUS IMMUNE GLOBULIN (IVIG) FOR THE TREATMENT OF PRIMARY IMMUNE DEFICIENCY DISEASES IN THE HOME.

(a) IN GENERAL.—Section 1861 (42 U.S.C. 1395x), as amended by sections 611(a) and 612(a) is amended—

(1) in subsection (s)(2)—

(A) by striking "and" at the end of subparagraph (W);

(B) by adding "and" at the end of subparagraph (X); and

(C) by adding at the end the following new subparagraph:

"(Y) intravenous immune globulin for the treatment of primary immune deficiency diseases in the home (as defined in subsection (yy));"; and

(2) by adding at the end the following new subsection:

"Intravenous Immune Globulin

"(yy) The term 'intravenous immune globulin' means an approved pooled plasma derivative for the treatment in the patient's home of a patient with a diagnosed primary immune deficiency disease, but not including items or services related to the administration of the derivative, if a physician determines administration of the derivative in the patient's home is medically appropriate.".

(b) PAYMENT AS A DRUG OR BIOLOGICAL.—Section 1833(a)(1)(S) (42 U.S.C. 1395l(a)(1)(S)) is amended by inserting "(including intravenous immune globulin (as defined in section 1861(yy)))" after "with respect to drugs and biologicals".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to items furnished administered on or after January 1, 2004.

TITLE VII—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

SEC. 701. UPDATE IN HOME HEALTH SERVICES.

(a) CHANGE TO CALENDER YEAR UPDATE.—

(1) IN GENERAL.—Section 1895(b) (42 U.S.C. 1395fff(b)(3)) is amended—

(A) in paragraph (3)(B)(i)—

(i) by striking "each fiscal year (beginning with fiscal year 2002)" and inserting "fiscal year 2002 and for fiscal year 2003 and for each subsequent year (beginning with 2004)"; and

(ii) by inserting "or year" after "the fiscal year";

(B) in paragraph (3)(B)(ii)(II), by striking "any subsequent fiscal year" and inserting "2004 and any subsequent year";

(C) in paragraph (3)(B)(iii), by inserting "or year" after "fiscal year" each place it appears;

(D) in paragraph (3)(B)(iv)—

(i) by inserting "or year" after "fiscal year" each place it appears; and

(ii) by inserting "or years" after "fiscal years"; and

(E) in paragraph (5), by inserting "or year" after "fiscal year".

(2) TRANSITION RULE.—The standard prospective payment amount (or amounts) under section 1895(b)(3) of the Social Security Act for the calendar quarter beginning on October 1, 2003, shall be such amount (or amounts) for the previous calendar quarter.

(b) CHANGES IN UPDATES FOR 2004, 2005, AND 2006.—Section 1895(b)(3)(B)(ii) (42 U.S.C. 1395fff(b)(3)(B)(ii)), as amended by subsection (a)(1)(B), is amended—

(1) by striking "or" at the end of subclause (I);
(2) by redesignating subclause (II) as subclause (III);
(3) in subclause (III), as so redesignated, by striking "2004" and inserting "2007"; and
(4) by inserting after subclause (I) the following new subclause:

"(II) each of 2004, 2005, and 2006 the home health market basket percentage increase minus 0.4 percentage points; or".

SEC. 702. ESTABLISHMENT OF REDUCED COPAYMENT FOR A HOME HEALTH SERVICE EPISODE OF CARE FOR CERTAIN BENEFICIARIES.

(a) PART A.—

(1) IN GENERAL.—Section 1813(a) (42 U.S.C. 1395e(a)) is amended by adding at the end the following new paragraph:

"(5)(A)(i) Subject to clause (ii), the amount payable for home health services furnished to the individual under this title for each episode of care beginning in a year (beginning with 2004) shall be reduced by a copayment equal to the copayment amount specified in subparagraph (B)(ii) for such year.

"(ii) The copayment under clause (i) shall not apply—

"(I) in the case of an individual who has been determined to be entitled to medical assistance under section 1902(a)(10)(A) or 1902(a)(10)(C) or to be a qualified medicare beneficiary (as defined in section 1905(p)(1)), a specified low-income medicare beneficiary described in section 1902(a)(10)(E)(iii), or a qualifying individual described in section 1902(a)(10)(E)(iv)(I); and

"(II) in the case of an episode of care which consists of 4 or fewer visits.

"(B)(i) The Secretary shall estimate, before the beginning of each year (beginning with 2004), the national average payment under this title per episode for home health services projected for the year involved.

"(ii) For each year the copayment amount under this clause is equal to 1.5 percent of the national average payment estimated for the year involved under clause (i). Any amount determined under the preceding sentence which is not a multiple of $5 shall be rounded to the nearest multiple of $5.

"(iii) There shall be no administrative or judicial review under section 1869, 1878, or otherwise of the estimation of average payment under clause (i).".

(2) TIMELY IMPLEMENTATION.—Unless the Secretary of Health and Human Services otherwise provides on a timely basis, the copayment amount specified under section 1813(a)(5)(B)(ii) of the Social Security Act (as added by paragraph (1)) for 2004 shall be deemed to be $40.

(b) CONFORMING PROVISIONS.—

(1) Section 1833(a)(2)(A) (42 U.S.C. 1395l(a)(2)(A)) is amended by inserting "less the copayment amount applicable under section 1813(a)(5)" after "1895".

(2) Section 1866(a)(2)(A)(i) (42 U.S.C. 1395cc(a)(2)(A)(i)) is amended—

(A) by striking "or coinsurance" and inserting ", coinsurance, or copayment"; and

(B) by striking "or (a)(4)" and inserting "(a)(4), or (a)(5)".

SEC. 703. MEDPAC STUDY ON MEDICARE MARGINS OF HOME HEALTH AGENCIES.

(a) STUDY.—The Medicare Payment Advisory Commission shall conduct a study of payment margins of home health agencies under the home health prospective payment system under section 1895 of the Social Security Act (42 U.S.C. 1395fff). Such study shall examine whether systematic differences in payment margins are related to differences in case mix (as measured by home health resource groups (HHRGs)) among such agencies. The study shall use the partial or full-year cost reports filed by home health agencies.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study under subsection (a).

Subtitle B—Direct Graduate Medical Education

SEC. 711. EXTENSION OF UPDATE LIMITATION ON HIGH COST PROGRAMS.

Section 1886(h)(2)(D)(iv) (42 U.S.C. 1395ww(h)(2)(D)(iv)) is amended—

(1) in subclause (I)—

(A) by inserting "AND 2004 THROUGH 2013" after "AND 2002"; and

(B) by inserting "or during the period beginning with fiscal year 2004 and ending with fiscal year 2013" after "during fiscal year 2001 or fiscal year 2002"; and

(2) in subclause (II)—

(A) by striking "fiscal year 2004, or fiscal year 2005," and

(B) by striking "For a" and inserting "For the".

Subtitle C—Chronic Care Improvement

SEC. 721. VOLUNTARY CHRONIC CARE IMPROVEMENT UNDER TRADITIONAL FEE-FOR-SERVICE.

Title XVIII, as amended by section 105(a), is amended by inserting after section 1807 the following new section:

"CHRONIC CARE IMPROVEMENT

"SEC. 1808. (a) IN GENERAL.—

"(1) IN GENERAL.—The Secretary shall establish a process for providing chronic care improvement programs in each CCIA region for medicare beneficiaries who are not enrolled under part C or E and who have certain chronic conditions, such as congestive heart failure, diabetes, chronic obstructive pulmonary disease (COPD), stroke, or other disease as identified by the Secretary as appropriate for chronic care improvement. Such a process shall begin to be implemented no later than 1 year after the date of the enactment of this section.

"(2) TERMINOLOGY.—For purposes of this section:

"(A) CCIA REGION.—The term 'CCIA region' means a chronic care improvement administrative region delineated under subsection (b)(2).

"(B) CHRONIC CARE IMPROVEMENT PROGRAM.—The terms 'chronic care improvement program' and 'program' means such a program provided by a contractor under this section.

"(C) CONTRACTOR.—The term 'contractor' means an entity with a contract to provide a chronic care improvement program in a CCIA region under this section.

"(D) INDIVIDUAL PLAN.—The term 'individual plan' means a chronic care improvement plan established under subsection (c)(5) for an individual.

"(3) CONSTRUCTION.—Nothing in this section shall be construed as expanding the amount, duration, or scope of benefits under this title.

"(b) COMPETITIVE BIDDING PROCESS.—

"(1) IN GENERAL.—Under this section the Secretary shall award contracts to qualified entities for chronic care improvement programs for each CCIA region under this section through a competitive bidding process.

"(2) PROCESS.—Under such process—

"(A) the Secretary shall delineate the United States into multiple chronic care improvement administrative regions; and

"(B) the Secretary shall select at least 2 winning bidders in each CCIA region on the basis of the ability of each bidder to carry out a chronic care improvement program in accordance with this section, in order to achieve improved health and financial outcomes.

"(3) ELIGIBLE CONTRACTOR.—A contractor may be a disease improvement organization, health insurer, provider organization, a group of physicians, or any other legal entity that the Secretary determines appropriate.

"(c) CHRONIC CARE IMPROVEMENT PROGRAMS.—

"(1) IN GENERAL.—Each contract under this section shall provide for the operation of a chronic care improvement program by a contractor in a CCIA region consistent with this subsection.

"(2) IDENTIFICATION OF PROSPECTIVE PROGRAM PARTICIPANTS.—Each contractor shall have a method for identifying medicare beneficiaries in the region to whom it will offer services under its program. The contractor shall identify such beneficiaries through claims or other data and other means permitted consistent with applicable disclosure provisions.

"(3) INITIAL CONTACT BY SECRETARY.—The Secretary shall communicate with each beneficiary identified under paragraph (2) as a prospective participant in one or more programs concerning participation in a program. Such communication may be made by the Secretary (or on behalf of the Secretary) and shall include information on the following:

"(A) A description of the advantages to the beneficiary in participating in a program.

"(B) Notification that the contractor offering a program may contact the beneficiary directly concerning such participation.

"(C) Notification that participation in a program is voluntary.

"(D) A description of the method for the beneficiary to select the single program in which the beneficiary wishes to participate and for declining to

participate and a method for obtaining additional information concerning such participation.

"(4) PARTICIPATION.—A medicare beneficiary may participate in only one program under this section and may terminate participation at any time in a manner specified by the Secretary.

"(5) INDIVIDUAL CHRONIC CARE IMPROVEMENT PLANS.—

"(A) IN GENERAL.—For each beneficiary participating in a program of a contractor under this section, the contractor shall develop with the beneficiary an individualized, goal-oriented chronic care improvement plan.

"(B) ELEMENTS OF INDIVIDUAL PLAN.—Each individual plan developed under subparagraph (A) shall include a single point of contact to coordinate care and the following, as appropriate:

"(i) Self-improvement education for the beneficiary and support education for health care providers, primary caregivers, and family members.

"(ii) Coordination of health care services, such as application of a prescription drug regimen and home health services.

"(iii) Collaboration with physicians and other providers to enhance communication of relevant clinical information.

"(iv) The use of monitoring technologies that enable patient guidance through the exchange of pertinent clinical information, such as vital signs, symptomatic information, and health self-assessment.

"(v) The provision of information about hospice care, pain and palliative care, and end-of-life care.

"(C) CONTRACTOR RESPONSIBILITIES.—In establishing and carrying out individual plans under a program, a contractor shall, directly or through subcontractors—

"(i) guide participants in managing their health, including all their co-morbidities, and in performing activities as specified under the elements of the plan;

"(ii) use decision support tools such as evidence-based practice guidelines or other criteria as determined by the Secretary; and

"(iii) develop a clinical information database to track and monitor each participant across settings and to evaluate outcomes.

"(6) ADDITIONAL REQUIREMENTS.—The Secretary may establish additional requirements for programs and contractors under this section.

"(7) ACCREDITATION.—The Secretary may provide that programs that are accredited by qualified organizations may be deemed to meet such requirements under this section as the Secretary may specify.

"(c) CONTRACT TERMS.—

"(1) IN GENERAL.—A contract under this section shall contain such terms and conditions as the Secretary may specify consistent with this section. The Secretary may not enter into a contract with an entity under this section unless the entity meets such clinical, quality improvement, financial, and other requirements as the Secretary deems to be appropriate for the population to be served.

"(2) USE OF SUBCONTRACTORS PERMITTED.—A contractor may carry out a program directly or through contracts with subcontractors.

"(3) BUDGET NEUTRAL PAYMENT CONDITION.—In entering into a contract with an entity under this subsection, the Secretary shall establish payment rates that assure that there will be no net aggregate increase in payments under this title over any period of 3 years or longer, as agreed to by the Secretary. Under this section, the Secretary shall assure that medicare program outlays plus administrative expenses (that would not have been paid under this title without implementation of this section), including contractor fees, shall not exceed the expenditures that would have been incurred under this title for a comparable population in the absence of the program under this section for the 3-year contract period.

"(4) AT RISK RELATIONSHIP.—For purposes of section 1128B(b)(3)(F), a contract under this section shall be treated as a risk-sharing arrangement referred to in such section.

"(5) PERFORMANCE STANDARDS.—Payment to contractors under this section shall be subject to the contractor's meeting of clinical and financial performance standards set by the Secretary.

"(6) CONTRACTOR OUTCOMES REPORT.—Each contractor offering a program shall monitor and report to the Secretary, in a manner specified by the Secretary, the quality of care and efficacy of such program in terms of—

"(A) process measures, such as reductions in errors of treatment and rehospitalization rates;

"(B) beneficiary and provider satisfaction;
"(C) health outcomes; and
"(D) financial outcomes.

"(7) PHASED IN IMPLEMENTATION.—Nothing in this section shall be construed as preventing the Secretary from phasing in the implementation of programs.

"(d) BIANNUAL OUTCOMES REPORTS.—The Secretary shall submit to the Congress biannual reports on the implementation of this section. Each such report shall include information on—

"(1) the scope of implementation (in terms of both regions and chronic conditions);
"(2) program design; and
"(3) improvements in health outcomes and financial efficiencies that result from such implementation.

"(e) CLINICAL TRIALS.—The Secretary shall conduct randomized clinical trials, that compare program participants with medicare beneficiaries who are offered, but decline, to participate, in order to assess the potential of programs to—

"(1) reduce costs under this title; and
"(2) improve health outcomes under this title.

"(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary, in appropriate part from the Hospital Insurance Trust Fund and the Supplementary Medical Insurance Trust Fund, such sums as may be necessary to provide for contracts with chronic care improvement programs under this section.

"(g) LIMITATION ON FUNDING.—In no case shall the funding under this section exceed $100,000,000 over a period of 3 years.".

SEC. 722. CHRONIC CARE IMPROVEMENT UNDER MEDICARE ADVANTAGE AND ENHANCED FEE-FOR-SERVICE PROGRAMS.

(a) UNDER MEDICARE ADVANTAGE PROGRAM.—Section 1852 (42 U.S.C. 1395w–22) is amended—

(1) by amending subsection (e) to read as follows:

"(e) IMPLEMENTATION OF CHRONIC CARE IMPROVEMENT PROGRAMS FOR BENEFICIARIES WITH MULTIPLE OR SUFFICIENTLY SEVERE CHRONIC CONDITIONS.—

"(1) IN GENERAL.—Each Medicare Advantage organization with respect to each Medicare Advantage plan it offers shall have in effect, for enrollees with multiple or sufficiently severe chronic conditions, a chronic care improvement program that is designed to manage the needs of such enrollees and that meets the requirements of this subsection.

"(2) ENROLLEE WITH MULTIPLE OR SUFFICIENTLY SEVERE CHRONIC CONDITIONS.—For purposes of this subsection, the term 'enrollee with multiple or sufficiently severe chronic conditions' means, with respect to an enrollee in a Medicare Advantage plan of a Medicare Advantage organization, an enrollee in the plan who has one or more chronic conditions, such as congestive heart failure, diabetes, COPD, stroke, or other disease as identified by the organization as appropriate for chronic care improvement.

"(3) GENERAL REQUIREMENTS.—

"(A) IN GENERAL.—Each chronic care improvement program under this subsection shall be conducted consistent with this subsection.

"(B) IDENTIFICATION OF ENROLLEES.—Each such program shall have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions that meet the organization's criteria for participation under the program.

"(C) DEVELOPMENT OF PLANS.—For an enrollee identified under subparagraph (B) for participation in a program, the program shall develop, with the enrollee's consent, an individualized, goal-oriented chronic care improvement plan for chronic care improvement.

"(D) ELEMENTS OF PLANS.—Each chronic care improvement plan developed under subparagraph (C) shall include a single point of contact to coordinate care and the following, as appropriate:

"(i) Self-improvement education for the enrollee and support education for health care providers, primary caregivers, and family members.

"(ii) Coordination of health care services, such as application of a prescription drug regimen and home health services.

"(iii) Collaboration with physicians and other providers to enhance communication of relevant clinical information.

"(iv) The use of monitoring technologies that enable patient guidance through the exchange of pertinent clinical information, such as vital signs, symptomatic information, and health self-assessment.

"(v) The provision of information about hospice care, pain and palliative care, and end-of-life care.

"(E) ORGANIZATION RESPONSIBILITIES.—In establishing and carrying out chronic care improvement plans for participants under this paragraph, a Medicare Advantage organization shall, directly or through subcontractors—

"(i) guide participants in managing their health, including all their co-morbidities, and in performing the activities as specified under the elements of the plan;

"(ii) use decision support tools such as evidence-based practice guidelines or other criteria as determined by the Secretary; and

"(iii) develop a clinical information database to track and monitor each participant across settings and to evaluate outcomes.

"(3) ADDITIONAL REQUIREMENTS.—The Secretary may establish additional requirements for chronic care improvement programs under this section.

"(4) ACCREDITATION.—The Secretary may provide that chronic care improvement programs that are accredited by qualified organizations may be deemed to meet such requirements under this subsection as the Secretary may specify.

"(5) OUTCOMES REPORT.—Each Medicare Advantage organization with respect to its chronic care improvement program under this subsection shall monitor and report to the Secretary information on the quality of care and efficacy of such program as the Secretary may require."; and

(2) by amending subparagraph (I) of subsection (c)(1) to read as follows:

"(I) CHRONIC CARE IMPROVEMENT PROGRAM.—A description of the organization's chronic care improvement program under subsection (e).".

(b) APPLICATION UNDER ENHANCED FEE-FOR-SERVICE PROGRAM.—Section 1860E–2(c)(3), as inserted by section 201(a), is amended by inserting ", including subsection (e) (relating to implementation of chronic care improvement programs)" after "The provisions of section 1852".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply for contract years beginning on or after 1 year after the date of the enactment of this Act.

SEC. 723. INSTITUTE OF MEDICINE REPORT.

(a) STUDY.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall contract with the Institute of Medicine of the National Academy of Sciences to conduct a study of the barriers to effective integrated care improvement for medicare beneficiaries with multiple or severe chronic conditions across settings and over time and to submit a report under subsection (b).

(2) SPECIFIC ITEMS.—The study shall examine the statutory and regulatory barriers to coordinating care across settings for medicare beneficiaries in transition from one setting to another (such as between hospital, nursing facility, home health, hospice, and home). The study shall specifically identify the following:

(A) Clinical, financial, or administrative requirements in the medicare program that present barriers to effective, seamless transitions across care settings.

(B) Policies that impede the establishment of administrative and clinical information systems to track health status, utilization, cost, and quality data across settings.

(C) State-level requirements that may present barriers to better care for medicare beneficiaries.

(3) CONSULTATION.—The study under this subsection shall be conducted in consultation with experts in the field of chronic care, consumers, and family caregivers, working to integrate care delivery and create more seamless transitions across settings and over time.

(b) REPORT.—The report under this subsection shall be submitted to the Secretary and Congress not later than 18 months after the date of the enactment of this Act.

SEC. 724. MEDPAC REPORT.

(a) EVALUATION.—shall conduct an evaluation that includes a description of the status of the implementation of chronic care improvement programs under section 1808 of the Social Security Act, the quality of health care services provided to individuals in such program, the health status of the participants of such program, and the cost savings attributed to implementation of such program.

(b) REPORT.—Not later than 2 years after the date of implementation of such chronic care improvement programs, the Commission shall submit a report on such evaluation.

Subtitle D—Other Provisions

SEC. 731. MODIFICATIONS TO MEDICARE PAYMENT ADVISORY COMMISSION (MEDPAC).

(a) EXAMINATION OF BUDGET CONSEQUENCES.—Section 1805(b) (42 U.S.C. 1395b–6(b)) is amended by adding at the end the following new paragraph:

"(8) EXAMINATION OF BUDGET CONSEQUENCES.—Before making any recommendations, the Commission shall examine the budget consequences of such recommendations, directly or through consultation with appropriate expert entities.".

(b) CONSIDERATION OF EFFICIENT PROVISION OF SERVICES.—Section 1805(b)(2)(B)(i) (42 U.S.C. 1395b–6(b)(2)(B)(i)) is amended by inserting "the efficient provision of" after "expenditures for".

(c) APPLICATION OF DISCLOSURE REQUIREMENTS.—

(1) IN GENERAL.—Section 1805(c)(2)(D) (42 U.S.C. 1395b–6(c)(2)(D)) is amended by adding at the end the following: "Members of the Commission shall be treated as employees of the Congress for purposes of applying title I of the Ethics in Government Act of 1978 (Public Law 95-521).".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on January 1, 2004.

(d) ADDITIONAL REPORTS.—

(1) DATA NEEDS AND SOURCES.—The Medicare Payment Advisory Commission shall conduct a study, and submit a report to Congress by not later than June 1, 2004, on the need for current data, and sources of current data available, to determine the solvency and financial circumstances of hospitals and other medicare providers of services. The Commission shall examine data on uncompensated care, as well as the share of uncompensated care accounted for by the expenses for treating illegal aliens.

(2) USE OF TAX-RELATED RETURNS.—Using return information provided under Form 990 of the Internal Revenue Service, the Commission shall submit to Congress, by not later than June 1, 2004, a report on the following:

(A) Investments, endowments, and fundraising of hospitals participating under the medicare program and related foundations.

(B) Access to capital financing for private and for not-for-profit hospitals.

SEC. 732. DEMONSTRATION PROJECT FOR MEDICAL ADULT DAY CARE SERVICES.

(a) ESTABLISHMENT.—Subject to the succeeding provisions of this section, the Secretary of Health and Human Services shall establish a demonstration project (in this section referred to as the "demonstration project") under which the Secretary shall, as part of a plan of an episode of care for home health services established for a medicare beneficiary, permit a home health agency, directly or under arrangements with a medical adult day care facility, to provide medical adult day care services as a substitute for a portion of home health services that would otherwise be provided in the beneficiary's home.

(b) PAYMENT.—

(1) IN GENERAL.—The amount of payment for an episode of care for home health services, a portion of which consists of substitute medical adult day care services, under the demonstration project shall be made at a rate equal to 95 percent of the amount that would otherwise apply for such home health services under section 1895 of the Social Security Act (42 u.s.c. 1395fff). In no case may a home health agency, or a medical adult day care facility under arrangements with a home health agency, separately charge a beneficiary for medical adult day care services furnished under the plan of care.

(2) BUDGET NEUTRALITY FOR DEMONSTRATION PROJECT.—Notwithstanding any other provision of law, the Secretary shall provide for an appropriate reduction in the aggregate amount of additional payments made under section 1895 of the Social Security Act (42 U.S.C. 1395fff) to reflect any increase in amounts expended from the Trust Funds as a result of the demonstration project conducted under this section.

(c) DEMONSTRATION PROJECT SITES.—The project established under this section shall be conducted in not more than 5 States selected by the Secretary that license or certify providers of services that furnish medical adult day care services.

(d) DURATION.—The Secretary shall conduct the demonstration project for a period of 3 years.

(e) VOLUNTARY PARTICIPATION.—Participation of medicare beneficiaries in the demonstration project shall be voluntary. The total number of such beneficiaries that may participate in the project at any given time may not exceed 15,000.

(f) PREFERENCE IN SELECTING AGENCIES.—In selecting home health agencies to participate under the demonstration project, the Secretary shall give preference to

those agencies that are currently licensed or certified through common ownership and control to furnish medical adult day care services.

(g) WAIVER AUTHORITY.—The Secretary may waive such requirements of title XVIII of the Social Security Act as may be necessary for the purposes of carrying out the demonstration project, other than waiving the requirement that an individual be homebound in order to be eligible for benefits for home health services.

(h) EVALUATION AND REPORT.—The Secretary shall conduct an evaluation of the clinical and cost effectiveness of the demonstration project. Not later 30 months after the commencement of the project, the Secretary shall submit to Congress a report on the evaluation, and shall include in the report the following:

(1) An analysis of the patient outcomes and costs of furnishing care to the medicare beneficiaries participating in the project as compared to such outcomes and costs to beneficiaries receiving only home health services for the same health conditions.

(2) Such recommendations regarding the extension, expansion, or termination of the project as the Secretary determines appropriate.

(i) DEFINITIONS.—In this section:

(1) HOME HEALTH AGENCY.—The term "home health agency" has the meaning given such term in section 1861(o) of the Social Security Act (42 U.S.C. 1395x(o)).

(2) MEDICAL ADULT DAY CARE FACILITY.—The term "medical adult day care facility" means a facility that—

(A) has been licensed or certified by a State to furnish medical adult day care services in the State for a continuous 2-year period;

(B) is engaged in providing skilled nursing services and other therapeutic services directly or under arrangement with a home health agency;

(C) meets such standards established by the Secretary to assure quality of care and such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the facility; and

(D) provides medical adult day care services.

(3) MEDICAL ADULT DAY CARE SERVICES.—The term "medical adult day care services" means—

(A) home health service items and services described in paragraphs (1) through (7) of section 1861(m) furnished in a medical adult day care facility;

(B) a program of supervised activities furnished in a group setting in the facility that—

(i) meet such criteria as the Secretary determines appropriate; and

(ii) is designed to promote physical and mental health of the individuals; and

(C) such other services as the Secretary may specify.

(4) MEDICARE BENEFICIARY.—The term "medicare beneficiary" means an individual entitled to benefits under part A of this title, enrolled under part B of this title, or both.

SEC. 733. IMPROVEMENTS IN NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS TO RESPOND TO CHANGES IN TECHNOLOGY.

(a) NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS.—

(1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended—

(A) in the third sentence of subsection (a) by inserting "consistent with subsection (k)" after "the Secretary shall ensure"; and

(B) by adding at the end the following new subsection:

"(k) NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS.—

"(1) CRITERIA AND EVIDENCE USED IN MAKING NATIONAL COVERAGE DETERMINATIONS.—The Secretary shall make available to the public the criteria the Secretary uses in making national coverage determinations, including how evidence to demonstrate that a procedure or device is reasonable and necessary is considered.

"(2) TIMEFRAME FOR DECISIONS ON REQUESTS FOR NATIONAL COVERAGE DETERMINATIONS.—In the case of a request for a national coverage determination that—

"(A) does not require a technology assessment from an outside entity or deliberation from the Medicare Coverage Advisory Committee, the decision on the request shall be made not later than 6 months after the date of the request; or

"(B) requires such an assessment or deliberation and in which a clinical trial is not requested, the decision on the request shall be made not later than 12 months after the date of the request.

"(3) PROCESS FOR PUBLIC COMMENT IN NATIONAL COVERAGE DETERMINATIONS.—At the end of the 6-month period that begins on the date a request for a national coverage determination is made, the Secretary shall—

"(A) make a draft of proposed decision on the request available to the public through the Medicare Internet site of the Department of Health and Human Services or other appropriate means;

"(B) provide a 30-day period for public comment on such draft;

"(C) make a final decision on the request within 60 days of the conclusion of the 30-day period referred to under subparagraph (B);

"(D) include in such final decision summaries of the public comments received and responses thereto;

"(E) make available to the public the clinical evidence and other data used in making such a decision when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and

"(F) in the case of a decision to grant the coverage determination, assign a temporary or permanent code during the 60-day period referred to in subparagraph (C).

"(4) CONSULTATION WITH OUTSIDE EXPERTS IN CERTAIN NATIONAL COVERAGE DETERMINATIONS.—With respect to a request for a national coverage determination for which there is not a review by the Medicare Coverage Advisory Committee, the Secretary shall consult with appropriate outside clinical experts.

"(5) LOCAL COVERAGE DETERMINATION PROCESS.—With respect to local coverage determinations made on or after January 1, 2004—

"(A) PLAN TO PROMOTE CONSISTENCY OF COVERAGE DETERMINATIONS.—The Secretary shall develop a plan to evaluate new local coverage determinations to determine which determinations should be adopted nationally and to what extent greater consistency can be achieved among local coverage determinations.

"(B) CONSULTATION.—The Secretary shall require the fiscal intermediaries or carriers providing services within the same area to consult on all new local coverage determinations within the area.

"(C) DISSEMINATION OF INFORMATION.—The Secretary should serve as a center to disseminate information on local coverage determinations among fiscal intermediaries and carriers to reduce duplication of effort.

"(6) NATIONAL AND LOCAL COVERAGE DETERMINATION DEFINED.—For purposes of this subsection, the terms 'national coverage determination' and 'local coverage determination' have the meaning given such terms in paragraphs (1)(B) and (2)(B), respectively, of section 1869(f).".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to national and local coverage determinations as of January 1, 2004.

(b) MEDICARE COVERAGE OF ROUTINE COSTS ASSOCIATED WITH CERTAIN CLINICAL TRIALS.—

(1) IN GENERAL.—With respect to the coverage of routine costs of care for beneficiaries participating in a qualifying clinical trial, as set forth on the date of the enactment of this Act in National Coverage Determination 30-1 of the Medicare Coverage Issues Manual, the Secretary shall deem clinical trials conducted in accordance with an investigational device exemption approved under section 520(g) of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 360j(g)) to be automatically qualified for such coverage.

(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as authorizing or requiring the Secretary to modify the regulations set forth on the date of the enactment of this Act at subpart B of part 405 of title 42, Code of Federal Regulations, or subpart A of part 411 of such title, relating to coverage of, and payment for, a medical device that is the subject of an investigational device exemption by the Food and Drug Administration (except as may be necessary to implement paragraph (1)).

(3) EFFECTIVE DATE.—This subsection shall apply to clinical trials begun before, on, or after the date of the enactment of this Act and to items and services furnished on or after such date.

(c) ISSUANCE OF TEMPORARY NATIONAL CODES.—Not later than January 1, 2004, the Secretary shall implement revised procedures for the issuance of temporary national HCPCS codes under part B of title XVIII of the Social Security Act.

SEC. 734. TREATMENT OF CERTAIN PHYSICIAN PATHOLOGY SERVICES.

(a) IN GENERAL.—Section 1848(i) (42 U.S.C. 1395w–4(i)) is amended by adding at the end the following new paragraph:

"(4) TREATMENT OF CERTAIN INPATIENT PHYSICIAN PATHOLOGY SERVICES.—

"(A) IN GENERAL.—With respect to services furnished on or after January 1, 2001, and before January 1, 2006, if an independent laboratory furnishes

the technical component of a physician pathology service to a fee-for-service medicare beneficiary who is an inpatient or outpatient of a covered hospital, the Secretary shall treat such component as a service for which payment shall be made to the laboratory under this section and not as an inpatient hospital service for which payment is made to the hospital under section 1886(d) or as a hospital outpatient service for which payment is made to the hospital under section 1833(t).

"(B) DEFINITIONS.—In this paragraph:

"(i) COVERED HOSPITAL.—

"(I) IN GENERAL.—The term 'covered hospital' means, with respect to an inpatient or outpatient, a hospital that had an arrangement with an independent laboratory that was in effect as of July 22, 1999, under which a laboratory furnished the technical component of physician pathology services to fee-for-service medicare beneficiaries who were hospital inpatients or outpatients, respectively, and submitted claims for payment for such component to a carrier with a contract under section 1842 and not to the hospital.

"(II) CHANGE IN OWNERSHIP DOES NOT AFFECT DETERMINATION.—A change in ownership with respect to a hospital on or after the date referred to in subclause (I) shall not affect the determination of whether such hospital is a covered hospital for purposes of such subclause.

"(ii) FEE-FOR-SERVICE MEDICARE BENEFICIARY.—The term 'fee-for-service medicare beneficiary' means an individual who is entitled to benefits under part A, or enrolled under this part, or both, but is not enrolled in any of the following:

"(I) A Medicare+Choice plan under part C.

"(II) A plan offered by an eligible organization under section 1876.

"(III) A program of all-inclusive care for the elderly (PACE) under section 1894.

"(IV) A social health maintenance organization (SHMO) demonstration project established under section 4018(b) of the Omnibus Budget Reconciliation Act of 1987 (Public Law 100–203).".

(b) CONFORMING AMENDMENT.—Section 542 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (114 Stat. 2763A–550), as enacted into law by section 1(a)(6) of Public Law 106–554, is repealed.

(c) EFFECTIVE DATES.—The amendments made by this section shall take effect as if included in the enactment of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Appendix F, 114 Stat. 2763A–463), as enacted into law by section 1(a)(6) of Public Law 106–554.

TITLE VIII—MEDICARE BENEFITS ADMINISTRATION

SEC. 801. ESTABLISHMENT OF MEDICARE BENEFITS ADMINISTRATION.

(a) IN GENERAL.—Title XVIII (42 U.S.C. 1395 et seq.), as amended by sections 105 and 721, is amended by inserting after 1808 the following new section:

"MEDICARE BENEFITS ADMINISTRATION

"SEC. 1809. (a) ESTABLISHMENT.—There is established within the Department of Health and Human Services an agency to be known as the Medicare Benefits Administration.

"(b) ADMINISTRATOR; DEPUTY ADMINISTRATOR; CHIEF ACTUARY.—

"(1) ADMINISTRATOR.—

"(A) IN GENERAL.—The Medicare Benefits Administration shall be headed by an administrator to be known as the 'Medicare Benefits Administrator' (in this section referred to as the 'Administrator') who shall be appointed by the President, by and with the advice and consent of the Senate. The Administrator shall be in direct line of authority to the Secretary.

"(B) COMPENSATION.—The Administrator shall be paid at the rate of basic pay payable for level III of the Executive Schedule under section 5314 of title 5, United States Code.

"(C) TERM OF OFFICE.—The Administrator shall be appointed for a term of 4 years. In any case in which a successor does not take office at the end of an Administrator's term of office, that Administrator may continue in office until the entry upon office of such a successor. An Administrator ap-

pointed to a term of office after the commencement of such term may serve under such appointment only for the remainder of such term.

"(D) GENERAL AUTHORITY.—The Administrator shall be responsible for the exercise of all powers and the discharge of all duties of the Administration, and shall have authority and control over all personnel and activities thereof.

"(E) RULEMAKING AUTHORITY.—The Administrator may prescribe such rules and regulations as the Administrator determines necessary or appropriate to carry out the functions of the Administration. The regulations prescribed by the Administrator shall be subject to the rulemaking procedures established under section 553 of title 5, United States Code. The Administrator shall provide for the issuance of new regulations to carry out parts C, D, and E.

"(F) AUTHORITY TO ESTABLISH ORGANIZATIONAL UNITS.—The Administrator may establish, alter, consolidate, or discontinue such organizational units or components within the Administration as the Administrator considers necessary or appropriate, except as specified in this section.

"(G) AUTHORITY TO DELEGATE.—The Administrator may assign duties, and delegate, or authorize successive redelegations of, authority to act and to render decisions, to such officers and employees of the Administration as the Administrator may find necessary. Within the limitations of such delegations, redelegations, or assignments, all official acts and decisions of such officers and employees shall have the same force and effect as though performed or rendered by the Administrator.

"(2) DEPUTY ADMINISTRATOR.—

"(A) IN GENERAL.—There shall be a Deputy Administrator of the Medicare Benefits Administration who shall be appointed by the President, by and with the advice and consent of the Senate.

"(B) COMPENSATION.—The Deputy Administrator shall be paid at the rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

"(C) TERM OF OFFICE.—The Deputy Administrator shall be appointed for a term of 4 years. In any case in which a successor does not take office at the end of a Deputy Administrator's term of office, such Deputy Administrator may continue in office until the entry upon office of such a successor. A Deputy Administrator appointed to a term of office after the commencement of such term may serve under such appointment only for the remainder of such term.

"(D) DUTIES.—The Deputy Administrator shall perform such duties and exercise such powers as the Administrator shall from time to time assign or delegate. The Deputy Administrator shall be Acting Administrator of the Administration during the absence or disability of the Administrator and, unless the President designates another officer of the Government as Acting Administrator, in the event of a vacancy in the office of the Administrator.

"(3) CHIEF ACTUARY.—

"(A) IN GENERAL.—There is established in the Administration the position of Chief Actuary. The Chief Actuary shall be appointed by, and in direct line of authority to, the Administrator of such Administration. The Chief Actuary shall be appointed from among individuals who have demonstrated, by their education and experience, superior expertise in the actuarial sciences. The Chief Actuary may be removed only for cause.

"(B) COMPENSATION.—The Chief Actuary shall be compensated at the highest rate of basic pay for the Senior Executive Service under section 5382(b) of title 5, United States Code.

"(C) DUTIES.—The Chief Actuary shall exercise such duties as are appropriate for the office of the Chief Actuary and in accordance with professional standards of actuarial independence.

"(4) SECRETARIAL COORDINATION OF PROGRAM ADMINISTRATION.—The Secretary shall ensure appropriate coordination between the Administrator and the Administrator of the Centers for Medicare & Medicaid Services in carrying out the programs under this title.

"(c) DUTIES; ADMINISTRATIVE PROVISIONS.—

"(1) DUTIES.—

"(A) GENERAL DUTIES.—The Administrator shall carry out parts C, D, and E, including—

"(i) negotiating, entering into, and enforcing, contracts with plans for the offering of Medicare Advantage plans under part C and EFFS plans under part E, including the offering of qualified prescription drug coverage under such plans; and

"(ii) negotiating, entering into, and enforcing, contracts with PDP sponsors for the offering of prescription drug plans under part D.

"(B) OTHER DUTIES.—The Administrator shall carry out any duty provided for under part C, part D, or part E, including demonstration projects carried out in part or in whole under such parts, the programs of all-inclusive care for the elderly (PACE program) under section 1894, the social health maintenance organization (SHMO) demonstration projects (referred to in section 4104(c) of the Balanced Budget Act of 1997), medicare cost contractors under section 1876(h), and through a Medicare Advantage project that demonstrates the application of capitation payment rates for frail elderly medicare beneficiaries through the use of a interdisciplinary team and through the provision of primary care services to such beneficiaries by means of such a team at the nursing facility involved).

"(C) PRESCRIPTION DRUG CARD.—The Administrator shall carry out section 1807 (relating to the medicare prescription drug discount card endorsement program).

"(D) NONINTERFERENCE.—In carrying out its duties with respect to the provision of qualified prescription drug coverage to beneficiaries under this title, the Administrator may not—

"(i) require a particular formulary or institute a price structure for the reimbursement of covered outpatient drugs;

"(ii) interfere in any way with negotiations between PDP sponsors and Medicare Advantage organizations and EFFS organizations and drug manufacturers, wholesalers, or other suppliers of covered outpatient drugs; and

"(iii) otherwise interfere with the competitive nature of providing such coverage through such sponsors and organizations.

"(E) ANNUAL REPORTS.—Not later March 31 of each year, the Administrator shall submit to Congress and the President a report on the administration of parts C, D, and E during the previous fiscal year.

"(2) STAFF.—

"(A) IN GENERAL.—The Administrator, with the approval of the Secretary, may employ, without regard to chapter 31 of title 5, United States Code, other than sections 3102 through 3108, 3110 through 3113, 3136m and 3151, such officers and employees as are necessary to administer the activities to be carried out through the Medicare Benefits Administration. The Administrator shall employ staff with appropriate and necessary expertise in negotiating contracts in the private sector.

"(B) FLEXIBILITY WITH RESPECT TO COMPENSATION.—

"(i) IN GENERAL.—The staff of the Medicare Benefits Administration shall, subject to clause (ii), be paid without regard to the provisions of chapter 51 (other than section 5101) and chapter 53 (other than section 5301) of such title (relating to classification and schedule pay rates).

"(ii) MAXIMUM RATE.—In no case may the rate of compensation determined under clause (i) exceed the rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

"(C) LIMITATION ON FULL-TIME EQUIVALENT STAFFING FOR CURRENT CMS FUNCTIONS BEING TRANSFERRED.—The Administrator may not employ under this paragraph a number of full-time equivalent employees, to carry out functions that were previously conducted by the Centers for Medicare & Medicaid Services and that are conducted by the Administrator by reason of this section, that exceeds the number of such full-time equivalent employees authorized to be employed by the Centers for Medicare & Medicaid Services to conduct such functions as of the date of the enactment of this Act.

"(3) REDELEGATION OF CERTAIN FUNCTIONS OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES.—

"(A) IN GENERAL.—The Secretary, the Administrator, and the Administrator of the Centers for Medicare & Medicaid Services shall establish an appropriate transition of responsibility in order to redelegate the administration of part C from the Secretary and the Administrator of the Centers for Medicare & Medicaid Services to the Administrator as is appropriate to carry out the purposes of this section.

"(B) TRANSFER OF DATA AND INFORMATION.—The Secretary shall ensure that the Administrator of the Centers for Medicare & Medicaid Services transfers to the Administrator of the Medicare Benefits Administration such information and data in the possession of the Administrator of the Centers for Medicare & Medicaid Services as the Administrator of the

Medicare Benefits Administration requires to carry out the duties described in paragraph (1).

"(C) CONSTRUCTION.—Insofar as a responsibility of the Secretary or the Administrator of the Centers for Medicare & Medicaid Services is redelegated to the Administrator under this section, any reference to the Secretary or the Administrator of the Centers for Medicare & Medicaid Services in this title or title XI with respect to such responsibility is deemed to be a reference to the Administrator.

"(d) OFFICE OF BENEFICIARY ASSISTANCE.—

"(1) ESTABLISHMENT.—The Secretary shall establish within the Medicare Benefits Administration an Office of Beneficiary Assistance to coordinate functions relating to outreach and education of medicare beneficiaries under this title, including the functions described in paragraph (2). The Office shall be separate operating division within the Administration.

"(2) DISSEMINATION OF INFORMATION ON BENEFITS AND APPEALS RIGHTS.—

"(A) DISSEMINATION OF BENEFITS INFORMATION.—The Office of Beneficiary Assistance shall disseminate, directly or through contract, to medicare beneficiaries, by mail, by posting on the Internet site of the Medicare Benefits Administration and through a toll-free telephone number, information with respect to the following:

"(i) Benefits, and limitations on payment (including cost-sharing, stop-loss provisions, and formulary restrictions) under parts C, D, and E.

"(ii) Benefits, and limitations on payment under parts A and B, including information on medicare supplemental policies under section 1882.

Such information shall be presented in a manner so that medicare beneficiaries may compare benefits under parts A, B, D, and medicare supplemental policies with benefits under Medicare Advantage plans under part C and EFFS plans under part E.

"(B) DISSEMINATION OF APPEALS RIGHTS INFORMATION.—The Office of Beneficiary Assistance shall disseminate to medicare beneficiaries in the manner provided under subparagraph (A) a description of procedural rights (including grievance and appeals procedures) of beneficiaries under the original medicare fee-for-service program under parts A and B, the Medicare Advantage program under part C, the Voluntary Prescription Drug Benefit Program under part D, and the Enhanced Fee-for-Service program under part E.

"(e) MEDICARE POLICY ADVISORY BOARD.—

"(1) ESTABLISHMENT.—There is established within the Medicare Benefits Administration the Medicare Policy Advisory Board (in this section referred to the 'Board'). The Board shall advise, consult with, and make recommendations to the Administrator of the Medicare Benefits Administration with respect to the administration of parts C, D, and E, including the review of payment policies under such parts.

"(2) REPORTS.—

"(A) IN GENERAL.—With respect to matters of the administration of parts C, D, and E the Board shall submit to Congress and to the Administrator of the Medicare Benefits Administration such reports as the Board determines appropriate. Each such report may contain such recommendations as the Board determines appropriate for legislative or administrative changes to improve the administration of such parts, including the topics described in subparagraph (B). Each such report shall be published in the Federal Register.

"(B) TOPICS DESCRIBED.—Reports required under subparagraph (A) may include the following topics:

"(i) FOSTERING COMPETITION.—Recommendations or proposals to increase competition under parts C, D, and E for services furnished to medicare beneficiaries.

"(ii) EDUCATION AND ENROLLMENT.—Recommendations for the improvement to efforts to provide medicare beneficiaries information and education on the program under this title, and specifically parts C, D, and E, and the program for enrollment under the title.

"(iii) IMPLEMENTATION OF RISK-ADJUSTMENT.—Evaluation of the implementation under section 1853(a)(3)(C) of the risk adjustment methodology to payment rates under that section to Medicare Advantage organizations offering Medicare Advantage plans (and the corresponding payment provisions under part E) that accounts for variations in per

capita costs based on health status, geography, and other demographic factors.

"(iv) RURAL ACCESS.—Recommendations to improve competition and access to plans under parts C, D, and E in rural areas.

"(C) MAINTAINING INDEPENDENCE OF BOARD.—The Board shall directly submit to Congress reports required under subparagraph (A). No officer or agency of the United States may require the Board to submit to any officer or agency of the United States for approval, comments, or review, prior to the submission to Congress of such reports.

"(3) DUTY OF ADMINISTRATOR OF MEDICARE BENEFITS ADMINISTRATION.—With respect to any report submitted by the Board under paragraph (2)(A), not later than 90 days after the report is submitted, the Administrator of the Medicare Benefits Administration shall submit to Congress and the President an analysis of recommendations made by the Board in such report. Each such analysis shall be published in the Federal Register.

"(4) MEMBERSHIP.—

"(A) APPOINTMENT.—Subject to the succeeding provisions of this paragraph, the Board shall consist of seven members to be appointed as follows:

"(i) Three members shall be appointed by the President.

"(ii) Two members shall be appointed by the Speaker of the House of Representatives, with the advice of the chairmen and the ranking minority members of the Committees on Ways and Means and on Energy and Commerce of the House of Representatives.

"(iii) Two members shall be appointed by the President pro tempore of the Senate with the advice of the chairman and the ranking minority member of the Senate Committee on Finance.

"(B) QUALIFICATIONS.—The members shall be chosen on the basis of their integrity, impartiality, and good judgment, and shall be individuals who are, by reason of their education and experience in health care benefits management, exceptionally qualified to perform the duties of members of the Board.

"(C) PROHIBITION ON INCLUSION OF FEDERAL EMPLOYEES.—No officer or employee of the United States may serve as a member of the Board.

"(5) COMPENSATION.—Members of the Board shall receive, for each day (including travel time) they are engaged in the performance of the functions of the board, compensation at rates not to exceed the daily equivalent to the annual rate in effect for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

"(6) TERMS OF OFFICE.—

"(A) IN GENERAL.—The term of office of members of the Board shall be 3 years.

"(B) TERMS OF INITIAL APPOINTEES.—As designated by the President at the time of appointment, of the members first appointed—

"(i) one shall be appointed for a term of 1 year;

"(ii) three shall be appointed for terms of 2 years; and

"(iii) three shall be appointed for terms of 3 years.

"(C) REAPPOINTMENTS.—Any person appointed as a member of the Board may not serve for more than 8 years.

"(D) VACANCY.—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office. A vacancy in the Board shall be filled in the manner in which the original appointment was made.

"(7) CHAIR.—The Chair of the Board shall be elected by the members. The term of office of the Chair shall be 3 years.

"(8) MEETINGS.—The Board shall meet at the call of the Chair, but in no event less than three times during each fiscal year.

"(9) DIRECTOR AND STAFF.—

"(A) APPOINTMENT OF DIRECTOR.—The Board shall have a Director who shall be appointed by the Chair.

"(B) IN GENERAL.—With the approval of the Board, the Director may appoint, without regard to chapter 31 of title 5, United States Code, such additional personnel as the Director considers appropriate.

"(C) FLEXIBILITY WITH RESPECT TO COMPENSATION.—

"(i) IN GENERAL.—The Director and staff of the Board shall, subject to clause (ii), be paid without regard to the provisions of chapter 51 and chapter 53 of such title (relating to classification and schedule pay rates).

"(ii) MAXIMUM RATE.—In no case may the rate of compensation determined under clause (i) exceed the rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

"(D) ASSISTANCE FROM THE ADMINISTRATOR OF THE MEDICARE BENEFITS ADMINISTRATION.—The Administrator of the Medicare Benefits Administration shall make available to the Board such information and other assistance as it may require to carry out its functions.

"(10) CONTRACT AUTHORITY.—The Board may contract with and compensate government and private agencies or persons to carry out its duties under this subsection, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

"(f) FUNDING.—There is authorized to be appropriated, in appropriate part from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund (including the Medicare Prescription Drug Account), such sums as are necessary to carry out this section.".

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act.

(2) DUTIES WITH RESPECT TO ELIGIBILITY DETERMINATIONS AND ENROLLMENT.—The Administrator of the Medicare Benefits Administration shall carry out enrollment under title XVIII of the Social Security Act, make eligibility determinations under such title, and carry out parts C and E of such title for years beginning or after January 1, 2006.

(3) TRANSITION.—Before the date the Administrator of the Medicare Benefits Administration is appointed and assumes responsibilities under this section and section 1807 of the Social Security Act, the Secretary of Health and Human Services shall provide for the conduct of any responsibilities of such Administrator that are otherwise provided under law.

(c) MISCELLANEOUS ADMINISTRATIVE PROVISIONS.—

(1) ADMINISTRATOR AS MEMBER OF THE BOARD OF TRUSTEES OF THE MEDICARE TRUST FUNDS.—Section 1817(b) and section 1841(b) (42 U.S.C. 1395i(b), 1395t(b)) are each amended by striking "and the Secretary of Health and Human Services, all ex officio," and inserting "the Secretary of Health and Human Services, and the Administrator of the Medicare Benefits Administration, all ex officio,".

(2) INCREASE IN GRADE TO EXECUTIVE LEVEL III FOR THE ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES; LEVEL FOR MEDICARE BENEFITS ADMINISTRATOR.—

(A) IN GENERAL.—Section 5314 of title 5, United States Code, by adding at the end the following:

"Administrator of the Centers for Medicare & Medicaid Services.

"Administrator of the Medicare Benefits Administration.".

(B) CONFORMING AMENDMENT.—Section 5315 of such title is amended by striking "Administrator of the Health Care Financing Administration.".

(C) EFFECTIVE DATE.—The amendments made by this paragraph take effect on January 1, 2004.

TITLE IX—REGULATORY REDUCTION AND CONTRACTING REFORM

Subtitle A—Regulatory Reform

SEC. 901. CONSTRUCTION; DEFINITION OF SUPPLIER.

(a) CONSTRUCTION.—Nothing in this title shall be construed—

(1) to compromise or affect existing legal remedies for addressing fraud or abuse, whether it be criminal prosecution, civil enforcement, or administrative remedies, including under sections 3729 through 3733 of title 31, United States Code (known as the False Claims Act); or

(2) to prevent or impede the Department of Health and Human Services in any way from its ongoing efforts to eliminate waste, fraud, and abuse in the medicare program.

Furthermore, the consolidation of medicare administrative contracting set forth in this Act does not constitute consolidation of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund or reflect any position on that issue.

(b) DEFINITION OF SUPPLIER.—Section 1861 (42 U.S.C. 1395x) is amended by inserting after subsection (c) the following new subsection:

"Supplier

"(d) The term 'supplier' means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.".

SEC. 902. ISSUANCE OF REGULATIONS.

(a) REGULAR TIMELINE FOR PUBLICATION OF FINAL RULES.—

(1) IN GENERAL.—Section 1871(a) (42 U.S.C. 1395hh(a)) is amended by adding at the end the following new paragraph:

"(3)(A) The Secretary, in consultation with the Director of the Office of Management and Budget, shall establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation.

"(B) Such timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but shall not be longer than 3 years except under exceptional circumstances. If the Secretary intends to vary such timeline with respect to the publication of a final regulation, the Secretary shall cause to have published in the Federal Register notice of the different timeline by not later than the timeline previously established with respect to such regulation. Such notice shall include a brief explanation of the justification for such variation.

"(C) In the case of interim final regulations, upon the expiration of the regular timeline established under this paragraph for the publication of a final regulation after opportunity for public comment, the interim final regulation shall not continue in effect unless the Secretary publishes (at the end of the regular timeline and, if applicable, at the end of each succeeding 1-year period) a notice of continuation of the regulation that includes an explanation of why the regular timeline (and any subsequent 1-year extension) was not complied with. If such a notice is published, the regular timeline (or such timeline as previously extended under this paragraph) for publication of the final regulation shall be treated as having been extended for 1 additional year.

"(D) The Secretary shall annually submit to Congress a report that describes the instances in which the Secretary failed to publish a final regulation within the applicable regular timeline under this paragraph and that provides an explanation for such failures.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act. The Secretary shall provide for an appropriate transition to take into account the backlog of previously published interim final regulations.

(b) LIMITATIONS ON NEW MATTER IN FINAL REGULATIONS.—

(1) IN GENERAL.—Section 1871(a) (42 U.S.C. 1395hh(a)), as amended by subsection (a), is amended by adding at the end the following new paragraph:

"(4) If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to final regulations published on or after the date of the enactment of this Act.

SEC. 903. COMPLIANCE WITH CHANGES IN REGULATIONS AND POLICIES.

(a) NO RETROACTIVE APPLICATION OF SUBSTANTIVE CHANGES.—

(1) IN GENERAL.—Section 1871 (42 U.S.C. 1395hh), as amended by section 902(a), is amended by adding at the end the following new subsection:

"(e)(1)(A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this title shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that—

"(i) such retroactive application is necessary to comply with statutory requirements; or

"(ii) failure to apply the change retroactively would be contrary to the public interest.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to substantive changes issued on or after the date of the enactment of this Act.

(b) TIMELINE FOR COMPLIANCE WITH SUBSTANTIVE CHANGES AFTER NOTICE.—

(1) IN GENERAL.—Section 1871(e)(1), as added by subsection (a), is amended by adding at the end the following:

"(B)(i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be, the substantive change.

"(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.

"(C) No action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to compliance actions undertaken on or after the date of the enactment of this Act.

(c) RELIANCE ON GUIDANCE.—

(1) IN GENERAL.—Section 1871(e), as added by subsection (a), is further amended by adding at the end the following new paragraph:

"(2)(A) If—

"(i) a provider of services or supplier follows the written guidance (which may be transmitted electronically) provided by the Secretary or by a medicare contractor (as defined in section 1889(g)) acting within the scope of the contractor's contract authority, with respect to the furnishing of items or services and submission of a claim for benefits for such items or services with respect to such provider or supplier;

"(ii) the Secretary determines that the provider of services or supplier has accurately presented the circumstances relating to such items, services, and claim to the contractor in writing; and

"(iii) the guidance was in error;

the provider of services or supplier shall not be subject to any sanction (including any penalty or requirement for repayment of any amount) if the provider of services or supplier reasonably relied on such guidance.

"(B) Subparagraph (A) shall not be construed as preventing the recoupment or repayment (without any additional penalty) relating to an overpayment insofar as the overpayment was solely the result of a clerical or technical operational error.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act but shall not apply to any sanction for which notice was provided on or before the date of the enactment of this Act.

SEC. 904. REPORTS AND STUDIES RELATING TO REGULATORY REFORM.

(a) GAO STUDY ON ADVISORY OPINION AUTHORITY.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to determine the feasibility and appropriateness of establishing in the Secretary authority to provide legally binding advisory opinions on appropriate interpretation and application of regulations to carry out the medicare program under title XVIII of the Social Security Act. Such study shall examine the appropriate timeframe for issuing such advisory opinions, as well as the need for additional staff and funding to provide such opinions.

(2) REPORT.—The Comptroller General shall submit to Congress a report on the study conducted under paragraph (1) by not later than one year after the date of the enactment of this Act.

(b) REPORT ON LEGAL AND REGULATORY INCONSISTENCIES.—Section 1871 (42 U.S.C. 1395hh), as amended by section 2(a), is amended by adding at the end the following new subsection:

"(f)(1) Not later than 2 years after the date of the enactment of this subsection, and every 2 years thereafter, the Secretary shall submit to Congress a report with respect to the administration of this title and areas of inconsistency or conflict among the various provisions under law and regulation.

"(2) In preparing a report under paragraph (1), the Secretary shall collect—

"(A) information from individuals entitled to benefits under part A or enrolled under part B, or both, providers of services, and suppliers and from the Medicare Beneficiary Ombudsman and the Medicare Provider Ombudsman with respect to such areas of inconsistency and conflict; and

"(B) information from medicare contractors that tracks the nature of written and telephone inquiries.

"(3) A report under paragraph (1) shall include a description of efforts by the Secretary to reduce such inconsistency or conflicts, and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.".

Subtitle B—Contracting Reform

SEC. 911. INCREASED FLEXIBILITY IN MEDICARE ADMINISTRATION.

(a) CONSOLIDATION AND FLEXIBILITY IN MEDICARE ADMINISTRATION.—

(1) IN GENERAL.—Title XVIII is amended by inserting after section 1874 the following new section:

"CONTRACTS WITH MEDICARE ADMINISTRATIVE CONTRACTORS

"SEC. 1874A. (a) AUTHORITY.—

"(1) AUTHORITY TO ENTER INTO CONTRACTS.—The Secretary may enter into contracts with any eligible entity to serve as a medicare administrative contractor with respect to the performance of any or all of the functions described in paragraph (4) or parts of those functions (or, to the extent provided in a contract, to secure performance thereof by other entities).

"(2) ELIGIBILITY OF ENTITIES.—An entity is eligible to enter into a contract with respect to the performance of a particular function described in paragraph (4) only if—

"(A) the entity has demonstrated capability to carry out such function;

"(B) the entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement;

"(C) the entity has sufficient assets to financially support the performance of such function; and

"(D) the entity meets such other requirements as the Secretary may impose.

"(3) MEDICARE ADMINISTRATIVE CONTRACTOR DEFINED.—For purposes of this title and title XI—

"(A) IN GENERAL.—The term 'medicare administrative contractor' means an agency, organization, or other person with a contract under this section.

"(B) APPROPRIATE MEDICARE ADMINISTRATIVE CONTRACTOR.—With respect to the performance of a particular function in relation to an individual entitled to benefits under part A or enrolled under part B, or both, a specific provider of services or supplier (or class of such providers of services or suppliers), the 'appropriate' medicare administrative contractor is the medicare administrative contractor that has a contract under this section with respect to the performance of that function in relation to that individual, provider of services or supplier or class of provider of services or supplier.

"(4) FUNCTIONS DESCRIBED.—The functions referred to in paragraphs (1) and (2) are payment functions, provider services functions, and functions relating to services furnished to individuals entitled to benefits under part A or enrolled under part B, or both, as follows:

"(A) DETERMINATION OF PAYMENT AMOUNTS.—Determining (subject to the provisions of section 1878 and to such review by the Secretary as may be provided for by the contracts) the amount of the payments required pursuant to this title to be made to providers of services, suppliers and individuals.

"(B) MAKING PAYMENTS.—Making payments described in subparagraph (A) (including receipt, disbursement, and accounting for funds in making such payments).

"(C) BENEFICIARY EDUCATION AND ASSISTANCE.—Providing education and outreach to individuals entitled to benefits under part A or enrolled under part B, or both, and providing assistance to those individuals with specific issues, concerns or problems.

"(D) PROVIDER CONSULTATIVE SERVICES.—Providing consultative services to institutions, agencies, and other persons to enable them to establish and maintain fiscal records necessary for purposes of this title and otherwise to qualify as providers of services or suppliers.

"(E) COMMUNICATION WITH PROVIDERS.—Communicating to providers of services and suppliers any information or instructions furnished to the medicare administrative contractor by the Secretary, and facilitating communication between such providers and suppliers and the Secretary.

"(F) PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.—Performing the functions relating to provider education, training, and technical assistance.

"(G) ADDITIONAL FUNCTIONS.—Performing such other functions as are necessary to carry out the purposes of this title.

"(5) RELATIONSHIP TO MIP CONTRACTS.—

"(A) NONDUPLICATION OF DUTIES.—In entering into contracts under this section, the Secretary shall assure that functions of medicare administrative contractors in carrying out activities under parts A and B do not duplicate activities carried out under the Medicare Integrity Program under section 1893. The previous sentence shall not apply with respect to the activity described in section 1893(b)(5) (relating to prior authorization of certain items of durable medical equipment under section 1834(a)(15)).

"(B) CONSTRUCTION.—An entity shall not be treated as a medicare administrative contractor merely by reason of having entered into a contract with the Secretary under section 1893.

"(6) APPLICATION OF FEDERAL ACQUISITION REGULATION.—Except to the extent inconsistent with a specific requirement of this title, the Federal Acquisition Regulation applies to contracts under this title.

"(b) CONTRACTING REQUIREMENTS.—

"(1) USE OF COMPETITIVE PROCEDURES.—

"(A) IN GENERAL.—Except as provided in laws with general applicability to Federal acquisition and procurement or in subparagraph (B), the Secretary shall use competitive procedures when entering into contracts with medicare administrative contractors under this section, taking into account performance quality as well as price and other factors.

"(B) RENEWAL OF CONTRACTS.—The Secretary may renew a contract with a medicare administrative contractor under this section from term to term without regard to section 5 of title 41, United States Code, or any other provision of law requiring competition, if the medicare administrative contractor has met or exceeded the performance requirements applicable with respect to the contract and contractor, except that the Secretary shall provide for the application of competitive procedures under such a contract not less frequently than once every five years.

"(C) TRANSFER OF FUNCTIONS.—The Secretary may transfer functions among medicare administrative contractors consistent with the provisions of this paragraph. The Secretary shall ensure that performance quality is considered in such transfers. The Secretary shall provide public notice (whether in the Federal Register or otherwise) of any such transfer (including a description of the functions so transferred, a description of the providers of services and suppliers affected by such transfer, and contact information for the contractors involved).

"(D) INCENTIVES FOR QUALITY.—The Secretary shall provide incentives for medicare administrative contractors to provide quality service and to promote efficiency.

"(2) COMPLIANCE WITH REQUIREMENTS.—No contract under this section shall be entered into with any medicare administrative contractor unless the Secretary finds that such medicare administrative contractor will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial responsibility, legal authority, quality of services provided, and other matters as the Secretary finds pertinent.

"(3) PERFORMANCE REQUIREMENTS.—

"(A) DEVELOPMENT OF SPECIFIC PERFORMANCE REQUIREMENTS.—In developing contract performance requirements, the Secretary shall develop performance requirements applicable to functions described in subsection (a)(4).

"(B) CONSULTATION.— In developing such requirements, the Secretary may consult with providers of services and suppliers, organizations representing individuals entitled to benefits under part A or enrolled under part B, or both, and organizations and agencies performing functions necessary to carry out the purposes of this section with respect to such performance requirements.

"(C) INCLUSION IN CONTRACTS.—All contractor performance requirements shall be set forth in the contract between the Secretary and the appropriate medicare administrative contractor. Such performance requirements—

"(i) shall reflect the performance requirements developed under subparagraph (A), but may include additional performance requirements;

"(ii) shall be used for evaluating contractor performance under the contract; and

"(iii) shall be consistent with the written statement of work provided under the contract.

"(4) INFORMATION REQUIREMENTS.—The Secretary shall not enter into a contract with a medicare administrative contractor under this section unless the contractor agrees—

"(A) to furnish to the Secretary such timely information and reports as the Secretary may find necessary in performing his functions under this title; and

"(B) to maintain such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of the information and reports under subparagraph (A) and otherwise to carry out the purposes of this title.

"(5) SURETY BOND.—A contract with a medicare administrative contractor under this section may require the medicare administrative contractor, and any of its officers or employees certifying payments or disbursing funds pursuant to the contract, or otherwise participating in carrying out the contract, to give surety bond to the United States in such amount as the Secretary may deem appropriate.

"(c) TERMS AND CONDITIONS.—

"(1) IN GENERAL.—A contract with any medicare administrative contractor under this section may contain such terms and conditions as the Secretary finds necessary or appropriate and may provide for advances of funds to the medicare administrative contractor for the making of payments by it under subsection (a)(4)(B).

"(2) PROHIBITION ON MANDATES FOR CERTAIN DATA COLLECTION.—The Secretary may not require, as a condition of entering into, or renewing, a contract under this section, that the medicare administrative contractor match data obtained other than in its activities under this title with data used in the administration of this title for purposes of identifying situations in which the provisions of section 1862(b) may apply.

"(d) LIMITATION ON LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTORS AND CERTAIN OFFICERS.—

"(1) CERTIFYING OFFICER.—No individual designated pursuant to a contract under this section as a certifying officer shall, in the absence of the reckless disregard of the individual's obligations or the intent by that individual to defraud the United States, be liable with respect to any payments certified by the individual under this section.

"(2) DISBURSING OFFICER.—No disbursing officer shall, in the absence of the reckless disregard of the officer's obligations or the intent by that officer to defraud the United States, be liable with respect to any payment by such officer under this section if it was based upon an authorization (which meets the applicable requirements for such internal controls established by the Comptroller General) of a certifying officer designated as provided in paragraph (1) of this subsection.

"(3) LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTOR.—

"(A) IN GENERAL.—No medicare administrative contractor shall be liable to the United States for a payment by a certifying or disbursing officer unless, in connection with such payment, the medicare administrative contractor acted with reckless disregard of its obligations under its medicare administrative contract or with intent to defraud the United States.

"(B) RELATIONSHIP TO FALSE CLAIMS ACT.—Nothing in this subsection shall be construed to limit liability for conduct that would constitute a violation of sections 3729 through 3731 of title 31, United States Code (commonly known as the 'False Claims Act').

"(4) INDEMNIFICATION BY SECRETARY.—

"(A) IN GENERAL.—Subject to subparagraphs (B) and (D), in the case of a medicare administrative contractor (or a person who is a director, officer, or employee of such a contractor or who is engaged by the contractor to participate directly in the claims administration process) who is made a party to any judicial or administrative proceeding arising from or relating directly to the claims administration process under this title, the Secretary may, to the extent the Secretary determines to be appropriate and as specified in the contract with the contractor, indemnify the contractor and such persons.

"(B) CONDITIONS.—The Secretary may not provide indemnification under subparagraph (A) insofar as the liability for such costs arises directly from conduct that is determined by the judicial proceeding or by the Secretary to be criminal in nature, fraudulent, or grossly negligent. If indemnification is provided by the Secretary with respect to a contractor before a deter-

mination that such costs arose directly from such conduct, the contractor shall reimburse the Secretary for costs of indemnification.

"(C) SCOPE OF INDEMNIFICATION.—Indemnification by the Secretary under subparagraph (A) may include payment of judgments, settlements (subject to subparagraph (D)), awards, and costs (including reasonable legal expenses).

"(D) WRITTEN APPROVAL FOR SETTLEMENTS.—A contractor or other person described in subparagraph (A) may not propose to negotiate a settlement or compromise of a proceeding described in such subparagraph without the prior written approval of the Secretary to negotiate such settlement or compromise. Any indemnification under subparagraph (A) with respect to amounts paid under a settlement or compromise of a proceeding described in such subparagraph are conditioned upon prior written approval by the Secretary of the final settlement or compromise.

"(E) CONSTRUCTION.—Nothing in this paragraph shall be construed—

"(i) to change any common law immunity that may be available to a medicare administrative contractor or person described in subparagraph (A); or

"(ii) to permit the payment of costs not otherwise allowable, reasonable, or allocable under the Federal Acquisition Regulations.".

(2) CONSIDERATION OF INCORPORATION OF CURRENT LAW STANDARDS.—In developing contract performance requirements under section 1874A(b) of the Social Security Act, as inserted by paragraph (1), the Secretary shall consider inclusion of the performance standards described in sections 1816(f)(2) of such Act (relating to timely processing of reconsiderations and applications for exemptions) and section 1842(b)(2)(B) of such Act (relating to timely review of determinations and fair hearing requests), as such sections were in effect before the date of the enactment of this Act.

(b) CONFORMING AMENDMENTS TO SECTION 1816 (RELATING TO FISCAL INTERMEDIARIES).—Section 1816 (42 U.S.C. 1395h) is amended as follows:

(1) The heading is amended to read as follows:

"PROVISIONS RELATING TO THE ADMINISTRATION OF PART A".

(2) Subsection (a) is amended to read as follows:

"(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.".

(3) Subsection (b) is repealed.

(4) Subsection (c) is amended—

(A) by striking paragraph (1); and

(B) in each of paragraphs (2)(A) and (3)(A), by striking "agreement under this section" and inserting "contract under section 1874A that provides for making payments under this part".

(5) Subsections (d) through (i) are repealed.

(6) Subsections (j) and (k) are each amended—

(A) by striking "An agreement with an agency or organization under this section" and inserting "A contract with a medicare administrative contractor under section 1874A with respect to the administration of this part"; and

(B) by striking "such agency or organization" and inserting "such medicare administrative contractor" each place it appears.

(7) Subsection (l) is repealed.

(c) CONFORMING AMENDMENTS TO SECTION 1842 (RELATING TO CARRIERS).—Section 1842 (42 U.S.C. 1395u) is amended as follows:

(1) The heading is amended to read as follows:

"PROVISIONS RELATING TO THE ADMINISTRATION OF PART B".

(2) Subsection (a) is amended to read as follows:

"(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.".

(3) Subsection (b) is amended—

(A) by striking paragraph (1);

(B) in paragraph (2)—

(i) by striking subparagraphs (A) and (B);

(ii) in subparagraph (C), by striking "carriers" and inserting "medicare administrative contractors"; and

(iii) by striking subparagraphs (D) and (E);

(C) in paragraph (3)—

(i) in the matter before subparagraph (A), by striking "Each such contract shall provide that the carrier" and inserting "The Secretary";

(ii) by striking "will" the first place it appears in each of subparagraphs (A), (B), (F), (G), (H), and (L) and inserting "shall";

(iii) in subparagraph (B), in the matter before clause (i), by striking "to the policyholders and subscribers of the carrier" and inserting "to the policyholders and subscribers of the medicare administrative contractor";

(iv) by striking subparagraphs (C), (D), and (E);

(v) in subparagraph (H)—

(I) by striking "if it makes determinations or payments with respect to physicians' services," in the matter preceding clause (i); and

(II) by striking "carrier" and inserting "medicare administrative contractor" in clause (i);

(vi) by striking subparagraph (I);

(vii) in subparagraph (L), by striking the semicolon and inserting a period;

(viii) in the first sentence, after subparagraph (L), by striking "and shall contain" and all that follows through the period; and

(ix) in the seventh sentence, by inserting "medicare administrative contractor," after "carrier,"; and

(D) by striking paragraph (5);

(E) in paragraph (6)(D)(iv), by striking "carrier" and inserting "medicare administrative contractor"; and

(F) in paragraph (7), by striking "the carrier" and inserting "the Secretary" each place it appears.

(4) Subsection (c) is amended—

(A) by striking paragraph (1);

(B) in paragraph (2)(A), by striking "contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B)," and inserting "contract under section 1874A that provides for making payments under this part";

(C) in paragraph (3)(A), by striking "subsection (a)(1)(B)" and inserting "section 1874A(a)(3)(B)";

(D) in paragraph (4), in the matter preceding subparagraph (A), by striking "carrier" and inserting "medicare administrative contractor"; and

(E) by striking paragraphs (5) and (6).

(5) Subsections (d), (e), and (f) are repealed.

(6) Subsection (g) is amended by striking "carrier or carriers" and inserting "medicare administrative contractor or contractors".

(7) Subsection (h) is amended—

(A) in paragraph (2)—

(i) by striking "Each carrier having an agreement with the Secretary under subsection (a)" and inserting "The Secretary"; and

(ii) by striking "Each such carrier" and inserting "The Secretary";

(B) in paragraph (3)(A)—

(i) by striking "a carrier having an agreement with the Secretary under subsection (a)" and inserting "medicare administrative contractor having a contract under section 1874A that provides for making payments under this part"; and

(ii) by striking "such carrier" and inserting "such contractor";

(C) in paragraph (3)(B)—

(i) by striking "a carrier" and inserting "a medicare administrative contractor" each place it appears; and

(ii) by striking "the carrier" and inserting "the contractor" each place it appears; and

(D) in paragraphs (5)(A) and (5)(B)(iii), by striking "carriers" and inserting "medicare administrative contractors" each place it appears.

(8) Subsection (l) is amended—

(A) in paragraph (1)(A)(iii), by striking "carrier" and inserting "medicare administrative contractor"; and

(B) in paragraph (2), by striking "carrier" and inserting "medicare administrative contractor".

(9) Subsection (p)(3)(A) is amended by striking "carrier" and inserting "medicare administrative contractor".

(10) Subsection (q)(1)(A) is amended by striking "carrier".

(d) EFFECTIVE DATE; TRANSITION RULE.—

(1) EFFECTIVE DATE.—

(A) IN GENERAL.—Except as otherwise provided in this subsection, the amendments made by this section shall take effect on October 1, 2005, and the Secretary is authorized to take such steps before such date as may be necessary to implement such amendments on a timely basis.

(B) CONSTRUCTION FOR CURRENT CONTRACTS.—Such amendments shall not apply to contracts in effect before the date specified under subparagraph (A) that continue to retain the terms and conditions in effect on such date (except as otherwise provided under this Act, other than under this section) until such date as the contract is let out for competitive bidding under such amendments.

(C) DEADLINE FOR COMPETITIVE BIDDING.—The Secretary shall provide for the letting by competitive bidding of all contracts for functions of medicare administrative contractors for annual contract periods that begin on or after October 1, 2010.

(D) WAIVER OF PROVIDER NOMINATION PROVISIONS DURING TRANSITION.—During the period beginning on the date of the enactment of this Act and before the date specified under subparagraph (A), the Secretary may enter into new agreements under section 1816 of the Social Security Act (42 U.S.C. 1395h) without regard to any of the provider nomination provisions of such section.

(2) GENERAL TRANSITION RULES.—The Secretary shall take such steps, consistent with paragraph (1)(B) and (1)(C), as are necessary to provide for an appropriate transition from contracts under section 1816 and section 1842 of the Social Security Act (42 U.S.C. 1395h, 1395u) to contracts under section 1874A, as added by subsection (a)(1).

(3) AUTHORIZING CONTINUATION OF MIP FUNCTIONS UNDER CURRENT CONTRACTS AND AGREEMENTS AND UNDER ROLLOVER CONTRACTS.—The provisions contained in the exception in section 1893(d)(2) of the Social Security Act (42 U.S.C. 1395ddd(d)(2)) shall continue to apply notwithstanding the amendments made by this section, and any reference in such provisions to an agreement or contract shall be deemed to include a contract under section 1874A of such Act, as inserted by subsection (a)(1), that continues the activities referred to in such provisions.

(e) REFERENCES.—On and after the effective date provided under subsection (d)(1), any reference to a fiscal intermediary or carrier under title XI or XVIII of the Social Security Act (or any regulation, manual instruction, interpretative rule, statement of policy, or guideline issued to carry out such titles) shall be deemed a reference to a medicare administrative contractor (as provided under section 1874A of the Social Security Act).

(f) REPORTS ON IMPLEMENTATION.—

(1) PLAN FOR IMPLEMENTATION.—By not later than October 1, 2004, the Secretary shall submit a report to Congress and the Comptroller General of the United States that describes the plan for implementation of the amendments made by this section. The Comptroller General shall conduct an evaluation of such plan and shall submit to Congress, not later than 6 months after the date the report is received, a report on such evaluation and shall include in such report such recommendations as the Comptroller General deems appropriate.

(2) STATUS OF IMPLEMENTATION.—The Secretary shall submit a report to Congress not later than October 1, 2008, that describes the status of implementation of such amendments and that includes a description of the following:

(A) The number of contracts that have been competitively bid as of such date.

(B) The distribution of functions among contracts and contractors.

(C) A timeline for complete transition to full competition.

(D) A detailed description of how the Secretary has modified oversight and management of medicare contractors to adapt to full competition.

SEC. 912. REQUIREMENTS FOR INFORMATION SECURITY FOR MEDICARE ADMINISTRATIVE CONTRACTORS.

(a) IN GENERAL.—Section 1874A, as added by section 911(a)(1), is amended by adding at the end the following new subsection:

"(e) REQUIREMENTS FOR INFORMATION SECURITY.—

"(1) DEVELOPMENT OF INFORMATION SECURITY PROGRAM.—A medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall implement a contractor-wide information security program to provide information security for the operation and assets of the contractor with respect to such functions under this title. An information security program under this paragraph shall meet the requirements for information security programs imposed on Federal agencies under paragraphs (1) through (8) of section 3544(b)

of title 44, United States Code (other than the requirements under paragraphs (2)(D)(i), (5)(A), and (5)(B) of such section).

"(2) INDEPENDENT AUDITS.—

"(A) PERFORMANCE OF ANNUAL EVALUATIONS.—Each year a medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall undergo an evaluation of the information security of the contractor with respect to such functions under this title. The evaluation shall—

"(i) be performed by an entity that meets such requirements for independence as the Inspector General of the Department of Health and Human Services may establish; and

"(ii) test the effectiveness of information security control techniques of an appropriate subset of the contractor's information systems (as defined in section 3502(8) of title 44, United States Code) relating to such functions under this title and an assessment of compliance with the requirements of this subsection and related information security policies, procedures, standards and guidelines, including policies and procedures as may be prescribed by the Director of the Office of Management and Budget and applicable information security standards promulgated under section 11331 of title 40, United States Code.

"(B) DEADLINE FOR INITIAL EVALUATION.—

"(i) NEW CONTRACTORS.—In the case of a medicare administrative contractor covered by this subsection that has not previously performed the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) as a fiscal intermediary or carrier under section 1816 or 1842, the first independent evaluation conducted pursuant subparagraph (A) shall be completed prior to commencing such functions.

"(ii) OTHER CONTRACTORS.—In the case of a medicare administrative contractor covered by this subsection that is not described in clause (i), the first independent evaluation conducted pursuant subparagraph (A) shall be completed within 1 year after the date the contractor commences functions referred to in clause (i) under this section.

"(C) REPORTS ON EVALUATIONS.—

"(i) TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.—The results of independent evaluations under subparagraph (A) shall be submitted promptly to the Inspector General of the Department of Health and Human Services and to the Secretary.

"(ii) TO CONGRESS.—The Inspector General of Department of Health and Human Services shall submit to Congress annual reports on the results of such evaluations, including assessments of the scope and sufficiency of such evaluations.

"(iii) AGENCY REPORTING.—The Secretary shall address the results of such evaluations in reports required under section 3544(c) of title 44, United States Code.".

(b) APPLICATION OF REQUIREMENTS TO FISCAL INTERMEDIARIES AND CARRIERS.—

(1) IN GENERAL.—The provisions of section 1874A(e)(2) of the Social Security Act (other than subparagraph (B)), as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(2) DEADLINE FOR INITIAL EVALUATION.—In the case of such a fiscal intermediary or carrier with an agreement or contract under such respective section in effect as of the date of the enactment of this Act, the first evaluation under section 1874A(e)(2)(A) of the Social Security Act (as added by subsection (a)), pursuant to paragraph (1), shall be completed (and a report on the evaluation submitted to the Secretary) by not later than 1 year after such date.

Subtitle C—Education and Outreach

SEC. 921. PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.

(a) COORDINATION OF EDUCATION FUNDING.—

(1) IN GENERAL.—Title XVIII is amended by inserting after section 1888 the following new section:

"PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

"SEC. 1889. (a) COORDINATION OF EDUCATION FUNDING.—The Secretary shall coordinate the educational activities provided through medicare contractors (as defined in subsection (g), including under section 1893) in order to maximize the effectiveness of Federal education efforts for providers of services and suppliers.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act.

(3) REPORT.—Not later than October 1, 2004, the Secretary shall submit to Congress a report that includes a description and evaluation of the steps taken to coordinate the funding of provider education under section 1889(a) of the Social Security Act, as added by paragraph (1).

(b) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE.—

(1) IN GENERAL.—Section 1874A, as added by section 911(a)(1) and as amended by section 912(a), is amended by adding at the end the following new subsection:

"(f) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE IN PROVIDER EDUCATION AND OUTREACH.—The Secretary shall use specific claims payment error rates or similar methodology of medicare administrative contractors in the processing or reviewing of medicare claims in order to give such contractors an incentive to implement effective education and outreach programs for providers of services and suppliers.".

(2) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(f) of the Social Security Act, as added by paragraph (1), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(3) GAO REPORT ON ADEQUACY OF METHODOLOGY.—Not later than October 1, 2004, the Comptroller General of the United States shall submit to Congress and to the Secretary a report on the adequacy of the methodology under section 1874A(f) of the Social Security Act, as added by paragraph (1), and shall include in the report such recommendations as the Comptroller General determines appropriate with respect to the methodology.

(4) REPORT ON USE OF METHODOLOGY IN ASSESSING CONTRACTOR PERFORMANCE.—Not later than October 1, 2004, the Secretary shall submit to Congress a report that describes how the Secretary intends to use such methodology in assessing medicare contractor performance in implementing effective education and outreach programs, including whether to use such methodology as a basis for performance bonuses. The report shall include an analysis of the sources of identified errors and potential changes in systems of contractors and rules of the Secretary that could reduce claims error rates.

(c) PROVISION OF ACCESS TO AND PROMPT RESPONSES FROM MEDICARE ADMINISTRATIVE CONTRACTORS.—

(1) IN GENERAL.—Section 1874A, as added by section 911(a)(1) and as amended by section 912(a) and subsection (b), is further amended by adding at the end the following new subsection:

"(g) COMMUNICATIONS WITH BENEFICIARIES, PROVIDERS OF SERVICES AND SUPPLIERS.—

"(1) COMMUNICATION STRATEGY.—The Secretary shall develop a strategy for communications with individuals entitled to benefits under part A or enrolled under part B, or both, and with providers of services and suppliers under this title.

"(2) RESPONSE TO WRITTEN INQUIRIES.—Each medicare administrative contractor shall, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, provide general written responses (which may be through electronic transmission) in a clear, concise, and accurate manner to inquiries of providers of services, suppliers and individuals entitled to benefits under part A or enrolled under part B, or both, concerning the programs under this title within 45 business days of the date of receipt of such inquiries.

"(3) RESPONSE TO TOLL-FREE LINES.—The Secretary shall ensure that each medicare administrative contractor shall provide, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, a toll-free telephone number at which such individuals, providers of services

and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate information under this title.

"(4) MONITORING OF CONTRACTOR RESPONSES.—

"(A) IN GENERAL.—Each medicare administrative contractor shall, consistent with standards developed by the Secretary under subparagraph (B)—

"(i) maintain a system for identifying who provides the information referred to in paragraphs (2) and (3); and

"(ii) monitor the accuracy, consistency, and timeliness of the information so provided.

"(B) DEVELOPMENT OF STANDARDS.—

"(i) IN GENERAL.—The Secretary shall establish and make public standards to monitor the accuracy, consistency, and timeliness of the information provided in response to written and telephone inquiries under this subsection. Such standards shall be consistent with the performance requirements established under subsection (b)(3).

"(ii) EVALUATION.—In conducting evaluations of individual medicare administrative contractors, the Secretary shall take into account the results of the monitoring conducted under subparagraph (A) taking into account as performance requirements the standards established under clause (i). The Secretary shall, in consultation with organizations representing providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, establish standards relating to the accuracy, consistency, and timeliness of the information so provided.

"(C) DIRECT MONITORING.—Nothing in this paragraph shall be construed as preventing the Secretary from directly monitoring the accuracy, consistency, and timeliness of the information so provided.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect October 1, 2004.

(3) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(g) of the Social Security Act, as added by paragraph (1), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(d) IMPROVED PROVIDER EDUCATION AND TRAINING.—

(1) IN GENERAL.—Section 1889, as added by subsection (a), is amended by adding at the end the following new subsections:

"(b) ENHANCED EDUCATION AND TRAINING.—

"(1) ADDITIONAL RESOURCES.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) $25,000,000 for each of fiscal years 2005 and 2006 and such sums as may be necessary for succeeding fiscal years.

"(2) USE.—The funds made available under paragraph (1) shall be used to increase the conduct by medicare contractors of education and training of providers of services and suppliers regarding billing, coding, and other appropriate items and may also be used to improve the accuracy, consistency, and timeliness of contractor responses.

"(c) TAILORING EDUCATION AND TRAINING ACTIVITIES FOR SMALL PROVIDERS OR SUPPLIERS.—

"(1) IN GENERAL.—Insofar as a medicare contractor conducts education and training activities, it shall tailor such activities to meet the special needs of small providers of services or suppliers (as defined in paragraph (2)).

"(2) SMALL PROVIDER OF SERVICES OR SUPPLIER.—In this subsection, the term 'small provider of services or supplier' means—

"(A) a provider of services with fewer than 25 full-time-equivalent employees; or

"(B) a supplier with fewer than 10 full-time-equivalent employees.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on October 1, 2004.

(e) REQUIREMENT TO MAINTAIN INTERNET SITES.—

(1) IN GENERAL.—Section 1889, as added by subsection (a) and as amended by subsection (d), is further amended by adding at the end the following new subsection:

"(d) INTERNET SITES; FAQS.—The Secretary, and each medicare contractor insofar as it provides services (including claims processing) for providers of services or suppliers, shall maintain an Internet site which—

"(1) provides answers in an easily accessible format to frequently asked questions, and

"(2) includes other published materials of the contractor,

that relate to providers of services and suppliers under the programs under this title (and title XI insofar as it relates to such programs).".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on October 1, 2004.

(f) ADDITIONAL PROVIDER EDUCATION PROVISIONS.—

(1) IN GENERAL.—Section 1889, as added by subsection (a) and as amended by subsections (d) and (e), is further amended by adding at the end the following new subsections:

"(e) ENCOURAGEMENT OF PARTICIPATION IN EDUCATION PROGRAM ACTIVITIES.—A medicare contractor may not use a record of attendance at (or failure to attend) educational activities or other information gathered during an educational program conducted under this section or otherwise by the Secretary to select or track providers of services or suppliers for the purpose of conducting any type of audit or prepayment review.

"(f) CONSTRUCTION.—Nothing in this section or section 1893(g) shall be construed as providing for disclosure by a medicare contractor of information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits.

"(g) DEFINITIONS.—For purposes of this section, the term 'medicare contractor' includes the following:

"(1) A medicare administrative contractor with a contract under section 1874A, including a fiscal intermediary with a contract under section 1816 and a carrier with a contract under section 1842.

"(2) An eligible entity with a contract under section 1893.

Such term does not include, with respect to activities of a specific provider of services or supplier an entity that has no authority under this title or title IX with respect to such activities and such provider of services or supplier.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act.

SEC. 922. SMALL PROVIDER TECHNICAL ASSISTANCE DEMONSTRATION PROGRAM.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary shall establish a demonstration program (in this section referred to as the "demonstration program") under which technical assistance described in paragraph (2) is made available, upon request and on a voluntary basis, to small providers of services or suppliers in order to improve compliance with the applicable requirements of the programs under medicare program under title XVIII of the Social Security Act (including provisions of title XI of such Act insofar as they relate to such title and are not administered by the Office of the Inspector General of the Department of Health and Human Services).

(2) FORMS OF TECHNICAL ASSISTANCE.—The technical assistance described in this paragraph is—

(A) evaluation and recommendations regarding billing and related systems; and

(B) information and assistance regarding policies and procedures under the medicare program, including coding and reimbursement.

(3) SMALL PROVIDERS OF SERVICES OR SUPPLIERS.—In this section, the term "small providers of services or suppliers" means—

(A) a provider of services with fewer than 25 full-time-equivalent employees; or

(B) a supplier with fewer than 10 full-time-equivalent employees.

(b) QUALIFICATION OF CONTRACTORS.—In conducting the demonstration program, the Secretary shall enter into contracts with qualified organizations (such as peer review organizations or entities described in section 1889(g)(2) of the Social Security Act, as inserted by section 5(f)(1)) with appropriate expertise with billing systems of the full range of providers of services and suppliers to provide the technical assistance. In awarding such contracts, the Secretary shall consider any prior investigations of the entity's work by the Inspector General of Department of Health and Human Services or the Comptroller General of the United States.

(c) DESCRIPTION OF TECHNICAL ASSISTANCE.—The technical assistance provided under the demonstration program shall include a direct and in-person examination of billing systems and internal controls of small providers of services or suppliers to determine program compliance and to suggest more efficient or effective means of achieving such compliance.

(d) AVOIDANCE OF RECOVERY ACTIONS FOR PROBLEMS IDENTIFIED AS CORRECTED.—The Secretary shall provide that, absent evidence of fraud and notwithstanding any other provision of law, any errors found in a compliance review for a small provider of services or supplier that participates in the demonstration program shall not be subject to recovery action if the technical assistance personnel under the program determine that—

(1) the problem that is the subject of the compliance review has been corrected to their satisfaction within 30 days of the date of the visit by such personnel to the small provider of services or supplier; and

(2) such problem remains corrected for such period as is appropriate.

The previous sentence applies only to claims filed as part of the demonstration program and lasts only for the duration of such program and only as long as the small provider of services or supplier is a participant in such program.

(e) GAO EVALUATION.—Not later than 2 years after the date of the date the demonstration program is first implemented, the Comptroller General, in consultation with the Inspector General of the Department of Health and Human Services, shall conduct an evaluation of the demonstration program. The evaluation shall include a determination of whether claims error rates are reduced for small providers of services or suppliers who participated in the program and the extent of improper payments made as a result of the demonstration program. The Comptroller General shall submit a report to the Secretary and the Congress on such evaluation and shall include in such report recommendations regarding the continuation or extension of the demonstration program.

(f) FINANCIAL PARTICIPATION BY PROVIDERS.—The provision of technical assistance to a small provider of services or supplier under the demonstration program is conditioned upon the small provider of services or supplier paying an amount estimated (and disclosed in advance of a provider's or supplier's participation in the program) to be equal to 25 percent of the cost of the technical assistance.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to carry out the demonstration program—

(1) for fiscal year 2005, $1,000,000, and

(2) for fiscal year 2006, $6,000,000.

SEC. 923. MEDICARE PROVIDER OMBUDSMAN; MEDICARE BENEFICIARY OMBUDSMAN.

(a) MEDICARE PROVIDER OMBUDSMAN.—Section 1868 (42 U.S.C. 1395ee) is amended—

(1) by adding at the end of the heading the following: "; MEDICARE PROVIDER OMBUDSMAN";

(2) by inserting "PRACTICING PHYSICIANS ADVISORY COUNCIL.—(1)" after "(a)";

(3) in paragraph (1), as so redesignated under paragraph (2), by striking "in this section" and inserting "in this subsection";

(4) by redesignating subsections (b) and (c) as paragraphs (2) and (3), respectively; and

(5) by adding at the end the following new subsection:

"(b) MEDICARE PROVIDER OMBUDSMAN.—The Secretary shall appoint within the Department of Health and Human Services a Medicare Provider Ombudsman. The Ombudsman shall—

"(1) provide assistance, on a confidential basis, to providers of services and suppliers with respect to complaints, grievances, and requests for information concerning the programs under this title (including provisions of title XI insofar as they relate to this title and are not administered by the Office of the Inspector General of the Department of Health and Human Services) and in the resolution of unclear or conflicting guidance given by the Secretary and medicare contractors to such providers of services and suppliers regarding such programs and provisions and requirements under this title and such provisions; and

"(2) submit recommendations to the Secretary for improvement in the administration of this title and such provisions, including—

"(A) recommendations to respond to recurring patterns of confusion in this title and such provisions (including recommendations regarding suspending imposition of sanctions where there is widespread confusion in program administration), and

"(B) recommendations to provide for an appropriate and consistent response (including not providing for audits) in cases of self-identified overpayments by providers of services and suppliers.

The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.".

(b) MEDICARE BENEFICIARY OMBUDSMAN.—Title XVIII, as previously amended, is amended by inserting after section 1809 the following new section:

"MEDICARE BENEFICIARY OMBUDSMAN

"SEC. 1810. (a) IN GENERAL.—The Secretary shall appoint within the Department of Health and Human Services a Medicare Beneficiary Ombudsman who shall have expertise and experience in the fields of health care and education of (and assistance to) individuals entitled to benefits under this title.

"(b) DUTIES.—The Medicare Beneficiary Ombudsman shall—

"(1) receive complaints, grievances, and requests for information submitted by individuals entitled to benefits under part A or enrolled under part B, or both, with respect to any aspect of the medicare program;

"(2) provide assistance with respect to complaints, grievances, and requests referred to in paragraph (1), including—

"(A) assistance in collecting relevant information for such individuals, to seek an appeal of a decision or determination made by a fiscal intermediary, carrier, Medicare+Choice organization, or the Secretary;

"(B) assistance to such individuals with any problems arising from disenrollment from a Medicare+Choice plan under part C; and

"(C) assistance to such individuals in presenting information under section 1860D–2(b)(4)(D)(v); and

"(3) submit annual reports to Congress and the Secretary that describe the activities of the Office and that include such recommendations for improvement in the administration of this title as the Ombudsman determines appropriate.

The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.

"(c) WORKING WITH HEALTH INSURANCE COUNSELING PROGRAMS.—To the extent possible, the Ombudsman shall work with health insurance counseling programs (receiving funding under section 4360 of Omnibus Budget Reconciliation Act of 1990) to facilitate the provision of information to individuals entitled to benefits under part A or enrolled under part B, or both regarding Medicare+Choice plans and changes to those plans. Nothing in this subsection shall preclude further collaboration between the Ombudsman and such programs.".

(c) DEADLINE FOR APPOINTMENT.—The Secretary shall appoint the Medicare Provider Ombudsman and the Medicare Beneficiary Ombudsman, under the amendments made by subsections (a) and (b), respectively, by not later than 1 year after the date of the enactment of this Act.

(d) FUNDING.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to carry out the provisions of subsection (b) of section 1868 of the Social Security Act (relating to the Medicare Provider Ombudsman), as added by subsection (a)(5) and section 1807 of such Act (relating to the Medicare Beneficiary Ombudsman), as added by subsection (b), such sums as are necessary for fiscal year 2004 and each succeeding fiscal year.

(e) USE OF CENTRAL, TOLL-FREE NUMBER (1–800–MEDICARE).—

(1) PHONE TRIAGE SYSTEM; LISTING IN MEDICARE HANDBOOK INSTEAD OF OTHER TOLL-FREE NUMBERS.—Section 1804(b) (42 U.S.C. 1395b–2(b)) is amended by adding at the end the following: "The Secretary shall provide, through the toll-free number 1–800–MEDICARE, for a means by which individuals seeking information about, or assistance with, such programs who phone such toll-free number are transferred (without charge) to appropriate entities for the provision of such information or assistance. Such toll-free number shall be the toll-free number listed for general information and assistance in the annual notice under subsection (a) instead of the listing of numbers of individual contractors.".

(2) MONITORING ACCURACY.—

(A) STUDY.—The Comptroller General of the United States shall conduct a study to monitor the accuracy and consistency of information provided to individuals entitled to benefits under part A or enrolled under part B, or both, through the toll-free number 1–800–MEDICARE, including an assessment of whether the information provided is sufficient to answer questions of such individuals. In conducting the study, the Comptroller General shall examine the education and training of the individuals providing information through such number.

(B) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subparagraph (A).

SEC. 924. BENEFICIARY OUTREACH DEMONSTRATION PROGRAM.

(a) IN GENERAL.—The Secretary shall establish a demonstration program (in this section referred to as the "demonstration program") under which medicare specialists employed by the Department of Health and Human Services provide advice and assistance to individuals entitled to benefits under part A of title XVIII of the Social Security Act, or enrolled under part B of such title, or both, regarding the medicare program at the location of existing local offices of the Social Security Administration.

(b) LOCATIONS.—

(1) IN GENERAL.—The demonstration program shall be conducted in at least 6 offices or areas. Subject to paragraph (2), in selecting such offices and areas, the Secretary shall provide preference for offices with a high volume of visits by individuals referred to in subsection (a).

(2) ASSISTANCE FOR RURAL BENEFICIARIES.—The Secretary shall provide for the selection of at least 2 rural areas to participate in the demonstration program. In conducting the demonstration program in such rural areas, the Secretary shall provide for medicare specialists to travel among local offices in a rural area on a scheduled basis.

(c) DURATION.—The demonstration program shall be conducted over a 3-year period.

(d) EVALUATION AND REPORT.—

(1) EVALUATION.—The Secretary shall provide for an evaluation of the demonstration program. Such evaluation shall include an analysis of—

(A) utilization of, and satisfaction of those individuals referred to in subsection (a) with, the assistance provided under the program; and

(B) the cost-effectiveness of providing beneficiary assistance through outstationing medicare specialists at local offices of the Social Security Administration.

(2) REPORT.—The Secretary shall submit to Congress a report on such evaluation and shall include in such report recommendations regarding the feasibility of permanently out-stationing medicare specialists at local offices of the Social Security Administration.

SEC. 925. INCLUSION OF ADDITIONAL INFORMATION IN NOTICES TO BENEFICIARIES ABOUT SKILLED NURSING FACILITY BENEFITS.

(a) IN GENERAL.—The Secretary shall provide that in medicare beneficiary notices provided (under section 1806(a) of the Social Security Act, 42 U.S.C. 1395b–7(a)) with respect to the provision of post-hospital extended care services under part A of title XVIII of the Social Security Act, there shall be included information on the number of days of coverage of such services remaining under such part for the medicare beneficiary and spell of illness involved.

(b) EFFECTIVE DATE.—Subsection (a) shall apply to notices provided during calendar quarters beginning more than 6 months after the date of the enactment of this Act.

SEC. 926. INFORMATION ON MEDICARE-CERTIFIED SKILLED NURSING FACILITIES IN HOSPITAL DISCHARGE PLANS.

(a) AVAILABILITY OF DATA.—The Secretary shall publicly provide information that enables hospital discharge planners, medicare beneficiaries, and the public to identify skilled nursing facilities that are participating in the medicare program.

(b) INCLUSION OF INFORMATION IN CERTAIN HOSPITAL DISCHARGE PLANS.—

(1) IN GENERAL.—Section 1861(ee)(2)(D) (42 U.S.C. 1395x(ee)(2)(D)) is amended—

(A) by striking "hospice services" and inserting "hospice care and post-hospital extended care services"; and

(B) by inserting before the period at the end the following: "and, in the case of individuals who are likely to need post-hospital extended care services, the availability of such services through facilities that participate in the program under this title and that serve the area in which the patient resides".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to discharge plans made on or after such date as the Secretary shall specify, but not later than 6 months after the date the Secretary provides for availability of information under subsection (a).

Subtitle D—Appeals and Recovery

SEC. 931. TRANSFER OF RESPONSIBILITY FOR MEDICARE APPEALS.

(a) TRANSITION PLAN.—

(1) IN GENERAL.—Not later than October 1, 2004, the Commissioner of Social Security and the Secretary shall develop and transmit to Congress and the Comptroller General of the United States a plan under which the functions of administrative law judges responsible for hearing cases under title XVIII of the Social Security Act (and related provisions in title XI of such Act) are transferred from the responsibility of the Commissioner and the Social Security Administration to the Secretary and the Department of Health and Human Services.

(2) GAO EVALUATION.—The Comptroller General of the United States shall evaluate the plan and, not later than the date that is 6 months after the date on which the plan is received by the Comptroller General, shall submit to Congress a report on such evaluation.

(b) TRANSFER OF ADJUDICATION AUTHORITY.—

(1) IN GENERAL.—Not earlier than July 1, 2005, and not later than October 1, 2005, the Commissioner of Social Security and the Secretary shall implement the transition plan under subsection (a) and transfer the administrative law judge functions described in such subsection from the Social Security Administration to the Secretary.

(2) ASSURING INDEPENDENCE OF JUDGES.—The Secretary shall assure the independence of administrative law judges performing the administrative law judge functions transferred under paragraph (1) from the Centers for Medicare & Medicaid Services and its contractors. In order to assure such independence, the Secretary shall place such judges in an administrative office that is organizationally and functionally separate from such Centers. Such judges shall report to, and be under the general supervision of, the Secretary, but shall not report to, or be subject to supervision by, another other officer of the Department.

(3) GEOGRAPHIC DISTRIBUTION.—The Secretary shall provide for an appropriate geographic distribution of administrative law judges performing the administrative law judge functions transferred under paragraph (1) throughout the United States to ensure timely access to such judges.

(4) HIRING AUTHORITY.—Subject to the amounts provided in advance in appropriations Act, the Secretary shall have authority to hire administrative law judges to hear such cases, giving priority to those judges with prior experience in handling medicare appeals and in a manner consistent with paragraph (3), and to hire support staff for such judges.

(5) FINANCING.—Amounts payable under law to the Commissioner for administrative law judges performing the administrative law judge functions transferred under paragraph (1) from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund shall become payable to the Secretary for the functions so transferred.

(6) SHARED RESOURCES.—The Secretary shall enter into such arrangements with the Commissioner as may be appropriate with respect to transferred functions of administrative law judges to share office space, support staff, and other resources, with appropriate reimbursement from the Trust Funds described in paragraph (5).

(c) INCREASED FINANCIAL SUPPORT.—In addition to any amounts otherwise appropriated, to ensure timely action on appeals before administrative law judges and the Departmental Appeals Board consistent with section 1869 of the Social Security Act (as amended by section 521 of BIPA, 114 Stat. 2763A–534), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to the Secretary such sums as are necessary for fiscal year 2005 and each subsequent fiscal year to—

(1) increase the number of administrative law judges (and their staffs) under subsection (b)(4);

(2) improve education and training opportunities for administrative law judges (and their staffs); and

(3) increase the staff of the Departmental Appeals Board.

(d) CONFORMING AMENDMENT.—Section 1869(f)(2)(A)(i) (42 U.S.C. 1395ff(f)(2)(A)(i)), as added by section 522(a) of BIPA (114 Stat. 2763A–543), is amended by striking "of the Social Security Administration".

SEC. 932. PROCESS FOR EXPEDITED ACCESS TO REVIEW.

(a) EXPEDITED ACCESS TO JUDICIAL REVIEW.—Section 1869(b) (42 U.S.C. 1395ff(b)) as amended by BIPA, is amended—

(1) in paragraph (1)(A), by inserting ", subject to paragraph (2)," before "to judicial review of the Secretary's final decision";

(2) in paragraph (1)(F)—

(A) by striking clause (ii);

(B) by striking "PROCEEDING" and all that follows through "DETERMINATION" and inserting "DETERMINATIONS AND RECONSIDERATIONS"; and

(C) by redesignating subclauses (I) and (II) as clauses (i) and (ii) and by moving the indentation of such subclauses (and the matter that follows) 2 ems to the left; and

(3) by adding at the end the following new paragraph:

"(2) EXPEDITED ACCESS TO JUDICIAL REVIEW.—

"(A) IN GENERAL.—The Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or an individual entitled to benefits under part A or enrolled under part B, or both, who has filed an appeal under paragraph (1) may obtain access to judicial review when a review panel (described in subparagraph (D)), on its own motion or at the request of the appellant, determines that no entity in the administrative appeals process has the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute. The appellant may make such request only once with respect to a question of law or regulation in a case of an appeal.

"(B) PROMPT DETERMINATIONS.—If, after or coincident with appropriately filing a request for an administrative hearing, the appellant requests a determination by the appropriate review panel that no review panel has the authority to decide the question of law or regulations relevant to the matters in controversy and that there is no material issue of fact in dispute and if such request is accompanied by the documents and materials as the appropriate review panel shall require for purposes of making such determination, such review panel shall make a determination on the request in writing within 60 days after the date such review panel receives the request and such accompanying documents and materials. Such a determination by such review panel shall be considered a final decision and not subject to review by the Secretary.

"(C) ACCESS TO JUDICIAL REVIEW.—

"(i) IN GENERAL.—If the appropriate review panel—

"(I) determines that there are no material issues of fact in dispute and that the only issue is one of law or regulation that no review panel has the authority to decide; or

"(II) fails to make such determination within the period provided under subparagraph (B);

then the appellant may bring a civil action as described in this subparagraph.

"(ii) DEADLINE FOR FILING.—Such action shall be filed, in the case described in—

"(I) clause (i)(I), within 60 days of date of the determination described in such subparagraph; or

"(II) clause (i)(II), within 60 days of the end of the period provided under subparagraph (B) for the determination.

"(iii) VENUE.—Such action shall be brought in the district court of the United States for the judicial district in which the appellant is located (or, in the case of an action brought jointly by more than one applicant, the judicial district in which the greatest number of applicants are located) or in the district court for the District of Columbia.

"(iv) INTEREST ON AMOUNTS IN CONTROVERSY.—Where a provider of services or supplier seeks judicial review pursuant to this paragraph, the amount in controversy shall be subject to annual interest beginning on the first day of the first month beginning after the 60-day period as determined pursuant to clause (ii) and equal to the rate of interest on obligations issued for purchase by the Federal Hospital Insurance Trust Fund and by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this paragraph is commenced, to be awarded by the reviewing court in favor of the prevailing party. No interest awarded pursuant to the preceding sentence shall be deemed income or cost for the purposes of determining reimbursement due providers of services or suppliers under this Act.

"(D) REVIEW PANELS.—For purposes of this subsection, a 'review panel' is a panel consisting of 3 members (who shall be administrative law judges, members of the Departmental Appeals Board, or qualified individuals associated with a qualified independent contractor (as defined in subsection (c)(2)) or with another independent entity) designated by the Secretary for purposes of making determinations under this paragraph.".

(b) APPLICATION TO PROVIDER AGREEMENT DETERMINATIONS.—Section 1866(h)(1) (42 U.S.C. 1395cc(h)(1)) is amended—

(1) by inserting "(A)" after "(h)(1)"; and

(2) by adding at the end the following new subparagraph:

"(B) An institution or agency described in subparagraph (A) that has filed for a hearing under subparagraph (A) shall have expedited access to judicial review under this subparagraph in the same manner as providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, may obtain expedited access to judicial review under the process established under section 1869(b)(2). Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1819 during the pendency of an appeal under this subparagraph.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to appeals filed on or after October 1, 2004.

(d) EXPEDITED REVIEW OF CERTAIN PROVIDER AGREEMENT DETERMINATIONS.—

(1) TERMINATION AND CERTAIN OTHER IMMEDIATE REMEDIES.—The Secretary shall develop and implement a process to expedite proceedings under sections 1866(h) of the Social Security Act (42 U.S.C. 1395cc(h)) in which the remedy of termination of participation, or a remedy described in clause (i) or (iii) of section 1819(h)(2)(B) of such Act (42 U.S.C. 1395i–3(h)(2)(B)) which is applied on an immediate basis, has been imposed. Under such process priority shall be provided in cases of termination.

(2) INCREASED FINANCIAL SUPPORT.—In addition to any amounts otherwise appropriated, to reduce by 50 percent the average time for administrative determinations on appeals under section 1866(h) of the Social Security Act (42 U.S.C. 1395cc(h)), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to the Secretary such additional sums for fiscal year 2005 and each subsequent fiscal year as may be necessary. The purposes for which such amounts are available include increasing the number of administrative law judges (and their staffs) and the appellate level staff at the Departmental Appeals Board of the Department of Health and Human Services and educating such judges and staffs on long-term care issues.

SEC. 933. REVISIONS TO MEDICARE APPEALS PROCESS.

(a) REQUIRING FULL AND EARLY PRESENTATION OF EVIDENCE.—

(1) IN GENERAL.—Section 1869(b) (42 U.S.C. 1395ff(b)), as amended by BIPA and as amended by section 932(a), is further amended by adding at the end the following new paragraph:

"(3) REQUIRING FULL AND EARLY PRESENTATION OF EVIDENCE BY PROVIDERS.—A provider of services or supplier may not introduce evidence in any appeal under this section that was not presented at the reconsideration conducted by the qualified independent contractor under subsection (c), unless there is good cause which precluded the introduction of such evidence at or before that reconsideration.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on October 1, 2004.

(b) USE OF PATIENTS' MEDICAL RECORDS.—Section 1869(c)(3)(B)(i) (42 U.S.C. 1395ff(c)(3)(B)(i)), as amended by BIPA, is amended by inserting "(including the medical records of the individual involved)" after "clinical experience".

(c) NOTICE REQUIREMENTS FOR MEDICARE APPEALS.—

(1) INITIAL DETERMINATIONS AND REDETERMINATIONS.—Section 1869(a) (42 U.S.C. 1395ff(a)), as amended by BIPA, is amended by adding at the end the following new paragraphs:

"(4) REQUIREMENTS OF NOTICE OF DETERMINATIONS.—With respect to an initial determination insofar as it results in a denial of a claim for benefits—

"(A) the written notice on the determination shall include—

"(i) the reasons for the determination, including whether a local medical review policy or a local coverage determination was used;

"(ii) the procedures for obtaining additional information concerning the determination, including the information described in subparagraph (B); and

"(iii) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination under this section; and

"(B) the person provided such notice may obtain, upon request, the specific provision of the policy, manual, or regulation used in making the determination.

"(5) REQUIREMENTS OF NOTICE OF REDETERMINATIONS.—With respect to a redetermination insofar as it results in a denial of a claim for benefits—

"(A) the written notice on the redetermination shall include—

"(i) the specific reasons for the redetermination;

"(ii) as appropriate, a summary of the clinical or scientific evidence used in making the redetermination;

"(iii) a description of the procedures for obtaining additional information concerning the redetermination; and

"(iv) notification of the right to appeal the redetermination and instructions on how to initiate such an appeal under this section;

"(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both; and

"(C) the person provided such notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.".

(2) RECONSIDERATIONS.—Section 1869(c)(3)(E) (42 U.S.C. 1395ff(c)(3)(E)), as amended by BIPA, is amended—

(A) by inserting "be written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include (to the extent appropriate)" after "in writing, "; and

(B) by inserting "and a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section" after "such decision,".

(3) APPEALS.—Section 1869(d) (42 U.S.C. 1395ff(d)), as amended by BIPA, is amended—

(A) in the heading, by inserting "; NOTICE" after "SECRETARY"; and

(B) by adding at the end the following new paragraph:

"(4) NOTICE.—Notice of the decision of an administrative law judge shall be in writing in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include—

"(A) the specific reasons for the determination (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination);

"(B) the procedures for obtaining additional information concerning the decision; and

"(C) notification of the right to appeal the decision and instructions on how to initiate such an appeal under this section.".

(4) SUBMISSION OF RECORD FOR APPEAL.—Section 1869(c)(3)(J)(i) (42 U.S.C. 1395ff(c)(3)(J)(i)) by striking "prepare" and inserting "submit" and by striking "with respect to" and all that follows through "and relevant policies".

(d) QUALIFIED INDEPENDENT CONTRACTORS.—

(1) ELIGIBILITY REQUIREMENTS OF QUALIFIED INDEPENDENT CONTRACTORS.—Section 1869(c)(3) (42 U.S.C. 1395ff(c)(3)), as amended by BIPA, is amended—

(A) in subparagraph (A), by striking "sufficient training and expertise in medical science and legal matters" and inserting "sufficient medical, legal, and other expertise (including knowledge of the program under this title) and sufficient staffing"; and

(B) by adding at the end the following new subparagraph:

"(K) INDEPENDENCE REQUIREMENTS.—

"(i) IN GENERAL.—Subject to clause (ii), a qualified independent contractor shall not conduct any activities in a case unless the entity—

"(I) is not a related party (as defined in subsection (g)(5));

"(II) does not have a material familial, financial, or professional relationship with such a party in relation to such case; and

"(III) does not otherwise have a conflict of interest with such a party.

"(ii) EXCEPTION FOR REASONABLE COMPENSATION.—Nothing in clause (i) shall be construed to prohibit receipt by a qualified independent contractor of compensation from the Secretary for the conduct of activities under this section if the compensation is provided consistent with clause (iii).

"(iii) LIMITATIONS ON ENTITY COMPENSATION.—Compensation provided by the Secretary to a qualified independent contractor in connection with reviews under this section shall not be contingent on any decision rendered by the contractor or by any reviewing professional.".

(2) ELIGIBILITY REQUIREMENTS FOR REVIEWERS.—Section 1869 (42 U.S.C. 1395ff), as amended by BIPA, is amended—

(A) by amending subsection (c)(3)(D) to read as follows:

"(D) QUALIFICATIONS FOR REVIEWERS.—The requirements of subsection (g) shall be met (relating to qualifications of reviewing professionals)."; and

(B) by adding at the end the following new subsection:

"(g) QUALIFICATIONS OF REVIEWERS.—

"(1) IN GENERAL.—In reviewing determinations under this section, a qualified independent contractor shall assure that—

"(A) each individual conducting a review shall meet the qualifications of paragraph (2);

"(B) compensation provided by the contractor to each such reviewer is consistent with paragraph (3); and

"(C) in the case of a review by a panel described in subsection (c)(3)(B) composed of physicians or other health care professionals (each in this subsection referred to as a 'reviewing professional'), a reviewing professional meets the qualifications described in paragraph (4) and, where a claim is regarding the furnishing of treatment by a physician (allopathic or osteopathic) or the provision of items or services by a physician (allopathic or osteopathic), a reviewing professional shall be a physician (allopathic or osteopathic).

"(2) INDEPENDENCE.—

"(A) IN GENERAL.—Subject to subparagraph (B), each individual conducting a review in a case shall—

"(i) not be a related party (as defined in paragraph (5));

"(ii) not have a material familial, financial, or professional relationship with such a party in the case under review; and

"(iii) not otherwise have a conflict of interest with such a party.

"(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

"(i) prohibit an individual, solely on the basis of a participation agreement with a fiscal intermediary, carrier, or other contractor, from serving as a reviewing professional if—

"(I) the individual is not involved in the provision of items or services in the case under review;

"(II) the fact of such an agreement is disclosed to the Secretary and the individual entitled to benefits under part A or enrolled under part B, or both, (or authorized representative) and neither party objects; and

"(III) the individual is not an employee of the intermediary, carrier, or contractor and does not provide services exclusively or primarily to or on behalf of such intermediary, carrier, or contractor;

"(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as a reviewer merely on the basis of having such staff privileges if the existence of such privileges is disclosed to the Secretary and such individual (or authorized representative), and neither party objects; or

"(iii) prohibit receipt of compensation by a reviewing professional from a contractor if the compensation is provided consistent with paragraph (3).

For purposes of this paragraph, the term 'participation agreement' means an agreement relating to the provision of health care services by the individual and does not include the provision of services as a reviewer under this subsection.

"(3) LIMITATIONS ON REVIEWER COMPENSATION.—Compensation provided by a qualified independent contractor to a reviewer in connection with a review under this section shall not be contingent on the decision rendered by the reviewer.

"(4) LICENSURE AND EXPERTISE.—Each reviewing professional shall be—

"(A) a physician (allopathic or osteopathic) who is appropriately credentialed or licensed in one or more States to deliver health care services and has medical expertise in the field of practice that is appropriate for the items or services at issue; or

"(B) a health care professional who is legally authorized in one or more States (in accordance with State law or the State regulatory mechanism provided by State law) to furnish the health care items or services at issue and has medical expertise in the field of practice that is appropriate for such items or services.

"(5) RELATED PARTY DEFINED.—For purposes of this section, the term 'related party' means, with respect to a case under this title involving a specific individual entitled to benefits under part A or enrolled under part B, or both, any of the following:

"(A) The Secretary, the medicare administrative contractor involved, or any fiduciary, officer, director, or employee of the Department of Health and Human Services, or of such contractor.

"(B) The individual (or authorized representative).

"(C) The health care professional that provides the items or services involved in the case.

"(D) The institution at which the items or services (or treatment) involved in the case are provided.

"(E) The manufacturer of any drug or other item that is included in the items or services involved in the case.

"(F) Any other party determined under any regulations to have a substantial interest in the case involved.".

(3) REDUCING MINIMUM NUMBER OF QUALIFIED INDEPENDENT CONTRACTORS.—Section 1869(c)(4) (42 U.S.C. 1395ff(c)(4)) is amended by striking "not fewer than 12 qualified independent contractors under this subsection" and inserting "with a sufficient number of qualified independent contractors (but not fewer than 4 such contractors) to conduct reconsiderations consistent with the timeframes applicable under this subsection".

(4) EFFECTIVE DATE.—The amendments made by paragraphs (1) and (2) shall be effective as if included in the enactment of the respective provisions of subtitle C of title V of BIPA, (114 Stat. 2763A–534).

(5) TRANSITION.—In applying section 1869(g) of the Social Security Act (as added by paragraph (2)), any reference to a medicare administrative contractor shall be deemed to include a reference to a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and a carrier under section 1842 of such Act (42 U.S.C. 1395u).

SEC. 934. PREPAYMENT REVIEW.

(a) IN GENERAL.—Section 1874A, as added by section 911(a)(1) and as amended by sections 912(b), 921(b)(1), and 921(c)(1), is further amended by adding at the end the following new subsection:

"(h) CONDUCT OF PREPAYMENT REVIEW.—

"(1) CONDUCT OF RANDOM PREPAYMENT REVIEW.—

"(A) IN GENERAL.—A medicare administrative contractor may conduct random prepayment review only to develop a contractor-wide or program-wide claims payment error rates or under such additional circumstances as may be provided under regulations, developed in consultation with providers of services and suppliers.

"(B) USE OF STANDARD PROTOCOLS WHEN CONDUCTING PREPAYMENT REVIEWS.—When a medicare administrative contractor conducts a random prepayment review, the contractor may conduct such review only in accordance with a standard protocol for random prepayment audits developed by the Secretary.

"(C) CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing the denial of payments for claims actually reviewed under a random prepayment review.

"(D) RANDOM PREPAYMENT REVIEW.—For purposes of this subsection, the term 'random prepayment review' means a demand for the production of records or documentation absent cause with respect to a claim.

"(2) LIMITATIONS ON NON-RANDOM PREPAYMENT REVIEW.—

"(A) LIMITATIONS ON INITIATION OF NON-RANDOM PREPAYMENT REVIEW.—A medicare administrative contractor may not initiate non-random prepayment review of a provider of services or supplier based on the initial identification by that provider of services or supplier of an improper billing practice unless there is a likelihood of sustained or high level of payment error (as defined in subsection (i)(3)(A)).

"(B) TERMINATION OF NON-RANDOM PREPAYMENT REVIEW.—The Secretary shall issue regulations relating to the termination, including termination dates, of non-random prepayment review. Such regulations may vary such a termination date based upon the differences in the circumstances triggering prepayment review.".

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in this subsection, the amendment made by subsection (a) shall take effect 1 year after the date of the enactment of this Act.

(2) DEADLINE FOR PROMULGATION OF CERTAIN REGULATIONS.—The Secretary shall first issue regulations under section 1874A(h) of the Social Security Act, as added by subsection (a), by not later than 1 year after the date of the enactment of this Act.

(3) APPLICATION OF STANDARD PROTOCOLS FOR RANDOM PREPAYMENT REVIEW.—Section 1874A(h)(1)(B) of the Social Security Act, as added by subsection (a), shall apply to random prepayment reviews conducted on or after such date (not later than 1 year after the date of the enactment of this Act) as the Secretary shall specify.

(c) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(h) of the Social Security Act, as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

SEC. 935. RECOVERY OF OVERPAYMENTS.

(a) IN GENERAL.—Section 1893 (42 U.S.C. 1395ddd) is amended by adding at the end the following new subsection:

"(f) RECOVERY OF OVERPAYMENTS.—

"(1) USE OF REPAYMENT PLANS.—

"(A) IN GENERAL.—If the repayment, within 30 days by a provider of services or supplier, of an overpayment under this title would constitute a hardship (as defined in subparagraph (B)), subject to subparagraph (C), upon request of the provider of services or supplier the Secretary shall enter into a plan with the provider of services or supplier for the repayment (through offset or otherwise) of such overpayment over a period of at least 6 months but not longer than 3 years (or not longer than 5 years in the case of extreme hardship, as determined by the Secretary). Interest shall accrue on the balance through the period of repayment. Such plan shall meet terms and conditions determined to be appropriate by the Secretary.

"(B) HARDSHIP.—

"(i) IN GENERAL.—For purposes of subparagraph (A), the repayment of an overpayment (or overpayments) within 30 days is deemed to constitute a hardship if—

"(I) in the case of a provider of services that files cost reports, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services for the cost reporting period covered by the most recently submitted cost report; or

"(II) in the case of another provider of services or supplier, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services or supplier for the previous calendar year.

"(ii) RULE OF APPLICATION.—The Secretary shall establish rules for the application of this subparagraph in the case of a provider of services or supplier that was not paid under this title during the previous year or was paid under this title only during a portion of that year.

"(iii) TREATMENT OF PREVIOUS OVERPAYMENTS.—If a provider of services or supplier has entered into a repayment plan under subparagraph (A) with respect to a specific overpayment amount, such payment amount under the repayment plan shall not be taken into account under clause (i) with respect to subsequent overpayment amounts.

"(C) EXCEPTIONS.—Subparagraph (A) shall not apply if—

"(i) the Secretary has reason to suspect that the provider of services or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in the program under this title; or

"(ii) there is an indication of fraud or abuse committed against the program.

"(D) IMMEDIATE COLLECTION IF VIOLATION OF REPAYMENT PLAN.—If a provider of services or supplier fails to make a payment in accordance with a repayment plan under this paragraph, the Secretary may immediately seek to offset or otherwise recover the total balance outstanding (including applicable interest) under the repayment plan.

"(E) RELATION TO NO FAULT PROVISION.—Nothing in this paragraph shall be construed as affecting the application of section 1870(c) (relating to no adjustment in the cases of certain overpayments).

"(2) LIMITATION ON RECOUPMENT.—

"(A) IN GENERAL.—In the case of a provider of services or supplier that is determined to have received an overpayment under this title and that seeks a reconsideration by a qualified independent contractor on such determination under section 1869(b)(1), the Secretary may not take any action (or authorize any other person, including any medicare contractor, as de-

fined in subparagraph (C)) to recoup the overpayment until the date the decision on the reconsideration has been rendered. If the provisions of section 1869(b)(1) (providing for such a reconsideration by a qualified independent contractor) are not in effect, in applying the previous sentence any reference to such a reconsideration shall be treated as a reference to a redetermination by the fiscal intermediary or carrier involved.

"(B) COLLECTION WITH INTEREST.—Insofar as the determination on such appeal is against the provider of services or supplier, interest on the overpayment shall accrue on and after the date of the original notice of overpayment. Insofar as such determination against the provider of services or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest at the same rate as would apply under the previous sentence for the period in which the amount was recouped.

"(C) MEDICARE CONTRACTOR DEFINED.—For purposes of this subsection, the term 'medicare contractor' has the meaning given such term in section 1889(g).

"(3) LIMITATION ON USE OF EXTRAPOLATION.—A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless—

"(A) there is a sustained or high level of payment error (as defined by the Secretary by regulation); or

"(B) documented educational intervention has failed to correct the payment error (as determined by the Secretary).

"(4) PROVISION OF SUPPORTING DOCUMENTATION.—In the case of a provider of services or supplier with respect to which amounts were previously overpaid, a medicare contractor may request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing.

"(5) CONSENT SETTLEMENT REFORMS.—

"(A) IN GENERAL.—The Secretary may use a consent settlement (as defined in subparagraph (D)) to settle a projected overpayment.

"(B) OPPORTUNITY TO SUBMIT ADDITIONAL INFORMATION BEFORE CONSENT SETTLEMENT OFFER.—Before offering a provider of services or supplier a consent settlement, the Secretary shall—

"(i) communicate to the provider of services or supplier—

"(I) that, based on a review of the medical records requested by the Secretary, a preliminary evaluation of those records indicates that there would be an overpayment;

"(II) the nature of the problems identified in such evaluation; and

"(III) the steps that the provider of services or supplier should take to address the problems; and

"(ii) provide for a 45-day period during which the provider of services or supplier may furnish additional information concerning the medical records for the claims that had been reviewed.

"(C) CONSENT SETTLEMENT OFFER.—The Secretary shall review any additional information furnished by the provider of services or supplier under subparagraph (B)(ii). Taking into consideration such information, the Secretary shall determine if there still appears to be an overpayment. If so, the Secretary—

"(i) shall provide notice of such determination to the provider of services or supplier, including an explanation of the reason for such determination; and

"(ii) in order to resolve the overpayment, may offer the provider of services or supplier—

"(I) the opportunity for a statistically valid random sample; or

"(II) a consent settlement.

The opportunity provided under clause (ii)(I) does not waive any appeal rights with respect to the alleged overpayment involved.

"(D) CONSENT SETTLEMENT DEFINED.—For purposes of this paragraph, the term 'consent settlement' means an agreement between the Secretary and a provider of services or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services or supplier agrees not to appeal the claims involved.

"(6) NOTICE OF OVER-UTILIZATION OF CODES.—The Secretary shall establish, in consultation with organizations representing the classes of providers of services and suppliers, a process under which the Secretary provides for notice to classes of providers of services and suppliers served by the contractor in cases in which

the contractor has identified that particular billing codes may be overutilized by that class of providers of services or suppliers under the programs under this title (or provisions of title XI insofar as they relate to such programs).

"(7) PAYMENT AUDITS.—

"(A) WRITTEN NOTICE FOR POST-PAYMENT AUDITS.—Subject to subparagraph (C), if a medicare contractor decides to conduct a post-payment audit of a provider of services or supplier under this title, the contractor shall provide the provider of services or supplier with written notice (which may be in electronic form) of the intent to conduct such an audit.

"(B) EXPLANATION OF FINDINGS FOR ALL AUDITS.—Subject to subparagraph (C), if a medicare contractor audits a provider of services or supplier under this title, the contractor shall—

"(i) give the provider of services or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider of services or supplier and permits the development of an appropriate corrective action plan;

"(ii) inform the provider of services or supplier of the appeal rights under this title as well as consent settlement options (which are at the discretion of the Secretary);

"(iii) give the provider of services or supplier an opportunity to provide additional information to the contractor; and

"(iv) take into account information provided, on a timely basis, by the provider of services or supplier under clause (iii).

"(C) EXCEPTION.—Subparagraphs (A) and (B) shall not apply if the provision of notice or findings would compromise pending law enforcement activities, whether civil or criminal, or reveal findings of law enforcement-related audits.

"(8) STANDARD METHODOLOGY FOR PROBE SAMPLING.—The Secretary shall establish a standard methodology for medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.".

(b) EFFECTIVE DATES AND DEADLINES.—

(1) USE OF REPAYMENT PLANS.—Section 1893(f)(1) of the Social Security Act, as added by subsection (a), shall apply to requests for repayment plans made after the date of the enactment of this Act.

(2) LIMITATION ON RECOUPMENT.—Section 1893(f)(2) of the Social Security Act, as added by subsection (a), shall apply to actions taken after the date of the enactment of this Act.

(3) USE OF EXTRAPOLATION.—Section 1893(f)(3) of the Social Security Act, as added by subsection (a), shall apply to statistically valid random samples initiated after the date that is 1 year after the date of the enactment of this Act.

(4) PROVISION OF SUPPORTING DOCUMENTATION.—Section 1893(f)(4) of the Social Security Act, as added by subsection (a), shall take effect on the date of the enactment of this Act.

(5) CONSENT SETTLEMENT.—Section 1893(f)(5) of the Social Security Act, as added by subsection (a), shall apply to consent settlements entered into after the date of the enactment of this Act.

(6) NOTICE OF OVERUTILIZATION.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall first establish the process for notice of overutilization of billing codes under section 1893A(f)(6) of the Social Security Act, as added by subsection (a).

(7) PAYMENT AUDITS.—Section 1893A(f)(7) of the Social Security Act, as added by subsection (a), shall apply to audits initiated after the date of the enactment of this Act.

(8) STANDARD FOR ABNORMAL BILLING PATTERNS.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall first establish a standard methodology for selection of sample claims for abnormal billing patterns under section 1893(f)(8) of the Social Security Act, as added by subsection (a).

SEC. 936. PROVIDER ENROLLMENT PROCESS; RIGHT OF APPEAL.

(a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is amended—

(1) by adding at the end of the heading the following: "; ENROLLMENT PROCESSES"; and

(2) by adding at the end the following new subsection:

"(j) ENROLLMENT PROCESS FOR PROVIDERS OF SERVICES AND SUPPLIERS.—

"(1) ENROLLMENT PROCESS.—

"(A) IN GENERAL.—The Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under this title.

"(B) DEADLINES.—The Secretary shall establish by regulation procedures under which there are deadlines for actions on applications for enrollment

(and, if applicable, renewal of enrollment). The Secretary shall monitor the performance of medicare administrative contractors in meeting the deadlines established under this subparagraph.

"(C) CONSULTATION BEFORE CHANGING PROVIDER ENROLLMENT FORMS.—The Secretary shall consult with providers of services and suppliers before making changes in the provider enrollment forms required of such providers and suppliers to be eligible to submit claims for which payment may be made under this title.

"(2) HEARING RIGHTS IN CASES OF DENIAL OR NON-RENEWAL.—A provider of services or supplier whose application to enroll (or, if applicable, to renew enrollment) under this title is denied may have a hearing and judicial review of such denial under the procedures that apply under subsection (h)(1)(A) to a provider of services that is dissatisfied with a determination by the Secretary.".

(b) EFFECTIVE DATES.—

(1) ENROLLMENT PROCESS.—The Secretary shall provide for the establishment of the enrollment process under section 1866(j)(1) of the Social Security Act, as added by subsection (a)(2), within 6 months after the date of the enactment of this Act.

(2) CONSULTATION.—Section 1866(j)(1)(C) of the Social Security Act, as added by subsection (a)(2), shall apply with respect to changes in provider enrollment forms made on or after January 1, 2004.

(3) HEARING RIGHTS.—Section 1866(j)(2) of the Social Security Act, as added by subsection (a)(2), shall apply to denials occurring on or after such date (not later than 1 year after the date of the enactment of this Act) as the Secretary specifies.

SEC. 937. PROCESS FOR CORRECTION OF MINOR ERRORS AND OMISSIONS WITHOUT PURSUING APPEALS PROCESS.

(a) CLAIMS.—The Secretary shall develop, in consultation with appropriate medicare contractors (as defined in section 1889(g) of the Social Security Act, as inserted by section 301(a)(1)) and representatives of providers of services and suppliers, a process whereby, in the case of minor errors or omissions (as defined by the Secretary) that are detected in the submission of claims under the programs under title XVIII of such Act, a provider of services or supplier is given an opportunity to correct such an error or omission without the need to initiate an appeal. Such process shall include the ability to resubmit corrected claims.

(b) PERMITTING USE OF CORRECTED AND SUPPLEMENTARY DATA.—

(1) IN GENERAL.—Section 1886(d)(10)(D)(vi) (42 U.S.C. 1395ww(d)(10)(D)(vi)) is amended by adding after subclause (II) at the end the following:

"Notwithstanding subclause (I), a hospital may submit, and the Secretary may accept upon verification, data that corrects or supplements the data described in such subclause without regard to whether the corrected or supplementary data relate to a cost report that has been settled.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to fiscal years beginning with fiscal year 2004.

(3) SUBMITTAL AND RESUBMITTAL OF APPLICATIONS PERMITTED FOR FISCAL YEAR 2004.—

(A) IN GENERAL.—Notwithstanding any other provision of law, a hospital may submit (or resubmit) an application for a change described in section 1886(d)(10)(C)(i)(II) of the Social Security Act for fiscal year 2004 if the hospital demonstrates on a timely basis to the satisfaction of the Secretary that the use of corrected or supplementary data under the amendment made by paragraph (1) would materially affect the approval of such an application.

(B) APPLICATION OF BUDGET NEUTRALITY.—If one or more hospital's applications are approved as a result of paragraph (1) and subparagraph (A) for fiscal year 2004, the Secretary shall make a proportional adjustment in the standardized amounts determined under section 1886(d)(3) of the Social Security Act (42 U.S.C. 1395ww(d)(3)) for fiscal year 2004 to assure that approval of such applications does not result in aggregate payments under section 1886(d) of such Act that are greater or less than those that would otherwise be made if paragraph (1) and subparagraph (A) did not apply.

SEC. 938. PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES; ADVANCE BENEFICIARY NOTICES.

(a) IN GENERAL.—Section 1869 (42 U.S.C. 1395ff(b)), as amended by sections 521 and 522 of BIPA and section 933(d)(2)(B), is further amended by adding at the end the following new subsection:

"(h) PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES.—

"(1) ESTABLISHMENT OF PROCESS.—

"(A) IN GENERAL.—With respect to a medicare administrative contractor that has a contract under section 1874A that provides for making payments under this title with respect to eligible items and services described in subparagraph (C), the Secretary shall establish a prior determination process that meets the requirements of this subsection and that shall be applied by such contractor in the case of eligible requesters.

"(B) ELIGIBLE REQUESTER.—For purposes of this subsection, each of the following shall be an eligible requester:

"(i) A physician, but only with respect to eligible items and services for which the physician may be paid directly.

"(ii) An individual entitled to benefits under this title, but only with respect to an item or service for which the individual receives, from the physician who may be paid directly for the item or service, an advance beneficiary notice under section 1879(a) that payment may not be made (or may no longer be made) for the item or service under this title.

"(C) ELIGIBLE ITEMS AND SERVICES.—For purposes of this subsection and subject to paragraph (2), eligible items and services are items and services which are physicians' services (as defined in paragraph (4)(A) of section 1848(f) for purposes of calculating the sustainable growth rate under such section).

"(2) SECRETARIAL FLEXIBILITY.—The Secretary shall establish by regulation reasonable limits on the categories of eligible items and services for which a prior determination of coverage may be requested under this subsection. In establishing such limits, the Secretary may consider the dollar amount involved with respect to the item or service, administrative costs and burdens, and other relevant factors.

"(3) REQUEST FOR PRIOR DETERMINATION.—

"(A) IN GENERAL.—Subject to paragraph (2), under the process established under this subsection an eligible requester may submit to the contractor a request for a determination, before the furnishing of an eligible item or service involved as to whether the item or service is covered under this title consistent with the applicable requirements of section 1862(a)(1)(A) (relating to medical necessity).

"(B) ACCOMPANYING DOCUMENTATION.—The Secretary may require that the request be accompanied by a description of the item or service, supporting documentation relating to the medical necessity for the item or service, and any other appropriate documentation. In the case of a request submitted by an eligible requester who is described in paragraph (1)(B)(ii), the Secretary may require that the request also be accompanied by a copy of the advance beneficiary notice involved.

"(4) RESPONSE TO REQUEST.—

"(A) IN GENERAL.—Under such process, the contractor shall provide the eligible requester with written notice of a determination as to whether—

"(i) the item or service is so covered;

"(ii) the item or service is not so covered; or

"(iii) the contractor lacks sufficient information to make a coverage determination.

If the contractor makes the determination described in clause (iii), the contractor shall include in the notice a description of the additional information required to make the coverage determination.

"(B) DEADLINE TO RESPOND.—Such notice shall be provided within the same time period as the time period applicable to the contractor providing notice of initial determinations on a claim for benefits under subsection (a)(2)(A).

"(C) INFORMING BENEFICIARY IN CASE OF PHYSICIAN REQUEST.—In the case of a request in which an eligible requester is not the individual described in paragraph (1)(B)(ii), the process shall provide that the individual to whom the item or service is proposed to be furnished shall be informed of any determination described in clause (ii) (relating to a determination of non-coverage) and the right (referred to in paragraph (6)(B)) to obtain the item or service and have a claim submitted for the item or service.

"(5) EFFECT OF DETERMINATIONS.—

"(A) BINDING NATURE OF POSITIVE DETERMINATION.—If the contractor makes the determination described in paragraph (4)(A)(i), such determination shall be binding on the contractor in the absence of fraud or evidence of misrepresentation of facts presented to the contractor.

"(B) NOTICE AND RIGHT TO REDETERMINATION IN CASE OF A DENIAL.—

"(i) IN GENERAL.—If the contractor makes the determination described in paragraph (4)(A)(ii)—

"(I) the eligible requester has the right to a redetermination by the contractor on the determination that the item or service is not so covered; and

"(II) the contractor shall include in notice under paragraph (4)(A) a brief explanation of the basis for the determination, including on what national or local coverage or noncoverage determination (if any) the determination is based, and the right to such a redetermination.

"(ii) DEADLINE FOR REDETERMINATIONS.—The contractor shall complete and provide notice of such redetermination within the same time period as the time period applicable to the contractor providing notice of redeterminations relating to a claim for benefits under subsection (a)(3)(C)(ii).

"(6) LIMITATION ON FURTHER REVIEW.—

"(A) IN GENERAL.—Contractor determinations described in paragraph (4)(A)(ii) or (4)(A)(iii) (and redeterminations made under paragraph (5)(B)), relating to pre-service claims are not subject to further administrative appeal or judicial review under this section or otherwise.

"(B) DECISION NOT TO SEEK PRIOR DETERMINATION OR NEGATIVE DETERMINATION DOES NOT IMPACT RIGHT TO OBTAIN SERVICES, SEEK REIMBURSEMENT, OR APPEAL RIGHTS.—Nothing in this subsection shall be construed as affecting the right of an individual who—

"(i) decides not to seek a prior determination under this subsection with respect to items or services; or

"(ii) seeks such a determination and has received a determination described in paragraph (4)(A)(ii),

from receiving (and submitting a claim for) such items services and from obtaining administrative or judicial review respecting such claim under the other applicable provisions of this section. Failure to seek a prior determination under this subsection with respect to items and services shall not be taken into account in such administrative or judicial review.

"(C) NO PRIOR DETERMINATION AFTER RECEIPT OF SERVICES.—Once an individual is provided items and services, there shall be no prior determination under this subsection with respect to such items or services.".

(b) EFFECTIVE DATE; TRANSITION.—

(1) EFFECTIVE DATE.—The Secretary shall establish the prior determination process under the amendment made by subsection (a) in such a manner as to provide for the acceptance of requests for determinations under such process filed not later than 18 months after the date of the enactment of this Act.

(2) TRANSITION.—During the period in which the amendment made by subsection (a) has become effective but contracts are not provided under section 1874A of the Social Security Act with medicare administrative contractors, any reference in section 1869(g) of such Act (as added by such amendment) to such a contractor is deemed a reference to a fiscal intermediary or carrier with an agreement under section 1816, or contract under section 1842, respectively, of such Act.

(3) LIMITATION ON APPLICATION TO SGR.—For purposes of applying section 1848(f)(2)(D) of the Social Security Act (42 U.S.C. 1395w–4(f)(2)(D)), the amendment made by subsection (a) shall not be considered to be a change in law or regulation.

(c) PROVISIONS RELATING TO ADVANCE BENEFICIARY NOTICES; REPORT ON PRIOR DETERMINATION PROCESS.—

(1) DATA COLLECTION.—The Secretary shall establish a process for the collection of information on the instances in which an advance beneficiary notice (as defined in paragraph (5)) has been provided and on instances in which a beneficiary indicates on such a notice that the beneficiary does not intend to seek to have the item or service that is the subject of the notice furnished.

(2) OUTREACH AND EDUCATION.—The Secretary shall establish a program of outreach and education for beneficiaries and providers of services and other persons on the appropriate use of advance beneficiary notices and coverage policies under the medicare program.

(3) GAO REPORT REPORT ON USE OF ADVANCE BENEFICIARY NOTICES.—Not later than 18 months after the date on which section 1869(g) of the Social Security Act (as added by subsection (a)) takes effect, the Comptroller General of the United States shall submit to Congress a report on the use of advance beneficiary notices under title XVIII of such Act. Such report shall include information concerning the providers of services and other persons that have provided such notices and the response of beneficiaries to such notices.

(4) GAO REPORT ON USE OF PRIOR DETERMINATION PROCESS.—Not later than 18 months after the date on which section 1869(g) of the Social Security Act (as added by subsection (a)) takes effect, the Comptroller General of the United States shall submit to Congress a report on the use of the prior determination process under such section. Such report shall include—

(A) information concerning the types of procedures for which a prior determination has been sought, determinations made under the process, and changes in receipt of services resulting from the application of such process; and

(B) an evaluation of whether the process was useful for physicians (and other suppliers) and beneficiaries, whether it was timely, and whether the amount of information required was burdensome to physicians and beneficiaries.

(5) ADVANCE BENEFICIARY NOTICE DEFINED.—In this subsection, the term "advance beneficiary notice" means a written notice provided under section 1879(a) of the Social Security Act (42 U.S.C. 1395pp(a)) to an individual entitled to benefits under part A or B of title XVIII of such Act before items or services are furnished under such part in cases where a provider of services or other person that would furnish the item or service believes that payment will not be made for some or all of such items or services under such title.

Subtitle V—Miscellaneous Provisions

SEC. 941. POLICY DEVELOPMENT REGARDING EVALUATION AND MANAGEMENT (E & M) DOCUMENTATION GUIDELINES.

(a) IN GENERAL.—The Secretary may not implement any new documentation guidelines for, or clinical examples of, evaluation and management physician services under the title XVIII of the Social Security Act on or after the date of the enactment of this Act unless the Secretary—

(1) has developed the guidelines in collaboration with practicing physicians (including both generalists and specialists) and provided for an assessment of the proposed guidelines by the physician community;

(2) has established a plan that contains specific goals, including a schedule, for improving the use of such guidelines;

(3) has conducted appropriate and representative pilot projects under subsection (b) to test modifications to the evaluation and management documentation guidelines;

(4) finds that the objectives described in subsection (c) will be met in the implementation of such guidelines; and

(5) has established, and is implementing, a program to educate physicians on the use of such guidelines and that includes appropriate outreach.

The Secretary shall make changes to the manner in which existing evaluation and management documentation guidelines are implemented to reduce paperwork burdens on physicians.

(b) PILOT PROJECTS TO TEST EVALUATION AND MANAGEMENT DOCUMENTATION GUIDELINES.—

(1) IN GENERAL.—The Secretary shall conduct under this subsection appropriate and representative pilot projects to test new evaluation and management documentation guidelines referred to in subsection (a).

(2) LENGTH AND CONSULTATION.—Each pilot project under this subsection shall—

(A) be voluntary;

(B) be of sufficient length as determined by the Secretary to allow for preparatory physician and medicare contractor education, analysis, and use and assessment of potential evaluation and management guidelines; and

(C) be conducted, in development and throughout the planning and operational stages of the project, in consultation with practicing physicians (including both generalists and specialists).

(3) RANGE OF PILOT PROJECTS.—Of the pilot projects conducted under this subsection—

(A) at least one shall focus on a peer review method by physicians (not employed by a medicare contractor) which evaluates medical record information for claims submitted by physicians identified as statistical outliers relative to definitions published in the Current Procedures Terminology (CPT) code book of the American Medical Association;

(B) at least one shall focus on an alternative method to detailed guidelines based on physician documentation of face to face encounter time with a patient;

(C) at least one shall be conducted for services furnished in a rural area and at least one for services furnished outside such an area; and

(D) at least one shall be conducted in a setting where physicians bill under physicians' services in teaching settings and at least one shall be conducted in a setting other than a teaching setting.

(4) BANNING OF TARGETING OF PILOT PROJECT PARTICIPANTS.—Data collected under this subsection shall not be used as the basis for overpayment demands or post-payment audits. Such limitation applies only to claims filed as part of the pilot project and lasts only for the duration of the pilot project and only as long as the provider is a participant in the pilot project.

(5) STUDY OF IMPACT.—Each pilot project shall examine the effect of the new evaluation and management documentation guidelines on—

(A) different types of physician practices, including those with fewer than 10 full-time-equivalent employees (including physicians); and

(B) the costs of physician compliance, including education, implementation, auditing, and monitoring.

(6) PERIODIC REPORTS.—The Secretary shall submit to Congress periodic reports on the pilot projects under this subsection.

(c) OBJECTIVES FOR EVALUATION AND MANAGEMENT GUIDELINES.—The objectives for modified evaluation and management documentation guidelines developed by the Secretary shall be to—

(1) identify clinically relevant documentation needed to code accurately and assess coding levels accurately;

(2) decrease the level of non-clinically pertinent and burdensome documentation time and content in the physician's medical record;

(3) increase accuracy by reviewers; and

(4) educate both physicians and reviewers.

(d) STUDY OF SIMPLER, ALTERNATIVE SYSTEMS OF DOCUMENTATION FOR PHYSICIAN CLAIMS.—

(1) STUDY.—The Secretary shall carry out a study of the matters described in paragraph (2).

(2) MATTERS DESCRIBED.—The matters referred to in paragraph (1) are—

(A) the development of a simpler, alternative system of requirements for documentation accompanying claims for evaluation and management physician services for which payment is made under title XVIII of the Social Security Act; and

(B) consideration of systems other than current coding and documentation requirements for payment for such physician services.

(3) CONSULTATION WITH PRACTICING PHYSICIANS.—In designing and carrying out the study under paragraph (1), the Secretary shall consult with practicing physicians, including physicians who are part of group practices and including both generalists and specialists.

(4) APPLICATION OF HIPAA UNIFORM CODING REQUIREMENTS.—In developing an alternative system under paragraph (2), the Secretary shall consider requirements of administrative simplification under part C of title XI of the Social Security Act.

(5) REPORT TO CONGRESS.—(A) Not later than October 1, 2005, the Secretary shall submit to Congress a report on the results of the study conducted under paragraph (1).

(B) The Medicare Payment Advisory Commission shall conduct an analysis of the results of the study included in the report under subparagraph (A) and shall submit a report on such analysis to Congress.

(e) STUDY ON APPROPRIATE CODING OF CERTAIN EXTENDED OFFICE VISITS.—The Secretary shall conduct a study of the appropriateness of coding in cases of extended office visits in which there is no diagnosis made. Not later than October 1, 2005, the Secretary shall submit a report to Congress on such study and shall include recommendations on how to code appropriately for such visits in a manner that takes into account the amount of time the physician spent with the patient.

(f) DEFINITIONS.—In this section—

(1) the term "rural area" has the meaning given that term in section 1886(d)(2)(D) of the Social Security Act, 42 U.S.C. 1395ww(d)(2)(D); and

(2) the term "teaching settings" are those settings described in section 415.150 of title 42, Code of Federal Regulations.

SEC. 942. IMPROVEMENT IN OVERSIGHT OF TECHNOLOGY AND COVERAGE.

(a) COUNCIL FOR TECHNOLOGY AND INNOVATION.—Section 1868 (42 U.S.C. 1395ee), as amended by section 921(a), is amended by adding at the end the following new subsection:

"(c) COUNCIL FOR TECHNOLOGY AND INNOVATION.—

"(1) ESTABLISHMENT.—The Secretary shall establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services (in this section referred to as 'CMS').

"(2) COMPOSITION.—The Council shall be composed of senior CMS staff and clinicians and shall be chaired by the Executive Coordinator for Technology and Innovation (appointed or designated under paragraph (4)).

"(3) DUTIES.—The Council shall coordinate the activities of coverage, coding, and payment processes under this title with respect to new technologies and procedures, including new drug therapies, and shall coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

"(4) EXECUTIVE COORDINATOR FOR TECHNOLOGY AND INNOVATION.—The Secretary shall appoint (or designate) a noncareer appointee (as defined in section 3132(a)(7) of title 5, United States Code) who shall serve as the Executive Coordinator for Technology and Innovation. Such executive coordinator shall report to the Administrator of CMS, shall chair the Council, shall oversee the execution of its duties, and shall serve as a single point of contact for outside groups and entities regarding the coverage, coding, and payment processes under this title.".

(b) METHODS FOR DETERMINING PAYMENT BASIS FOR NEW LAB TESTS.—Section 1833(h) (42 U.S.C. 1395l(h)) is amended by adding at the end the following:

"(8)(A) The Secretary shall establish by regulation procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005 (in this paragraph referred to as 'new tests').

"(B) Determinations under subparagraph (A) shall be made only after the Secretary—

"(i) makes available to the public (through an Internet site and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount under this subsection is being considered for a year;

"(ii) on the same day such list is made available, causes to have published in the Federal Register notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis under this subsection for establishing payment amounts for the tests on such list;

"(iii) not less than 30 days after publication of such notice convenes a meeting, that includes representatives of officials of the Centers for Medicare & Medicaid Services involved in determining payment amounts, to receive such comments and recommendations (and data on which the recommendations are based);

"(iv) taking into account the comments and recommendations (and accompanying data) received at such meeting, develops and makes available to the public (through an Internet site and other appropriate mechanisms) a list of proposed determinations with respect to the appropriate basis for establishing a payment amount under this subsection for each such code, together with an explanation of the reasons for each such determination, the data on which the determinations are based, and a request for public written comments on the proposed determination; and

"(v) taking into account the comments received during the public comment period, develops and makes available to the public (through an Internet site and other appropriate mechanisms) a list of final determinations of the payment amounts for such tests under this subsection, together with the rationale for each such determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

"(C) Under the procedures established pursuant to subparagraph (A), the Secretary shall—

"(i) set forth the criteria for making determinations under subparagraph (A); and

"(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

"(D) The Secretary may convene such further public meetings to receive public comments on payment amounts for new tests under this subsection as the Secretary deems appropriate.

"(E) For purposes of this paragraph:

"(i) The term 'HCPCS' refers to the Health Care Procedure Coding System.

"(ii) A code shall be considered to be 'substantially revised' if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test).".

(c) GAO STUDY ON IMPROVEMENTS IN EXTERNAL DATA COLLECTION FOR USE IN THE MEDICARE INPATIENT PAYMENT SYSTEM.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study that analyzes which external data can be collected in a shorter time frame by the Centers for Medicare & Medicaid Services for use in computing payments for inpatient hospital services. The study may include an evaluation of the feasibility and appropriateness of using of quarterly samples or special surveys or any other methods. The study shall include an analysis of whether other executive agencies, such as the Bureau of Labor Statistics in the Department of Commerce, are best suited to collect this information.

(2) REPORT.—By not later than October 1, 2004, the Comptroller General shall submit a report to Congress on the study under paragraph (1).

(d) PROCESS FOR ADOPTION OF ICD CODES AS DATA STANDARD.—Section 1172(f) (42 U.S.C. 1320d–1(f)) is amended by inserting after the first sentence the following: "Notwithstanding the preceding sentence, if the National Committee on Vital and Health Statistics has not made a recommendation to the Secretary before the date of the enactment of this sentence, with respect to the adoption of the International Classification of Diseases, 10th Revision, Procedure Coding System ('ICD–10–PCS') and the International Classification of Diseases, 10th Revision, Clinical Modification ('ICD–10–CM') as a standard under this part for the reporting of diagnoses, the Secretary may adopt ICD–10–PCS and ICD–10–CM as such a standard on or after 1 year after such date without receiving such a recommendation.".

SEC. 943. TREATMENT OF HOSPITALS FOR CERTAIN SERVICES UNDER MEDICARE SECONDARY PAYOR (MSP) PROVISIONS.

(a) IN GENERAL.—The Secretary shall not require a hospital (including a critical access hospital) to ask questions (or obtain information) relating to the application of section 1862(b) of the Social Security Act (relating to medicare secondary payor provisions) in the case of reference laboratory services described in subsection (b), if the Secretary does not impose such requirement in the case of such services furnished by an independent laboratory.

(b) REFERENCE LABORATORY SERVICES DESCRIBED.—Reference laboratory services described in this subsection are clinical laboratory diagnostic tests (or the interpretation of such tests, or both) furnished without a face-to-face encounter between the individual entitled to benefits under part A or enrolled under part B, or both, and the hospital involved and in which the hospital submits a claim only for such test or interpretation.

SEC. 944. EMTALA IMPROVEMENTS.

(a) PAYMENT FOR EMTALA-MANDATED SCREENING AND STABILIZATION SERVICES.—

(1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended by inserting after subsection (c) the following new subsection:

"(d) For purposes of subsection (a)(1)(A), in the case of any item or service that is required to be provided pursuant to section 1867 to an individual who is entitled to benefits under this title, determinations as to whether the item or service is reasonable and necessary shall be made on the basis of the information available to the treating physician or practitioner (including the patient's presenting symptoms or complaint) at the time the item or service was ordered or furnished by the physician or practitioner (and not on the patient's principal diagnosis). When making such determinations with respect to such an item or service, the Secretary shall not consider the frequency with which the item or service was provided to the patient before or after the time of the admission or visit.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to items and services furnished on or after January 1, 2004.

(b) NOTIFICATION OF PROVIDERS WHEN EMTALA INVESTIGATION CLOSED.—Section 1867(d) (42 U.S.C. 42 U.S.C. 1395dd(d)) is amended by adding at the end the following new paragraph:

"(4) NOTICE UPON CLOSING AN INVESTIGATION.—The Secretary shall establish a procedure to notify hospitals and physicians when an investigation under this section is closed.".

(c) PRIOR REVIEW BY PEER REVIEW ORGANIZATIONS IN EMTALA CASES INVOLVING TERMINATION OF PARTICIPATION.—

(1) IN GENERAL.—Section 1867(d)(3) (42 U.S.C. 1395dd(d)(3)) is amended—

(A) in the first sentence, by inserting "or in terminating a hospital's participation under this title" after "in imposing sanctions under paragraph (1)"; and

(B) by adding at the end the following new sentences: "Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall also request such a review before making a compliance de-

termination as part of the process of terminating a hospital's participation under this title for violations related to the appropriateness of a medical screening examination, stabilizing treatment, or an appropriate transfer as required by this section, and shall provide a period of 5 days for such review. The Secretary shall provide a copy of the organization's report to the hospital or physician consistent with confidentiality requirements imposed on the organization under such part B.".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to terminations of participation initiated on or after the date of the enactment of this Act.

(d) MODIFICATION OF REQUIRMENT FOR MEDICAL SCREENING EXAMINATIONS FOR PATIENTS NOT REQUESTING EMERGENCY DEPARTMENT SERVICES.—

(1) IN GENERAL.—Section 1867(a) (42 U.S.C. 1395dd(a)) is amended—

(A) by designating all that follows "(a) MEDICAL SCREENING REQUIREMENT.—" as paragraph (1) with the heading "IN GENERAL.—";

(B) by aligning such paragraph with the paragraph added by paragraph (3); and

(C) by adding at the end the following new paragraph:

"(2) EXCEPTION FOR CERTAIN CASES.—The requirement for an appropriate medical screening examination under paragraph (1) shall not apply in the case of an individual who comes to the emergency department and does not request examination or treatment for an emergency medical condition (such as a request solely for prescription refills, blood pressure screening, and non-emergency laboratory and diagnostic tests).".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to terminations of participation initiated on or after the date of the enactment of this Act.

SEC. 945. EMERGENCY MEDICAL TREATMENT AND ACTIVE LABOR ACT (EMTALA) TECHNICAL ADVISORY GROUP.

(a) ESTABLISHMENT.—The Secretary shall establish a Technical Advisory Group (in this section referred to as the "Advisory Group") to review issues related to the Emergency Medical Treatment and Labor Act (EMTALA) and its implementation. In this section, the term "EMTALA" refers to the provisions of section 1867 of the Social Security Act (42 U.S.C. 1395dd).

(b) MEMBERSHIP.—The Advisory Group shall be composed of 19 members, including the Administrator of the Centers for Medicare & Medicaid Services and the Inspector General of the Department of Health and Human Services and of which—

(1) 4 shall be representatives of hospitals, including at least one public hospital, that have experience with the application of EMTALA and at least 2 of which have not been cited for EMTALA violations;

(2) 7 shall be practicing physicians drawn from the fields of emergency medicine, cardiology or cardiothoracic surgery, orthopedic surgery, neurosurgery, pediatrics or a pediatric subspecialty, obstetrics-gynecology, and psychiatry, with not more than one physician from any particular field;

(3) 2 shall represent patients;

(4) 2 shall be staff involved in EMTALA investigations from different regional offices of the Centers for Medicare & Medicaid Services; and

(5) 1 shall be from a State survey office involved in EMTALA investigations and 1 shall be from a peer review organization, both of whom shall be from areas other than the regions represented under paragraph (4).

In selecting members described in paragraphs (1) through (3), the Secretary shall consider qualified individuals nominated by organizations representing providers and patients.

(c) GENERAL RESPONSIBILITIES.—The Advisory Group—

(1) shall review EMTALA regulations;

(2) may provide advice and recommendations to the Secretary with respect to those regulations and their application to hospitals and physicians;

(3) shall solicit comments and recommendations from hospitals, physicians, and the public regarding the implementation of such regulations; and

(4) may disseminate information on the application of such regulations to hospitals, physicians, and the public.

(d) ADMINISTRATIVE MATTERS.—

(1) CHAIRPERSON.—The members of the Advisory Group shall elect a member to serve as chairperson of the Advisory Group for the life of the Advisory Group.

(2) MEETINGS.—The Advisory Group shall first meet at the direction of the Secretary. The Advisory Group shall then meet twice per year and at such other times as the Advisory Group may provide.

(e) TERMINATION.—The Advisory Group shall terminate 30 months after the date of its first meeting.

(f) WAIVER OF ADMINISTRATIVE LIMITATION.—The Secretary shall establish the Advisory Group notwithstanding any limitation that may apply to the number of advisory committees that may be established (within the Department of Health and Human Services or otherwise).

SEC. 946. AUTHORIZING USE OF ARRANGEMENTS TO PROVIDE CORE HOSPICE SERVICES IN CERTAIN CIRCUMSTANCES.

(a) IN GENERAL.—Section 1861(dd)(5) (42 U.S.C. 1395x(dd)(5)) is amended by adding at the end the following:

"(D) In extraordinary, exigent, or other non-routine circumstances, such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program's service area, a hospice program may enter into arrangements with another hospice program for the provision by that other program of services described in paragraph (2)(A)(ii)(I). The provisions of paragraph (2)(A)(ii)(II) shall apply with respect to the services provided under such arrangements.

"(E) A hospice program may provide services described in paragraph (1)(A) other than directly by the program if the services are highly specialized services of a registered professional nurse and are provided non-routinely and so infrequently so that the provision of such services directly would be impracticable and prohibitively expensive.".

(b) CONFORMING PAYMENT PROVISION.—Section 1814(i) (42 U.S.C. 1395f(i)) is amended by adding at the end the following new paragraph:

"(4) In the case of hospice care provided by a hospice program under arrangements under section 1861(dd)(5)(D) made by another hospice program, the hospice program that made the arrangements shall bill and be paid for the hospice care.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to hospice care provided on or after the date of the enactment of this Act.

SEC. 947. APPLICATION OF OSHA BLOODBORNE PATHOGENS STANDARD TO CERTAIN HOSPITALS.

(a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is amended—

(1) in subsection (a)(1)—

(A) in subparagraph (R), by striking "and" at the end;

(B) in subparagraph (S), by striking the period at the end and inserting ", and"; and

(C) by inserting after subparagraph (S) the following new subparagraph:

"(T) in the case of hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970, to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations (or as subsequently redesignated).."; and

(2) by adding at the end of subsection (b) the following new paragraph:

"(4)(A) A hospital that fails to comply with the requirement of subsection (a)(1)(T) (relating to the Bloodborne Pathogens standard) is subject to a civil money penalty in an amount described in subparagraph (B), but is not subject to termination of an agreement under this section.

"(B) The amount referred to in subparagraph (A) is an amount that is similar to the amount of civil penalties that may be imposed under section 17 of the Occupational Safety and Health Act of 1970 for a violation of the Bloodborne Pathogens standard referred to in subsection (a)(1)(T) by a hospital that is subject to the provisions of such Act.

"(C) A civil money penalty under this paragraph shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.".

(b) EFFECTIVE DATE.—The amendments made by this subsection (a) shall apply to hospitals as of July 1, 2004.

SEC. 948. BIPA-RELATED TECHNICAL AMENDMENTS AND CORRECTIONS.

(a) TECHNICAL AMENDMENTS RELATING TO ADVISORY COMMITTEE UNDER BIPA SECTION 522.—(1) Subsection (i) of section 1114 (42 U.S.C. 1314)—

(A) is transferred to section 1862 and added at the end of such section; and

(B) is redesignated as subsection (j).

(2) Section 1862 (42 U.S.C. 1395y) is amended—

(A) in the last sentence of subsection (a), by striking "established under section 1114(f)"; and

(B) in subsection (j), as so transferred and redesignated—

(i) by striking "under subsection (f)"; and

(ii) by striking "section 1862(a)(1)" and inserting "subsection (a)(1)".

(b) TERMINOLOGY CORRECTIONS.—(1) Section 1869(c)(3)(I)(ii) (42 U.S.C. 1395ff(c)(3)(I)(ii)), as amended by section 521 of BIPA, is amended—

(A) in subclause (III), by striking "policy" and inserting "determination"; and

(B) in subclause (IV), by striking "medical review policies" and inserting "coverage determinations".

(2) Section 1852(a)(2)(C) (42 U.S.C. 1395w–22(a)(2)(C)) is amended by striking "policy" and "POLICY" and inserting "determination" each place it appears and "DETERMINATION", respectively.

(c) REFERENCE CORRECTIONS.—Section 1869(f)(4) (42 U.S.C. 1395ff(f)(4)), as added by section 522 of BIPA, is amended—

(1) in subparagraph (A)(iv), by striking "subclause (I), (II), or (III)" and inserting "clause (i), (ii), or (iii)";

(2) in subparagraph (B), by striking "clause (i)(IV)" and "clause (i)(III)" and inserting "subparagraph (A)(iv)" and "subparagraph (A)(iii)", respectively; and

(3) in subparagraph (C), by striking "clause (i)", "subclause (IV)" and "subparagraph (A)" and inserting "subparagraph (A)", "clause (iv)" and "paragraph (1)(A)", respectively each place it appears.

(d) OTHER CORRECTIONS.—Effective as if included in the enactment of section 521(c) of BIPA, section 1154(e) (42 U.S.C. 1320c–3(e)) is amended by striking paragraph (5).

(e) EFFECTIVE DATE.—Except as otherwise provided, the amendments made by this section shall be effective as if included in the enactment of BIPA.

SEC. 949. CONFORMING AUTHORITY TO WAIVE A PROGRAM EXCLUSION.

The first sentence of section 1128(c)(3)(B) (42 U.S.C. 1320a–7(c)(3)(B)) is amended to read as follows: "Subject to subparagraph (G), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be not less than five years, except that, upon the request of the administrator of a Federal health care program (as defined in section 1128B(f)) who determines that the exclusion would impose a hardship on individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, or both, the Secretary may waive the exclusion under subsection (a)(1), (a)(3), or (a)(4) with respect to that program in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community.".

SEC. 950. TREATMENT OF CERTAIN DENTAL CLAIMS.

(a) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended by adding after subsection (g) the following new subsection:

"(h)(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v)) providing supplemental or secondary coverage to individuals also entitled to services under this title shall not require a medicare claims determination under this title for dental benefits specifically excluded under subsection (a)(12) as a condition of making a claims determination for such benefits under the group health plan.

"(2) A group health plan may require a claims determination under this title in cases involving or appearing to involve inpatient dental hospital services or dental services expressly covered under this title pursuant to actions taken by the Secretary.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date that is 60 days after the date of the enactment of this Act.

SEC. 951. FURNISHING HOSPITALS WITH INFORMATION TO COMPUTE DSH FORMULA.

Beginning not later than 1 year after the date of the enactment of this Act, the Secretary shall furnish to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Social Security Act, 42 U.S.C. 1395ww(d)(1)(B)) the data necessary for such hospitals to compute the number of patient days described in subclause (II) of section 1886(d)(5)(F)(vi) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(F)(vi)) used in computing the disproportionate patient percentage under such section for that hospital. Such data shall also be furnished to other hospitals which would qualify for additional payments under part A of title XVIII of the Social Security Act on the basis of such data.

SEC. 952. REVISIONS TO REASSIGNMENT PROVISIONS.

(a) IN GENERAL.—Section 1842(b)(6)(A) (42 U.S.C. 1395u(b)(6)(A)) is amended by striking "or (ii) (where the service was provided in a hospital, critical access hospital, clinic, or other facility) to the facility in which the service was provided if there is a contractual arrangement between such physician or other person and such facility under which such facility submits the bill for such service," and inserting "or (ii) where the service was provided under a contractual arrangement between such physician or other person and an entity (as defined by the Secretary), to the entity if, under the contractual arrangement, the entity submits the bill for the service and the contractual arrangement meets such other program integrity and other safeguards as the Secretary may determine to be appropriate,".

(b) CONFORMING AMENDMENT.—The second sentence of section 1842(b)(6) (42 U.S.C. 1395u(b)(6)) is amended by striking "except to an employer or facility" and inserting "except to an employer, entity, or other person".

(c) EFFECTIVE DATE.—The amendments made by section shall apply to payments made on or after the date that is one year after the date of the enactment of this Act.

SEC. 953. OTHER PROVISIONS.

(a) GAO REPORTS ON THE PHYSICIAN COMPENSATION.—

(1) SUSTAINABLE GROWTH RATE AND UPDATES.—Not later than 6 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the appropriateness of the updates in the conversion factor under subsection (d)(3) of section 1848 of the Social Security Act (42 U.S.C. 1395w–4), including the appropriateness of the sustainable growth rate formula under subsection (f) of such section for 2002 and succeeding years. Such report shall examine the stability and predictability of such updates and rate and alternatives for the use of such rate in the updates.

(2) PHYSICIAN COMPENSATION GENERALLY.—Not later than 12 months after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on all aspects of physician compensation for services furnished under title XVIII of the Social Security Act, and how those aspects interact and the effect on appropriate compensation for physician services. Such report shall review alternatives for the physician fee schedule under section 1848 of such title (42 U.S.C. 1395w–4).

(b) ANNUAL PUBLICATION OF LIST OF NATIONAL COVERAGE DETERMINATIONS.—The Secretary shall provide, in an appropriate annual publication available to the public, a list of national coverage determinations made under title XVIII of the Social Security Act in the previous year and information on how to get more information with respect to such determinations.

(c) GAO REPORT ON FLEXIBILITY IN APPLYING HOME HEALTH CONDITIONS OF PARTICIPATION TO PATIENTS WHO ARE NOT MEDICARE BENEFICIARIES.—Not later than 6 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the implications if there were flexibility in the application of the medicare conditions of participation for home health agencies with respect to groups or types of patients who are not medicare beneficiaries. The report shall include an analysis of the potential impact of such flexible application on clinical operations and the recipients of such services and an analysis of methods for monitoring the quality of care provided to such recipients.

(d) OIG REPORT ON NOTICES RELATING TO USE OF HOSPITAL LIFETIME RESERVE DAYS.—Not later than 1 year after the date of the enactment of this Act, the Inspector General of the Department of Health and Human Services shall submit a report to Congress on—

(1) the extent to which hospitals provide notice to medicare beneficiaries in accordance with applicable requirements before they use the 60 lifetime reserve days described in section 1812(a)(1) of the Social Security Act (42 U.S.C. 1395d(a)(1)); and

(2) the appropriateness and feasibility of hospitals providing a notice to such beneficiaries before they completely exhaust such lifetime reserve days.

SEC. 954. TEMPORARY SUSPENSION OF OASIS REQUIREMENT FOR COLLECTION OF DATA ON NON-MEDICARE AND NON-MEDICAID PATIENTS.

(a) IN GENERAL.—During the period described in subsection (b), the Secretary may not require, under section 4602(e) of the Balanced Budget Act of 1997 or otherwise under OASIS, a home health agency to gather or submit information that relates to an individual who is not eligible for benefits under either title XVIII or title XIX of the Social Security Act (such information in this section referred to as "non-medicare/medicaid OASIS information").

(b) PERIOD OF SUSPENSION.—The period described in this subsection—

(1) begins on the date of the enactment of this Act; and

(2) ends on the last day of the 2nd month beginning after the date as of which the Secretary has published final regulations regarding the collection and use by the Centers for Medicare & Medicaid Services of non-medicare/medicaid OASIS information following the submission of the report required under subsection (c).

(c) REPORT.—

(1) STUDY.—The Secretary shall conduct a study on how non-medicare/medicaid OASIS information is and can be used by large home health agencies. Such study shall examine—

(A) whether there are unique benefits from the analysis of such information that cannot be derived from other information available to, or collected by, such agencies; and

(B) the value of collecting such information by small home health agencies compared to the administrative burden related to such collection.

In conducting the study the Secretary shall obtain recommendations from quality assessment experts in the use of such information and the necessity of small, as well as large, home health agencies collecting such information.

(2) REPORT.—The Secretary shall submit to Congress a report on the study conducted under paragraph (1) by not later than 18 months after the date of the enactment of this Act.

(d) CONSTRUCTION.—Nothing in this section shall be construed as preventing home health agencies from collecting non-medicare/medicaid OASIS information for their own use.

I. INTRODUCTION

A. PURPOSE AND SUMMARY, AND

B. BACKGROUND AND NEED FOR LEGISLATION

Nearly four decades ago, Congress enacted the Medicare program to help provide health care to our nation's seniors. Medicare has improved and lengthened the lives of millions of people. In recent years, Congress has both successfully slowed Medicare's growth rate and added new preventive benefits to keep seniors healthier. Yet Medicare has still not met its true promise because it remains mired in a rigid administrative structure that can only change when Congress enacts a law.

When Medicare was enacted, there were few prescription drugs, and most care was delivered in hospitals and physician offices. Consequently, Medicare did not cover prescription drugs. While about two-thirds of seniors have some prescription drug coverage through various sources, access to such coverage has been declining and oftentimes remains inadequate. Many other seniors lack prescription drug coverage, and therefore, they lack the bargaining power to reduce their drug costs.

Prescription drugs are an integral part of health care today. They prevent and manage diseases and most often are less invasive and costly than alternative health care options (e.g. surgery, hospitalization, nursing home admission, etc.). Most private health plans have voluntarily integrated prescription drugs into their benefits. Nobody today with a blank sheet of paper would design a health care program for seniors that excluded prescription drugs. Yet, the absence of a prescription drug benefit epitomizes how Medicare has not kept pace with modern medicine. While a Medicare prescription drug benefit is long overdue, it is not the only problem afflicting a program so many cherish and want to strengthen.

Irrational and unpredictable payments to physicians are just one example of what is wrong with Medicare's reimbursement policy. While health costs are escalating under the current Sustainable Growth Rate formula, payments to physicians under current law would be substantially reduced. Patients' access to physicians will suffer and the doctors beneficiaries rely on will only become more demoralized. Similarly, rural hospitals continue to struggle and are not paid equitably compared to large urban hospitals. In addition, numerous Medicare+Choice plans are withdrawing from the program and are substantially cutting benefits because government

payments are not related to the actual cost of providing health care.

At the same time, Medicare is overpaying on other counts, such as for durable medical equipment. The Office of Inspector General has documented that taxpayers and Medicare beneficiaries are paying millions more for durable medical equipment than other programs, such as the Federal Employees Health Benefit Program (FEHBP). Similarly, numerous studies by the General Accounting Office, Office of Inspector General and others have documented tremendous overpayments to oncologists and other physicians for currently covered prescription drugs. In some cases, the beneficiary copay exceeds the actual acquisition cost of the drug.

In addition, the health care professionals serving Medicare beneficiaries are being crushed by more than 130,000 pages of overly burdensome regulations—four times more than those governing the Internal Revenue Code. This over-regulation hampers efforts to provide quality care to seniors, and it must be changed.

Finally, and most importantly, Medicare's long-term viability is not on stable ground. When Medicare was enacted, there were more than six workers per beneficiary. Today, there are about four workers per beneficiary. After the baby-boom generation retires (which starts at the end of this decade), there will be about two workers per beneficiary. Absent any change in law, Medicare costs will nearly double over the next 10 years. Medicare needs to become more efficient.

This bill addresses all of these issues and more.

First and foremost, the bill provides a voluntary, affordable prescription drug benefit as an entitlement to all beneficiaries. The proposal is within the $400 billion over 10 years allocated under the budget resolution. Under the bill, Medicare beneficiaries would pay a $250 deductible and then receive 80 percent coverage of their annual drug costs up to $2,000. This 80–20 benefit looks like standard coverage offered by employer plans, and today nearly two-thirds of beneficiaries spend less than $2,000 on drugs annually. In addition, the bill provides catastrophic protection after an individual has incurred $3,500 in out-of-pocket costs. At that threshold, 100 percent of costs will be covered. The Congressional Budget Office (CBO) estimates the average monthly beneficiary premium to be about $35.

Additionally, the bill targets resources to those who need them most. For low-income seniors up to 135 percent of poverty, premiums would be fully subsidized and all cost-sharing, except for nominal copays, would be covered. Those with incomes between 135 and 150 percent would also receive assistance for their premiums. Seniors with incomes above $60,000 or couples with incomes above $120,000 would have a higher catastrophic threshold, but would receive the same front-end benefit. This higher threshold would affect only about five percent of individuals.

The prescription drug benefit would be delivered through competing integrated health plans and private sector entities that already deliver pharmaceutical benefits for millions of people, including every Member of Congress. The bill permits and encourages these plans to utilize private sector tools to aggressively negotiate lower drug prices and provide better service for beneficiaries. By exempting prices negotiated for Medicare beneficiaries from the

Medicaid "best price" provision, the bill encourages steep discounting by pharmaceutical manufacturers that would save taxpayers and beneficiaries billions of dollars. The private sector delivery of benefits is backed up by a government guarantee that all seniors in every area of the country must be covered. Indeed, the Congressional Budget Office and the Centers for Medicare and Medicaid Services (CMS) Office of the Actuary predicts that more than 95 percent of the seniors that lack coverage would voluntarily sign up for this benefit.

The bill would provide seniors with more and better choices for the delivery of their health care. The Medicare+Choice program would be fundamentally reformed by re-linking payments to fee-for-service costs and permitting plans to bid their actual costs, beginning in 2006. Plans would be paid what they bid and savings would be split 75 percent–25 percent between the beneficiary and government for plans that bid below the benchmark. The bill would also implement the President's "enhanced fee-for-service" program, which provides for regional, open-network plans offering better integrated care.

In 2010, the bill would put Medicare on a more stable funding path by moving to a FEHBP-style of competition between plans. Nothing would change Medicare's entitlement to a defined set of benefits, but costs between fee-for-service and private plans would be directly compared. Beneficiaries would be rewarded for enrolling in more efficient plans, regardless of whether the plans are private or traditional fee-for-service. This program would only apply in areas with significant private plan penetration (at least equal to the national average market share), and the fee-for-service plan would have disproportionate influence in establishing the benchmark. This transition would be phased in over five years. This provision provides Medicare the best chance to bend its growth rate in the out-years by enabling beneficiaries to make efficient and rational choices, and by permitting the government to share in the savings when beneficiaries select cost-effective plans.

More than 179 different patient groups, provider groups, and employers have endorsed this legislation because it provides a meaningful benefit, modernizes irrational reimbursements, and reduces burdensome regulatory structures that undermine the quality and accessibility of care. The bill reforms physician payments, addresses payment inequities for rural hospitals and home health providers, and makes responsible decisions on provider reimbursements based on the Medicare Payment Advisory Commission's recommendations. More importantly, the legislation sets Medicare on a path of more rational pricing—determined by the marketplace, rather than government edict—through moving durable medical equipment, currently covered drugs, and Medicare's contractors into a competitive system. In addition to creating a more rational system that saves money over time, these changes get Congress out of the business of micro-managing payments to providers across communities in America based on political decisions in Washington.

The bill provides clear improvements for preventive benefits for beneficiaries. For the first time, in order to diagnose problems early and keep seniors healthy, Medicare would cover initial physicals and provide coverage for cholesterol screening. The bill would also

provide better-coordinated care for the numerous Medicare beneficiaries who suffer from multiple chronic illnesses.

The bill also includes regulatory and contracting reforms—reforms that passed the House twice in the 107th Congress—to reduce unnecessary regulation and modernize how Medicare selects its contractors.

Finally, the bill also establishes a new Medicare Benefits Administration (MBA) to manage and oversee the Medicare Advantage and Enhanced Fee-for-Service Programs as well as the prescription drug benefit. Creating of the MBA eliminates the inherent conflict-of-interest in requiring a government-run fee-for-service plan to regulate competing private plans.

C. LEGISLATIVE HISTORY

Legislative Hearings

During the 107th and 108th Congresses, the Committee on Ways and Means, and its Subcommittee on Health, held 24 hearings exploring how Medicare should be strengthened and modernized. These hearings, which examined all aspects of the Medicare program, included expert testimony from academic, beneficiary and provider representatives. The following lists the hearings in the 107th and 108th Congresses in reverse chronological order:

108TH CONGRESS

May 1, 2003: Medicare Cost-Sharing and Medigap Reform (Subcommittee on Health)

Witnesses

Glenn M. Hackbarth, Chairman, Medicare Payment Advisory Commission.

Stephen W. Still, Esq., Maynard, Cooper & Gale, P.C., Birmingham, Alabama, on behalf of Torchmark Corporation, Birmingham, Alabama, and United American Insurance Company, McKinney, Texas.

Richard White, Vice President, Individual Project Management, Southeast Region, Anthem Blue Cross and Blue Shield, Roanoke, Virginia.

Patricia Neuman, Sc. D., Vice President and Director, Medicare Policy Project, Kaiser Medicare Policy Project, Henry J. Kaiser Family Foundation.

April 9, 2003: Hearing on Expanding Coverage of Prescription Drugs in Medicare (Full Committee)

Witnesses

Douglas Holtz-Eakin, Ph.D., Director, Congressional Budget Office.

The Honorable David M. Walker, Comptroller General, U.S. General Accounting Office.

Bruce Stewart, Ph.D., Director, Peter Lamy Center on Drug Therapy and Aging, University of Maryland, Baltimore, Maryland.

Mark V. Pauly, Ph.D., Chairperson, Health Care Systems Department, The Wharton School, University of Pennsylvania, Philadelphia, Pennsylvania.

Uwe Reinhardt, Ph.D., Professor, Economics and Public Affairs, Department of Economics, and Woodrow Wilson School of Public and International Affairs, Princeton University, Princeton, New Jersey

March 6, 2003: Hearing on the MedPAC Report on Medicare Payment Policies (Subcommittee on Health)

Witnesses

Glenn M. Hackbarth, Chairman, MedPAC.

James Jaruzewicz, President and Chief Executive Officer, Visiting Nurses Association of Erie County, Erie, Pennsylvania, on behalf of the Visiting Nurses Association of America.

Larry C. Buckelew, President and Chief Executive Officer, Gambro Healthcare U.S., and Chairman, Renal Leadership Council.

William G. Plested, III, M.D., Chair-Elect, American Medical Association.

Mary K. Ousley, Chairman, American Health Care Association.

Dennis Barry, President and Chief Executive Officer, Moses Cone Health System, Greensboro, North Carolina, and Chairman, Board of Trustees, American Hospital Association.

Betty Severyn, Member, Board of Directors, AARP.

February 25, 2003: Hearing on Eliminating Barriers to Chronic Care Management in Medicare (Subcommittee on Health)

Witnesses

Stuart Guterman, Director, Office of Research, Development and Information, Centers for Medicare and Medicaid Services.

Jeff Lemieux, Senior Economist, Progressive Policy Institute.

Ed Wagner, M.D., Director, MacColl Institute for Healthcare Innovation, Center for Health Studies, Group Health Cooperative, Seattle, Washington.

George A. Taler, M.D., Director, Long Term Care, Department of Medicine, Washington Hospital Center, on behalf of the American Geriatric Society.

Jan Berger, M.D., Senior Vice President, Clinical Quality and Support, Caremark Rx Incorporated, Northbrook, Illinois.

February 13, 2003: Hearing on Medicare Regulatory and Contracting Reform (Subcommittee on Health)

Witnesses

The Honorable Thomas A. Scully, Administrator, Centers for Medicare and Medicaid Services.

Douglas L. Wood, M.D., Vice Chair, Department of Medicine, Mayo Clinic and Foundation, Rochester, Minnesota.

Michael Luebke, President, Verizon Information Technologies Inc., Tampa, Florida.

Tony Fay, Vice President, Government Affairs, Province Healthcare Company, Brentwood, Tennessee, on behalf of the American Hospital Association.

J. Edward Hill, M.D., Chairman, Board of Trustees, American Medical Association.

Janet B. Wolf, President, Munson Home Health, Traverse City, Michigan, and Past President, Board of Directors, Michigan Home Health Association, Okemos, Michigan, on behalf of the National Association for Home Care and Hospice.

Judith A. Ryan, Ph.D., President and Chief Executive Officer, Evangelical Lutheran Good Samaritan Society, Sioux Falls, South Dakota, on behalf of the American Health Care Association.

Michael Carius, M.D., Immediate Past President, American College of Emergency Physicians, Norwalk, Connecticut, and Founding Member, Alliance of Specialty Medicine.

Vicki Gottlich, Attorney, Healthcare Rights Project, Center for Medicare Advocacy, Inc.

February 6, 2003: Hearing on the President's Fiscal Year 2004 Budget with U.S. Department of Health and Human Services (Full Committee)

Witness

The Honorable Tommy G. Thompson, Secretary, U.S. Department of Health and Human Services.

107TH CONGRESS

October 3, 2002: Medicare Payments for Currently Covered Prescription Drugs (Subcommittee on Health)

July 23, 2002: Medicare's Geographic Cost Adjusters (Subcommittee on Health)

April 17, 2002: Integrating Prescription Drugs into Medicare (Full Committee)

April 16, 2002: Promoting Disease Management in Medicare (Subcommittee on Health)

March 14, 2002: Medicare Supplemental Insurance (Subcommittee on Health)

March 7, 2002: Health Quality and Medical Errors (Subcommittee on Health)

February 28, 2002: Reforming Physician Payments (Subcommittee on Health)

December 4, 2001: Status of the Medicare+Choice Program (Subcommittee on Health)

September 25, 2001: H.R. 2768, Medicare Regulatory and Contracting Reform Act (Subcommittee on Health)

July 19, 2001: Administration's Principles to Strengthen and Modernize Medicare (Full Committee)

June 12, 2001: Rural Health Care in Medicare (Subcommittee on Health)

May 9, 2001: Strengthening Medicare: Modernizing Beneficiary Cost-Sharing (Subcommittee on Health)

May 1, 2001: Medicare+Choice: Lessons for Reform (Subcommittee on Health)

March 27, 2001: Laying the Groundwork for a Prescription Drug Benefit (Subcommittee on Health)

March 20, 2001: Medicare Solvency (Full Committee)

March 15, 2001: Bringing Regulatory Relief to Beneficiaries and Providers (Subcommittee on Health)

March 14, 2001: Administration's Health and Welfare Priorities (Full Committee)

February 28, 2001: Perspectives on Medicare Reform (Subcommittee on Health)

On April 11, 2003, Congress agreed to the conference report for H. Con. Res. 95, "Establishing the congressional budget for the United States Government for fiscal year 2004 and setting forth appropriate budgetary levels for fiscal years 2003 and 2005 through 2013," which provided $400 billion over 10 years for Medicare modernization and prescription drugs.

On June 16, 2003, Committee on Ways and Means Chairman Bill Thomas and Committee on Energy and Commerce Chairman Billy Tauzin introduced H.R. 2473, the "Medicare Prescription Drug and Modernization Act of 2003". (Identical language in the form of a report was released publicly June 13, 2003.) On June 17, 2003, H.R. 2473 was marked up by the full Committee on Ways and Means and ordered favorably reported by a vote of 25–15, after adopted amendments—including the Thomas amendment in the nature of a substitute—were accepted into the bill. The amendments that were accepted to the Thomas amendment in the nature of a substitute were: (1) an amendment offered by Mrs. Johnson to instruct the Secretary of the U.S. Department of Health and Human Services to promptly evaluate existing codes for physician services associated with the administration of covered outpatient drugs; and to use existing processes to establish relative values for such services; (2) an en bloc amendment offered by Mr. Collins to exempt MA private FFS plans from compliance with the drug utilization management program, negotiation of discounts from manufacturers, disclosure of fact that generic drug is available at a lower cost, and TRICARE standards for participation; and (3) an amendment offered by Mr. Nussle and Mr. Pomeroy to adjust the Medicare inpatient hospital prospective payments system wage index to revise the labor-related share of such index, and to provide a five percent bonus payment to physicians operating in physician scarcity areas.

II. EXPLANATION OF PROVISIONS

A. Title I—Medicare Prescription Drug Benefit

Section 101. Establishment of a Medicare Prescription Drug Benefit

CURRENT LAW

Medicare does not cover most outpatient prescription drugs. Beneficiaries in hospitals or skilled nursing facilities may receive drugs as part of their treatment. Medicare payments made to the facilities cover these costs. Medicare also makes payments to physicians for drugs or biologicals that are not usually self-administered. This means that coverage is generally limited to drugs or biologicals administered by injection. However, if the injection is generally self-administered (e.g., insulin), it is not covered.

Despite the general limitation on coverage for outpatient drugs, Medicare statute specifically authorizes coverage for the following: (1) drugs used in immunosuppressive therapy (such as cyclosporin) following discharge from a hospital for a Medicare-covered organ transplant, (2) erythropoietin (EPO) for the treatment of anemia for persons with chronic renal failure who are on dialysis, (3) drugs taken orally during cancer chemotherapy provided they have the

same active ingredients and are used for the same indications as chemotherapy drugs which would be covered if they were not self-administered and were administered as incident to a physician's professional service, and (4) hemophilia clotting factors for hemophilia patients competent to use such factors to control bleeding without medical supervision, and items related to the administration of such factors. The program also pays for supplies (including drugs) that are necessary for the effective use of covered durable medical equipment, including those that must be put directly into equipment (e.g., tumor chemotherapy agents used with an infusion pump). Medicare also covers pneumococcal pneumonia vaccines, hepatitis B vaccines, and influenza virus vaccines.

EXPLANATION OF PROVISION

The provision would establish a new voluntary prescription drug benefit program under a new Medicare Part D of Title XVIII of the Social Security Act. Effective January 1, 2006, a new voluntary benefit would be established. Beneficiaries could purchase either "standard coverage" or actuarially equivalent coverage approved by the Secretary of Health and Human Services. In 2006, "standard coverage" would have a $250 deductible, 80 percent coverage for costs between $251 and $2,000, and all costs after the individual has borne $3,500 in out-of-pocket spending (a.k.a. the catastrophic threshold). The catastrophic threshold would be raised for individuals with income above $60,000 and couples with income above $120,000. Subsidies would be provided for persons with income below 150 percent of poverty. Coverage would be provided through PDPs, Medicare Advantage (MA) plans (formerly known as Medicare+Choice plans), or Enhanced Fee-For-Service plans (EFFS). The program would rely on private plans to provide coverage and to bear some of the financial risk for drug costs. Federal subsidies would be provided to encourage participation. Plans would be expected to negotiate prices for drugs. A new Medicare Benefits Administration (MBA), within the Department of Health and Human Services (HHS), would contract with plans.

New Section 1860D–1. Benefits; Eligibility; Enrollment; and Coverage Period

The new Section 1860A would specify that each individual entitled to Medicare Part A or enrolled in Medicare Part B would be entitled to obtain qualified prescription drug coverage under Medicare. MA plans and EFFS plans (MA–EFFS plans) would be required to offer qualified prescription drug coverage. An individual enrolled in a MA–EFFS plan would obtain their drug coverage through the plan. An individual not enrolled in either a Medicare Advantage or EFFS plan could enroll in a new PDP. The provision would specify that an individual eligible to make an election to enroll in a PDP, or with a MA–EFFS plan, would do so in accordance with regulations issued by the Administrator of the new MBA. Enrollments and changes in enrollment could occur only during a specified election period. The election periods would generally be the same as those established for MA–EFFS programs including annual coordinated election periods and special election periods. An individual discontinuing a MA election during the first year of eligibility would be permitted to enroll in a PDP at the same time as

the election of coverage under the original fee-for-service plan (FFS).

An initial six month election period, beginning on October 1, 2005, would be established for persons entitled to Part A or enrolled under Part B on that date. For persons first entitled to Part A or enrolled in Part B after that date, an initial election period that would be the same as that for initial Part B enrollment, would be established. The MBA Administrator would be required to establish special election periods for persons in specific circumstances, such as having and then involuntarily losing prescription drug coverage; enrollment delays or non-enrollment attributable to government action; becoming eligible for Medicaid drug coverage; or any such exceptional circumstance specified by the MBA Administrator (including circumstances pertaining to MA enrollment).

Guaranteed issue and community-rating protections would be established for beneficiaries. Individuals electing qualified prescription drug coverage under a PDP plan or MA–EFFS plan could not be denied enrollment based on health status or other factor. MA provisions relating to priority enrollment (where capacity limits have been reached) and limitations on terminations of elections would apply to PDP sponsors.

The provision would specify that PDP sponsors and MA–EFFS organizations providing qualified prescription drug coverage could not deny, limit, or condition the coverage or provision of benefits or increase the premium based on any health-related status factor in the case of persons who maintained continuous prescription drug coverage since the date they first qualified to elect drug coverage under Part D. Individuals who did not maintain continuous coverage could be subject to an adjusted premium in a manner reflecting the additional actuarial risk involved. Such risk would be established through an appropriate actuarial opinion.

An individual would be considered to have had continuous prescription drug coverage if the individual could establish that he or she had coverage under one of the following (and coverage in one plan occurred no more than 63 days after termination of coverage in another plan): (1) a qualified PDP or MA–EFFS plan, (2) Medicaid, (3) a group health plan, but only if benefits were at least equivalent to benefits under a qualified PDP, (4) a Medigap plan, but only if the policy was in effect on January 1, 2006, and only if the benefits were at least equivalent to benefits under a qualified PDP, (5) a state pharmaceutical assistance program, but only if benefits were at least equivalent to benefits under a qualified PDP, or (6) a veteran's plan, but only if benefits were at least equivalent to benefits under a qualified PDP. Individuals could apply to the MBA Administrator to waive the requirement that such coverage be at least equivalent to benefits under a qualified PDP if they could establish that they were not adequately informed that the coverage did not provide such level of coverage.

PDP sponsors would make drug coverage available to all eligible individuals residing in the area—without regard to their health, economic status, or place of residence.

Elections would take effect at the same time that they do for MA plans; however, no election could take effect before January 1, 2006. The MBA Administrator would provide for the termination of an election in the case of termination of Part A and Part B cov-

erage or termination of an election for cause (including failure to pay the required premium).

New Section 1860D–2. Requirements for Qualified Prescription Drug Coverage

The new Section 1860D–2 would specify the requirements for qualified prescription drug coverage. Qualified coverage would be defined as either "standard coverage" or actuarially equivalent coverage.

For 2006, "standard coverage" would have a $250 deductible, 80 percent coverage for costs between $251 and $2,000, and full coverage for all costs after the individual has borne $3,500 in out-of-pocket spending (a.k.a. the catastrophic threshold). Beneficiaries would have access to negotiated discounts even where there would be no insurance benefit (between $2,000 in spending and $3,500 in out-of-pocket spending). Beginning in 2007, standard coverage thresholds would be increased by the annual percent increase in average per capita expenditures for covered outpatient drugs for beneficiaries (for the 12-month period ending in July of the previous year).

Plans would be permitted to substitute cost-sharing schedules for costs up to the initial coverage limit ($2,000) that are actuarially consistent with the average expected 20 percent cost-sharing up to the initial coverage limit. They could also apply tiered coinsurance, provided such coinsurance was actuarially consistent with the average 20 percent cost-sharing requirements.

Costs that would count toward meeting the catastrophic limit would only be considered incurred if they were paid for the deductible, cost-sharing, or benefits not paid because of application to the initial coverage limit. Costs would be treated as incurred costs only if they are paid by the individual (or by another family member on behalf of the individual), paid on behalf of a low-income individual under the subsidy provisions, under the Medicaid program, or by a state pharmaceutical assistance program. Substantial new assistance would be provided to those states with pharmaceutical assistance programs through the catastrophic benefit by requiring Medicare to pay 80 percent of the costs above the catastrophic limit. Any costs for which the individual was reimbursed by insurance or otherwise would not count toward incurred costs.

The provision would increase the annual out-of-pocket threshold for each enrollee whose adjusted gross income exceeds a specified income threshold. The portion of income exceeding this income threshold ($60,000 for individuals and $120,000 for couples in 2006), but below an income threshold limit ($200,000 in 2006), would be considered in making this calculation. The increase would be calculated as follows: first, the ratio of the annual out-of-pocket limit to the income limit would be calculated and expressed as a percent; for 2006, this would be $3,500 divided by $60,000, equaling about 5.8 percent. This percentage would be multiplied by income over the income threshold, not exceeding $140,000. Thus, the catastrophic out-of-pocket limit would be $5,820 for an enrollee with an income of $100,000 and $11,620 for persons with incomes at $200,000 or above. Beginning in 2007, the income threshold and income threshold limit would be increased by the percentage in-

crease in the consumer product index (CPI) for all urban consumers, rounding to the nearest $100.

The amount used for making the income determination would be adjusted gross income Individuals filing joint returns would be treated separately with each person considered to have an adjusted gross income equal to one-half of the total. The determination would be the most recent return information disclosed by the Secretary of the Treasury to the Secretary of HHS before the beginning of the year. The Secretary, in coordination with the Secretary of the Treasury, would provide a procedure under which an enrollee could elect to use more recent information, including information for a taxable year ending in the current calendar year. Through the 1–800 toll free Medicare beneficiary line, individuals would have assistance in appealing a determination from the Medicare Ombudsman. The process would require: (1) the enrollee to provide the Secretary with the relevant portion of the more recent return, (2) verification by the Secretary of the Treasury, and (3) payment by the Secretary to the enrollee equal to the benefit payments that would have been payable under the plan if more recent information had been used. If such payments were made, the PDP sponsor would pay the Secretary the requisite amount, less the applicable reinsurance that would have applied.

The Secretary would be required to provide, through the annual Medicare handbook, general information on the calculation of catastrophic out-of-pocket thresholds. The Secretary would periodically transmit to the Secretary of the Treasury the names and Social Security Numbers (SSNs) of enrollees in PDPs or MA–EFFS plans and request that the Secretary of the Treasury disclose income information. The Secretary would disclose to entities offering the plan the amount of the out-of-pocket threshold that would apply to a specified taxpayer. New confidentiality protections and severe criminal and civil penalties would apply to any unauthorized disclosure of information.

The provision would permit a PDP or MA–EFFS sponsor to offer, subject to approval by the MBA Administrator, alternative coverage providing certain requirements were met. The actuarial value of total coverage would have to be at least equal to the actuarial value of standard coverage. The unsubsidized value of the coverage (i.e. the value of the coverage exceeding subsidy payments) would have to be equal to the unsubsidized value of standard coverage. The coverage would be designed (based on actuarially representative patterns of utilization) to provide for payment of incurred costs up to the initial coverage limit of at least the same percentage of costs provided under standard coverage. Further, catastrophic protection would have to be the same as that under standard coverage. It could not vary.

Both standard coverage and actuarially equivalent coverage would offer access to negotiated prices, including applicable discounts. Access would be provided even when no benefits were payable because of the application of cost-sharing or initial coverage limits. Insofar as a State elected to use these negotiated prices for its Medicaid program, the Medicaid drug payment provisions would not apply. Further, the negotiated prices would not be taken into account in making "best price" determinations under Medicaid. Under the current Medicaid best price policy, the largest discount

a pharmaceutical manufacturer negotiates in the private market must be passed along to the Medicaid program as well. Since manufacturers can only influence market share and volume in the private sector, not Medicaid, the "best price" policy has led to less discounting by manufacturers. As a result, arbitrary price floors are created and consumers pay the price as competing manufacturers have had less incentive to steeply discount their prices. This provision saves Medicare billions of dollars by encouraging pharmaceutical manufacturers to offer the same discounts that private plans currently receive. For transparency reasons, the PDP or MA–EFFS sponsor would be required to disclose to the MBA Administrator the extent to which manufacturer discounts or rebates or other remunerations or price concessions are made available to the sponsor or organization and passed through to enrollees through pharmacies. Manufacturers would be required to disclose pricing information to the MBA Administrator under the same conditions currently required for Medicaid. Transparency in pricing and rebate arrangements is a key factor in ensuring beneficiaries and taxpayers are receiving the best value for their resources.

Qualified prescription drug coverage could include coverage exceeding that specified for standard coverage or actuarially equivalent coverage. However, any additional coverage would be limited to covered outpatient drugs. The MBA Administrator could terminate a contract with a PDP or MA–EFFS sponsor if a determination was made that the sponsor or organizations engaged in activities intended to discourage enrollment of classes of eligible Medicare beneficiaries obtaining coverage through the plan on the basis of their higher likelihood of utilizing prescription drug coverage.

Covered outpatient drugs would be defined to include: (1) a drug which may only be dispensed subject to a prescription and which is described in subparagraph (A)(i) or (A)(ii) of Section 1927(k)(2) of the Social Security Act (relating to drugs covered under Medicaid), (2) a biological product described in paragraph B of such subsection, (3) insulin described in subparagraph C of such section, and (4) vaccines licensed under Section 351 of the Public Health Service Act. Drugs excluded from Medicaid coverage would be excluded from the definition except for smoking cessation drugs. The definition includes any use of a covered outpatient drug for a medically accepted indication. Drugs paid for under Medicare Part B would not be covered under Part D. A plan could elect to exclude a drug that would otherwise be covered, if the drug was excluded under the formulary and the exclusion was not successfully appealed under the new Section 1860D–3. In addition, a PDP or MA–EFFS sponsor could exclude from coverage, subject to reconsideration and appeals provisions, any drug that either does not meet Medicare's definition of medical necessity or is not prescribed in accordance with the plan or Part D. Beneficiaries could appeal the placement of a drug in a higher coinsurance tier to an external, independent entity.

New Section 1860D–3. Beneficiary Protections for Qualified Prescription Drug Coverage

The new Section 1860D–3 would specify required beneficiary protections. Plans would have to comply with guaranteed issue and community-rated premium requirements specified in the new Sec-

tion 1860D–1, access to negotiated prices as specified in the new Section 1860D–2, and the non-discrimination provisions specified in the new Section 1860D–6.

The PDP sponsors would be required to disclose to each enrolling beneficiary information about the plan's benefit structure, including information on: (1) access to covered drugs, including access through pharmacy networks, (2) how any formulary used by the sponsor functioned, (3) copayment and deductible requirements (including any applicable tiered copayment requirements), and (4) grievance and appeals procedures. In addition, beneficiaries would have the right to obtain more detailed plan information. The sponsor would be required to make available, through an Internet site and, on request, in writing, information regarding the basis for exclusion of any drug from the formulary. Plans must notify enrollees when a change has been made in the preferred status of a drug or biological, or if there has been a change in a beneficiary's coinsurance. Plans would be required to furnish to enrollees a detailed explanation of benefits, including information on benefits compared to the initial coverage limit and the applicable out-of-pocket threshold.

PDP and MA–EFFs sponsors would be required to permit the participation of any pharmacy that met the plan's terms and conditions. Beneficiaries would be ensured access to any convenient local pharmacy that chose to participate in the plan. PDP and MA–EFFS sponsors could reduce coinsurance for their enrolled beneficiaries below the otherwise applicable level for drugs dispensed through in-network pharmacies; in no case could the reduction result in an increase in subsidy payments made by the MBA Administrator to the plan. Sponsors would be required to secure participation in its network of a sufficient number of pharmacies that dispense drugs directly to patients to assure convenient access. Mail order only pharmacy would be prohibited so that beneficiaries have access to a convenient bricks and mortar pharmacy. The MBA Administrator would establish convenient access rules that were no less favorable to enrollees than rules for convenient access established by the Secretary of Defense on June 1, 2003, for the TRICARE Retail Pharmacy program. The TRICARE standard specifies that, in an urban area, 90 percent of beneficiaries must be within two miles of a participating pharmacy; in a suburban area, 90 percent of beneficiaries must be within five miles of a participating pharmacy; and in rural areas, 70 percent of beneficiaries must be within fifteen miles of a participating pharmacy. According to the Department of Defense, the TRICARE Retail Pharmacy program receives minimal access complaints each year, and problems and disputes related to access are resolved quickly. The rules would include adequate emergency access for enrolled beneficiaries. Sponsors would permit enrollees to receive benefits through a community pharmacy, rather than through mail-order, with any differential in cost paid by enrollees. Pharmacies could not be required to accept insurance risk as a condition of participation. It is important that pharmacies are not put at risk for events they cannot control, such as volume and frequency of prescriptions.

PDP and MA–EFFS sponsors would be required to issue (and reissue as appropriate) a card or other technology that could be used by an enrolled beneficiary to assure access to negotiated prices for

drugs when coverage is not otherwise provided under the plan. The MBA Administrator would provide for the development of uniform standards relating to a standardized format for the card or other technology. These standards would be compatible with the administrative simplification requirements of Title XI of the Social Security Act.

There is no requirement to use a formulary, however, if a PDP or MA–EFFS sponsor uses a formulary, it would have to meet certain requirements. It would be required to establish an independent pharmaceutical and therapeutic committee free of conflict with the plan to develop and review the formulary. The committee would include at least one physician and one pharmacist with expertise in the care of elderly or disabled persons, and the majority of members would be physicians or pharmacists. The committee would be required, when developing and reviewing the formulary, to base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and such other information the committee determined appropriate. Arbitrary determinations to exclude products from the formulary would not be permitted.

The P&T committee would also take into account whether including a particular covered drug had therapeutic advantages in terms of safety and efficacy. In addition, the formulary would have to include at least two drugs within each therapeutic category and class of covered outpatient drugs, although not necessarily all drugs within such categories or classes. When establishing such classes, the committee would take into account the standards published in the United States Pharmacopoeia Drug Information. It would be required to make available to plan enrollees, through the Internet or otherwise, the clinical basis for the coverage of any drug on the formulary. The committee would be required to establish policies and procedures to educate and inform health care providers concerning the formulary. Any removal of a drug from the formulary could not occur until appropriate notice had been provided to beneficiaries and physicians. The plan would provide for periodic evaluation and analysis of treatment protocols and procedures. Further, the PDP or MA–EFFS sponsor would be required to provide for, as part of its overall appeals process, appeals of coverage denials regarding application of the formulary.

Each PDP or MA–EFFS sponsor would ensure that each pharmacy or other dispenser informed enrolled beneficiaries at the time of purchase, of any price differential between their prescribed drug and the price of the lowest cost generic drug covered under the plan that was therapeutically equivalent and bioequivalent.

The PDP or MA–EFFS sponsor would be required to have (directly, or indirectly through arrangements): (1) an effective cost and drug utilization management program, (2) quality assurance measures including a medication therapy management program, (3) for years beginning with 2007, an electronic prescription drug program, and (4) a program to control waste, fraud, and abuse. Utilization management programs would be required to include medically appropriate incentives to use generic drugs and therapeutic interchange where appropriate. Medication therapy management programs would be designed to assure, for beneficiaries at risk for

potential medication problems such as beneficiaries with complex or chronic diseases (such as diabetes, asthma, hypertension, and congestive heart failure) or multiple prescriptions, that drugs under the plan were appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events, including adverse drug interactions. The program would be developed in cooperation with licensed pharmacists and physicians. The PDP sponsor would be required, when establishing fees for pharmacists and other providers, to take into account the resources and time associated with the medication therapy management program. MA private fee-for-service plans would not be required to comply with the drug utilization management program, negotiate discounts from manufacturers, meet the TRICARE standards for participation, or disclose the fact that a lower priced generic drug is available at the time of purchase.

The electronic prescription drug program would have to be consistent with national standards developed by the MBA Administrator. The program would be required to provide for electronic transmittal of prescriptions (except in emergencies and exceptional cases) and for provision of information to the prescribing health professional. To the extent feasible, the program would permit the prescribing health professional to provide, and be provided, information on an interactive real-time basis. The electronic prescribing program would permit health professionals to access information on the different medications a senior may be taking—making it easier to prevent adverse drug interactions and side effects. In addition, electronic prescribing would cut down on both the costs and hassle that pharmacists incur trying to decipher a handwritten script. These systems will increase drug compliance and properly monitor drug utilization.

The MBA Administrator would be required to provide for the development of national standards relating to the electronic prescription drug program. The standards would be compatible with those established for the administrative simplification program established under title XI of the Social Security Act. The MBA Administrator would establish an advisory task force that included representatives of physicians, hospitals, pharmacies, beneficiaries, pharmacy benefit managers, technology experts, and pharmacy benefit experts of the Department of Veterans Affairs, Defense and other appropriate Federal agencies. The task force would provide recommendations to the MBA Administrator on standards including recommendations relating to: (1) range of available computerized prescribing software and hardware and their costs to develop and implement, (2) extent to which such standards and systems reduce medication errors and can be readily implemented by physicians, pharmacies, and hospitals, (3) efforts to develop uniform standards and a common software platform for the secure electronic transmission of medication history, eligibility, benefit and prescription information, (4) efforts to develop and promote universal connectivity and interoperability for the secure exchange of information, (5) cost of implementing such systems in hospital and physician office settings and pharmacies, and (6) implementation issues as they relate to administrative simplification requirements and current Federal and State prescribing laws and regulations and their impact on implementation of computerized prescribing.

The MBA Administrator would be required to establish the task force by April 1, 2004. The task force would be required to submit recommendations to the MBA Administrator by January 1, 2005. The MBA Administrator would be required to promulgate national standards by January 1, 2006. Given current available technology, the committee supports the timely development of standards to facilitate a secure electronic prescription information program between prescribing health care professionals, pharmacists, and pharmacy benefit managers (PBMs) to reduce dangerous drug interactions as well as errors due to poor handwriting and transcribing errors. To this end, the committee believes that it would be to the benefit of the patient for prescribing professionals to have real-time, "up-front" access to the patient's medication history, eligibility for benefits, drug formulary (if applicable), and coverage, when making prescribing decisions.

Each PDP sponsor would be required to have meaningful procedures for the hearing and resolving of any grievances between the organization (including any entity or individual through which the organization provides covered benefits) and enrollees. Enrollees would be afforded access to expedited determinations and reconsiderations, in the same manner afforded under MA. A beneficiary in a plan that provided for tiered cost-sharing could request coverage of a non-preferred drug on the same conditions applicable to preferred drugs if the prescribing physician determines that the preferred drug for the treatment of the same condition was not as effective for the enrollee or could have adverse effects for the enrollee. Such decisions could also be appealed under the MA appeals structure.

In general, PDP sponsors would be required to meet for independent review standards for coverage denials and appeals in the same manner that such standards apply to MA organizations. An individual enrolled in a PDP could appeal to obtain coverage for a drug not on the formulary or in a different cost sharing tier if the prescribing physician determined that the formulary drug for treatment of the same condition was not as effective for the individual or had adverse effects for the individual. The PDP sponsor would be required to meet requirements related to confidentiality and accuracy of enrollee records in the same manner that such requirements apply to MA organizations.

New Section 1860D–4. Requirements for and Contracts With Prescription Drug Plan (PDP) Sponsors

New Section 1860D–4 would specify organizational plan requirements for entities seeking to become PDP sponsors. In general, the section would require a PDP sponsor to be licensed under state law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each state in which it offers a prescription drug plan. Alternatively it could meet solvency standards established by the MBA Administrator for entities not licensed by the state. Plans would be required to assume full financial risk on a prospective basis for covered benefits except: (1) as covered by federal subsidy payments and reinsurance payments for high-cost enrollees, or (2) as covered by federal incentive payments to encourage plans to expand service areas for existing plans or establish

new plans. The entity could obtain insurance or make other arrangements for the cost of coverage provided to enrollees.

PDP sponsors would be required to enter into a contract with the MBA Administrator under which the sponsor agrees to comply both with the applicable requirements and standards and the terms and conditions of payment. The contract could cover more than one plan. The MBA Administrator would have the same authority to negotiate the terms and conditions of the plans as the Director of the Office of Personnel Management has with respect to FEHB plans. The MBA Administrator would be required to take into account subsidy payments for covered benefits in negotiating the terms and conditions regarding premiums. The MBA Administrator would designate at least 10 service areas consistent with the areas established for EFFS plans.

The new section would incorporate, by reference, many of the contract requirements applicable to MA plans, including minimum enrollment, contract periods, allowable audits to protect against fraud and abuse, intermediate sanctions, and contract terminations. Pro rated user fees could be established to help finance enrollment activities; in no case could the amount of the fee exceed 20 percent of the maximum fee permitted for a MA plan.

The new Section would permit the MBA Administrator to waive the state licensure requirement under circumstances similar to those permitted under Part C for provider-sponsored organizations. In such cases, plans would be required to meet financial solvency and capital adequacy standards established by the MBA Administrator. The MBA Administrator would establish such standards by regulation by October 1, 2004.

The standards established under Part D would supersede any state law or regulation (other than state licensing laws or laws relating to plan solvency). In addition, states would be prohibited from imposing premium taxes or similar taxes with respect to premiums paid to PDP sponsors or payments made to such sponsors by the MBA Administrator.

New Section 1860D–5. Process for Beneficiaries To Select Qualified Prescription Drug Coverage

The new Section 1860D–5 would require the MBA Administrator to establish a process for the selection of a PDP or MA–EFFS sponsor that provided qualified prescription drug coverage. The process would include the conduct of annual coordinated election periods under which individuals could change the qualifying plans through which they obtained coverage. The process would also include the active dissemination of information to promote an informed selection among qualifying plans (based on price, quality, and other features) in a manner consistent with and in coordination with the dissemination of information under MA. Further, the process would provide for the coordination of elections through filing with a PDP or MA–EFFS sponsor in a manner consistent with that provided under MA. The plan would have to inform each enrollee at the beginning of the year of the enrollee's annual out-of-pocket threshold.

The section would specify that an EFFS enrollee could only elect to receive drug coverage through the plan.

The MBA Administrator would assure that all eligible individuals residing in the United States would have a choice of enroll-

ment in at least two qualifying plan options, at least one of which is a PDP, in their area of residence. The requirement would not be satisfied if only one PDP or MA–EFFS sponsor offers all the qualifying plans in the area. If necessary to ensure such access, the MBA Administrator would be authorized to provide partial underwriting of risk for a PDP sponsor to expand its service area under an existing prescription drug plan to adjoining or additional areas, or to establish such a plan, including offering such plan on a regional or nationwide basis. The assistance would be available only so long as, and to the extent necessary, to assure the guaranteed access. However, the MBA Administrator could never provide for the full underwriting of financial risk for any PDP sponsor. Additionally, the MBA Administrator would be directed to seek to maximize the assumption of financial risk by PDP sponsors and entities offering MA–EFFS plans. The MBA Administrator would be required to report to Congress annually on the exercise of this authority and recommendations to minimize the exercise of such authority.

New Section 1860D–6. Submission of Bids

The new Section 1860D–6 would require each PDP sponsor to submit to the MBA Administrator specified information in the same manner MA organizations submit information. The submitted information would be the qualified drug coverage to be provided, the actuarial value of the coverage, and details of the bid and coverage premium. The PDP sponsor would include: (1) actuarial certification of the bid and premium, (2) the portion of the bid and premium attributable to benefits in excess of the standard coverage, (3) the reduction in the premium resulting from reinsurance subsidies, (4) the reduction in the bid resulting from direct and reinsurance subsidy payments, and (5) such other information required by the MBA Administrator.

The MBA Administrator would review the submitted information for purposes of conducting negotiations with the plan. The MBA Administrator would approve the premium only if it accurately reflected the actuarial value of the benefits and the 73 percent average subsidy provided for under the new Section 1860D–8. The MBA Administrator would apply actuarial principles to approval of a premium in a manner similar to that used for establishing the monthly Part B premium. These requirements would not apply to MA plans.

The bid and premium for a PDP could not vary among individuals enrolled in the plan in the same service area, provided they were not subject to late enrollment penalties. A PDP sponsor would permit each enrollee to have their premiums withheld from their Social Security checks in the same manner as is currently done for Part B premiums and transferred to the plan in which they are enrolled. Beneficiaries could also make payment of the premium through an electronic funds transfer mechanism. The amount would be credited to the Medicare Prescription Drug Trust Fund. Reductions in Part B premiums attributable to enrollment in MA plans could be used to reduce the premium otherwise applicable.

Under certain conditions, PDP or MA–EFFS sponsors in an area would be required to accept, for an individual eligible for a low-income premium subsidy, the reference premium amount (premium

for standard coverage) as payment in full for the premium for qualified prescription coverage. This requirement would apply if there was no standard coverage available in the area.

New Section 1860D–7. Premium and Cost-Sharing Subsidies for Low-Income Individuals

The new Section 1860D–7 would provide subsidies for low-income individuals. Low-income persons would receive a premium subsidy (based on the value of standard coverage). Individuals with incomes below 135 percent of poverty (and assets below $4,000) would have a subsidy equal to 100 percent of the value of standard drug coverage provided under the plan. For individuals between 135 percent and 150 percent of poverty, there would be a sliding scale premium subsidy ranging from 100 percent of such value at 135 percent of poverty to zero percent of such value at 150 percent of poverty. The asset test for this part is twice the asset test used for determining Supplemental Security Income (SSI) eligibility, indexed to inflation. (Note: the asset test has not previously been indexed.) Not all resources are counted. Excluded resources include: a home (with no limit on its value) if the individual lives in it; household goods and personal effects up to $2,000; one car used to provide necessary transportation regardless of value or if not used to provide transportation, excluded up to $4,500 in value; the value of a burial space; other property essential for self support of the individual; life insurance up to $1,500; the value of a trust, but trusts must meet very specific criteria; and other exclusions. Sponsors and entities could not charge individuals receiving cost-sharing subsidies more than five dollars per prescription. Sponsors and entities could reduce the cost-sharing to zero, which would otherwise be applicable for generic drugs.

State Medicaid programs or the Social Security Administration (SSA) would determine whether an individual would be eligible for a low-income subsidy, as well as the amount of the subsidy. SSA would be appropriated the necessary funds. The Congressional Budget Office (CBO) estimates that 152,000 seniors who would otherwise not enroll in the low-income subsidy program would participate since the enrollment process through SSA avoids the stigma of signing up at a welfare office. Individuals not in the 50 States or the District of Columbia could not be subsidy eligible individuals but could be eligible for financial assistance with drug costs under new Section 1935(e) added by Section 103.

Whether offered by a PDP or MA–EFFS sponsor, the premium subsidy amount would be defined as the benchmark premium amount for the qualified prescription drug coverage chosen by the beneficiary. The benchmark premium amount for a plan means the premium amount for enrollment under the plan (without regard to any subsidies or late enrollment penalties) for standard coverage (or alternative coverage if the actuarial value is equivalent). If a plan provides alternative coverage with a higher actuarial value than that for standard coverage, the benchmark amount would bear the same ratio to the total premium as the actuarial value of standard coverage was to the actuarial value of alternative coverage.

The MBA Administrator would provide a process whereby the PDP or MA–EFFS sponsor would notify an individual that he or

she is eligible for a subsidy as well as the amount of the subsidy. The sponsor would reduce the individual's premium or cost-sharing otherwise imposed by the amount of the subsidy. The MBA Administrator would periodically, and on a timely basis, reimburse the sponsor or entity for the amount of such reductions.

Part D benefits would be primary to any coverage available under Medicaid. The MBA Administrator would be required to develop and implement a plan for the coordination of Part D benefits and Medicaid benefits. Particular attention would be given to coordination of payments and preventing fraud and abuse. The MBA Administrator would be required to involve the Secretary, the States, the data processing industry, pharmacists, pharmaceutical manufacturers, and other experts in the development and administration of the plan.

New Section 1860D–8. Subsidies for All Medicare Beneficiaries for Qualified Prescription Drug Coverage

New Section 1860D–8 would provide for subsidy payments to qualifying entities. The payments would reduce premiums for all enrolled beneficiaries consistent with an overall subsidy level of 73 percent, reduce adverse selection among plans, and promote the participation of PDP sponsors. Such payments would be made as direct subsidies and through reinsurance. The section would constitute budget authority in advance of appropriations and represent the obligation of the MBA Administrator to provide for subsidy payments specified under the section.

Direct subsidies would be made for individuals enrolled in a PDP or MA–EFFS plan, equal to 43 percent of the national weighted average monthly bid amount. Each year, the MBA Administrator would compute a national average monthly bid amount equal to the average of the benchmark bid amounts for each drug plan (not including those offered by private plans) adjusted to add back in the value of reinsurance subsidies. The benchmark bid amount would be defined as the portion of the bid attributable to standard coverage or actuarial equivalent coverage. The bid amount would be a weighted average with the weight for each plan equal to the average number of beneficiaries enrolled in the plan for the previous year. (The MBA Administrator would establish a procedure for determining the weighted average for 2005).

Reinsurance payments would be made for specified costs incurred in providing prescription drug coverage for individuals enrolled in either a PDP or MA–EFFS plan. The MBA Administrator would provide for reinsurance payments to PDP sponsors, and entities offering MA or EFFS plans. Reinsurance payments would be provided for 30 percent of an individual's allowable drug costs over the initial reinsurance threshold ($1,000 in 2006) but not over the initial coverage limit ($2,000 in 2006). Reinsurance of 80 percent would also be provided for allowable costs over the out-of-pocket threshold ($3,500 in 2006). These reinsurance payments would provide additional assistance to those plans that enroll beneficiaries who have multiple or very expensive prescription drug regimens. In the aggregate, reinsurance payments would equal 30 percent of total payments made by qualifying entities for standard coverage.

For purposes of calculating reinsurance payments, allowable costs would be defined as the portion of gross covered prescription

drug costs that were actually paid by the plan, but in no case more than the part of such costs that would have been paid by the plan if the drug coverage under the plan were standard coverage. Gross covered drug costs would be defined as costs (including administrative costs) incurred under the plan for covered prescription drugs dispensed during the year, including costs related to the deductible, whether paid by the enrollee or the plan, regardless of whether coverage under the plan exceeded standard coverage and regardless of when the payment for the drugs was made.

The MBA Administrator would be required to estimate the total reinsurance subsidy payments that would be made during the year (including those made to qualified retiree plans) and total benefit payments to be made by qualifying entities for standard coverage during the year. The MBA Administrator would proportionately adjust payments such that total subsidy payments during the year were equal to 30 percent of total payments made by qualifying plans for standard coverage during the year. The MBA Administrator could adjust direct subsidy payments in order to avoid risk selection. The MBA Administrator would determine the payment method and could use an interim payment system based on estimates. Payments would be made from the Medicare Prescription Drug Trust Fund.

Special subsidy payments would be made to a qualified retiree prescription drug plan. A qualified plan would be defined as employment-based retiree health coverage (including coverage offered pursuant to one or more collective bargaining agreements) meeting certain requirements. The MBA Administrator would approve coverage with at least the same actuarial value as standard coverage. The sponsor (and the plan) would be required to maintain and provide access to records needed to ensure the adequacy of coverage and the accuracy of payments made. Further, the sponsor would be required to provide certifications of coverage. Payment could not be made for an individual unless the individual was covered under the retiree plan and entitled to enroll under a PDP or MA–EFFS plan but elected not to. Subsidy payments would equal 28 percent of allowable costs between $250 and $5,000. (The dollar amounts would be adjusted annually by the percentage increase in Medicare per capita prescription drug costs.)

About one-third of Medicare beneficiaries receive retiree coverage from their former employers. While most of these people are satisfied with their coverage, employers are under increasing pressure to drop or reduce prescription drug coverage. This subsidy provides employers and union plans with maximum flexibility, encouraging them to maintain or expand their retiree plans. Thus, Medicare would reap significant savings from subsidizing employer plans at two-thirds of the cost of other Medicare prescription drug plans.

New Section 1860D–9. Medicare Prescription Drug Trust Fund

New Section 1860D–9 would create a Medicare Prescription Drug Trust Fund. Requirements applicable to the Part B trust fund would apply in the same manner to the Drug Trust Fund as they apply to the Part B Trust Fund. The Managing Trustee would pay from the account, from time to time, low-income subsidy payments, subsidy payments, and payments for administrative expenses. The

Managing Trustee would transfer, from time to time, to the Medicaid account amounts attributable to allowable increases in administrative costs associated with identifying and qualifying beneficiaries eligible for low-income subsidies. Amounts deposited into the Trust Fund would include the federal amount which would otherwise be payable by Medicaid except for the fact that Medicaid becomes the secondary payer of drug benefits for the dual-eligibles. The provision would authorize appropriations to the Trust Fund an amount equal to the amount of payments from the Trust Fund reduced by the amount transferred to the Trust Fund.

The provision would specify that any provision of law relating to the solvency of the Trust Fund would take into account the amounts received by, or payable from, the Trust Fund.

EFFECTIVE DATE

Upon enactment.

New Section 1860D–10. Definitions; Treatment of References to Provisions in Part C

New section 1860D–10 would include definitions of terms and specify how cross-references to Part C would be applied. It would further provide that any reduction or waiver of cost-sharing would not be in violation of kickback and similar prohibitions. The section would further require the Secretary to submit a report to Congress within 6 months of enactment that makes recommendations regarding providing benefits under Part D.

Also within six months of enactment, the Secretary would be required to review the current standards of practice for pharmacy services provided to patients in nursing facilities. Specifically, the Secretary would assess: (1) the current standards of practice, clinical services, and other service requirements generally utilized for such pharmacy services, (2) evaluate the impact of those standards with respect to patient safety, reduction of medication errors, and quality of care, and (3) recommend necessary actions.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Prescription drugs are just as important to modern health care as hospitals and physician services were when Medicare was enacted in nearly 40 years ago. Prescription drugs are more often than not, the health care solution of choice. Most often, they prevent, treat or manage diseases more effectively and less invasively than hospitals and nursing homes. The typical senior now takes more than 20 prescriptions a year to improve their health or manage their diseases. While seniors are taking more drugs than any other demographic group, they are often paying the highest prices because more than one-third of seniors have no prescription drug coverage. Similarly, low-income beneficiaries must often make unacceptable choices between life-savings medicines and other essentials.

The addition of a prescription drug benefit to Medicare, while providing seniors additional choices in how they receive their

health services, is a critical modernization of the program. In designing how these benefits are delivered, the Committee believes competition among plans will lead to the most efficient allocation of resources and will create opportunities to increase the availability of certain drugs, to reduce the cost of drugs, and the cost of the program to taxpayers.

Importantly, guaranteeing issuance of policies, providing uniform plan premiums, ensuring two plans in each area and providing a worst case fall back ensure beneficiaries have the coverage to which they are entitled. Important new beneficiary protections, such as allowing any willing pharmacy to participate, ensuring convenient access to bricks and mortar pharmacies, creating a level playing field for mail order and retail pharmacy, and prohibiting plans from pushing insurance risk onto pharmacists ensure seniors can get the drugs at the pharmacy of their choice. Establishing new appeal rights for coverage denials or tiered cost sharing problems helps beneficiaries access the drugs most appropriate to their medical condition.

In addition, by providing new tools to improve health, such as electronic prescribing, medication therapy management, and utilization review, the provision would greatly improve the quality of services provided to beneficiaries.

In combination, these provisions will provide important new benefits where Medicare is lacking, create new choices for seniors, and create new protections to achieve the goals of reduced costs and improved health.

Section 102. Offering of Qualified Prescription Drug Coverage Under the Medicare Advantage and Enhanced Fee-For-Service Program

CURRENT LAW

Under current law, Medicare+Choice plans may elect to offer prescription drug coverage under Part C. The extent of these benefits varies and is not subject to any explicit standardization requirements. However, as with all Medicare+Choice benefit specifics, the financing and design of such benefits must meet the approval of the Secretary under the adjusted community rate (ACR) approval process. Generally, plans offering drugs must either finance such benefits from the differences between the applicable county payment rate and their costs in providing Medicare's basic benefits, or by assessing beneficiaries who enroll in the plan supplemental premiums.

EXPLANATION OF PROVISION

The provision would specify that, beginning January 1, 2006, a MA organization could not offer a coordinated care MA plan unless either that plan or another plan offered by the organization in the area included qualified drug coverage. It could not offer drug coverage (other than that already required under Medicare) unless the coverage was at least qualified prescription drug coverage. An individual not electing qualified prescription drug coverage under Part D would be treated as ineligible to enroll in a MA plan offering such coverage.

The organization would be required to meet beneficiary protections outlined in the new Section 1860D–3, including requirements relating to information dissemination and grievance and appeals. The organization would also be required to submit the same information required of PDP sponsors when submitting a bid. The MBA Administrator could waive such requirements to the extent the MBA Administrator determined they were duplicative of requirements otherwise applicable to the organization or plan. MA organizations providing qualified drug coverage would receive low-income subsidy payments, and direct and reinsurance subsidies. A single premium would be established for drug and non-drug coverage.

The same requirements would be applicable to an EFFS organization.

EFFECTIVE DATE

Applies to coverage provided on or after January 1, 2006

REASON FOR CHANGE

Ensures MA–EFFS plans offer qualified prescription drug coverage if they offer coverage, consistent with Section 101.

Section 103. Medicaid Amendments

CURRENT LAW

Some low-income aged and disabled Medicare beneficiaries are also eligible for full or partial coverage under Medicaid. Within broad federal guidelines, each state sets its own eligibility criteria, including income eligibility standards. Persons meeting the state standards are entitled to full coverage under Medicaid. Persons entitled to full Medicaid protection generally have all of their health care expenses met by a combination of Medicare and Medicaid. For these "dual-eligibles" Medicare pays first for services both programs cover. Medicaid picks up Medicare cost-sharing charges and provides protection against the costs of services generally not covered by Medicare, including prescription drugs. State Medicaid programs have the option to include prescription drugs in their Medicaid benefit packages. All states include drugs for at least some of their Medicaid beneficiaries and many offer it to all program recipients entitled to full Medicaid benefits.

Federal law specifies several population groups that are entitled to more limited Medicaid protection. These are qualified Medicare beneficiaries (QMBs), specified low-income Medicare beneficiaries (SLMBs), and certain qualifying individuals. QMBs are aged or disabled persons with incomes at or below the federal poverty level and assets below $4,000 for an individual and $6,000 for a couple. QMBs are entitled to have their Medicare cost-sharing charges, including the Part B premium, paid by the federal-state Medicaid program. SLMBs are persons who meet the QMB criteria, except that their income is over the QMB limit; the SLMB limit is 120 percent of the federal poverty level. Medicaid protection for SLMBs is limited to payment of the Medicare Part B premium. QMBs and SLMBs are not entitled to Medicaid's prescription drug benefit unless they are also entitled to full Medicaid coverage under their state's Medicaid program.

Qualifying individuals (QIs) are never entitled to Medicaid drug coverage (because, by definition, they are not eligible for full Medicaid benefits). QI–1s are persons who meet the QMB criteria, except that their income is between 120 percent and 135 percent of poverty. Medicaid protection for QI–1s is limited to payment of the monthly Medicare Part B premium. QI–2s are persons who meet the QMB criteria, except that their income is between 135 percent and 175 percent of poverty. Medicaid protection for QI–2s is limited to payment of that portion of the Part B premium attributable to the gradual transfer of some home health visits from Medicare Part A to Medicare Part B. Expenditures under the QI–1 and QI–2 programs are paid for 100 percent by the Federal government (from the Part B Trust Fund) up to the state's allocation level. A state is only required to cover the number of persons which would bring its spending on these population groups in a year up to its allocation level. Any expenditure beyond that level would be paid by the state. Assistance under the QI–1 and QI–2 programs is available for the period January 1, 1998 to December 31, 2002.

EXPLANATION OF PROVISION

Section 103 would add a new Section 1935 to the Social Security Act entitled "Special Provisions Relating to Medicare Prescription Drug Benefit." The provision requires states, as a condition of receiving Federal Medicaid assistance, to make eligibility determinations for low-income premium and cost-sharing subsidies, inform the MBA Administrator of cases where eligibility has been established, and otherwise provide the MBA Administrator with information that may be needed to carry out Part D. In 2005, the federal matching rate would be increased to 100 percent over 15 years. Beginning in 2020 the, the federal matching rate would be 100 percent. The states would be required to provide the MBA Administrator with the appropriate information needed to properly allocate administrative expenditures that could be made for similar eligibility determinations.

The provision would provide for the Federal phase-in of the costs of premiums and cost-sharing subsidies for dual-eligibles (i.e. persons eligible for Medicare and full Medicaid benefits, including drugs). Over the 2006–2020 period, the Federal matching rate for these costs would be increased to cover 100 percent of what would otherwise be state costs. States would be required to maintain Medicaid benefits as a wrap-around to Medicare benefits for dual-eligibles; states could require that these persons elect Part D drug coverage.

Residents of territories would not be eligible for regular low-income subsidies. However, territories would be able to get additional Medicaid funds, beginning at $25 million in 2006 and increasing in subsequent years by the annual percentage increase in prescription drug costs for Medicare beneficiaries. In order to obtain these funds, territories would be required to formulate a plan on how they would dedicate the funds to assist low-income Medicare beneficiaries in obtaining covered outpatient prescription drugs. The MBA Administrator would be required to report to Congress on the application of the law in the territories.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Seniors should be treated as seniors first and low-income second. The patchwork of state Medicaid programs that can vary from state to state is confusing and demoralizing for many seniors. By federalizing the drug costs of the dual eligibles, we ensure beneficiaries have access to a uniform, Medicare benefit.

Section 104. Medigap Transition

CURRENT LAW

Most beneficiaries have some health insurance coverage in addition to basic Medicare benefits. Some individuals obtain private supplemental coverage through an individually purchased policy, commonly referred to as a "Medigap" policy. Beneficiaries with Medigap insurance typically have coverage for Medicare's deductibles and coinsurance; they may also have coverage for some items and services not covered by Medicare. Individuals generally select from one of ten standardized plans, though not all ten plans are offered in all states. The plans are known as Plans A through plan J. Plan A covers a basic package of benefits. Each of the other nine plans includes the basic benefits plus a different combination of additional benefits. Plan J is the most comprehensive. Plans H, I, and J offer some drug coverage.

The law provided for the development by the National Association of Insurance Commissioners (NAIC) of standardized benefit packages. It also provides for modifications of such packages when Medicare benefit changes are enacted.

All insurers offering Medigap policies are required to offer open enrollment for 6 months from the date a person first enrolls in Medicare Part B (generally when the enrollee turns 65). The law also guarantees issuance of specified Medigap policies for certain persons whose previous supplemental coverage was terminated. Guaranteed issue also applies to certain persons who elect to try out a managed care option under the Medicare+Choice plan program.

EXPLANATION OF PROVISION

The provision would prohibit, effective January 1, 2006, the issuance of new Medigap policies with prescription drug coverage. The prohibition would not apply to policies replacing another policy with drug coverage. Further, it would not apply to policies meeting new standards, or pre-standards, as outlined below. Beneficiaries could keep their existing H, I, and J plans.

The provision would guarantee issuance of a substitute Medigap policy for persons, enrolling in Part D, who at the time of such enrollment were enrolled in and terminated enrollment in a Medigap H, I, or J plan. The guaranteed enrollment would be for any of the Plans A through Plan G. The guarantee would apply for enrollments occurring in the new Medigap plan within 63 days of termination of enrollment in a Medigap H, I, or J plan. The insurer could not impose an exclusion based on a pre-existing condition for

such individuals. Further, the insurer would be prohibited from discriminating in the pricing of such policy on the basis of the individual's health status, claims experience, receipt of health care or medical condition.

The provision would provide for the development by the NAIC of two new standardized Medigap plans and would outline the standards for these policies. The first new policy would have the following benefits (notwithstanding other provisions of law relating to core benefits): (1) coverage of 50 percent of the cost-sharing otherwise applicable (except coverage of 100 percent cost-sharing applicable for preventive benefits), (2) no coverage of the Part B deductible, (3) coverage of all hospital coinsurance for long stays (as in current core package), and (4) a limitation on annual out-of-pocket costs for Part A and Part B beneficiaries of $4,000 in 2005 (increased in future years by an appropriate inflation adjustment as specified by the Secretary). The second new policy would have the same benefit structure as the first new policy, except that: (1) coverage would be provided for 75 percent, rather than 50 percent, of cost-sharing otherwise applicable, and (2) the limitation on out-of-pocket costs would be $2,000, rather than $4,000. Both policies could provide for coverage of Part D cost-sharing; however, neither policy could cover the Part D deductible.

The NAIC would make recommendations to Congress on modernizing the Medigap market.

It is the Committee's intent that the offering of these new Medigap policies would be voluntary on the part of insurers, as is the case for all other Medigap standardized policies beyond plan type A, basic Medigap coverage.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The two new Medigap policies would provide additional cost sharing for beneficiaries without first dollar coverage. This ensures beneficiaries have additional access to cover cost sharing for the new prescription drug benefit if they so choose.

Section 105. Medicare Prescription Drug Discount Card Endorsement Program

CURRENT LAW

On July 12, 2001, the President announced a new national drug discount card program for Medicare beneficiaries. Under this program, CMS would endorse drug card programs that meet certain requirements. This program was intended to be an interim step until a legislative reform package, including both a drug benefit and other Medicare reforms, is enacted. Implementation of the drug discount card program was suspended by court action.

EXPLANATION OF PROVISION

The provision would require the Secretary or Administrator to establish a program to: (1) endorse prescription drug discount card programs that meet certain requirements, and (2) make available

information on such programs to beneficiaries. The Secretary would begin operating the program within 90 days of enactment. The Secretary would provide for an appropriate transition and discontinuation at the time a drug benefit first becomes available under Part D.

Programs endorsed by the Secretary must meet certain requirements. Programs shall pass negotiated discounts on drugs to enrollees. Programs could not be limited to mail order drugs and must provide support services to educate patients and prevent adverse events. Programs must also provide, through the Internet or otherwise, information to enrollees that the Secretary deems necessary for beneficiaries to make informed choices among all endorsed programs. This information would include information on enrollment fees, prices charged to beneficiaries, and services offered under the program. Program sponsors would be required to demonstrate experience and expertise in operating such a program. The sponsor would also be required to have in place adequate procedures for quality assurance. The annual enrollment fee could not exceed $30 (which could be paid in whole or in part by states). Further, the program would be required to meet additional requirements identified by the Secretary to protect and promote the interest of Medicare beneficiaries, including requirements that assure that beneficiaries were not charged more than the lower of the negotiated retail price or the usual and customary price.

The Secretary would provide for the dissemination of information that compared the costs and benefits of available programs. This activity would be coordinated with the dissemination of educational information on MA plans. The Secretary would also oversee the endorsed programs' compliance with the requirements of this section, including verification of discounts, and services provided, the amount of dispensing fees, and audits. The Secretary would be required to provide, through the use of the Medicare toll-free number, for the receipt and response to inquiries and complaints. The Secretary would be required to revoke the endorsement of any program that no longer meets requirements or engages in false or misleading marketing practices. The provision would specify that a beneficiary could only be enrolled in one endorsed program at a time. A beneficiary could change enrollment after he or she has been enrolled in a plan for a minimum period specified by the Secretary.

The provision creates a two-year, temporary, transitional low-income assistance program. Medicare beneficiaries with incomes below 150 percent of poverty would be eligible for assistance in 2004 and 2005. The program provides additional funds in conjunction with the discount card to help low-income seniors purchase prescription drugs prior to the implementation of the drug benefit in 2006. The bill provides for $2 billion in 2004 and $3 billion in 2005.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Immediate help for those without prescription drug coverage will provide a transition into the new Part D drug benefit while ensur-

ing those who cannot afford prescription drugs receive assistance. In addition, drug discount cards can be up and running within 90 days, which will provide savings to seniors at retail between 10 and 20 percent, according to HHS. Discounts must be provided by both manufacturers and pharmacies and must be passed on to beneficiaries.

Section 106. Disclosure of Return Information for Purpose of Carrying Out Medicare Catastrophic Prescription Drug Program

CURRENT LAW

Current law authorizes, under specified circumstances, the Secretary of the Treasury to disclose returns and return information for purposes other than tax administration.

EXPLANATION OF PROVISION

The provision would permit the Secretary of the Treasury, upon written request from the Secretary of the Department of Health and Human Services (HHS), to disclose to officers and employees of HHS specific information with respect to a specified taxpayer for a specific tax year. Information that could be disclosed would be taxpayer identification information and adjusted gross income, or, simply the income threshold limit specified under the new Part D ($200,000 in 2006). A specified taxpayer would be either: (1) an individual who had adjusted gross income for the year in question in excess of the income threshold specified in the new Part D ($60,000 per individual), or (2) an individual who elected to use more recent income information as permitted under Part D. Individuals filing joint returns would be treated separately, each considered to have an adjusted gross income equal to one-half of the total.

Officers and employees of HHS would be authorized to use tax return information only for administering the prescription drug benefit. HHS could disclose a beneficiary's determined annual out-of-pocket threshold to a beneficiary's PDP sponsor. The sponsor could use such information only for the purposes of administering the benefit.

EFFECTIVE DATE

Upon enactment.

Section 107. State Pharmaceutical Assistance Transition Commission

CURRENT LAW

A number of states currently have programs to provide low-income persons, not qualifying for Medicaid, with financial assistance in meeting their drug costs. The state programs differ substantially in both design and coverage.

EXPLANATION OF PROVISION

The provision would establish a State Pharmaceutical Assistance Transition Commission to develop a proposal for dealing with the transitional issues facing state programs and participants due to implementation of the new Part D prescription drug program. The Commission, to be established on the first day of the third month

following enactment, would include: (1) a representative of each governor from each state with a program that the Secretary identifies as having a benefit package comparable to or more generous than the new Part D, (2) representatives from other states that have pharmaceutical assistance programs, as appointed by the Secretary, (3) representatives (not exceeding the total under (1) or (2) above) of organizations that represent interests of participants, appointed by the Secretary, (4) representatives of Medicare Advantage organizations; and (5) the Secretary or the Secretary's designee and other members specified by the Secretary. The Commission would develop the proposal in accordance with specified principles, namely: (1) protection of the interests of program participants in the least disruptive manner, (2) protection of the financial and flexibility interests of states so they are not financially worse off, and (3) principles of Medicare modernization outlined in Title II of the Act. It is the intent of the Committee that Medicare beneficiaries use one prescription drug card for their benefit. The Committee believes presenting beneficiaries with more than one card would be confusing and administratively inefficient.

The Commission would report to the President and Congress by January 1, 2005. The report would contain specific proposals including specific legislative or administrative recommendations, if any. The Commission would terminate 30 days later.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

States, especially those with comprehensive pharmaceutical assistance programs, would benefit significantly. States would receive billions of dollars in assistance under the proposal, with the most help going to those states that have already provided pharmaceutical drug assistance to seniors. Since some states have initiated pharmaceutical assistance for low-income seniors, these states would reap the most savings, as Medicare would become the primary insurer for these beneficiaries. States have several options in relation to the new benefit. First, they could design their pharmacy programs to "wrap around" the Medicare drug benefit. Second, their pharmacy program could subsidize low-income individuals with costs between $2,000 and the $3,500 catastrophic benefit. This spending would count toward the catastrophic cap. Further, state pharmacy assistance programs could use money saved from the Medicare drug benefit to extend their assistance to persons with incomes above 150 percent of poverty. Finally, state pharmacy programs could work to encourage low-income individuals to enroll in a PDP, thereby creating a seamless transition from the perspective of the individual. Their cost-sharing still could not exceed $5 per prescription, and they could get the prescription drugs they need at a convenient pharmacy. From the beneficiary's perspective nothing will have changed.

It is difficult to foresee every issue that may impact states that have already provided substantial assistance to seniors. A State Pharmaceutical Assistance Transition Commission would be established under the bill. This commission would develop a proposal to address the unique transition issues facing these states.

B. TITLE II—MEDICARE ENHANCED FEE-FOR-SERVICE AND MEDICARE ADVANTAGE PROGRAMS; MEDICARE COMPETITION

Section 200. Medicare Modernization and Revitalization

CURRENT LAW

Health Maintenance Organizations (HMOs) and other types of managed care plans have been allowed to participate in the Medicare program, beginning with private health plan contracts in the 1970s and the Medicare risk contract program in the 1980s. BBA 97 replaced the risk contract program with the Medicare+Choice (M+C) program.

EXPLANATION OF PROVISION

This title would establish the Medicare Enhanced Fee-for-Service (EFFS) program, under which Medicare beneficiaries would be provided access to a range of EFFS plans that may include preferred provider networks. It would establish a Medicare Advantage (MA) program to offer improved managed care plans with coordinated care. It would also use competitive bidding, in the same style as FEHBP for certain areas, beginning in 2010, to promote greater efficiency and responsiveness to Medicare beneficiaries.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This title modernizes and revitalizes private plans under Medicare. BBA 97 altered payments for private plans and expanded the types of plans that could be offered under Medicare. Since payment rate changes were implemented, enrollment in private plans has fallen from 6.2 million beneficiaries in 1998 to 4.6 million beneficiaries in May 2003, and the number of plans has decreased from 346 risk plans in 1998 to 153 (149 coordinated care plans and 4 private FFS plans) in May 2003. This disruption has been due, in part, to unpredictable and insufficient payments. BBA 97 fundamentally de-linked payments to plans from FFS payment growth.

To increase beneficiary choice, Title II reforms the payment system in 2004. All plans would be paid at a rate at least as high as the rate for traditional FFS Medicare, as recommended by the Medicare Payment Advisory Commission (MedPAC). After 2004, private plans' capitation rates would grow at the same rate as FFS Medicare. To increase beneficiary choice in more rural areas, Title II would establish the Enhanced Fee-for-Service (EFFS) program, which would encourage private plans to serve Medicare beneficiaries in larger regions, beginning in 2006. Private plans in both Medicare Advantage (MA) and EFFS plans would bid competitively against a benchmark beginning in 2006.

Once private plans became established, and enrollment in private plans increased, plans in certain areas would enter a FEHBP-style competitive bidding program, beginning in 2010. Plan bids from private plans and rates for traditional FFS Medicare would be averaged to create a benchmark for competitive bidding. The competitive program would encourage beneficiaries to enroll in the

most efficient plan, producing savings for both beneficiaries, through reduced premiums, and for taxpayers, through relatively lower Medicare costs.

Subtitle A—Medicare Enhanced Fee-for-Service Program

Section 201. Establishment of Enhanced Fee-for-Service (EFFS) Program under Medicare

CURRENT LAW

Payment. Under current law, Medicare+Choice (M+C) plans are paid an administered monthly payment, called the M+C payment rate, for each enrollee. The per capita rate for a payment area is set at the highest one of three amounts, calculated according to formulas established in statute and updated by law. The three amounts are:

- A minimum payment (or floor) rate,
- A rate calculated as a blend of an area-specific (local) rate and a national rate, or
- A rate reflecting a minimum increase from the previous year's rate.

After preliminary M+C payment rates are determined for each payment area (typically a county), a budget neutrality adjustment is required by law to determine final payment rates. This adjustment is made so that estimated total M+C payments in a given year would be equal to the total payments that would be made if payments were based solely on area-specific rates. The budget neutrality adjustment may only be applied to the blended rates because rates cannot be reduced below the floor or minimum increase amounts. The blend payment is also adjusted to remove the costs of direct and indirect graduate medical education. The blend payment amount is based on a weighted average of local and national rates for all Medicare beneficiaries. Blend payments have been made only once since 1998 (in the year 2000) because of the budget neutrality provision.

Each year, the three payment amounts are updated by formulas set in statute. Both the floor and the blend are updated each year by a measure of growth in program spending per capita, the national growth percentage. The minimum increase provides an additional two percent over the previous year's amount.

Eligibility: Medicare beneficiaries who are entitled to Medicare Part A and are enrolled in Part B may receive benefits through traditional FFS or they may enroll in a M+C plan.

EXPLANATION OF PROVISION

Beginning January 1, 2006 the MBA Administrator would establish an EFFS program to offer EFFS plans to EFFS-eligible individuals in one of not less than 10 regions established by the MBA Administrator. Before establishing regions, the MBA Administrator must conduct a market survey and analysis to determine how regions should be established.

The EFFS plans would be required to provide open network plans—either Fee-for-Service (FFS) or preferred provider coverage. Under FFS coverage, plans would: (1) reimburse hospitals, physicians and other providers at a rate determined by the plan on a

FFS basis, without placing providers at financial risk, (2) not vary rates based on utilization related to the provider, and (3) not restrict the selection of providers from among those who are lawfully authorized to provide covered services and agree to accept the plan's terms and conditions. Preferred Provider Organization (PPO) coverage plans would: (1) require a network of providers who agreed to a contractually specified reimbursement for covered benefits with the organization, and (2) provide for reimbursement for all covered benefits regardless of whether they were provided within the network.

The EFFS-eligible individuals would be those individuals who were entitled to Medicare Part A and enrolled in Part B. EFFS plans could only be offered in a region, if the plan was: (1) available to all EFFS beneficiaries in an entire region, (2) complied with statutory access requirements, (3) uniformly provided all required Parts A and B benefits, and other benefits as may be required, (4) included a single deductible for benefits under Parts A and B, and a catastrophic limit on out-of-pocket expenses, and (5) provided prescription drug coverage for each enrollee electing Part D drug coverage. The MBA Administrator would not approve an EFFS plan if benefits were designed to substantially discourage enrollment by certain eligible individuals.

Each year, beginning in 2006, an EFFS organization would submit a monthly bid amount for each plan in each region, referred to as the "EFFS monthly bid amount". The bid could not vary among EFFS eligible individuals in the EFFS region involved. The EFFS organization would be required to provide the following information: (1) the bid amount for the provision of all required items and services, based on average costs for a typical enrollee residing in the region and the actuarial basis for determining such amount, (2) the proportion of the bid attributed to the provision of statutory non-drug benefits (the "unadjusted EFFS statutory non-drug monthly bid amount"), statutory prescription drug benefits, and non-statutory benefits, (3) the actuarial basis for determining these proportions, and (4) additional information as the MBA Administrator may require. The MBA Administrator would have the negotiation authority that the Director of the Office of Personnel Management has with regard to FEHBP to negotiate the bid amount and could also reject a bid amount or proportion, if it was not supported by the actuarial basis. The MBA Administrator could enter into contract for up to three EFFS plans in any region.

Certain plans, based in part on their monthly bid amount, may be able to provide beneficiary savings. The EFFS plan would provide the enrollee a monthly rebate equal to 75 percent of the average per capita savings, if any. (Calculation of average per capita savings is discussed below.) The rebate could be in the form of a credit towards the EFFS monthly prescription drug premium or the EFFS monthly supplemental beneficiary premium, a direct monthly payment, or other means approved by the MBA Administrator.

The MBA Administrator would determine, at the same time payment rates were announced (beginning in 2006), the average of the risk adjustment factors, by region. For plans offered in the previous year, the MBA Administrator could compute the average based on a previous year's risk adjustment factors. For plans entering a region, in which no plan was offered in the previous year, the MBA

Administrator would estimate the average, and could use factors applied in comparable regions or on a national basis.

For each EFFS plan, the MBA Administrator would adjust the EFFS region-specific non-drug monthly benchmark amount and the unadjusted EFFS statutory non-drug monthly bid amount by the applicable average risk adjustment factor. The average per capita monthly savings would equal the amount by which the risk-adjusted benchmark exceeds the risk-adjusted bid. The EFFS region-specific non-drug monthly benchmark amount would be an amount equal to 1/12 of the average (weighted by the number of EFFS-eligible individuals in each payment area) of the annual capitation rate calculated for that area.

The MBA Administrator would pay plans as follows. For plans with bids below the benchmark (for which there were average per capita monthly savings), the payment would equal the unadjusted EFFS statutory non-drug monthly bid amount, with three adjustments. Payment would be adjusted for demographics factors including age, disability, gender, institutional status, health status, and other factors; intra-regional geographic variations; and the amount of the monthly rebate for the plan and year. For plans with bids at or above the benchmark (for which there were no average per capita monthly savings), the payment amount would equal the EFFS region-specific non-drug monthly benchmark amount, with the demographic, health status and geographic adjustments. Additionally, for an EFFS enrollee who enrolls in Part D and elects qualified prescription drug coverage through the plan, the plan would receive reimbursement for prescription drugs. This reimbursement would include a direct subsidy payment, a reinsurance subsidy payment and reimbursement for premiums and cost-sharing reductions for certain low-income individuals.

Beneficiary EFFS premiums are defined as follows. In the case where a plan provides a rebate, the EFFS monthly basic beneficiary premium would be zero. In the case where a plan does not provide a rebate (the plan's unadjusted EFFS statutory non-drug bid is above the EFFS region specific non-drug benchmark), the EFFS monthly basic beneficiary premium would be the difference between the bid and the benchmark amount. The EFFS monthly prescription drug beneficiary premium would be the portion of the plan's total monthly bid that the statutory drug benefit represents. The EFFS monthly supplemental beneficiary premium would be the portion of the plan's total monthly bid that is attributable to the supplemental non-statutory benefits.

Most of the statutory requirements concerning payment rules (other than the requirements for rates, service areas and MSA payments), organization and financial requirements, the establishment of standards, and contracts, would apply to EFFS plans. However, unlike current law, EFFS plans would not be permitted to segment a region. No Medicare supplemental policy could provide coverage of the single deductible or more than 50 percent of the other cost-sharing imposed under an EFFS plan under Part E.

EFFECTIVE DATE

On or after January 1, 2006.

REASON FOR CHANGE

The EFFS program would encourage the development of regional plans, by requiring EFFS plans to serve all beneficiaries throughout the region. Because enrollees in an EFFS plan must have the same benefits, cost-sharing obligations, and premiums, EFFS would decrease the variation in private plan offerings in the M+C program today. EFFS plans would also encourage plans to enter rural areas, where few M+C plans currently exist.

In carrying out these programs, the Committee believes the existing experience of the Medicare Quality Improvement Organizations (QIOs) would be employed to offer assistance to beneficiaries, providers and plans operating in Parts C, D and E, particularly as it relates to quality improvement. QIOs are currently required to offer assistance with clinical improvement under Parts A and B in hospitals, physicians' offices, nursing homes and home health agencies and to all MA organizations under part C. Expanding the QIOs' work to include the new entities and benefits created in this legislation will help improve the quality of care for Medicare beneficiaries.

Subtitle B—Medicare Advantage Program

CHAPTER 1—IMPLEMENTATION OF PROGRAM

Section 211. Implementation of Medicare Advantage Program

CURRENT LAW

Health Maintenance Organizations (HMOs) and other types of managed care plans have been allowed to participate in the Medicare program, beginning with private health plan contracts in the 1970s and the Medicare risk contract program in the 1980s. BBA 97 replaced the risk contract program with the Medicare+Choice (M+C) program.

EXPLANATION OF PROVISION

This provision would establish the Medicare Advantage (MA) program under Part C of Medicare, replacing the Medicare+Choice provision.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Medicare Advantage would reform Medicare+Choice to increase beneficiary choice.

Section 212. Medicare Advantage Improvements

CURRENT LAW

Payment. Under current law, Medicare+Choice (M+C) plans are paid an administered monthly payment, called the M+C payment rate, for each enrollee. The per capita rate for a payment area is set at the highest one of three amounts, calculated according to formulas established in statute and updated by law. The three amounts are:

- A minimum payment (or floor) rate,
- A rate calculated as a blend of an area-specific (local) rate and a national rate, or
- A rate reflecting a minimum increase from the previous year's rate.

After preliminary M+C payment rates are determined for each payment area (typically a county), a budget neutrality adjustment is required by law to determine final payment rates. This adjustment is made so that estimated total M+C payments in a given year would be equal to the total payments that would be made if payments were based solely on area-specific rates. The budget neutrality adjustment may only be applied to the blended rates because rates cannot be reduced below the floor or minimum increase amounts. The blend payment is also adjusted to remove the costs of direct and indirect graduate medical education. The blend payment amount is based on a weighted average of local and national rates for all Medicare beneficiaries. Blend payments have been made only once since 1998 (in the year 2000) because of the budget neutrality provision.

Each year, the three payment amounts are updated by formulas set in statute. Both the floor and the blend are updated each year by a measure of growth in program spending per capita, the national growth percentage. The minimum increase provides an additional two percent over the previous year's amount.

Eligibility. Medicare beneficiaries who are entitled to Medicare Part A and are enrolled in Part B may receive benefits through the traditional FFS program or they may enroll in a M+C plan.

EXPLANATION OF PROVISION

This provision would change payments for MA plans. A fourth payment option would be added: 100 percent of the adjusted FFS rate for the area (the Adjusted Average Per Capita Cost (AAPCC) for the year, for the MA payment area for services covered under Parts A and B for individuals entitled to benefits under Part A, enrolled under Part B, and who are not enrolled in a MA plan). The AAPCC would be adjusted to include the additional payments that would have been made if Medicare beneficiaries had not received services from facilities of the Department of Veterans Affairs (VA) and the Department of Defense (DoD), and would include payments for indirect medical education costs. The minimum payment (floor) would be increased as under current law. The minimum percentage increase amount would also be changed. For 2004 and beyond, the minimum percent increase would be the greater of: (1) a two percent increase over the previous year, as under current law, or (2) the annual MA capitation rate for the area for the previous year, increased by the national per capita growth percentage increase. There would be no adjustment to the national growth percentage for prior years' errors before 2004, for purposes of calculating the minimum percentage increase in 2004. For 2005, the annual rate would equal the previous year's rate increased by the greater of two percent or the national per capita growth percentage.

No later than 18 months after enactment of this legislation, the Medicare Payment Advisory Commission would report to Congress providing an assessment of the method used for determining the adjusted average per capita cost (AAPCC). The report would exam-

ine: (1) the variation in costs between different areas, including differences in input prices, utilization and practice patterns, (2) the appropriate geographic area for payment, and (3) the accuracy of the risk adjustment methods in reflecting differences in the cost of providing care.

No later than July 1, 2006, the MBA Administrator would submit a report to Congress that describes the impact of additional financing provided under this Act and other Acts, including the Balanced Budget Refinement Act of 1999 (BBRA) and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) on the availability of MA plans in different areas and its impact on lowering premiums and increasing benefits under such plans.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

In some M+C payment areas, the M+C payment rate is lower than the costs of providing FFS care to enrollees in traditional Medicare. Many private plans have seen their Medicare payment rates rise much less rapidly than the costs of FFS Medicare, as they have been held to increases of two percent annually every year since 1998, except for 2001 when a three percent increase was paid due to the BIPA. Health costs in general are running much higher than the two percent payment increases that most plans are receiving in the areas where most of the beneficiaries are enrolled in Medicare+Choice. Plans find it difficult—if not impossible—to contract with providers if FFS Medicare can reimburse providers at higher rates than private plans may offer, given their Medicare payments. If paid less than FFS Medicare, private plans may be forced to increase enrollee premiums or cost-sharing, or decrease supplemental benefits, such as prescription drug coverage. Since 1998, the number of plans participating in M+C has declined from 346 to 153. To level the playing field between traditional Medicare and private plans, under this provision all private plans would be paid at a minimum of the FFS rate. In addition, private plan rates would increase at the same rate as growth in FFS Medicare. The goal is to increase beneficiary choice, by increasing private plan participation in Medicare.

CHAPTER 2—IMPLEMENTATION OF COMPETITION PROGRAM

Section 221. Competition Program Beginning in 2006

CURRENT LAW

See Section 200. Medicare Modernization and Revitalization and Section 201. Establishment of Enhanced Fee-For-Service (EFFS) Program under Medicare.

EXPLANATION OF PROVISION

Each year, beginning in 2006, an MA organization would be required to provide the following information: (1) the bid amount for the provision of all required items and services, based on average

costs for a typical enrollee residing in the area and the actuarial basis for determining such amount, (2) the proportion of the bid attributed to the provision of statutory non-drug benefits (the "unadjusted MA statutory non-drug monthly bid amount"), statutory prescription drug benefits, and non-statutory benefits, (3) the actuarial basis for determining these proportions, and (4) additional information as the MBA Administrator may require. The MBA Administrator would have the negotiation authority that the Director of the Office of Personnel Management has with regard to the FEHBP to negotiate the bid amount and could also reject a bid amount or proportion, if it was not supported by the actuarial basis. Private fee-for-service (PFFS) plans would be exempt from this negotiation and rejection.

Certain plans, based in part on their monthly bid amount, may be able to provide beneficiary savings. The MA plan would provide the enrollee a monthly rebate equal to 75 percent of the average per capita savings, if any, as discussed below. The rebate could be in the form of a credit towards the MA monthly supplemental beneficiary premium or the MA monthly prescription drug premium, a direct monthly payment, or other means approved by the MBA Administrator.

The MBA Administrator would determine, at the same time payment rates were announced (beginning in 2006), the average of the risk adjustment factors, by state, or on a basis other than the state. For plans offered in the previous year, the MBA Administrator could compute the average based on the previous year's risk adjustment factors. For plans entering a state, in which no plan was offered in the previous year, the MBA Administrator would estimate the average, and could use factors applied in comparable states or on a national basis.

For each MA plan, the MBA Administrator would adjust the FFS area-specific non-drug monthly benchmark amount and the unadjusted MA statutory non-drug monthly bid amount by the applicable average risk adjustment factor. The average per capita monthly savings would equal the amount by which the risk-adjusted benchmark exceeds the risk-adjusted bid. The FFS area-specific non-drug monthly benchmark amount would be an amount equal to 1/12 of the annual MA capitation rate calculated for that area.

Beginning in 2006, the MBA Administrator would pay plans as follows. For plans below the benchmark (for which there were average per capita monthly savings), the payment would equal the unadjusted MA statutory non-drug monthly bid amount, with two adjustments. Payment would be adjusted for demographic factors including age, disability, gender, health status, and other factors, and the amount of the monthly rebate for the plan and year. For plans with bids at or above the benchmark (for which there were no average per capita monthly savings), the payment amount would equal the FFS area-specific non-drug monthly benchmark amount, with the demographic and health status adjustments. Additionally, for an MA enrollee who enrolls in Part D and elects qualified prescription drug coverage through the plan, the plan would receive reimbursement for prescription drugs. This reimbursement would include a direct subsidy payment, a reinsurance

subsidy payment and reimbursement for premiums and cost-sharing reductions for certain low-income individuals.

The MBA Administrator would not approve a plan if benefits were designed to discourage enrollment by certain MA-eligible individuals. The MA monthly bid amount, the MA monthly basic and supplemental beneficiary premium and the MA monthly MSA premium, would not vary among individuals enrolled in the plan.

EFFECTIVE DATE

On or after January 1, 2006.

REASON FOR CHANGE

Competitive bidding against a benchmark would encourage plans to become more efficient, in order to lower their bids and gain market share. Beneficiaries, because they would benefit from enrolling in plans with lower bids by receiving 75 percent of the difference between the plan's bid and the benchmark, would be encouraged to enroll in more efficient plans. Plan efficiency and beneficiary enrollment in more efficient plans would reduce the costs of Medicare, easing the threat to insolvency of the Medicare Part A Trust Fund and easing the taxpayers' burden. Indeed, the Congressional Budget Office has estimated that the increased benchmarks are fully paid for through the 25 percent savings to the government. The government would share in the savings as beneficiaries make rational and efficient choices.

CHAPTER 3—ADDITIONAL REFORMS

Section 231. Making Permanent Change in Medicare Advantage Reporting Deadlines and Annual, Coordinated Election Period

CURRENT LAW

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107–188) made temporary changes to reporting dates and deadlines: (1) the plan deadline for submitting adjusted community rates (ACRs) and other information moved from no later than July 1 to no later than the second Monday in September for 2002, 2003, and 2004, (2) the annual coordinated election period moved from the month of November to November 15 through December 31 for 2002, 2003, and 2004, and (3) the M+C payment rate announcement moved from no later than March 1 to no later than the second Monday in May for 2003 and 2004. The Secretary is required to mail information to enrollees at least 15 days before each annual open season, including a list of plan and plan options.

EXPLANATION OF PROVISION

This provision would permanently: (1) move the plan deadline for submitting information to the second Monday in September; (2) change the annual coordinated election period to November 15 through December 31, and (3) move the annual payment rate announcement to no later than the second Monday in May. The requirement for providing information comparing plan options would be amended to require that the information would be provided to

the extent possible at the time of preparation of material for mailing.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The deadlines for reporting and election periods were moved to allow for more accurate information from both CMS and plans. As these dates were shifted to later in the year, consistent changes were made to allow for the annual open season for beneficiary enrollment in private plans. A provision was added to limit CMS' responsibility for mailing to only those materials available at the time of the mailing.

Section 232. Avoiding Duplicative State Regulations

CURRENT LAW

Medicare law currently preempts State law or regulation from applying to M+C plans to the extent that they are inconsistent with Federal requirements imposed on M+C plans, and specifically, relating to benefit requirements, the inclusion or treatment of providers, and coverage determinations (including related appeals and grievance processes).

EXPLANATION OF PROVISION

This provision would stipulate that Federal standards established by this legislation would supersede any state law or regulation (other than state licensing laws or state laws relating to plan solvency), with respect to MA plans offered by MA organizations.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This clarifies that the MA program is a Federal program operated under Federal rules. State laws, do not, and should not apply, with the exception of state licensing laws or state laws related to plan solvency. There has been some confusion in recent court cases. This provision would apply prospectively; thus, it would not affect previous and ongoing litigation.

Section 233. Specialized Medicare Advantage Plans for Special Needs Beneficiaries

CURRENT LAW

One model for providing a specialized M+C plan, EverCare, operates as a demonstration program. EverCare is designed to study the effectiveness of managing acute-care needs of nursing home residents by pairing physicians and geriatric nurse practitioners. EverCare receives a fixed capitated payment, based on a percentage of the adjusted average per capita costs (AAPCC), for all nursing home resident Medicare enrollees.

EXPLANATION OF PROVISION

This provision would establish a new MA option—specialized MA plans for special needs beneficiaries (such as the EverCare demonstration). Special needs beneficiaries are defined as those MA-eligible individuals who are institutionalized, entitled to Medicaid, or meet requirements determined by the Secretary. Enrollment in specialized MA plans could be limited to special needs beneficiaries until January 1, 2007. No later than December 31, 2005 the MBA Administrator would be required to submit a report to Congress that assesses the impact of specialized MA plans for special needs beneficiaries on the cost and quality of services provided. No later than 6 months after enactment of this Act, the Secretary would be required to issue final regulations to establish requirements for special needs beneficiaries.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Specialized MA plans for special needs beneficiaries are designed to serve beneficiaries with certain needs, thus these plans are not meant to handle beneficiaries without special needs. This provision allows these plans to serve beneficiaries for whom their programs were designed.

Section 234. Medicare MSAs

CURRENT LAW

BBA 97 authorized a demonstration to test the feasibility of medical savings accounts (MSA) for the Medicare population. This M+C option is a combination of a health insurance plan with a large deductible and an M+C MSA. Contributions to an M+C MSA may be made annually from the enrollee's capitation rate after the plan's insurance premium has been paid. These contributions, as well as account earnings, are exempt from taxes. Withdrawals used to pay unreimbursed enrollee medical expenses are exempt from taxes if they would be deductible under the Internal Revenue Code. New enrollment is not allowed after 2003, or after the number of enrollees reaches 390,000, if earlier.

EXPLANATION OF PROVISION

This provision would permanently extend Medicare MSAs and remove the enrollment cap. It would eliminate the requirement that Medicare MSA plans report on enrollee encounters since MSAs are not plans but bank accounts. Non-contract providers furnishing services to enrollees of MSAs would be subject to the same balanced billing limitations as non-contract providers furnishing services to enrollees of coordinated care plans.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Medicare MSAs are not being offered in the Medicare program today, despite the legislative authority granted in 1997 and despite the fact that non-Medicare MSAs are being offered. By eliminating the cap on enrollment, the time constraint, and the reporting requirements, the Committee hopes to encourage this additional choice for seniors.

Section 235. Extension of Reasonable Cost Contracts

CURRENT LAW

Medicare reimburses cost-based plans for the actual cost of furnishing covered services, less the estimated value of beneficiary cost-sharing. The Secretary may not extend or renew a reasonable cost reimbursement contract for any period beyond December 31, 2004.

EXPLANATION OF PROVISION

This provision would allow reasonable cost contracts to be extended or renewed indefinitely, with an exception that would begin January 1, 2008. These contracts could not be extended or renewed for a service area, if during the entire previous year, the area had 2 or more coordinated care MA plans or 2 or more EFFS plans which met the following minimum enrollment requirements: (1) at least 5,000 enrollees for the portion of the area within a metropolitan statistical area with a population of more than 250,000 and counties contiguous to such a metropolitan statistical area, and (2) at least 1,500 enrollees for any other portion of such area.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The uncertainty about the continuation of cost contracts would be removed, allowing these plans to operate indefinitely, unless two other plans of the same type (i.e., either 2 MA or 2(c) EFFS plans) enter the cost contract's service area. If other plans are willing to enter the cost contract's service area, then the cost contract would be required to operate under the same provisions as these other private plans.

Section 236. Extension of Municipal Health Service Demonstration Projects

CURRENT LAW

The Municipal Health Services Demonstration Project operates in four cities. These cities use their existing public health programs as the nucleus of a coordinated system to provide community-based health care for the underserved urban poor. The project provides comprehensive health services, including a prescription drug benefit and dental services.

BBA 97 extended the program through 2000. The BBRA extended it through 2002, and the BIPA extended it through December 31, 2004.

EXPLANATION OF PROVISION

This provision would extend the program until December 31, 2009, and permit the programs to enroll up to the number of individuals who were enrolled as of January 1, 1996.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

BBA 97 required demonstration participants to become M+C enrollees. In Baltimore, no M+C plans, and in the other, smaller sites, private sector options for Medicare beneficiaries are also limited. This provision also closed the program to new enrollees. The programs need a certain number of enrollees to remain viable; opening enrollment with a cap at levels from 1996 would permit these programs to reach the enrollment levels they need to operate efficiently.

Subtitle C—Application of FEHBP-Style Competitive Reforms

Section 241. Application of FEHBP-Style Competitive Reform Beginning in 2010

CURRENT LAW

See Section 200. Medicare Modernization and Revitalization and Section 201. Establishment of Enhanced Fee-For-Service (EFFS) Program under Medicare.

EXPLANATION OF PROVISION

Beginning in 2010, FEHBP-style competition would begin nationwide in competitive areas. Competitive areas are defined as areas in which Medicare beneficiaries have access to two private plans—either two MA or two EFFS plans—along with traditional FFS Medicare. Private plan enrollment in the area must be at least as great as private plan enrollment nationwide, or at least 20 percent. For example, if private plan enrollment nationwide is 15 percent, the area must have private plan enrollment of at least 15 percent to become a competitive area. If private plan enrollment nationwide is 40 percent, the area must have private plan enrollment of at least 20 percent to trigger competition. In addition, competitive MA (CMA) areas would be limited to metropolitan statistical areas, or areas with substantial numbers of MA enrollees. The two private plans must be offered during the open season by different organizations, and each must meet minimum enrollment requirements as of March of the previous year.

In competitive areas, private plans would submit bids and the MBA Administrator would calculate FFS amounts, based on the adjusted average per capita cost (AAPCC) in the area or region. The AAPCC would be adjusted to remove costs associated with direct graduate medical education, and to include costs of services provided to Medicare beneficiaries by VA and DoD military facilities. In addition, payments would be adjusted for health and other demographic factors.

The competitive benchmark would be set at the weighted average of the private plan bids and the FFS amount in the competitive area. In order to provide traditional FFS disproportionate influence in competitive areas, the weight of the benchmark for FFS would equal the nationwide proportion of Medicare beneficiaries enrolled in FFS, or the competitive area's proportion, if higher. The weights for all other private plans would equal the national proportion of beneficiaries enrolled in private plans, or the regional proportion if lower.

For the first 5 years of competition, the benchmarks for private plans would be a blend of the competitive benchmark and the older, pre-2010 benchmark. For the first year of competition, the private plan benchmark would be based 80 percent on the older benchmark and 20 percent on the newer benchmark. For the second year, the private plan benchmark would be based 60 percent on the older benchmark and 40 percent on the new benchmark. By the fifth year, the private plan's benchmark would be fully phased in, and equal the new competitive benchmark. This phase-in allows for a transition to a more competitive system based on the new competitive benchmark.

Premium adjustments for beneficiaries remaining in traditional FFS in competitive areas would also be phased-in over the first 5 years as a competitive area. The FFS amount would be compared to the new competitive benchmark. During the first year of competition, 20 percent of the change in beneficiary premiums would occur. During the second year of competition, 40 percent of the change would be implemented, and so forth, until 100 percent of the premium change would be implemented during the fifth year of competition.

Beneficiaries enrolling in plans with bids or FFS amounts below the competitive benchmark would receive 75 percent of the difference between the benchmark and bid/FFS amount, and the government would receive 25 percent of the difference. Beneficiaries enrolling in plans with bids/FFS amounts above the benchmark would pay the excess. Premium adjustments would be moderated over a 5-year period for beneficiaries remaining in traditional FFS in competitive areas. The traditional FFS beneficiary premium would be unaffected in non-competitive areas or regions.

Beginning in 2010, the MBA Administrator would announce the MA area-specific non-drug benchmark yearly. If applicable, the MBA Administrator would also announce, for the year and CMA area: the competitive MA non-drug benchmark; the national FFS market share percentage; the demographic, end-stage renal disease, and health status adjustment factors; the MA area-wide non-drug benchmark amount; the FFS area-specific non-drug amount; and MA enrollment.

To carry out this section, the MBA Administrator would transmit the name, social security number, and adjustment amount to the Commissioner of SSA at the beginning of each year and at periodic times throughout the year.

EFFECTIVE DATE

On or after January 1, 2010.

REASON FOR CHANGE

Market-oriented policymakers have maintained that the best way to reform Medicare is to provide beneficiaries with a choice of plans, similar to the choice available to members of Congress under the Federal Employees Health Benefits Program (FEHBP). The Bipartisan Commission on the Future of Medicare came to the same conclusion.

Medicare must be transformed to bend the growth curve in expenditures to put the program on a sound financial footing. To reduce program growth, true competition, including both traditional fee-for-service and private plans, would begin in 2010 in certain competitive areas.

As areas of the country show increased enrollment in private plans, a more competitive system, based on the structure of the FEHBP, would provide for greater beneficiary savings and reductions in government costs. Allowing for competition for enrollees, between private plans and traditional FFS Medicare, would level the playing field between all options available to Medicare beneficiaries.

If traditional FFS Medicare is able to provide benefits at a lower cost than some or all private plans in a competitive area, then beneficiaries remaining in traditional FFS would see their premiums decline. In this case, beneficiaries enrolling in higher-cost private plans would be required to pay the extra price stemming from that decision. Likewise, if a private plan is able to offer Medicare beneficiaries coverage at a lower cost, then beneficiaries would be encouraged to enroll in the private plan by lowering the beneficiaries' costs of coverage under the private plan. In any case, beneficiaries would be entitled to the same defined benefit package and payments to plans would be fully adjusted for health and other demographic factors. If the traditional FFS plan disproportionately enrolls beneficiaries with poor risk, the beneficiary premium would be adjusted to compensate.

This reform is the only provision in the bill that has the potential to produce the savings needed for long-term solvency. Although the bill provides for bidding against a benchmark prior to 2010, the benchmarks prior to 2010 increase each year, by the rate of growth in Medicare. Without this stage of competition, private plans would not be able to influence the benchmark and would have an incentive to shadow price their benchmarks. A floating benchmark rewards more efficient plans, and it allows these more efficient plans to lower the benchmark and government outlays in future years, as their market share rises.

Several features were added in the Chairman's amendment in the nature of a substitute to allow for a smooth transition to a more competitive system in 2010 in competitive areas/regions, and to prevent shock to the current system. The competitive benchmark, based on private plan bids and traditional FFS rates, would be calculated based on the relative enrollment in FFS versus private plans nationwide (or the area/region if FFS enrollment is a larger proportion in the area/region). This feature ensures that the competitive benchmark is closer to the traditional FFS rate than would otherwise occur. Premium changes for beneficiaries remaining in traditional FFS in competitive areas would be phased-in over

five years to prevent oscillations. In addition, the competitive benchmark would be phased-in over a 5-year period for private plans. This would allow for a more gradual change from the benchmarks under the pre-2010 system to the new competitive benchmark for private plans in competitive areas.

C. TITLE III—COMBATTING WASTE, FRAUD, AND ABUSE

Section 301. Medicare Secondary Payer (MSP) Provisions

CURRENT LAW

In certain instances, Medicare is prohibited from making payment for a health care claim if payment is expected to be made promptly under a worker's compensation law or plan, under automobile or liability insurance (including a self-insured plan), or under no-fault insurance on behalf of a beneficiary. Medicare is permitted to make a conditional payment in certain circumstances including if Medicare could reasonably expect payment to be made under a workers' compensation plan or no-fault insurance claim and Medicare determines that the payment will not be made promptly, as determined in accordance with regulations.

EXPLANATION OF PROVISION

The Secretary would be able to make a Medicare payment if a worker's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan), or a no-fault insurance plan, has not been made or cannot reasonably be expected to be made promptly (as determined in accordance with regulations). This payment would be contingent on reimbursement by the primary plan to the Medicare Trust Funds.

The list of primary plans for which conditional payment could be made would be expanded; an entity engaging in a business, trade, or profession would be deemed as having a self-insured plan if it carries its own risk. Failure to obtain insurance would be required as evidence of carrying risk. A primary plan, as well as an entity that receives payment from a primary plan, would be required to reimburse the Medicare Trust Funds for any payment made by the Secretary if the primary plan was obligated to make payment. The Secretary's authority to recover payment from any and all responsible entities and bring action, including the collection of double damages, to recover payment under the Medicare Secondary Payer provisions also would be clarified.

EFFECTIVE DATE

Subsection (a) would be effective as if included in the enactment of Title III of the Medicare and Medicaid Budget Reconciliation Amendments of 1984 (P.L. 98–369). Subsection (b) would be effective upon enactment.

REASON FOR CHANGE

Recent court decisions such as *Thompson* v. *Goetzmann* resulted in a narrow interpretation of the statutory reference to "promptly." Liability insurers would have been able to draw out their settlements and avoid repaying Medicare for payment of medical expenses. Moreover, firms that self-insure for product liability would

have been able to avoid paying Medicare for past medical payments related to the claim. This provision guards the Medicare trust fund and saves nearly nine-billion dollars over 10 years.

Section 302. Competitive Acquisition of Certain Items and Services

CURRENT LAW

In general, durable medical equipment (DME) is paid for under a set of local (or state) fee schedules subject to certain floors and ceilings as well as limited to the lower of the actual charge for the equipment or the fee schedule amount. Fee schedule amounts received an update of the full consumer price index for urban consumers (CPI–U) in 2003.

BBA 97 authorized the Secretary to conduct up to five demonstration projects to test competitive bidding as a way for Medicare to price and pay for Part B services other than physician services. The Secretary was required to establish up to three competitive acquisition areas for this purpose. Three competitive bidding demonstrations for durable medical equipment, prosthetics, orthotics, and supplies were successfully implemented: two in Polk County, Florida and one in the San Antonio, Texas area.

EXPLANATION OF PROVISION

The Secretary would be required to establish and implement competitive acquisition programs for durable medical equipment, medical supplies, items used in infusion, drugs and supplies used in conjunction with durable medical equipment, parenteral nutrition, and off-the-shelf orthotics (requiring minimal self-adjustment for appropriate use) that would replace the Medicare fee schedule payments. Class III devices—devices that sustain or support life, are implanted, or present potential unreasonable risk (e.g. implantable infusion pumps and heart valve replacements)—are subject to premarket approval by the Food and Drug Administration and would not be covered by the competitive bidding system.

In starting the competitive bidding programs, the Secretary would be required to establish competitive acquisition areas, but would be able to exempt rural areas and areas with low population density within urban areas that are not competitive, unless a significant national market exists through mail order for a particular item or service. The programs would be phased-in over three years with one-third of the areas implemented each year. High-cost and high-volume items and services would be required to be phased-in first. The Secretary would be able to exempt items and services for which competitive acquisition would not likely result in significant savings. The Secretary would be required to establish a process where existing rental agreements for covered DME items entered into contract before implementation of this program would not be affected. The supplier would be required to provide for appropriate servicing and replacement of these rental items.

Certain requirements for the competitive acquisition program would be established. Specifically, the Secretary would be allowed to award contracts in an area only when the following conditions were met: entities met quality and financial standards specified by the Secretary or the Program Advisory and Oversight Committee; total amounts paid under the contracts would be expected to be

less than would be paid otherwise; and beneficiary access to multiple suppliers would be maintained. Beneficiary liability would be reduced to 20 percent of the applicable contract award price.

Contracts would be required to be re-competed at least every three years. The Secretary would be required to award contracts to multiple entities submitting bids in each area for an item or service and would also have the authority to limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for covered items and services. The Secretary would be permitted to waive certain provisions of the Federal Acquisition Regulation that are necessary for the efficient implementation of this program, other than those relating to confidentiality of information. The Secretary would be required to report to Congress annually on savings, reductions in cost-sharing, access to items and services, and beneficiary satisfaction under the competitive acquisition program.

A Program Advisory and Oversight Committee with members appointed by the Secretary would be established. The Committee would be required to provide advice and technical assistance to the Secretary regarding the implementation of the program, data collection requirements, proposals for efficient interaction among manufacturers and distributors of the items and services, providers, and beneficiaries, and other functions specified by the Secretary. The provisions of the Federal Advisory Committee Act would not apply to this Committee.

The Secretary would be required to conduct a demonstration program on using competitive acquisition for clinical laboratory tests that are furnished without a face-to-face encounter between the individual and the hospital personnel or physician performing the tests. The same quality and financial conditions specified for the DME competitive acquisition program would apply for clinical laboratory test competitive acquisition. An initial report to Congress would be required of the Secretary and must be submitted by December 31, 2005 with progress and final reports, as the Secretary would determine appropriate. The General Accounting Office (GAO) would be required to report to Congress on the differences in reimbursement between public and private payors of clinical diagnostic services. The Secretary would be required to study whether suppliers of DME are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability.

The covered items and services included in the competitive acquisition program would be paid as determined under this program. The Secretary would be able to use this payment information to adjust the payment amounts for DME not located in a competitive acquisition area. In this instance, the inherent reasonableness rule would not be applied. Orthotics included in a competitive acquisition program would also be paid the amounts determined by this program. The Secretary would be able to use this payment information to adjust the payment amounts for such items. In this instance, the regular payment rules established by regulation, including the inherent reasonableness rule, would not be applied.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Numerous studies conducted by the HHS Office of the Inspector General (OIG) as well as GAO have found the government-determined fee schedule for durable medical equipment (DME) too high for certain items. For example, the OIG found that Medicare's reasonable payment methodology paid too much for parenteral nutrition. The OIG also found that Medicare payments for hospital beds were substantially higher than rates paid by other payors. Further, the OIG discovered that payments for albuterol were six times the catalog price for the drug.

The DME competitive bidding demonstration has been a success. The taxpayers and beneficiaries saved significantly and quality standards were higher under the demonstration. More, that three-quarters of the DME winners were small businesses and beneficiary satisfaction remained high.

Section 303. Competitive Acquisition of Covered Outpatient Drugs and Biologicals

(a) Adjustment to the Physician Fee Schedule

CURRENT LAW

The relative value associated with a particular physician service is the sum of three components: physician work, practice expense, and malpractice expense. Practice expense includes both direct costs (such as clinical staff time and medical supplies used to provide a specific service to an individual patient) as well as indirect costs such as rent, utilities, and business costs associated with running a practice. When the physician fee schedule was implemented, reimbursement for practice expenses was based on historic charges. The Social Security Act Amendments of 1994 (PL. 103–432) required the Secretary to develop a methodology for a resource-based system for calculating practice expenses for use in CY1998. BBA 97 delayed the implementation of the methodology until CY1999 and established a transition period with full implementation by CY2002. BBRA required the Secretary to establish a data collection process and data standards for determining practice expense relative values. Under this survey process, the Secretary was required to use data collected or developed outside HHS, to the maximum extent practicable, consistent with sound data collection practices.

The Secretary is required to periodically review and adjust the relative values affecting physician payment to account for changes in medical practice, coding changes, new data on relative value components, or the addition of new procedures. Under the budget-neutrality requirement, changes in these factors cannot cause expenditures to differ by more than $20 million from what would have been spent if such adjustments had not been made.

EXPLANATION OF PROVISION

As part of the annual process of establishing the physician fee schedule, the Secretary would be required to increase the practice expense relative values using supplemental survey data provided by entities and organizations. This survey data must meet the Secretary's criteria for acceptance and include expenses for the administration of drugs and biologicals.

The Secretary would be directed to cooperate with representatives of physician specialties affected by reform of the Average Wholesale Price (AWP) method of reimbursement for outpatient prescription drugs. The Secretary would be required to expedite consideration of the Current Procedural Terminology (CPT) codes used to bill for the costs associated with the administration of outpatient drugs affected by AWP reform. In addition, the Secretary would be required to consult with representatives of advisory physician groups, such as the Practice Expense Advisory Committee, when reviewing CPT codes.

Increases in practice expenses resulting from the use of new survey data submitted by the date of enactment, or consideration of CPT codes for drug administration services for drugs affected by AWP reform would not be subject to the budget neutrality. The Secretary would not be prevented from adjusting the practice expense relative values in subsequent years. The Secretary would be required to consult with GAO and groups representing the affected physician specialties before publishing the notice of proposed rulemaking.

The resulting adjustments in practice expense relative value units would not be subject to administrative or judicial review. They would be considered as a change in law and regulation for purposes of determining the sustainable growth rate, used to set the payment update for physician services.

The Secretary would be required to adjust the non-physician work pool methodology so that practice expense relative values for these services are not disproportionately reduced as a result of the above changes.

Any physician specialty would be permitted to submit survey data related to practice expenses through December 31, 2004. Budget neutrality would not be waived.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Physicians would be paid appropriate amounts for the administration of outpatient drugs covered by Medicare. It is the Committee's intent that the Secretary should use the survey data submitted by the American Society of Clinical Oncologists (ASCO) since the data meets all requirements for inclusion. The Committee directs the Secretary to depart from typical procedures and not average new ASCO survey data on practice expenses with older survey data from the American Medical Associations' socioeconomic monitoring system data. The Committee also directs the Secretary not to alter the ASCO survey data by removing any responses, including outliers. The Committee intends that the Secretary use the new ASCO survey data in the Secretary's normal methodology for determining practice expenses.

Furthermore, it is the Committee's intent that the Secretary use current procedures for consideration of CPT codes and modifications to those codes. The provision directs the Secretary to work with specialties affected by AWP reform to ensure that CPT codes, which would permit appropriate payment for drug administration, are in place before AWP reform occurs.

(b) Payment Based on Competition

CURRENT LAW

Although Medicare does not currently provide an outpatient prescription drug benefit, coverage of certain outpatient drugs is specifically authorized by statute. Specifically, under Medicare Part B, outpatient prescription drugs and biologicals are covered if they are usually not self-administered and are provided incident to a physician's services. Drugs and biologicals are also covered if they are necessary for the effective use of covered durable medical equipment, including those that must be put directly into equipment. In addition, Medicare will pay for certain self-administered oral cancer and anti-nausea drugs, erythropoietin (used to treat anemia), immunosuppressive drugs after covered Medicare organ transplants and hemophilia clotting factors. Vaccines for diseases like influenza, pneumonia, and hepatitis B are considered drugs and are covered by Medicare. Payments for covered outpatient drugs are made under Medicare Part B and are based on 95 percent of AWP. The term "AWP" is not defined in statute or regulation, but generally, AWP is intended to represent the average price used by wholesalers to sell drugs to their customers. It has been based on reported prices as published in industry reference publications or drug price compendia. There are no uniform criteria for reporting these numbers. Moreover, these reported prices do not reflect the discounts that manufacturers and wholesalers customarily offer to providers and physicians. To differing degrees, the published prices on which Medicare payment's are based are higher than the amounts actually paid to acquire a given prescription drug.

Since covered outpatient prescription drugs are Part B services, Medicare pays 80 percent of the recognized amount and the beneficiary is liable for the remaining 20 percent coinsurance amount, except in the case of vaccines where no beneficiary cost-sharing is imposed. Also, beneficiaries cannot be charged for any amounts in excess of the recognized payment amount.

EXPLANATION OF PROVISION

New sections 1847A and 1847B in Title XVIII of the Social Security Act would be established to provide physicians in the Medicare program with an annual choice between two payment and delivery systems: (1) a contractor who would deliver drugs to the physician and would be reimbursed on prices established through a competitive bidding process, or (2) the physician would be reimbursed for covered drugs at the Average Sales Price (ASP).

Under Section 1847A, the Secretary would be required to establish a competitive acquisition program to acquire and pay for covered outpatient drugs. Under this program, at least two contractors would be established in each competitive acquisition area (which would be defined as an appropriate geographic region) throughout the United States. Each year, a physician would be required to select contractors who would deliver covered drugs and biologicals to the physician. There would be two categories of drugs under this program: the oncology category (which would include drugs determined by the Secretary as typically primarily billed by oncologists or are otherwise used to treat cancer) that would be implemented beginning in 2005, and the non-oncology category that would be im-

plemented beginning in 2006. In this case, covered drugs means certain drugs currently covered under Section 1842(o) of the Social Security Act which are not covered as part of the competitive acquisition for durable medical equipment. Blood clotting factors, erythropoetin furnished as treatment for end-stage renal disease (ESRD), and radiopharmaceuticals would not be considered covered drugs under the competitive acquisition program. Nothing in the section would affect the carrier invoice pricing method used to pay for radiopharmaceuticals. The Secretary would also be able to exclude other drugs and biologicals or classes of drugs and biologicals that are not appropriate for competitive bidding or would not produce savings.

Certain contractor selection and contracting requirements for the competitive acquisition program would be established. Specifically, the Secretary would be required to establish an annual selection process for contractors in each area for each of the two categories of drugs. The Secretary may not award the two-year contract to any entity that does not have the capacity to supply covered outpatient drugs within the applicable category, or does not meet quality, service, or financial performance and solvency standards established by the Secretary. Specifically the contractor would be required to have: (1) arrangements to ship covered drugs at least 5 days of the week and on an emergency basis, (2) procedures for the prompt response and resolution of physician and beneficiary complaints and inquiries, and (3) grievance resolution procedures, including review by the Medicare Provider Ombudsman established in this legislation. At the Secretary's discretion, the Secretary could refuse to contract with an entity that has had its license for distributing drugs (including controlled substances) suspended or revoked by the Federal or a State government or that has been excluded from Medicare program participation. A contractor would be required to comply with a specified code of conduct, including conflict of interest provisions and all applicable provisions relating to the prevention of fraud and abuse. A contract would include specifications to ensure secure facilities, safe and appropriate storage of covered drugs, maintain record keeping, provide written policies and procedures to ensure drug safety, and retain compliance personnel. Either the Secretary or the entity could terminate contracts with appropriate advance notice. The Secretary would make the list of the available contractors accessible to physicians on an ongoing basis, through a directory posted on the Internet and provided by request.

The Secretary would be able to limit the number of qualified entities in each category and area, but not below two. The Secretary would be required to base selection on bid prices for covered drugs, bid prices for distribution of those drugs, ability to ensure product integrity, customer service, past experience with drug distribution, and other factors. Drugs dispensed under this program would be acquired directly from the manufacturer or from a distributor directly from the manufacturer. Contractors may be required to comply with additional product integrity safeguards for drugs susceptible to counterfeiting or diversion. The bid prices in an area would be effective for that area throughout the two-year contract period, but the contract would allow for appropriate price adjustments to reflect significant increases or decreases in a contractor's reason-

able, net acquisition costs as disclosed to the Secretary. The Secretary would not be able to accept a contract for an area if its aggregate average prices exceed 120 percent of the Average Sales Price established under 1847B. Under the program, the Secretary would be required to compute an area average of the submitted bid prices. For drugs and biologicals for which an average bid price has not been established due to its establishment as a new Medicare covered product, the payment rate would be the payment rate established under 1847B. The Secretary would be able to establish average sales price as the reimbursement amount in other exceptional cases. Beneficiary liability would be limited to 20 percent of the payment basis for the covered drug or biological, and would be collected by the contractor upon drug administration.

The Secretary would be permitted to waive certain provisions of the Federal Acquisition Regulation that are necessary for the efficient implementation of this program, other than those relating to confidentiality of information. The contractor supplying the physician in the area would submit the claim for the drug and would collect the cost-sharing amount from the beneficiary after administration of the drug. Both program payment and beneficiary cost sharing amounts would only be made to the contractor; would only be made upon the administration of the drug; and would be based on the average bid of prices for the drug and biological in the area. The Secretary would be required to establish a process for recovery of payments billed at the time of dispensing for drugs that were not actually administered.

The appropriate contractor, as selected by the physician, would supply covered drugs directly to the physician, except under the circumstances when a beneficiary is able to receive a drug at home. The Secretary would be able to specify other non-physician office settings where a beneficiary would be able to receive a covered drug directly. However, the contractor would not be able to deliver drugs to a physician without first receiving a prescription as well as other necessary information specified by the Secretary. A physician would not be required to submit a prescription for each individual treatment. The Secretary would establish requirements, including adequate safeguards against fraud and abuse and consistent with safe drug practices, in order for a physician to maintain an inventory of drugs in cases where: the drugs or biologicals are immediately required, where the physician could not have reasonably anticipated the immediate requirement, where the contractor could not deliver the product in a timely manner, and in emergency situations related to the patient's health. No applicable State requirements relating to the licensing of pharmacies would be waived.

Current rules related to physician assignment and beneficiary appeal rights in cases of medical necessity denial would remain unchanged. New physician appeal rights would be established similar to those provided to physicians who prescribe durable medical equipment or laboratory tests.

The Secretary would be required to establish an advisory committee to assist in the implementation of this program. The Secretary would be required to report to Congress on savings, reductions in cost-sharing, access to items and services, the availability of contractors as well as beneficiary and provider satisfaction under

the competitive acquisition program. These reports would be due each year from 2005 through 2007.

The new section 1847B would establish an alternative choice for physician reimbursement for covered Part B drugs based on an Average Sales Price methodology (ASP). ASP is calculated for multiple source drugs based on the average of all sales net of volume discounts, prompt pay discounts, cash discounts, free goods to physicians, charge backs and rebates other than Medicaid rebates. For single source products, ASP is calculated using the above methodology or the Wholesale Acquisition Cost, which ever is lower. In an initial period for which sales data is not available, the Secretary may determine the amount payable under the section without regard to the manufacturer's average sales price. In response to a public health emergency, the Secretary may use the wholesale acquisition cost instead of the average sales price until the price and availability of the drug has stabilized. Prices would be reported to the Secretary on a quarterly and confidential basis.

The Secretary would submit an annual report to the Congress on trends in average sales prices, administrative costs associated with compliance with this section, the total value of payments made under this section, and a comparison of the average manufacturer price reported under Medicaid with the average sales price. GAO would be required to assess the impact of this program on the delivery of services, particularly with respect to beneficiary access to drugs and the site of delivery. MedPAC would be required to submit to Congress specific recommendations with respect to payment for blood clotting factors in its 2004 annual report.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The Balanced Budget Act of 1997 (BBA 97, P.L. 105–33) specified that Medicare payment for covered outpatient prescription drugs would equal 95 percent of AWP. Law or regulation does not define AWP. Publishing organizations report AWPs provided by drug manufacturers. Medicare carriers use the published data to payment for Medicare covered drugs, but AWPs are not grounded in any real market transaction, and do not reflect the actual price paid by purchasers. Congress has long recognized AWP is a list price and not a measure of actual prices. Congress is now able to adopt an alternative basis for payment that will more accurately reflect actual acquisition costs for physicians. This will ensure that Medicare no longer bases its payments on prices that do not reflect prices otherwise available through market incentives and transactions.

AWP for a product is often far greater than the acquisition cost paid by suppliers and physicians. Some drug manufacturers use AWP to inflate payments made for drugs. As a result of abuses in the current system, beneficiaries are paying hundreds of millions of dollars in inflated co-payments every year. Medicare also pays upwards of one billion dollars in excess payments every year.

Some physicians assert that the overpayment for drugs covers underpayment for practice expenses. They contend that Medicare does not adequately reimburse them for the practice expenses asso-

ciated with providing care in outpatient settings. This section reduces the overpayment for drugs and biologics, while increasing physician practice expenses.

Over the past 6 years, the OIG has issued a number of reports, all of which have reached the conclusion that Medicare and its beneficiaries pay too much for prescription drugs. The OIG studied the prices for 24 Medicare covered drugs that accounted for $3.1 billion of the $3.9 billion in Medicare drug expenditures in 1999. The OIG compared Medicare reimbursement to prices available to the physician/supplier community, the Department of Veterans Affairs, and Medicaid. They found that Medicare and its beneficiaries would have saved substantial amounts of money on their coinsurance. The savings would have been $761 million a year by paying the actual wholesale prices available to physicians and suppliers. For each drug, Medicare paid more than the wholesale price available to physicians and suppliers.

Subsequently, the findings of the report were updated with more current drug pricing information and estimated that, of the $3.7 billion Medicare spent for 24 drugs in 2000, had Medicare paid the actual wholesale prices available to physicians and suppliers for these 24 drugs, the program and its beneficiaries would save $887 million a year. If Medicare had paid for these drugs based on catalog prices, according to the OIG, beneficiaries would have paid over $175 million less in coinsurance.

GAO's September 2001 report found that physicians can obtain Medicare-covered drugs at prices below current Medicare payments. In fact, wholesalers' and Group Purchasing Organizations' (GPO) prices are less than the AWP currently used to establish Medicare reimbursement for covered drugs. GAO found that the average discount from AWP ranged from 13 percent to 34 percent, and that two drugs had discounts of 65 percent and 86 percent.

In its recommendations to the Congress, the GAO urged CMS to take steps to begin reimbursing providers for part B-covered drugs and related services at levels reflecting providers' acquisition costs using information about actual market transaction prices. CMS should also evaluate expanding competitive bidding approaches to setting payment levels, according to the GAO, and that CMS should monitor beneficiary access to covered drugs in light of any changes to reimbursement.

The GAO also debunked some common myths generally held by many in the health care community. Specifically, the GAO found that despite concerns that the discounts available to large purchasers would not be available to physicians with a small number of drug claims, physicians with low volumes reported that their purchase prices were the same or less than the widely available prices GAO documented. GAO also believes that Medicare should pay for each service appropriately and not rely on overpayments for some services to offset inadequate payments for complementary services. The Committee shares this view, and believes the legislation achieves this goal.

Section 304. Demonstration Project for Use of Recovery Audit Contractors

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The Secretary would be required to conduct a demonstration project for up to three years on the use of recovery audit contractors under the Medicare Integrity Program. The recovery audit contractors would identify underpayments and overpayments in the Medicare program and would recoup overpayments made to providers. Payment would be made to these contractors by providing incentives for good performance. The Secretary would be able to waive Medicare statutory provisions to pay for the services of the recovery audit contractors. The Secretary would be required to examine the efficacy of using these contractors with respect to duplicative payments, accuracy of coding, and other payment policies in which inaccurate payments arise. The demonstration project would be required to cover at least two states among the states with the highest per-capita utilization rates of Medicare services and have at least three contractors.

Recovery of an overpayment through this project would not prohibit the Secretary or the Attorney General from investigating and prosecuting appropriate allegations of fraud and abuse. Fiscal intermediaries, carriers, and Medicare Administrative Contractors would not be eligible to participate as a recovery audit contractor. The Secretary would be required to show preference to contracting with entities that have demonstrated more than three years direct management experience and a proficiency in recovery audits. Within six months of completion, the Secretary would be required to report to Congress on the project's savings to the Medicare program, including recommendations on the cost-effectiveness of extending or expanding the program.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This is a common approach used in the private sector including physicians and hospitals to recover payments from insurers. It provides a useful check on whether the other CMS contractors are paying accurately and identifying potential fraud problems.

D. Title IV—Rural Health Care Improvements

Section 401. Enhanced Disproportionate Share Hospital (DSH) Treatment for Rural Hospitals and Urban Hospitals With Fewer Than 100 Beds

CURRENT LAW

Medicare makes additional payments to certain acute hospitals that serve a large number of low-income Medicare and Medicaid patients as part of its inpatient prospective payment system (PPS). As specified by BIPA, starting with discharges occurring on or after

April 1, 2001, all hospitals are eligible to receive Medicare disproportionate share hospital (DSH) payments when their DSH percentage or threshold amount exceeds fifteen.

Different formulas are used to establish a hospital's DSH payment, depending upon the hospital's location, number of beds and status as a rural referral center (RRC) or sole community hospital (SCH). The DSH adjustment that a small urban or rural hospital can receive is limited to 5.25 percent of total Medicare inpatient payments.

EXPLANATION OF PROVISION

For discharges after October 1, 2003, a small rural or urban hospital that qualifies for a DSH adjustment would potentially receive an increase in DSH payments. The DSH adjustment for these hospitals, except for rural referral centers, would be almost doubled but not to exceed a maximum of 10 percent.

EFFECTIVE DATE

The provision would apply to discharges occurring on or after October 1, 2003.

REASON FOR CHANGE

MedPAC, an independent advisory committee that advises Congress, recommended this policy in its March 2003 report. MedPAC believes this change would mitigate the effects of uncompensated care for many rural hospitals and thereby protect Medicare beneficiaries' access to care in rural communities. Historically, rural and small urban hospitals have been treated unfairly with respect to DSH payments.

Section 402. Immediate Establishment of Uniform Standardized Amount in Rural and Small Urban Areas

CURRENT LAW

Medicare pays for inpatient services in acute hospitals in large urban areas using a standardized amount that is 1.6 percent larger than the standardized amount used to reimburse hospitals in other areas (both rural areas and smaller urban areas). The Consolidated Appropriations Act of 2003 (P.L. 108–7) provided for a temporary payment increase to rural and small urban hospitals; all Medicare discharges from April 1, 2003, to September 30, 2003, would be paid on the basis of the large urban area amount.

EXPLANATION OF PROVISION

Beginning for discharges in FY2004, the standardized amount for hospitals located in areas other than large urban areas would be equal to the amount used to pay hospitals located in large urban areas. Technical conforming amendments would also be adopted.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

MedPAC recommends eliminating this differential in payment. MedPAC found no statistically significant difference in costs between the cost of hospitals in large urban areas (over one million) and other hospitals, after removing the effect of geographic differences in wages, teaching and other Medicare adjustments.

Section 403. Establishment of Essential Rural Hospital Classification

CURRENT LAW

No provision in current law.

EXPLANATION OF PROVISION

An Essential Rural Hospital would be a new designation for the purposes of Medicare reimbursement. To be eligible for the Essential Rural Hospital designation, the hospital must have more than 25 beds and must be located in a rural area. The Secretary must then determine that the closure of the hospital would significantly diminish the ability of beneficiaries to obtain essential health care services based on certain criteria. Specifically, the Secretary must determine that (1) a high proportion of Medicare beneficiaries residing in the hospital's service area receive basic inpatient care from the hospital, and (2) there exists, in the service area, a hospital with more than 200 licensed beds that provides specialized surgical care to a high percentage of beneficiaries. Regardless of the size of the hospital, almost all physicians in the area must have admitting privileges and provide their inpatient services primarily at the hospital. Also, the Secretary must determine that the closure of the hospital would have a significant adverse impact on the availability of health care service in the absence of the hospital.

In making such determination, the Secretary may also consider: (1) whether ambulatory care providers in the hospital's service area are insufficient to handle the outpatient care of the hospital, (2) whether beneficiaries would have difficulty accessing care, and (3) whether the hospital has a commitment to provide graduate medical education in a rural area. The essential rural hospital would have to have a quality of care score above the median state scores.

A hospital classified as an essential rural hospital would not be able to change such classification. An essential rural hospital would not be able to be treated as a sole community hospital, Medicare dependent hospital, or rural referral center. A hospital that is classified as an essential rural hospital for a cost reporting period beginning on or after October 1, 2004 would be reimbursed 102 percent of its reasonable Medicare costs for inpatient and outpatient services. Beneficiary cost-sharing amounts would not be affected and required billing for such services would not be waived.

EFFECTIVE DATE

The provision would apply to cost reporting periods beginning on or after October 1, 2004.

REASON FOR CHANGE

The purpose of this provision is to recognize the impact of certain hospitals whose existence is essential in the health care delivery system of the community. Some rural hospitals have high fixed costs because of the necessity for providing the capacity for essential services in a community. There are also problems with the definition and payment for some communities and rural referral hospitals. This would provide a new crosscutting designation field for hospitals that can meet the criteria.

Section 404. More Frequent Update in Weights Used in Hospital Market Basket

CURRENT LAW

Medicare's standardized amounts, which serve as the basis for its payment per discharge from acute hospitals, are increased annually using an update factor which is determined in part by the projected increase in the hospital market basket. The market basket is a fixed-weight hospital input price index, which measures the average change in the price of goods and services hospitals purchased in order to furnish inpatient care. CMS revises the cost category weights, reevaluates the price proxies for such categories, and rebases (or changes the base period) for the market basket every five years. CMS implemented a revised and rebased market basket using 1997 cost data for use in the FY2003 Medicare hospital payment rates.

EXPLANATION OF PROVISION

The Secretary would be required to revise the market basket cost weights including the labor share to reflect the most currently available data and to establish a schedule for revising the cost weights more often than once every five years. The Secretary would be required to submit a report to Congress by October 1, 2004 on the reasons for and the options considered in establishing such a schedule.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

At the current time the hospital market basket is only updated every ten years using five-year-old data for the weights including the labor share. Statisticians at the Department of Labor and other experts believe the measures of inflation should be updated on a more regular basis to correct consistent inaccuracies over time.

Section 405. Improvements to the Critical Access Hospital (CAH) Program

(a) Increase in Payment Amounts

CURRENT LAW

Generally, a critical access hospital (CAH) receives reasonable, cost-based reimbursement for care rendered to Medicare beneficiaries. CAHs may elect either a cost-based hospital outpatient

service payment or an all-inclusive rate, which is equal to a reasonable cost payment for facility services plus 115 percent of the fee schedule payment for professional services. Ambulance services that are owned and operated by CAHs are reimbursed on a reasonable cost basis if these ambulance services are 35 miles from another ambulance system.

EXPLANATION OF PROVISION

Inpatient, outpatient, and covered skilled nursing facility services provided by a CAH would be reimbursed at 102 percent of reasonable costs of services furnished to Medicare beneficiaries.

EFFECTIVE DATE

This provision would apply to cost reporting periods beginning on or after October 1, 2003.

REASON FOR CHANGE

Small hospitals need the ability to build up reserves and to finance new capital expenditures. This provides a margin for these hospitals under the Medicare program, often their most important payor.

(b) Coverage of Costs for Certain Emergency Room On-Call Providers

CURRENT LAW

BIPA required the Secretary to include the costs of compensation (and related costs) of on-call emergency room physicians who are not present on the premises of a CAH, are not otherwise furnishing services, and are not on-call at any other provider or facility when determining the allowable, reasonable cost of outpatient CAH services.

EXPLANATION OF PROVISION

Reimbursement of on-call emergency room providers would be expanded to include the costs associated with physician assistants, nurse practitioners, and clinical nurse specialists as well as emergency room physicians for covered Medicare services.

EFFECTIVE DATE

This provision would apply to costs for services provided on or after January 1, 2004.

REASON FOR CHANGE

In sparsely populated areas, it is often the physician assistant or nurse practitioner employed by a physician practice or operating independently who is providing the on call services for the emergency room. This recognizes the bonuses that hospitals pay for their services.

(c) Modification of the Isolation Test for Cost-Based CAH Ambulance Services

CURRENT LAW

Ambulance services provided by a CAH or provided by an entity that is owned or operated by a CAH is paid on a reasonable cost basis and not the ambulance fee schedule, if the CAH or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of the CAH.

EXPLANATION OF PROVISION

The 35-mile requirement would not apply to the ambulance services that are furnished by a provider or supplier of ambulance services who is determined by the Secretary to be a first responder to emergencies.

EFFECTIVE DATE

This provision would apply to ambulance services furnished on or after the first cost reporting period that begins after the date of enactment.

REASON FOR CHANGE

CAHs may not be eligible for cost-based reimbursement because other ambulances may come into the area to transport patients between hospitals or to transfer patients to/from nursing homes. This would ensure that CAHs owned-and-operated ambulances would be paid cost when they are the first responders to an emergency.

(d) Reinstatement of Periodic Interim Payment (PIP)

CURRENT LAW

Eligible hospitals, skilled nursing facilities, and hospices, which meet certain requirements, receive Medicare periodic interim payments (PIP) every two weeks; these payments are based on estimated annual costs without regard to the submission of individual claims. At the end of the year, a settlement is made to account for any difference between the estimated PIP payment and the actual amount owed. A CAH is not eligible for PIP payments.

EXPLANATION OF PROVISION

An eligible CAH would be able to receive payments made on a PIP basis for its inpatient services. The Secretary would be required to develop alternative methods based on the expenditures of the hospital for these PIP payments.

EFFECTIVE DATE

This provision would apply to payments made on or after January 1, 2004.

REASON FOR CHANGE

Small rural hospitals often have significant changes in volume due to the season or just on a day-to-day basis. This provision averages payments over time to aid the hospital's financial stability.

(e) Condition for Application of Special Physician Payment Adjustment

CURRENT LAW

As specified by BBRA, CAHs can elect to be paid for outpatient services using cost-based reimbursement for its facility fee and at 115 percent of the fee schedule for professional services otherwise included within its outpatient critical access hospital services for cost reporting periods starting on or after October 1, 2000.

EXPLANATION OF PROVISION

The Secretary would not be able to require that all physicians providing services in a CAH assign their billing rights to the entity in order for the CAH to be able to be paid on the basis of 115 percent of the fee schedule for the professional services provided by the physicians. However, a CAH would not receive payment based on 115 percent of the fee schedule for any individual physician who did not assign billing rights to the CAH.

EFFECTIVE DATE

This provision would be effective as if it had been included as part of BBRA.

REASON FOR CHANGE

This provision ensures that the intent of Congress is for CMS to provide these payments in order to attract physicians to CAHs.

(f) Flexibility in Bed Limitation for Hospitals

CURRENT LAW

A CAH is a limited service facility that must provide 24-hour emergency services and operate a limited number of inpatient beds in which hospital stays can average no more than 96 hours. A CAH cannot operate more than 15 acute-care beds at one time, but can have an additional 10 swing beds that are set up for skilled nursing facility (SNF) level care. SNF beds in a unit of the facility that is licensed as a distinct-part skilled nursing facility at the time of the facility's application for CAH designation are not counted toward these bed limits.

EXPLANATION OF PROVISION

The Secretary would be required to specify standards for determining whether a CAH has seasonal variations in patient admissions that would justify a 5-bed increase in the number of beds it can maintain (and still retain its classification as a CAH). CAHs that operate swing beds would be able to use up to 25 beds for acute care services as long as no more than 10 beds at any time are used for non-acute services. Those CAHs with swing beds that made this election would not be eligible for the 5-bed seasonal adjustment. A CAH with swing beds that elects to operate only 15 of its 25 beds as acute care beds would be eligible for the 5-bed seasonal adjustment.

EFFECTIVE DATE

These provisions would only apply to CAH designations made before, on or after January 1, 2004.

REASON FOR CHANGE

These provisions allow some needed flexibility in the CAH program designation to ensure that if there is a flu epidemic or major accident that the hospital would have the capacity to treat those patients.

(g) Additional 5-Year Period of Funding for Grant Program

CURRENT LAW

The Secretary is able to make grants for specified purposes to States or eligible small rural hospitals that apply for such awards. The authorization to award the grants expired in FY2002.

EXPLANATION OF PROVISION

The authorization to award grants would be established from FY2004 through FY2008 from the Federal Hospital Insurance Trust Fund at amounts of up $25 million each year.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This would continue the planning and monitoring aspects of the states for the CAH program. The Committee expects that the states would work in cooperation with the critical access hospitals in determining the best use of the funds.

Section 406. Redistribution of Unused Resident Positions

CURRENT LAW

Medicare has different resident limits for counting residents, its indirect medical education (IME) adjustment and for reimbursement for a teaching hospital's direct graduate medical education (DGME) costs. Generally, a hospital's IME adjustment depends on a hospital's teaching intensity as measured by the ratio of the number of interns and residents per bed. Prior to BBA 97, the number of residents that could be counted for IME purposes included only those in the hospital inpatient and outpatient departments. Effective October 1, 1997, under certain circumstances a hospital may now count residents in non-hospital sites for the purposes of IME. Medicare's DGME payment to teaching hospital is based on its updated cost per resident (subject to a locality adjustment and certain payment corridors), the weighted number of approved full-time-equivalent (FTE) residents, and Medicare's share of inpatient days in the hospital. Generally, the resident counts of both IME and DGME payments are based on the number of residents in approved allopathic and osteopathic teaching programs that were reported by the hospital for the cost reporting period ending in calendar year 1996. The DGME resident limit is based on the unweighted resident counts. Hospitals that established new training programs be-

fore August 5, 1997 are partially exempt from the cap. Other exceptions apply to certain hospitals including those with new programs established after that date. Hospitals in rural areas (and non-rural hospitals operating training programs in rural areas) can be reimbursed for 130 percent of the number of residents allowed by their cap. Under certain conditions, an affiliated group of hospitals under a specific arrangement may combine their resident limits into an aggregate limit. Subject to these resident limits, a teaching hospital's IME and DGME payments are based on a three-year rolling average of resident counts, that is, the resident count will be based on the average of the resident count in the current year and the two preceding years. The rolling average calculation includes podiatry and dental residents.

EXPLANATION OF PROVISION

A teaching hospital's total number of potentially Medicare-reimbursed resident positions would be reduced for cost reporting periods, starting January 1, 2004, if the resident reference level is less than its applicable resident limit. If so, the reduction would equal to 75 percent of the difference between the hospital's limit and its resident reference level. The resident reference level would be the highest number of allopathic and osteopathic resident positions (before the application of any weighting factors) for the hospital during the reference period. A hospital's reference period would be the 3 most recent consecutive cost reporting periods for which a hospital's cost reports have been settled (or in the absence of such settled cost reports, submitted reports) on or before September 30, 2002. The Secretary would be able to adjust a hospital's resident reference level, upon the timely request for such an adjustment, for the cost reporting period that includes July 1, 2003.

The Secretary would be authorized to increase the applicable resident limits for other hospitals by an aggregate number that does not exceed the overall reduction in such limits. No increase would be permitted for any portion of cost reporting period that occurs before July 1, 2003 or before the date of a hospital's application for such an increase. No increase would be permitted unless the hospital has applied for such an increase by December 1, 2005.

The Secretary would consider the need for an increase in the physician specialty and the location involved. The Secretary would first distribute the increased resident count to programs in hospitals located in rural areas and hospitals that are not in large urban areas on a first-come-first-serve basis. The hospital would have to demonstrate that the resident positions would be filled; not more than 25 positions would be given to any one hospital. These hospitals would be reimbursed for DGME for the increase in resident positions at the locality adjusted national average per resident amount. Changes in a hospital's resident count established under this section would increase a hospital's IME payments. These provisions would not apply to reductions in residency programs that occurred as part of the voluntary reduction program or would affect the ability of certain hospitals to establish a new medical residency training programs. The Secretary would be required to submit a report, including recommendations, on whether to extend the application deadline for increases in resident limits no later than July 1, 2005.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

An unintended effect of the resident cap was to lock in a maldistribution of DGME and IME resident training positions in the country. Due to the strong link between the location of a resident's training and their eventual practice, it is critical to get more residents into training programs in rural areas and small urban cities. This provision redistributes unused residency slots, over a five-year period, to hospitals that have either reached their cap or have been providing DGME residencies without Medicare funding.

Section 407. Two-Year Extension of Hold Harmless Provisions for Small Rural Hospitals and Sole Community Hospitals Under Prospective Payment System for Hospital Outpatient Department Services

CURRENT LAW

The PPS for hospital outpatient departments (HOPDs) was implemented in August 2000 for most acute care hospitals. Under the HOPD PPS, Medicare pays for covered services using a fee schedule based on ambulatory payment classifications (APCs). Rural hospitals with no more than 100 beds are paid no less under this PPS system than they would have received under the prior reimbursement system for covered HOPD services because of hold harmless provisions. The hold harmless provisions apply to services provided before January 1, 2004.

EXPLANATION OF PROVISION

The hold harmless provisions governing HOPD reimbursement for small rural hospitals would be extended to January 1, 2006. The hold harmless provisions would be extended to sole community hospitals located in a rural area starting for services furnished on or after January 1, 2004 until January 1, 2006. The Secretary would be required to conduct a study to determine if the costs by APC groups incurred by rural providers exceed such costs incurred by urban providers. If appropriate, the Secretary would provide a payment adjustment to reflect the higher costs of rural providers by January 1, 2005.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

During the proposed rule for the start of the HOPD PPS, CMS found that rural hospital costs were higher than other hospitals. CMS did not recommend adjusting payments due to the poor quality of the data. This continues the hold harmless from any negative effect from the PPS for small rural hospitals and extends it to sole community hospitals until the Secretary reexamines this issue.

Section 408. Exclusion of Certain Rural Health Clinic and Federally Qualified Health Center Services from the Prospective Payment System for Skilled Nursing Facilities

CURRENT LAW

Under the PPS, skilled nursing facilities (SNFs) are paid a predetermined amount to cover all services provided in a day, including the costs associated with room and board, nursing, therapy, and drugs; the daily payment would vary depending upon a patient's therapy, nursing and special care needs as established by one of 44 resource utilization groups (RUGs). Certain services and items provided a SNF resident, such as physicians' services, specified ambulance services, chemotherapy items and services, and certain outpatient services from a Medicare-participating hospital or critical access hospital, are excluded from the SNF PPS and paid separately under Part B.

EXPLANATION OF PROVISION

Services provided by a rural health clinic (RHCs) and a federally qualified health center (FQHC) after January 1, 2004 would be excluded from SNF PPS, if such services were excluded if furnished by an physician or practitioner who was not affiliated with a RHC or FQHC.

EFFECTIVE DATE

The provision would apply to services furnished on or after January 1, 2004.

REASON FOR CHANGE

In some rural areas, local physicians may be employed in a rural health clinic or federally qualified health clinic. This would allow them to get paid for their professional services to skilled nursing patients like other physicians.

Section 409. Recognition of Attending Nurse Practitioners as Attending Physicians To Serve Hospice Patients

CURRENT LAW

Medicare covers hospice services to care for the terminal illnesses of the beneficiary. In general, beneficiaries who elect the hospice benefit give up other Medicare services that seek to treat the terminal illness or that duplicate services provided by the hospice. Services are provided primarily in the patient's home by a Medicare-approved hospice. Reasonable and necessary medical and support services for the management of the terminal illness are furnished under a written plan-of-care established and periodically reviewed by the patient's attending physician and the hospice. To be eligible for Medicare's hospice care, a beneficiary must be certified as terminally ill by an attending physician and the medical director or other physician at the hospice and elect hospice treatment. An attending physician who may be an employee of the hospice is identified by the patient as having the most significant role in the determination and delivery of his or her medical care when the patient makes an election to receive hospice care.

EXPLANATION OF PROVISION

A beneficiary would be able to identify a nurse practitioner (who is not employed by the hospice) as an attending physician. The nurse practitioner would not be able to certify the beneficiary as terminally ill.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

In rural areas, the independent nurse practitioner provides a significant amount of the care to patients up to and during their terminal illness. This allows them to continue in their clinical role with the patient.

Section 410. Improvement in Payments To Retain Emergency Capacity for Ambulance Services in Rural Areas

CURRENT LAW

Traditionally, Medicare has paid suppliers of ambulance services on a reasonable charge basis and paid provider-based ambulances on a reasonable cost basis. BBA 97 provided for the establishment of a national fee schedule, which was to be implemented in phases. The required fee schedule became effective April 1, 2002 with full implementation by January 2006. In the transition period, a gradually decreasing portion of the payment is to be based on the prior payment methodology (either reasonable costs or reasonable charges which were subject to national limitation amounts).

The fee schedule payment amount equals the base rate for the level of service plus payment for mileage and specified adjustment factors. Additional mileage payments are made in rural areas. BIPA increased payment for rural ambulance mileage for distances greater than 17 miles and up to 50 miles for services provided before January 1, 2004. The amount of the increase was at least one-half of the payment per mile established in the fee schedule for the first 17 miles of transport.

EXPLANATION OF PROVISION

The Secretary would be required to increase the base rate of the fee schedule for ground ambulance services that originate in a qualified rural area to account for the higher average costs incurred by providers furnishing a low volume of services. A qualified rural area is a county that has not been assigned to a metropolitan statistical area (MSA) with a population density of Medicare beneficiaries in the lowest quartile of all rural county populations.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The current adjustment may overpay rural ambulances in more populated areas and underpays them in less populated areas. Recent analyses by the General Accounting Office suggest that it is fixed costs—represented by the base rate—not mileage that are the

significant factor for increased costs in rural areas. In particular, the ambulances in the lowest 25 percent of rural counties may have less than one trip per day.

Section 411. Two-Year Increase for Home Health Services Furnished in a Rural Area

CURRENT LAW

The Medicare home health PPS, implemented on October 1, 2000, provides a standardized payment for a 60–day episode of care furnished to a Medicare beneficiary. Medicare's payment is adjusted to reflect the type and intensity of care furnished and area wages as measured by the hospital wage index. BIPA increased PPS payments by 10 percent for home health services furnished in the home of beneficiaries living in rural areas during the two-year period beginning April 1, 2001, through March 31, 2003, without regard to certain budget-neutrality provisions applying to home health PPS. The temporary additional payment is not included in the base for determination of payment updates.

EXPLANATION OF PROVISION

The provision would extend a five percent additional payment for home health care services furnished in a rural area during FY 2004 and 2005 without regard to certain budget-neutrality requirements.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

MedPAC recommends extending the five percent add-on for one-year while further analysis is done on rural agency home health margins. The two-year extension is to provide Congress with time to evaluate that information and decide what action is needed, if any.

Section 412. Providing Safe Harbor for Certain Collaborative Efforts that Benefit Medically Underserved Populations

CURRENT LAW

People who knowingly and willfully offer or pay a kickback, a bribe, or rebate to directly or indirectly induce referrals or the provision of services under a Federal program may be subject to financial penalties and imprisonment. Certain exceptions or safe harbors that are not considered violations of the anti-kickback statute have been established.

EXPLANATION OF PROVISION

Remuneration in the form of a contract, lease, grant, loan or other agreement between a public or non-profit private health center and an individual or entity providing goods or services to the health center would not be a violation of the anti-kickback statute if such an agreement would contribute to the ability of the health center to maintain or increase the availability or quality of services provided to a medically underserved population. The Secretary would be required to establish standards, on an expedited basis, re-

lated to this safe harbor that would consider whether the arrangement: (1) results in savings of Federal grant funds or increased revenues to the health center, (2) expands or limits a patient's freedom of choice, and (3) protects a health care professional's independence regarding the provision of medically appropriate treatment. The Secretary would also be able to include other standards that are consistent with Congressional intent in enacting this exception. The Secretary would be required to publish an interim final rule in the Federal Register no later than 180 days from enactment that would establish these standards. The rule would be effective immediately, subject to change after a public comment period of not more than 60 days.

EFFECTIVE DATE

Upon enactment

REASON FOR CHANGE

This would finalize policy under development at the Department of Health and Human Services.

Section 413. GAO Study of Geographic Differences

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

GAO would be required to study geographic differences in payment amounts in the physician fee schedule including: (1) an assessment of the validity of each component of the geographic adjustment factors; (2) an evaluation of the measures and the frequency with which they are revised; and (3) an evaluation of the methods used to establish the costs of professional liability insurance including the variation between physician specialties and among different states, the update to the geographic cost of practice index, and the relative weights for the malpractice component. The study, including recommendations concerning use of more current data and use of cost data rather than price proxies, would be due to Congress within 1 year of enactment.

EFFECTIVE DATE

Upon enactment.

Section 414. Treatment of Missing Cost Reporting Periods for Sole Community Hospitals

CURRENT LAW

Sole community hospitals (SCHs) are hospitals that, because of factors such as isolated location, weather conditions, travel conditions, or absence of other hospitals, are the sole source of inpatient services reasonably available in a geographic area, or are located more than 35 road miles from another hospital. The primary advantage of an SCH classification is that these hospitals receive Medicare payments based on the current national PPS national standardize amount or on hospital-specific per discharge costs from either FY 1982, FY1987 or FY1996 updated to the current year,

whatever amount would provide the highest Medicare reimbursement. The FY1996 base year option became effective for discharges on or after FY2001 on a phased in basis and would be fully implemented for SCH discharges on or after FY2004.

EXPLANATION OF PROVISION

A hospital would not be able to be denied treatment as a SCH or receive payment as a SCH because data are unavailable for any cost reporting period due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances, so long as data from at least one applicable base cost reporting period is available.

EFFECTIVE DATE

The provision would apply to cost reporting periods beginning on or after January 1, 2004.

REASON FOR CHANGE

During changes in fiscal intermediaries or in a change of ownership, historical information on a provider can be lost or misplaced. The purpose of the sole community hospital program is to provide for additional payment to protect access, which should not be stymied due to human error. Since sole community hospitals are paid the higher of any of the base years or the Federal rate, this does not result in preferential payments for these hospitals compared to other sole community hospitals.

Section 415. Extension of Telemedicine Demonstration Project

CURRENT LAW

BBA 97 authorized a telemedicine demonstration project for beneficiaries with diabetes mellitus in medically underserved rural or inner-city areas. BBRA required the Secretary to award the demonstration to the best technical proposal as of the bill's enactment date, no later than three months after enactment without additional review. BBRA also clarified that qualified medically underserved rural or urban inner-city areas are federally designated medically underserved areas or Health Provider Shortage Areas (HPSAs) at the time of enrollment in the project. Furthermore, it made changes in the project's data requirements, and limited beneficiary cost-sharing. The demonstration would expire in February 2004.

EXPLANATION OF PROVISION

This provision would extend the demonstration for an additional four years.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Difficulty finding appropriate participants delayed the demonstration's start. This extension would provide additional time to fully evaluate the clinical effectiveness of the program, and to de-

termine the long-term effectiveness of the approach. It would also provide more time to collect clinical data to evaluate the project's cost-effectiveness.

Section 416. Adjustment to the Medicare Inpatient Hospital PPS Wage Index to Revise the Labor-Related Share of Such Index

CURRENT LAW

Hospitals' DRG payments are adjusted by the hospital wage index. The adjusted portion of the payment is determined by the labor share. The labor share has three components: wages (50.7 percent), fringe benefits (11 percent), and rest is the so-called labor related costs.

EXPLANATION OF PROVISION

It reduces the labor share down to 62 percent of wages and fringe benefits for those areas with wage index values under 1.0. All other areas are held harmless from the change in the labor share.

EFFECTIVE DATE

October 1, 2003.

REASON FOR CHANGE

MedPAC and others have questioned whether some or all of the labor related costs in the labor share should be included. This eliminates these costs from the labor share for the areas that benefit from such a change.

Section 417. Medicare Incentive Payment Program Improvements for Physician Scarcity

CURRENT LAW

Under the Medicare Incentive Program, physicians receive a 10 percent bonus payment for services provided in health professional shortage areas. Physicians are responsible for indicating their eligibility for this bonus on their billing forms.

EXPLANATION OF PROVISION

This provision would establish a new five percent bonus payment program for physicians providing care to Medicare beneficiaries in physician scarcity areas. The Secretary would calculate two measures of scarcity. A primary care scarcity area would be determined based on the number of primary care physicians per Medicare beneficiary—the primary care ratio. A specialty care scarcity area would be based on the number of specialty care physicians per Medicare beneficiary—the specialty care ratio. The number of physicians would be based on physicians who actively practice medicine or osteopathy, and would exclude physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services.

The Secretary would rank each county or area based on its primary care ratio. Primary care scarcity counties or areas would be those counties or areas with the lowest primary care ratios, such that 20 percent of Medicare beneficiaries reside in these counties,

when each county or area is weighted by the number of Medicare beneficiaries in the county or area. Specialty care scarcity counties or areas would be identified in the same manner, using the specialty care ratio. There would be no administrative or judicial review of the identification of counties or areas, or of a specialty of any physician.

To the extent feasible, the Secretary would treat a rural census tract of a metropolitan statistical area, as determined under the most recent modification of the Goldsmith Modification, as an equivalent area for purposes of qualifying as a primary care scarcity area or specialty care scarcity area.

The Secretary would be required to publish a list of all areas which would qualify as primary care scarcity counties or specialty care scarcity counties as part of the proposed and final rules to implement the physician fee schedule.

The provision would also include improvement to the Medicare Incentive Payment Program, which provides a 10 percent bonus to physicians in shortage areas. The Secretary would be required to establish procedures under which the Secretary, and not the physician furnishing the service, would be responsible for determining when a bonus payment should be made. As part of the physician proposed and final rule for the physician fee schedule, the Secretary would be required to include a list of all areas which would qualify as a health professional shortage area for the upcoming year.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The new five percent bonus for physicians in either primary care scarcity counties or specialty care scarcity counties would increase financial incentives for physicians to provide care to Medicare beneficiaries in these areas with a shortage of physicians. This bonus payment would make it easier to recruit and retain physicians in these scarcity areas.

Improvements to the Medicare Incentive Program would shift responsibility for identifying eligibility for the 10 percent bonus from physicians to the Secretary.

E. TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

Section 501. Revision of Acute Hospital Payment Updates

CURRENT LAW

Each year, Medicare's operating payments to hospitals are increased or updated by a factor that is determined in part by the projected annual change in the hospital market basket. Congress establishes the update for Medicare's inpatient PPS for operating costs, often several years in advance.

EXPLANATION OF PROVISION

Acute hospitals would receive a market basket update minus 0.4 percent for three years. This results in an average 3.1 percent update for FY2004 through FY2006, equivalent to market basket minus 0.4 percent. The Secretary is also directed to compile and clarify the procedures and policies for billing for blood and blood costs in the hospital outpatient setting as well as the operation of the collection of the blood deductible.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

MedPAC unanimously recommended that Congress increase payments by 3.1 percent instead of the scheduled 3.5 percent. This results in a $3 billion increase in hospital payments for FY 2004. This is 0.4 percent less than current law due to expected increases in productivity. According to MedPAC, the modest expected productivity increase for hospitals is lower than would be considered to be sufficient for many private industries.

There is little precedent for hospitals to receive a full market basket increase. Congress has only given hospitals the full inflationary increase twice since the start of the hospital prospective payment system. Congress has legislated multiple-year changes in every Medicare bill except in the Omnibus Budget Reconciliation Act of 1989. Finally, this is a comparatively generous provision since Congress has typically reduced the inflationary offset by 1.2 percent—three times greater than the 0.4 percent recommended by MedPAC and presented in the bill.

The proposal replaces a historical saw tooth pattern of updates ranging from zero to full market basket to put hospitals' Medicare payments on a predictable stable funding path.

Section 502. Recognition of New Medical Technologies Under Inpatient Hospital PPS

CURRENT LAW

BIPA established that Medicare's inpatient hospital payment system should include a mechanism to recognize the costs of new medical services and technologies for discharges beginning on or after October 1, 2001. The additional hospital payments can be made by means of new technology groups, an add-on payment, a payment adjustment, or other mechanism, but cannot be a separate fee schedule and must be budget-neutral. A medical service or technology will be considered to be new if it meets criteria established by the Secretary after notice and the opportunity for public comment. CMS published the final regulation implementing these provisions on September 7, 2001. This regulation changed the meeting schedule for decisions on the creation and implementation of new billing codes (ICD–9–CM codes). The regulation also established that technology providing a substantial improvement to existing treatments would qualify for additional payments. The add-on payment for eligible new technology would occur when the standard diagnosis-related group (DRG) payment was inadequate; this thresh-

old was established as one standard deviation above the mean standardized DRG. In these cases, the add-on payment for new technology would be the lesser of (a) 50 percent of the costs of the new technology, or (b) 50 percent of the amount by which the costs exceeded the standard DRG payment; however, if the new technology payments are estimated to exceed the budgeted target amount of one percent of the total operating inpatient payments, the add-on payments are reduced prospectively.

Medicare pays hospitals additional amounts for atypical cases that have extraordinarily high costs compared to most discharges classified in the same DRG. The additional payment amount is equal to 80 percent of the difference between the hospital's entire cost for the stay and the threshold amount.

EXPLANATION OF PROVISION

The Secretary would be required to add new diagnosis and procedure codes in April 1 of each year that would not be required to affect Medicare's payment or DRG classification until the fiscal year that begins after that date. The Secretary would not be able to deny a service or technology treatment as a new technology because the service (or technology) has been in use prior to the 2-to-3 year period before it was issued a billing code and a sample of specific discharges where the service has been used can be identified. When establishing whether DRG payments are inadequate, the Secretary would be required to apply a threshold that is 75 percent of one standard deviation for the DRG involved.

The Secretary would be required to provide additional clarification in regulating the criteria used to determine whether a new service represents an advance in technology that substantially improves the existing diagnosis or treatment. The Secretary would be required to deem that a technology provides a substantial improvement on an existing treatment if the technology in question: (1) is a drug or a biological that is designated under section 506 of the Federal Food, Drug, and Cosmetic Act, approved under section 314.510 or 601.41 of Title 21, Code of Federal Regulations, designated for priority review when the marketing application was filed, or (2) is a medical device for which an exemption has been granted under section 520(m) of such Act, or for which priority or expedited review has been provided under section 515(d)(5). For other technologies that may be substantial improvements, the Secretary would be required to: (1) maintain and update a public list of pending applications for specific services and technologies to be evaluated for eligibility for additional payment; (2) accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial improvement; and (3) provide for a meeting at which organizations representing physicians, beneficiaries, manufacturers or other interested parties may present comments, recommendations, and data to the clinical staff of CMS regarding whether a service or technology represents a substantial improvement. These actions would occur prior to the publication of the proposed regulation.

Before establishing an add-on payment as the appropriate reimbursement mechanism, the Secretary would be directed to identify one or more DRGs and assign the technology to that DRG, taking into account similar clinical or anatomical characteristics and the

relative cost of the technology. The Secretary would assign an eligible technology into a DRG where the average cost of care most closely approximates the cost of the new technology. In such a case, no add-on payment would be made; the application of the budget-neutrality requirement with respect to annual DRG reclassifications and recalculation of associated DRG weights would not be affected. The Secretary would be required to increase the percentage associated with add-on payments from 50 percent to the marginal rate or the percentage that Medicare reimburses inpatient outlier cases.

The Secretary would be directed to automatically reconsider an application as a new technology that was denied for FY2003 as a FY2004 application under these new provisions. If such an application were granted, the maximum time period otherwise permitted for such classification as a new technology would be extended by 12 months.

EFFECTIVE DATE

These provisions would be effective for classifications beginning in FY2004.

REASON FOR CHANGE

CMS has only approved one new technology since these provisions were passed. This provision would allow more technologies to be covered and recognizes that the breakthrough technologies are new costs to the system.

Section 503. Increase in Federal Rate for Hospitals in Puerto Rico

CURRENT LAW

Under Medicare's prospective payment system for inpatient services, a separate standardized amount is used to establish payments for discharges from short-term general hospitals in Puerto Rico. BBA 97 provides for an adjustment of the Puerto Rico rate from a blended amount based on 25 percent of the federal national amount and 75 percent of the local amount to a blended amount based on a 50/50 split between national and local amounts.

EXPLANATION OF PROVISION

Hospitals in Puerto Rico would receive Medicare payments based on a 50/50 split between federal and local amounts before October 1, 2003. From FY2004–FY2007, an increasing amount of the payment rate would be based on federal national rates as follows: during FY2004, payment would be 59 percent national and 41 percent local; this would change to 67 percent national and 33 percent local during FY2005 and 75 percent national and 25 percent local during FY2006 and subsequent years.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Puerto Ricans pay the full Hospital Insurance payroll tax but they are not afforded equal Medicare payments to their hospitals.

This partially redresses the inequality between the rates, and is consistent with the MedPAC recommendation.

Section 504. Wage Index Adjustment Reclassification Reform

CURRENT LAW

Acute hospitals may apply to the Medicare Geographic Classification Review Board (MGCRB) for a change in classification from a rural area to an urban area, or reassignment from one urban area to another urban area, based on the level of wages. The MGCRB was created to determine whether a hospital should be redesignated to an area of close proximity for purposes of using that area's standardized amount, wage index, or both. If the MGCRB grants reclassification, the new wage index would be used to calculate Medicare's payment for inpatient and outpatient services. Generally, hospitals must demonstrate a close proximity to the areas where they seek to be reclassified. A hospital can meet this criteria if one of two conditions are met: (1) an urban hospital is no more than 15 miles and a rural hospital is no more than 35 miles from the area where it wants to be reclassified, or (2) at least 50 percent of the hospital's employees are residents of the area. A rural referral center (RRC) or a sole community hospital (SCH) or a hospital that is both a RRC and a SCH does not have to meet the proximity criteria. After establishing appropriate proximity, a hospital may qualify for the payment rate of another area if it proves that its incurred costs are comparable to those of hospitals in that area under established criteria. To use an area's wage index, a rural hospital must demonstrate that its average hourly wage is equal to at least 82 percent of the average hourly wage of hospitals in the area to which it seeks redesignation; an urban hospital must demonstrate that its average hourly wage is at least 84 percent of such an area. In addition, an urban hospital cannot be reclassified unless its average hourly wage is at least 108 percent of the average hourly wage of the area in which it is located. This standard is 106 percent for rural hospitals seeking reclassification to another area.

For redesignations starting in FY2003, the average hourly wage comparisons used to determine whether a hospital can use another area's wage index are based on 3 years worth of lagged data submitted by hospitals as part of their cost report. For instance, FY2003 wage index reclassifications were based on weighted three-year averages of average hourly wages using data from FY1997, FY1998, and FY1999 cost reports. Wage index reclassifications are effective for 3 years unless the hospital notifies the MCGRB and withdraws or terminates its reclassification.

EXPLANATION OF PROVISION

The Secretary would be required to establish an application process and payment adjustment to recognize the commuting patterns of hospital employees. A hospital that qualified for such a payment adjustment would have average hourly wages that exceed the average wages of the area in which it is located and have at least ten percent of its employees living in one or more areas that have higher wage index values. This qualifying hospital would have its wage index value increased by the average difference in wage index values between the higher areas and its own, weighted by the percent-

age of its employees who live in these areas. The process would be based on the MGCRB reclassification process and schedule with respect to data submitted. Such an adjustment would be effective for three years unless a hospital withdraws or terminates its payment. A hospital that receives a commuting wage adjustment would not be eligible for reclassification into another area by the MCGRB for the purposes of using its wage index or standardized amount. These commuting wage adjustments would not affect the computation of the wage index of the area in which the hospital is located or any other area. It would also be exempt from certain budget neutrality requirements.

ENACTMENT DATE

Upon enactment.

REASON FOR CHANGE

Labor market areas may differ from the distance requirements in the regulations on reclassification. Thus, using commuting patterns of employees more clearly reflects the underlying labor market that hospitals confront. This policy will have the effect of blurring the current hard line of payment adjustments between two adjacent MSAs.

Section 505. MedPAC Report on Specialty Hospitals

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

MedPAC would be required to conduct a study of specialty hospitals compared with other similar general acute hospitals including the number and extent of patients referred by physicians with an investment interest in the facility, the quality of care furnished, the impact of the specialty hospital on the acute general hospital, and the differences in the scope of services, Medicaid utilization and the amount of uncompensated care that is furnished. The report, including recommendations, would be due to Congress no later than 1 year from enactment.

ENACTMENT DATE

Upon enactment.

Subtitle B—Other Services

Section 511. Payment for Covered Skilled Nursing Facility Services

CURRENT LAW

Medicare uses a system of daily rates to pay for care in a skilled nursing facility (SNF). There are 44 daily rate categories, known as resource utilization groups (RUGs), and each group reflects a different case mix and intensity of services, such as skilled nursing care and/or various therapies and other services.

EXPLANATION OF PROVISION

The per diem RUG payment for a SNF resident with acquired immune deficiency syndrome (AIDS) would be increased by 128 percent. This payment increase would not apply after the date when the Secretary certifies that the SNF case mix adjustment adequately compensates for the facility's increased costs associated with caring for a resident with AIDS.

ENACTMENT DATE

The provision would be effective for services on or after October 1, 2003.

REASON FOR CHANGE

According to prior work by the Urban Institute, AIDS patients have much higher costs than other patients in the same resource utilization groups in skilled nursing facilities. The adjustment is based on that data analysis.

Section 512. Coverage of Hospice Consultation Services

CURRENT LAW

Current law authorized coverage of hospice services, in lieu of certain other Medicare benefits, for terminally ill beneficiaries who elect such coverage.

EXPLANATION OF PROVISION

Coverage of certain physicians' services for certain terminally ill individuals would be authorized. Persons entitled to these services would be individuals who have not elected the hospice benefit and have not previously received these physicians' services. Covered services would be those furnished by a physician who is the medical director or employee of a hospice program. Services would include evaluating the individual's need for pain and symptom management, counseling the individual with respect to end-of-life issues and care options, and advising the individual regarding advanced care planning. Payment for such services would equal the amount established for similar services under the physician fee schedule, excluding the practice expense component.

EFFECTIVE DATE

The provision would apply to consultation services provided by a hospice program on or after January 1, 2004.

REASON FOR CHANGE

Many patients, especially those with congestive heart failure, are not educated about the option of receiving hospice services to alleviate their pain and suffering. Moreover, hospice lengths of stay keep dropping, suggesting that patients are referred too late in their illness. This provision would encourage physicians to talk more with patients about hospice.

F. TITLE VI—PROVISIONS RELATING TO PART B

Subtitle A—Physicians' Services

Section 601. Revision of Updates for Physicians' Services

CURRENT LAW

Medicare pays for services of physicians and certain non-physician practitioners on the basis of a fee schedule. The fee schedule, in place since 1992, is intended to relate payments for a given service to the actual resources used in providing that service. The fee schedule assigns relative values to services. These relative values reflect physician work (i.e., the time, skill, and intensity it takes to provide the service), practice expenses, and malpractice costs. The relative values are adjusted for geographic variations in costs. The adjusted relative values are then converted into a dollar payment amount by a conversion factor.

The law provides a specific formula for calculating the annual update to the conversion factor. The intent of the formula is to place a restraint on overall increases in spending for physicians' services. Several factors enter into the calculation of the formula. These include: (1) the sustainable growth rate (SGR), which is essentially a target for Medicare spending growth for physicians' services, (2) the Medicare economic index (MEI), which measures inflation in the inputs needed to produce physicians' services, and (3) an adjustment that modifies the update, which would otherwise be allowed by the MEI, to bring spending in line with the SGR target. The SGR target is not a limit on expenditures. Rather, the fee schedule update reflects the success or failure in meeting the target. If expenditures exceed the target, the update for a future year is reduced.

The annual percentage update to the conversion factor equals the MEI, subject to an adjustment (known as the update adjustment factor) to match target spending for physicians' services under the SGR system. (During a transition period, 2001–2005, an additional adjustment is made to achieve budget neutrality.) The update adjustment sets the conversion factor at a level so that projected spending for the year would meet allowed spending by the end of the year. Allowed spending for the year is calculated using the SGR. However, in no case can the update adjustment factor be less than minus seven percent or more than plus three percent.

The update adjustment factor is the sum of: (1) the prior year adjustment component, and (2) the cumulative adjustment component. The prior year adjustment component is determined by: (1) computing the difference between allowed expenditures for physicians' services for the prior year and the amount of actual expenditures for that year, (2) dividing this amount by the actual expenditures for that year, and (3) multiplying that amount by 0.75. The cumulative adjustment component is determined by: (1) computing the difference between allowed expenditures for physicians' services from April 1, 1996 through the end of the prior year and the amount of actual expenditures during such period, (2) dividing that difference by actual expenditures for the prior year as increased by the SGR for the year for which the update adjustment factor is to be determined, and (3) multiplying that amount by 0.33.

The law also specifies a formula for calculating the SGR that is based on changes in four factors: (1) the estimated change in fees, (2) the estimated change in average number of Part B enrollees (excluding Medicare+Choice beneficiaries), (3) the estimated projected growth in real gross domestic product (GDP) per capita, and (4) the estimated change in expenditure due to changes in law or regulations. This formula is designed to adjust for how well actual expenditures meet SGR target expenditures.

Provisions in the Consolidated Appropriations Resolution of 2003 (P.L. 108–7) permitted redeterminations of SGR for prior years to correct for faulty data for the number of FFS beneficiaries in 1998 and 1999. As a result, the conversion factor for 2003 was increased 1.6 percent over the 2002 level. Other aspects of the formula for the annual payment rate were not addressed.

CMS estimates an update of −4.2 percent for 2004, followed by a smaller negative update in 2005.

EXPLANATION OF PROVISION

The update to the conversion factor for 2004 and 2005 would be not less than 1.5 percent.

The formula for calculating the sustainable growth rate would be modified. Starting in 2003, the GDP factor would be based on the annual average change over the preceding 10 years (a 10-year rolling average.) The current GDP factor measures the 1-year change from the preceding year.

EFFECTIVE DATE

Upon enactment. The 10-year rolling average calculation of the GDP would apply to computations of the SGR starting in 2003.

REASON FOR CHANGE

CMS actuaries project a −4.2 percent update for 2004 and a smaller negative update for 2005. This provision would prevent those negative updates from occurring, and provide for modest increases in physician payment rates. These modest increases would ensure continuing access to physician services for Medicare beneficiaries.

The provision also includes a 10-year rolling average calculation of GDP as a modest change to the update formula. This change would promote stability in the physician updates over time by limiting the volatility of the SGR payments, which now oscillate dramatically based on year-to-year changes in economic performance.

Section 602. Studies on Access to Physicians Services

CURRENT LAW

Periodic analyses by the Physician Payment Review Commission, MedPAC, and CMS showed that access to physicians' services remained generally adequate for most beneficiaries through 1999. Detailed data is not available for a subsequent period; however, several recent surveys show a decline in the percentage of physicians accepting new Medicare patients.

EXPLANATION OF PROVISION

GAO would be required to conduct a study on access of Medicare beneficiaries to physicians' services under Medicare. The study would include an assessment of beneficiaries' use of services through an analysis of claims data. It would also examine changes in use of physicians' services over time. Further, it would examine the extent to which physicians are not accepting new Medicare beneficiaries as patients. GAO would be required to submit a report to Congress on this study within 18 months of enactment. The report would include a determination whether data from claims submitted by physicians indicate potential access problems for beneficiaries in certain geographic areas. The report would also include a determination whether access by beneficiaries to physicians' services has improved, remained constant, or deteriorated over time.

The Secretary would be required to request the Institute of Medicine to conduct a study on the adequacy of the supply of physicians (including specialists) in the country and the factors that affect supply. The Secretary would be required to submit the results of the study in a report to Congress no later than 2 years of the date of enactment.

EFFECTIVE DATE

Upon enactment.

Section 603. MedPAC Report on Payment for Physicians' Services

CURRENT LAW

Medicare pays for physicians' services on the basis of a fee schedule. The fee schedule assigns relative values to services. These relative values reflect physician work, practice expenses and malpractice expenses. Resource-based practice expense relative values were phased-in beginning in 1999. Beginning in 2002, the values were totally resource-based.

Certain services have a professional component and a technical component. The technical component does not include a relative value for physician work. A global value includes both the professional and technical components. The physician must bill for the global value if the physician furnishes both the professional component and the technical component.

EXPLANATION OF PROVISION

MedPAC would be required to report to Congress on the effects of refinements to the practice expense component in the case of services for which there are no physician work relative value units. The report is to examine the following by specialty: (1) the effects of refinements on payments for physicians services, (2) interaction of the practice expense component with other components of and adjustments to payment for physicians' services, (3) appropriateness of the amount of compensation by reason of such refinements, (4) effect of such refinements on access to care by Medicare beneficiaries to physicians' services, and (5) effect of such refinements on physician participation under the Medicare program. The report would be due within one year of enactment.

EFFECTIVE DATE

Upon enactment.

Subtitle B—Preventive Services

Section 611. Coverage of an Initial Preventive Physical Examination

CURRENT LAW

Medicare covers a number of preventive services. However, it does not cover routine physical examinations.

EXPLANATION OF PROVISION

Medicare would cover an initial free preventive physical examination. The physical examination would be defined as physicians' services consisting of a physical examination with the goal of health promotion and disease detection. It would include items and services (excluding clinical laboratory tests) consistent with the recommendations of the United States Preventive Services Task Force as determined by the Secretary. A covered initial preventive physical examination would be one performed no later than six months after the individual's initial coverage date under Part B. Initial preventive physical exams would be included in the definition of physicians' services for purposes of the physician fee schedule. The Part B deductible and coinsurance would be waived for initial preventive physical exams.

EFFECTIVE DATE

The provision would apply to services furnished on or after January 1, 2004 for those individuals whose coverage begins on or after such date.

REASON FOR CHANGE

The US Preventive Services Task Force has recommended coverage of a preventive physical exam. An initial physical exam for new Medicare beneficiaries would permit identification of any health problems and allow for initiation of appropriate treatment, thereby reducing more acute and expensive interactions with the health care system in the future.

Section 612. Coverage of Cholesterol and Blood Lipid Screening

CURRENT LAW

Medicare covers a number of preventive services. However, it does not cover cholesterol and blood lipid screening.

EXPLANATION OF PROVISION

Medicare coverage of cholesterol and blood lipid screening would be authorized. The screening would be defined as diagnostic testing of cholesterol and other lipid levels of the blood for the purpose of early detection of abnormal cholesterol and other lipid levels. The Secretary would be required to establish standards regarding the frequency and type of these screening tests, but not more often than once every two years.

EFFECTIVE DATE

The provision would apply to services furnished on or after January 1, 2005.

REASON FOR CHANGE

The US Preventive Services Task Force has recommended coverage of cholesterol and blood lipid screening for the elderly. This preventive care benefit would allow for early detection and treatment of health problems.

Section 613. Waiver of Deductible for Colorectal Cancer Screening Tests

CURRENT LAW

Covered colorectal screening tests for prevention purposes include: (1) an annual fecal-occult blood test for individuals age 50 and older, (2) flexible sigmoidoscopy every four years for individuals age 50 and older, (3) colonoscopy for high-risk individuals every two years and for other individuals every 10 years, and (4) screening barium enemas every four years for individuals age 50 and older who are not at high risk of developing colorectal cancer or every two years for high risk individuals. Payment is made according to the applicable payment system for the provider performing the test.

Colorectal cancer screening tests are subject to beneficiary cost sharing amounts, including an annual deductible and coinsurance amount.

EXPLANATION OF PROVISION

The Part B deductibles would be waived for colorectal cancer screening tests.

EFFECTIVE DATE

The provision would apply to items and services furnished on or after January 1, 2004.

REASON FOR CHANGE

Beneficiaries have not availed themselves of preventive colorectal cancer screening tests to the extent anticipated after Medicare coverage of these tests became available under BBA 97. This provision would waive the deductible to increase beneficiary use of these important screening tests.

Section 614. Improved Payment for Certain Mammography Services

CURRENT LAW

Screening mammography coverage includes the radiological procedure as well as the physician's interpretation of the results of the procedure. The usual Part B deductible is waived for tests. Payment is made under the physician fee schedule.

Certain services paid under fee schedules or other payment systems including ambulance services, services for patients with end-stage renal disease paid under the ESRD composite rate, professional services of physicians and non-physician practitioners paid

under the physician fee schedule, and laboratory services paid under the clinical diagnostic laboratory fee schedule are excluded from Medicare's HOPD PPS.

EXPLANATION OF PROVISION

Unilateral and bilateral diagnostic mammography as well as screening mammography services would be excluded from the HOPD PPS. The Secretary would be required to provide an appropriate adjustment to the physician fee schedule for the technical component of the diagnostic mammography based on the most recent cost data available. This adjustment would be applied to services provided on or after January 1, 2004.

EFFECTIVE DATE

The provision would apply to mammography performed on or after January 1, 2004.

REASON FOR CHANGE

Mammography services are paid at a much lower rate under the HOPD PPS than in the physician office. This establishes a level playing field across sites of service, thereby increasing beneficiary access to important preventive services.

Subtitle C—Other Services

Section 621. Hospital Outpatient Department (HOPD) Payment Reform

(a) Payment for Drugs

CURRENT LAW

Under the HOPD PPS, the unit of payment is the individual service or procedure as assigned to one of about 570 ambulatory payment classifications (APCs) groups. Services are classified into APCs based on their Health Care Common Procedure Coding System (HCPCS), a standardized coding system used to identify products, supplies, and services for claims processing and payment purposes. To the extent possible, integral services and items including drugs are bundled or packaged within each APC. For instance, an APC for a surgical procedure would include operating and recovery room services, anesthesia and surgical supplies. Medicare's payment for HOPD services is calculated by multiplying the relative weight associated with an APC by a geographically adjusted conversion factor. The conversion factor is updated on a calendar year schedule and the annual updates are based on the hospital market basket (MB). Currently, the CY 2004 HOPD update would equal the projected change in the MB.

Medicare pays for covered outpatient drugs in one of three ways: (1) as a transitional pass-through, (2) as a separate APC, or (3) packaged into an APC with other services.

Transitional pass-through payments are supplemental payments to cover the incremental cost associated with certain medical devices, drugs and biologicals that are inputs to an existing service. The additional payment for a given item is established for two or three years and then the costs are incorporated into the APC rel-

ative weights. BBRA specified that pass-through payments would be made for current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current cancer therapy drugs, biologicals, and brachytherapy; current radiophamaceutical drugs and biological products; and new drugs and biological agents.

Generally, CMS has established that a pass-through payment for an eligible drug is based on the difference between 95 percent of its average wholesale price and the portion of the otherwise applicable APC payment rate attributable to the existing drug, subject to a budget neutrality provision. The pass-through amount for new drugs with a substitute drug recognized in a separate drug APC payment is the difference between 95 percent of new drug AWP and the payment rate for the comparable dose of the associated drug APC.

Hospital costs for these drugs are used to establish the beneficiary copayment amounts as well as to project the amount of pass-through spending to calculate the uniform reduction to payments under the budget neutrality constraint. These hospital costs are imputed by multiplying the drug's AWP by the applicable cost to charge ratio, which varies by the class of drug. Although transitional pass-through payments are subject to a budget neutrality requirement, the applicable budget neutrality requirement (2.5 percent through CY2003) was not effective until April 2002.

Current drugs and biologicals that have been in transitional pass-through status on or prior to January 1, 2000, were removed from that payment status effective January 1, 2003. CMS established separate APC payments for certain drugs, including orphan drugs, blood and blood products, and selected higher cost drugs in CY2003. CMS established a threshold of $150 for a drug to qualify for a separate APC payment as a higher-cost drug. Other drugs that had qualified for a transitional pass-through payment were packaged in to procedural APCs. For example, in some instances, brachytherapy seeds (radioactive isotopes used in cancer treatments) were packaged into payments for brachytherapy procedures. Essentially, the payment rates for these drug-related APCs are based on a relative weight calculated in the same way as procedural APCs are calculated.

Temporary HCPCS codes are used exclusively to bill pass-through payments for new technology items paid under the HOPD PPS. These codes cannot be used to bill other Medicare payment systems. These codes are added, changed or deleted on a quarterly basis to expedite the processing of requests for pass-through status.

EXPLANATION OF PROVISION

Starting for services furnished on or after January 1, 2004, certain covered HOPD drugs would be paid no more than 95 percent of AWP or less than the transition percentage of the AWP from CY2004 through CY2006. In subsequent years, payment would be equal to average price for the drug in the area and year established by the competitive acquisition program under 1847A. The covered HOPD drugs affected by this provision are radiopharmaceuticals and outpatient drugs that were paid on a pass-through basis on or before December 31, 2002. These would not include drugs for which pass-through payments are first made on or after January 1, 2003,

or those drugs for which a temporary HCPCS code has not been assigned. Drugs for which a temporary HCPCS code has not been assigned would be reimbursed at 95 percent of AWP.

The transition percentage to AWP for sole-source drugs manufactured by one entity is 83 percent in CY2004, 77 percent in CY2005, and 71 percent in CY2006. The transition percentage to AWP for innovator multiple source drugs is 81.5 percent in CY2004, 75 percent in CY2005, and 68 percent in CY2006. The transition percentage to AWP for multiple source drugs with generic drug competitors is no more than 46 percent in CY2004 through CY2006. Generally, a multiple source drug is a covered drug for which there are two or more therapeutically equivalent drug products. An innovator multiple source drug is a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration (FDA). A sole source drug is not a multiple source drug. The additional expenditures resulting from these provisions would not be subject to the budget neutrality requirement.

Starting in CY2004, the Secretary would be required to lower the threshold for establishing a separate APC group for higher cost drugs from $150 to $50. These separate drug APC groups would not be eligible for outlier payments because their payment already increases when the dose increases.

Starting in CY2004, Medicare's transitional pass-through payments for drugs and biologicals covered under a competitive acquisition contract would reflect the amount paid under that contract, not 95 percent of AWP.

REASON FOR CHANGE

A GAO study found significant problems with the reimbursement for drugs and biologicals under the hospital outpatient system. Some drugs were reimbursed a small amount of AWP while others were paid far in excess of AWP. Hospital charges were not designed to specifically capture the resource costs for specific items. Some hospitals charge a flat markup on all drugs; some hospitals charge a lower markup on low cost drugs compared to high cost drugs while others do the opposite. As a result, the APC drug prices ranged from paying 0.2 percent of AWP to 29,000 percent of 95 percent AWP, and paid the median generic drugs more than sole source drugs. This provision establishes a glide path to the hospital acquisition cost numbers from the Kathpol survey undertaken by CMS. Thereafter, a level playing field with drug prices across sites of service would be established. CMS is asked to collect data from hospitals on their acquisition to be used to adjust the rates if necessary.

(b) Special Payment for Brachytherapy

CURRENT LAW

Current drugs and biologicals that have been in transitional pass-through status on or prior to January 1, 2000 were removed from that payment status effective January 1, 2003. CMS established separate APC payments for certain drugs, including orphan drugs, blood and blood products, and selected higher cost drugs in CY2003. CMS established a threshold of $150 per claim for a drug

to qualify for a separate APC payment as a higher-cost drug. Other drugs that had qualified for a transitional pass-through payment were packaged into procedural APCs. For example, in some instances, brachytherapy seeds (radioactive isotopes used in cancer treatments) were packaged into payments for brachytherapy procedures. Essentially, the payment rates for these drug-related APCs are based on a relative weight calculated in the same way as procedural APCs are calculated.

EXPLANATION OF PROVISION

From January 1, 2004 through December 31, 2006, Medicare's payments for brachytherapy devices would equal the hospital's charges adjusted to costs. The Secretary would be required to create separate APCs to pay for these devices that reflect to the number, isotope, and radioactive intensity of such devices. This would include separate groups for palladium-103 and iodine-125 devices. GAO would be required to study the appropriateness of payments for brachytherapy devices and submit a report including recommendations to Congress no later than January 1, 2005.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The amount of seeds necessary to treat the patient can vary significantly. This changes the payment methodology to reflect differences in clinical resources.

(c) Functional Equivalence

CURRENT LAW

In the November 1, 2002, Federal Register final rule, CMS decided that a new anemia treatment for cancer patients was no longer eligible for pass-though payments because it was functionally equivalent (although not structurally identical or therapeutically equivalent) to an existing treatment. The transitional pass-through rate for the drug was reduced to zero starting for services in 2003.

EXPLANATION OF PROVISION

The Secretary would be prohibited from applying a functional equivalence standard or any similar standard that deems a particular drug or biological to be similar or identical to another drug (and therefore ineligible for pass-through payment status) without first developing these standards by regulation. Such regulation would be required to: (1) be published after a public comment period, (2) contain criteria that provides for coordination with the Food and Drug Administration, and (3) be based on scientific studies that demonstrate the clinical relationship between the drugs in question. This provision would apply to the application of a functional equivalent determination on or after the date of enactment. The provision prohibits the application of this standard to a drug or biological prior to June 13, 2003.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The concept of functional equivalence is new to the Medicare program and should be open to comment by Congress and the public through proposed rulemaking. The FDA should be involved since these are scientific issues for which CMS lacks expertise.

(d) Hospital Acquisition Cost Study

CURRENT LAW

CMS estimates hospital costs to establish beneficiary copayment amounts as well as to project the amount of pass-through spending to calculate the uniform reduction to payments under the budget neutrality constraint. These hospital costs are imputed by multiplying AWP for the drug by the applicable cost to charge ratio, which varies by the class of drug.

EXPLANATION OF PROVISION

The Secretary would be required to study the hospital acquisition costs related to covered outpatient drugs that cost $50 and more that are reimbursed under the HOPD PPS. The study would encompass a representative sample of urban and rural hospitals. The report should include recommendations on the usefulness of the cost data and frequency of subsequent data collection and would be due to Congress no later than January 1, 2006. The report should also discuss whether the data is appropriate for making adjustments to payments made under the competitive acquisition contract established by section 1847A and whether separate estimates should be made for overhead costs (i.e. handling and administering drugs).

EFFECTIVE DATE

Upon enactment.

Section 622. Payment for Ambulance Services

CURRENT LAW

Traditionally, Medicare has paid suppliers of ambulance services on a reasonable charge basis and paid provider-based ambulances on a reasonable cost basis. BBA 97 provided for the establishment of a national fee schedule, which was to implemented in phases, in an efficient and fair manner. The required fee schedule became effective April 1, 2002, with full implementation by January 2006. In the transition period, a gradually decreasing portion of the payment is to be based on the prior payment methodology (either reasonable costs or reasonable charges).

The fee schedule payment amount equals the base rate for the level of service plus payment for mileage and specified adjustment factors. Additional mileage payments are made in rural areas. BIPA increased payment for rural ambulance mileage for distances greater than 17 miles and up to 50 miles for services provided before January 1, 2004. The amount of the increase was at least one-

half of the payment per mile established in the fee schedule for the first 17 miles of transport.

EXPLANATION OF PROVISION

The phase-in methodology and schedule for full implementation of the ambulance fee schedule would be modified. The calculation of ambulance fees in the phase-in period would incorporate a decreasing portion of the payment based on regional fee schedules calculated for each of nine census regions for those regions that lose financially under the fee schedule. Generally, the regional fee schedules would be based on the same methodology and data used to construct the national fee schedule. For services provided in 2004, the blended rate would be based on 20 percent of the national fee schedule and 80 percent of the regional fee schedule; in 2005 blended rate would be based on a 40 percent national and 60 percent regional split; in 2006, the blended rate would be based on a 60 percent national and 40 percent regional split; from 2007–2009, the blended rate would be based on an 80 percent national and 20 percent regional split; and in 2010 and subsequently, the ambulance fee schedule would be based on the national fee schedule.

Medicare's payments for ground ambulance services would be increased by one quarter of the amount otherwise established for trips longer than 50 miles occurring on or after January 1, 2004 and before January 1 2009. The payment increase would apply regardless of where the transportation originated. GAO would be required to submit an initial report to Congress on the access and supply of ambulance services in regions and states where ambulance payments are reduced by December 31, 2005. GAO would be required to submit a final report to Congress by January 1, 2004.

EFFECTIVE DATE

The provision would apply to ambulance services furnished on or after January 1, 2004.

REASON FOR CHANGE

New PPS systems cannot capture all the reasons for past regional differences in cost. This proposal is modeled on the transition of the hospital inpatient PPS and acts to slow down the losses in regions that lose significantly under the new fee schedule.

Section 623. Renal Dialysis Services

(a) Demonstration of Alternative Delivery Models

CURRENT LAW

The Secretary announced a demonstration project establishing a disease-management program that would allow organizations experienced with treating end-stage renal disease (ESRD) patients to develop financing and delivery approaches to better meet the needs of beneficiaries with ESRD. CMS is soliciting a variety of types of organizations to coordinate care to patients with ESRD, encourage the provision of disease-management services for these patients, collect clinical performance data and provide incentives for more effective care.

EXPLANATION OF PROVISION

The provision would require the Secretary to establish an advisory board for the ESRD disease management demonstration. The advisory board would be comprised of representatives patient organizations, clinicians, MedPAC, the National Kidney Foundation, the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health, ESRD networks, Medicare contractors to monitor quality of care, providers of services and renal dialysis facilities furnishing end-stage renal disease services, economists, and researchers.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This provision would allow more patient oversight of the demonstration of changes to the payments system for such a frail population.

(b) Restoring Composite Rate Exceptions for Pediatric Facilities

CURRENT LAW

Prior to BIPA, an increase in the composite rate would trigger an opportunity for facilities to request an exception to the composite rate in order to receive higher payments. BIPA prohibited the Secretary from granting new exceptions to the composite rate from applications received after July 1, 2001.

EXPLANATION OF PROVISION

The prohibition on exceptions would not apply to pediatric ESRD facilities as of October 1, 2002. Pediatric facilities would be defined as a renal facility with 50 percent of its patients under 18 years old.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Pediatric patients require more nursing oversight and more time to receive dialysis treatment. This would recognize the higher costs of facilities that treat these patients.

(c) Increase in Renal Dialysis Composite Rate for Services Furnished in 2004

CURRENT LAW

Dialysis facilities providing care to beneficiaries with end-stage renal disease (ESRD) receive a fixed prospectively determined payment amount (the composite rate) for each dialysis treatment. BBRA increased the composite rates by 1.2 percent for dialysis services furnished in both 2000 and 2001. BIPA subsequently increased the mandated 2001 update to 2.4 percent, an increase that was to be implemented on the following schedule in order to avoid

a disruption in claims processing: for services furnished from January through March, 2001, the 1.2 percent increase specified by BBRA applied; for the remainder of 2001, a transition increase of 2.79 percent applied. Effective January 1, 2002, the composite rates reflected the 2.4 percent increase. There is no rate increase scheduled for ESRD composite payment rate in 2004.

EXPLANATION OF PROVISION

The provision would increase the ESRD composite payment rate by 1.6 percent for 2004.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The Medicare Payment Advisory Commission recommended this increase in the composite rate for 2004.

Section 624. One-Year Moratorium on Therapy Caps; Provisions Relating to Reports

CURRENT LAW

BBA 97 established annual payment limits per beneficiary for all outpatient therapy services provided by non-hospital providers. The limits applied to services provided by independent therapists as well as to those provided by comprehensive outpatient rehabilitation facilities (CORFs) and other rehabilitation agencies. There are two beneficiary limits. The first is a $1,500 per beneficiary annual cap for all outpatient physical therapy services and speech language pathology services. The second is a $1,500 per beneficiary annual cap for all outpatient occupational therapy services. Beginning in 2002, the amount increases by the Medicare Economic Index (MEI), rounded to the nearest multiple of $10. The limits do not apply to outpatient services provided by hospitals. BBRA 99 percent suspended application of the therapy limits in 2000 and 2001. BIPA extended the suspension through 2002. Although the therapy caps were scheduled for implementation in January 2003, they are not yet being enforced. CMS has scheduled implementation for July 2003.

Therapy patients must be under the care of a physician. The physician or therapist must develop a treatment plan, and the physician must review the plan periodically.

BBA 97 required the Secretary to report to Congress by January 1, 2001, on recommendations for a revised coverage policy of outpatient physical therapy and occupational therapy services based on a classification of individuals by diagnostic category and prior use of services, in both inpatient and outpatient settings, in place of uniform dollar limitations. BIPA required the Secretary to conduct a study on the implications of eliminating Medicare's in-room supervision requirement for physical therapy assistants supervised by physical therapists its implication on the physical therapy cap. A report on the study was due within 18 months of enactment.

EXPLANATION OF PROVISION

Application of the therapy caps would be suspended during CY 2004. The Secretary would be required to submit the reports required by BBA 97 and BIPA by December 31, 2003. The Secretary would be required to request the Institute of Medicine to identify conditions or diseases that should justify conducting an assessment of the need to waive the therapy caps. The Secretary would be required to submit to Congress a preliminary report on the conditions and diseases identified by July 1, 2004. A final report, including recommendations, would be due by October 1, 2004.

GAO would be required to conduct a study on access to physical therapist services in states authorizing access to such services without a physician referral compared to states that require such a physician referral. The study would: (1) examine the use of and referral patterns for physical therapist services for patients age 50 and older in states that authorize such services without a physician referral and in states that require such a referral, (2) examine the use of and referral patterns for physical therapist services for patients who are Medicare beneficiaries, (3) examine the physical therapist services within the facilities of the Department of Defense, and (4) analyze the potential impact on beneficiaries and on Medicare expenditures of eliminating the need for a physician referral for physical therapist services under the Medicare program. GAO would be required to submit a report to Congress on the study within one year of enactment.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The Secretary has not provided a recommendation to Congress of criteria, with respect to conditions and diseases, under which a waiver of therapy caps would apply for individual Medicare beneficiaries. The implementation of therapy caps would be waived for 2004 because the Secretary has failed to provide a recommendation. The Secretary would have until October 1, 2004 to provide a recommendation to Congress.

Section 625. Adjustment to Payments for Services Furnished in Ambulatory Surgical Centers

CURRENT LAW

Medicare uses a fee schedule to pay for the facility services related to a surgery provided in an ACS. The associated physician services (surgery and anesthesia) are reimbursed under the physician fee schedule. CMS maintains the list of approved ASC procedures that is required to be updated every 2 years. The Secretary is required to update ASC rates based on a survey of the actual audited costs incurred by a representative sample of ASCs every 5 years beginning no later than January 1, 1995. Between revisions, the rates are to be updated annually on a calendar year schedule using the CPI–U. From FY1998 through FY2002, the update was established as the CPI–U minus 2.0 percentage points, but not less than zero.

EXPLANATION OF PROVISION

The update would be reduced two percentage points for five years. ASCs would get an increase calculated as the CPI–U minus 2.0 percentage points (but not less than zero) in each of the fiscal years from 2004 through 2008.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

MedPAC made three recommendations regarding ASCs, including a freeze on payments for 2004. This update would allow ASCs a small increase in payments while a more permanent solution is developed. The Committee urges CMS and ASCs to complete the collection of recent ASC charge and cost data, so that the ASC payment system can be analyzed and revised. Furthermore, the Committee recognizes the inconsistency in payments to ASCs and HOPD PPS rates for the same procedures. ASCs are urged to cooperate with CMS in providing recent charge and cost data to prevent changes to ASC payments that might not be supported if full data were available.

Section 626. Payment for Certain Shoes and Inserts under the Fee Schedule for Orthotics and Prosthetics

CURRENT LAW

Subject to specified limits and under certain circumstances, Medicare would pay for extra-depth shoes with inserts or custom molded shoes with inserts for an individual with severe diabetic foot disease. Coverage is limited to one of the following within a calendar year: (1) one pair of custom-molded shoes (including inserts provided with such shoes) and two additional pairs of inserts, or (2) one pair of extra-depth shoes (not including inserts provided with such shoes) and three pairs of inserts. An individual may substitute modifications of custom-molded or extra-depth shoes instead of obtaining one pair of inserts, other than the initial pair of inserts. Footwear must be fitted and furnished by a podiatrist or other qualified individual such as a pedorthist, orthotist, or prosthetist. The certifying physician may not furnish the therapeutic shoe unless the physician is the only qualified individual in the area.

Payment is made on a reasonable charge basis, subject to upper limits established by the Secretary. These limits are based on 1988 amounts that were set forth in Section 1833(o) of the Act and then adjusted by the same percentage increases allowed for DME fees except that if the updated limit is not a multiple of $1, it is rounded to the nearest multiple of $1. The Secretary or a carrier may establish lower payment limits than established by statute if shoes and inserts of an appropriate quality are readily available at lower amounts.

Although updates in payment for diabetic shoes is related to that used to increase the DME fee schedule, the shoes are not subject to DME coverage rules or the DME fee schedule. In addition, dia-

betic shoes are neither considered DME nor orthotics, but a separate category of coverage under Medicare Part B.

EXPLANATION OF PROVISION

Payment for diabetic shoes would be limited by the amount that would be paid if they were considered to be a prosthetic or orthotic device. The Secretary or a carrier would be able to establish lower payment limits than these amounts if shoes and inserts of an appropriate quality are readily available at lower amounts. The Secretary would be required to establish a payment amount for an individual substituting modifications to the covered shoe that would assure that there is no net increase in Medicare expenditures.

EFFECTIVE DATE

The provision would apply to items furnished on or after January 1, 2004.

REASON FOR CHANGE

The payment for shoes was determined based on an arbitrary amount set in the statute. The amount exceeded the retail price for some comparable items. This treats diabetic shoes the same as all other durable medical equipment.

Section 627. Waiver of Part B Late Enrollment Penalty for Certain Military Retirees; Special Enrollment Period

CURRENT LAW

A late enrollment penalty is imposed on beneficiaries who do not enroll in Medicare Part B upon becoming eligible for Medicare.

EXPLANATION OF PROVISION

Congress enacted TRICARE for Life, which re-established TRICARE health care coverage as a wraparound to Medicare for military retirees, age 65 and older. To take advantage of the TRICARE for Life program, military retirees must be enrolled in Medicare Part B. There is a late enrollment penalty for military retirees who do not enroll in Medicare Part B upon becoming eligible for Medicare. This provision would waive the late enrollment penalty for military retirees, 65 and older, who enroll(ed) in the TRICARE for Life program from 2001–2004.

The Secretary would also be required to provide a special enrollment period for these military retirees beginning as soon as possible after enactment and ending December 31, 2004. For the individual who enrolls during the special enrollment period, coverage would begin on the first day of the month, following the month in which the individual enrolled.

EFFECTIVE DATE

The provision would apply to premiums for months beginning with January 2004. A method would be established to provide rebates of premium penalties paid for by military retirees for months on or after January 2004.

REASON FOR CHANGE

The Floyd A. Spence National Defense Authorization Act for FY 2001 opened TRICARE to Medicare-eligible military retirees for the first time, allowing them to keep their military health benefits past the age of 65. This benefit became available for the first time on January 1, 2001.

This provision would eliminate two barriers prevent many retirees from accessing these benefits. First, many retirees who received military care in military health facilities on a space-available basis did not purchase Part B coverage when initially eligible. Upon late enrollment, they must pay a 10 percent penalty for each year that enrollment was delayed. Second, because Medicare enrollment is only available during an annual open enrollment season, from January 1 to March 31 each year, many retirees would have to wait until 2004 to secure coverage.

The waiver of the late-enrollment penalty and provision for a special enrollment period would remove these barriers.

Section 628. Part B Deductible

CURRENT LAW

Under Part B, Medicare generally pays 80 percent of the approved amount for covered services after the beneficiary pays an annual deductible of $100. The Part B deductible has set at $100 since 1991.

EXPLANATION OF PROVISION

The Medicare Part B deductible would rise from $100 in 2003 to $104 in 2004, and grow with Medicare inflation thereafter. As a result, the Part B deductible would grow at the same rate as expenditures per capita for Part B services. The amount would be rounded to the nearest dollar.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

In 1966, Medicare's $50 Part B deductible equaled about 45 percent of Part B charges. Today's $100 deductible equals about three percent of such charges. Indexing the Part B deductible to grow at the same rate as total Part B spending per beneficiary would maintain the deductible at 3 percent of such charges over time.

An unchanged Part B deductible is a benefit increase over time, as costs of medical care rise. Beneficiaries pay about 25 percent of this benefit increase, through increased Part B premiums; taxpayers finance the remaining 75 percent. The Part B deductible has increased only three times since the beginning of Medicare, when it was $50. The deductible has since been increased to $60 in 1973, $75 in 1982, and $100 in 1991. About one-half of beneficiaries are insulated from Part B deductibles through Medigap, Medicaid, or employer-sponsored supplemental insurance that covers the Part B deductible.

Section 629. Extension of Coverage of Intravenous Immune Globulin (IVIG) for the Treatment of Primary Immune Deficiency Diseases in the Home

CURRENT LAW

Currently, Medicare provides reimbursement under Part B for the infusion of IVIG in a hospital outpatient or physician office setting.

EXPLANATION OF CHANGE

The proposal would permit patients with primary immune deficiency to receive IVIG at home instead of in the currently covered settings. Unlike the other settings, however, home coverage would include only the cost of the drug; patients would be responsible for the cost of a nurse or other health care professional to administer the infusion.

EFFECTIVE DATE

Applies to items furnished on or after January 1, 2004.

REASON FOR CHANGE

Primary immune deficiency diseases are inherited disorders in which parts of the body's immune system are missing or do not function properly. These disorders affect more than 50,000 Americans. In order to maintain their health, most primary immune deficiency patients require monthly infusions of a plasma derivative known as intravenous immune globulin (IVIG). Without this life saving therapy, primary immune deficient patients would be subject to serious infection, illness and premature death.

Given their compromised immune systems, these patients are particularly vulnerable to the many infections to which individuals in a hospital or other health care facility are exposed. Home coverage of these infusions for appropriate patients would reduce this health risk and be significantly more convenient.

The Balanced Budget Refinement Act directed the Department of Health and Human Services to study the feasibility of allowing the existing covered drug to be reimbursed when delivered in the home. The study, conducted by the Lewin Group, examined issues such as cost, safety, access to care, and the practices of private insurers. The study concluded home coverage of IVIG is appropriate.

G. Title VII—Provisions Relating to Parts A and B

Subtitle A—Home Health Services

Section 701. Update in Home Health Services

CURRENT LAW

Home health service payments are increased on a federal fiscal year basis that begins in October. The FY 2004 statutory update would be the full increase in the market basket index.

EXPLANATION OF PROVISION

This provision would increase home health agency payments by the home health market basket percentage increase minus 0.4 per-

centage points for 2004 through 2006. The update for subsequent years would be the full market basket percentage increase. The provision would also change the time frame for the update from the federal fiscal year to a calendar year basis. The home health prospective payment rates would not increase for the October 1 through December 31, 2003, period.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The Medicare Payment Advisory Commission recommended that Congress should eliminate the update to payment rates for home health services for fiscal year 2004. The Medicare margins for all agencies are 23.3 percent, even given the October 1, 2003 reduction. The mb-0.4 provides substantial payment increases for home heath agencies. However, they would be lower than current law and would provide stability.

Section 702. Establishment of Reduced Copayment for a Home Health Service Episode of Care for Certain Beneficiaries

CURRENT LAW

The home health benefit does not have any cost sharing requirement.

EXPLANATION OF PROVISION

This provision would establish a beneficiary copayment for each 60–day episode of care beginning January 1, 2004. The amount of the copayment would be 1.5 percent of the national average payment per episode in a calendar year, as projected by the Secretary before the beginning of the year. The copayment amount would be rounded to the nearest multiple of five dollars. For 2004, the copayment would be $40 unless the Secretary provides the results of the statutory formula in a timely manner. Medicare payment for each episode would be reduced to reflect the copayment amount. Qualified Medicare beneficiaries (low-income beneficiaries for whom Medicaid pays Medicare premiums, deductibles, and coinsurance), beneficiaries dually eligible for Medicare and Medicaid, and beneficiaries receiving five or fewer home health visits per episode of care would not face any cost-sharing requirements. Administrative and judicial review of the calculated copayment amounts would be prohibited.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Unlike almost all Part B services, the Medicare home health benefit does not have a copayment. The typical beneficiary receives about $3,000 worth of free home health care (CBO estimate). At the same time, home health spending is increasing rapidly rising almost 13 percent a year between 2004 and 2012 (CBO). In fact, the Congressional Budget Office estimates home health spending

will have almost tripled in size in that same period. When spending increases, so do beneficiary premiums because they are tied to program's costs.

Part of the reason for the spending increases it because it is difficult to determine if the beneficiary really needs home health (GAO and CMS). Requiring even nominal copays encourages beneficiaries to use care more prudently.

For the 90 percent of beneficiaries that have supplemental policies or other coverage, the Medicare program collects the copayments by automatically crossing over the claim to their insurance companies. Thus, the copayments generate little administrative cost for an agency.

Section 703. MedPAC Study of Medicare Margins of Home Health Agencies

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The provision would require MedPAC to study payment margins of home health agencies paid under the Medicare prospective payment system. The study would examine whether systematic differences in payment margins were related to differences in case mix, as measured by home health resource groups (HHRGs). MedPAC would be required to submit a report to Congress on the study within two years of enactment.

EFFECTIVE DATE

Upon enactment.

Subtitle B—Direct Graduate Medical Education

Section 711. Extension of Update Limitation on High Cost Programs

CURRENT LAW

Medicare pays hospitals for its share of direct graduate medical education (DGME) costs in approved programs using a count of the hospitals number of full-time equivalent residents and a hospital-specific historic cost per resident, updated for inflation. BBRA changed Medicare's methodology for calculating DGME payments to teaching hospitals to incorporate a new benchmark set at the national average amount based on FY1997 hospital specific per resident amounts. Starting in FY2001, hospitals received no less than 70 percent of a geographically adjusted national average amount. BIPA increased this floor to 85 percent of the locality adjusted, updated, and weighted national per resident amounts starting for cost report periods beginning during FY2002. Hospitals with per resident amounts above 140 percent of the geographically adjusted national average amount had payments frozen at current levels for FY2001 and FY2002, and in FY2003–FY2005 would receive an update equal to the Consumer Price Index (CPI) increase minus two percentage points. Currently, hospitals with per resident amounts between 85 percent and 140 percent of the geographically adjusted

national average would continue to receive payments based on their hospital-specific per resident amounts updated for inflation.

EXPLANATION OF PROVISION

The hospitals with per resident amounts above 140 percent of the geographically adjusted national average amount would not get an update from FY2004 through FY2013.

EFFECTIVE DATE

Upon enactment

REASON FOR CHANGE

The DGME amounts in these high cost hospitals are far higher that can be explained by the cost of living and legitimate difference in overhead. High quality medical training is delivered in most facilities for a fraction of the cost of high-cost institutions. The Medicare payments to these institutions have nothing to do with actual costs of training these physicians.

Subtitle C—Chronic Care Improvement

Section 721. Voluntary Chronic Care Improvement Under Traditional Fee-for-Service

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The Secretary would be required to establish a process for providing chronic care improvement programs for Medicare beneficiaries in FFS Medicare (Parts A and B) who have certain chronic conditions such as congestive heart failure, diabetes, chronic obstructive pulmonary disease, stroke or other diseases as identified by the Secretary. The Secretary would establish administrative regions, Chronic Care Improvement Administrative regions (CCIAs) within the United States for chronic care improvement programs. Within each CCIA, the Secretary would select at least two contractors under a competitive bidding process on the basis of the ability of each bidder to achieve improved health outcomes of the participating beneficiaries and improved financial outcomes of the Medicare program. A contractor would be a disease improvement organization, health insurer, provider organization, group of physicians, or any other legal entity that the Secretary determines appropriate. Contractors would be required to meet certain clinical, quality improvement, financial, and other requirements specified by the Secretary either directly or indirectly through the use of subcontractors. The Secretary would be able to phase-in implementation of the program beginning one-year after enactment.

Each program would be required to have a method for identifying targeted Medicare beneficiaries who would be offered participation in the program. The Secretary would be required to assist the program in identifying beneficiaries. Each beneficiary would be assigned to only one contractor that would be responsible for guiding beneficiaries in managing their health including all co-morbidities. Initial contact with a Medicare beneficiary would be from the Sec-

retary who would provide information about the program, including a description of advantages in participating. The Secretary would inform the beneficiary that the contractor would contact the beneficiary directly concerning participation, the voluntary nature of program participation, and a means of declining to participate or decline being contacted by the program. Each program would be required to develop an individualized, goal-oriented chronic care improvement plan with the beneficiary. The chronic care improvement plan would be required to contain: a single point of contact to coordinate care; self-improvement education for the individual and support education for health care providers, primary caregivers, and family members; coordination between prescription drug benefits, home health, and other health care services; collaboration with physicians and other providers to enhance communication of relevant clinical information; the use of monitoring technologies, where appropriate; and information about hospice care, pain and palliative care, and end-of-life care, as appropriate. In developing the chronic care improvement plan, programs would be required to use decision support tools such as evidence-based practice guidelines and a clinical information database to track and monitor each beneficiary across care settings and evaluate outcomes. The program would be required to meet any additional requirements that the Secretary finds appropriate. Programs would be accredited by qualified organizations to be deemed to have met such requirements as specified by the Secretary.

Contractor payments for each chronic care improvement program would be required to result in Medicare program outlays that would otherwise have been incurred in the absence of the program for the three-year contract period. The Secretary would be required to assure that there would be no net aggregate increase in Medicare payments, in entering into a contract for the program over the three-year period. Contracts for chronic care improvement programs would be treated as a risk-sharing arrangement. In addition, payment to contractors would be subject to the contractor meeting clinical and financial performance standards established by the Secretary.

Program contractors would be required to report to the Secretary on the quality of care and efficacy of the program in terms of process measures (such as reductions in errors and re-hospitalization rates), beneficiary and provider satisfaction, health outcomes, and financial outcomes. The Secretary would be required to submit to Congress annual reports on the program including information on progress made toward national coverage, common delivery models, and information on improvements in health outcomes, as well as financial efficiencies resulting from the program. The Secretary would also be required to conduct a randomized clinical trial to assess the potential for cost reductions under Medicare by comparing costs of beneficiaries enrolled in chronic care improvement programs and beneficiaries who are eligible to participate but are not enrolled.

Appropriations of such sums as necessary to provide for contracts with chronic care improvement programs would be authorized from the Medicare Trust Funds.

EFFECTIVE DATE

The provision would be effective upon enactment and the Secretary would be required to begin implementing the chronic care improvement programs no later than one-year after enactment.

REASON FOR CHANGE

Under current law, FFS Medicare does not offer coordinated care programs for the chronically ill. Chronic care management is an important issue, because 84 percent of seniors have one or more chronic conditions. In addition, individuals with chronic conditions account for 80 percent of all health care spending, with two-thirds of Medicare spending being spent on seniors with five or more chronic conditions. CMS has run demonstration programs in the Medicare program, particularly for high cost or especially frail adults. CMS is currently managing more than a dozen demonstration programs on disease and case management. A permanent program should be established within FFS Medicare that offers chronic care management to high-cost chronically ill seniors.

Section 722. Chronic Care Improvement Under Medicare Advantage and Enhanced Fee-for-Service Programs

CURRENT LAW

Under the Medicare+Choice program, organizations are required to have quality assurance programs that include measuring outcomes, monitoring and evaluating high volume and high risk services and the care of acute and chronic conditions, and evaluating the effectiveness of the efforts.

EXPLANATION OF PROVISION

Each Medicare Advantage plan offered would be required to have a chronic care improvement program for enrollees with multiple or sufficiently severe chronic conditions such as congestive heart failure, diabetes, chronic obstructive pulmonary disease, stroke or other disease as identified by the Secretary. The program would be required to have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions and to develop with an enrollee's consent an individualized, goal-oriented chronic care improvement plan.

The chronic care improvement plan would be required to include: a single point of contact to coordinate care; self-improvement education for the individual and support education for health care providers, primary caregivers, and family members; coordination between prescription drug benefits, home health, and other health care services; collaboration with physicians and other providers to enhance communication of relevant clinical information; the use of monitoring technologies, where appropriate; and information about hospice care, pain and palliative care, and end-of-life care, as appropriate. In developing the chronic care improvement plan, programs would be required to use decision support tools such as evidence-based practice guidelines and a clinical information database to track and monitor each beneficiary across care settings and evaluate health outcomes. The program would be required to meet any additional requirements that the Secretary finds appropriate.

Programs that have been accredited by qualified organizations would be deemed to have met such requirements as specified by the Secretary.

Each Medicare Advantage organization would be required to report to the Secretary on the quality of care and efficacy of the chronic care improvement program.

EFFECTIVE DATE

The provision would apply for contract years beginning on or after one year after enactment.

REASON FOR CHANGE

Many Medicare Health Maintenance Organizations (HMOs) already provide chronic care management programs. These programs target high-cost beneficiaries suffering from one or more chronic conditions and coordinate their care within plan. This requirement for private plans would continue the chronic care/disease management programs most Medicare HMOs already have in place.

Section 723. Institute of Medicine Report

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The Secretary would be required to contract with the Institute of Medicine of the National Academy of Sciences to study the barriers to effective integrated chronic care improvement for Medicare beneficiaries with multiple or severe chronic conditions across settings and over time. The study would examine the statutory and regulatory barriers to coordinating care across settings for Medicare beneficiaries in transition from one setting to another. The Institute of Medicine would be required to submit the report of the study to the Secretary and Congress no later than 18 months after enactment.

EFFECTIVE DATE

Upon enactment.

Section 724. MedPAC Report

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

MedPAC would be required to evaluate the chronic care improvement program. The evaluation would include a description of the status concerning implementation of the program, the quality of health care services provided to individuals participating in the program, and the cost savings attributed to implementation. The report of the evaluation would be submitted to Congress not later than two years after implementation of the program.

EFFECTIVE DATE

Upon enactment.

Subtitle D—Other Provisions

Section 731. Modifications to MedPAC

CURRENT LAW

The Medicare Payment Advisory Commission is a 17-member body that reports and makes recommendations to Congress regarding Medicare payment policies. The Comptroller General is required to establish a public disclosure system for Commissioners to disclose financial and other potential conflicts of interest.

EXPLANATION OF PROVISION

MedPAC would be required to examine the budgetary consequences of a recommendation before making the recommendation and to review the factors affecting the efficient provision of expenditures for services in different health care sectors under FFS Medicare. MedPAC would be required to submit two additional reports no later than June 1, 2003. The first report would study the need for current data, and the sources of current data available, to determine the solvency and financial circumstances of hospitals and other Medicare providers. MedPAC would be required to examine data on uncompensated care, as well as the share of uncompensated care accounted for by the expenses for treating illegal aliens. The second report would address investments and capital financing of hospitals participating under Medicare and access to capital financing for private and not-for-profit hospitals. The provision would also require that members of the Commission be treated as employees of Congress for purposes of financial disclosure requirements.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Congress needs to ensure that the Commission remains the objective impartial agency that it is today. Moreover, the Commission cannot be removed from the same constraints that Congress itself must face through considerations of the budget.

Section 732. Demonstration Project for Medical Adult Day Care Services

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

Subject to earlier provisions, the Secretary would be required to establish a demonstration project under which a home health agency, directly or under arrangement with a medical adult day care facility, provide medical adult day care services as a substitute for a portion of home health services otherwise provided in a bene-

ficiary's home. Such services would have to be provided as part of a plan for an episode of care for home health services established for a beneficiary. Payment for the episode would equal 95 percent of the amount that would otherwise apply. In no case would the agency or facility be able to charge the beneficiary separately for the medical adult day care services. The Secretary would reduce payments made under the home health prospective payment system to offset any amounts spent on the demonstration project. The three-year demonstration project would be conducted at not more than five sites, selected by the Secretary, in states that license or certify providers of medical adult day care services. Participation of up to 15,000 Medicare beneficiaries would be on a voluntary basis.

When selecting participants, the Secretary would give preference to home health agencies that are currently licensed to furnish medical adult day care services and have furnished such services to Medicare beneficiaries on a continuous basis for a prior two-year period. A medical adult day care facility would: (1) have been licensed or certified by a State to furnish medical adult day care services for a continuous two-year period, (2) have been engaged in providing skilled nursing services or other therapeutic services directly or under arrangement with a home health agency, and (3) would meet quality standards and other requirements as established by the Secretary. The Secretary would be able to waive necessary Medicare requirements except that beneficiaries must be homebound in order to be eligible for home health services.

The Secretary would be required to evaluate the project's clinical and cost effectiveness and submit a report to Congress no later than 30 months after its commencement. The report would include: (1) an analysis of patient outcomes and comparative costs relative to beneficiaries who receive only home health services for the same health conditions, and (2) recommendations concerning the extension, expansion, or termination of the project.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This demonstration would test the delivery of home health services in a group setting. While many of these patients are very frail, social interaction may prove to have a clinical benefit. At the same time, the current quality standards remain for delivering home health care.

Section 733. Improvements in National and Local Coverage Determination Process To Respond to Changes in Technology

(a) National and Local Coverage Determination Process

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

Subsection (a) would require the Secretary to make available to the public the general guidelines used in making national coverage determinations under Medicare. These determinations would be re-

quired to include the way in which the Secretary considers evidence to assess whether a procedure or device is reasonable or necessary. The provision would establish a time frame for decisions regarding national coverage determinations of six months after a request when a technology assessment is not required and 12 months when a technology assessment is required and in which a clinical trial is not requested. Following the six- or 12-month period, the Secretary would be required to make a draft of the proposed decision available in the HHS website or by other means; to provide a 30-day public comment period; to make a final decision on the request with 60 days following the conclusion of the public comment period; and make the clinical evidence and data used in making the decision available to the public. In instances where the Medicare Coverage Advisory Committee does not review a request for a national coverage determination, the Secretary would be required to consult with appropriate outside clinical experts.

The Secretary would also be required to develop a plan to evaluate new local coverage determinations to decide which local decisions should be adopted nationally and to decide to what extent greater consistency can be achieved among local coverage decisions, to require the Medicare contractors within an area to consult on new local coverage policies, and to disseminate information on local coverage determination among Medicare contractors to reduce duplication of effort.

EFFECTIVE DATE

The provision would be effective for determinations as of January 1, 2004.

REASON FOR CHANGE

The General Accounting Office reported in April 2003 problems with both the national coverage and local coverage process. Even though CMS assigned a 90-day process for coverage decisions, the average time was seven months with several taking over a year. GAO recommended establishing new time frames and a public process. GAO also found the local coverage process resulted in inequities for beneficiaries and wasteful duplication of administrative costs.

(b) Medicare Coverage of Routine Costs Associated With Certain Clinical Trials

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

Subsection (b) would provide for the coverage of the routine costs of care for Medicare beneficiaries participating in clinical trials that are conducted in accordance with an investigational device exemption approved under section 530(g) of the Federal Food, Drug, and Cosmetic Act.

EFFECTIVE DATE

The provision would be effective for clinical trials begun before, on, or after the date of enactment and to items and services furnished on or after enactment.

REASON FOR CHANGE

There is a discontinuity between the coverage of clinical trials using breakthrough devices and the coverage afforded other routine clinical trials. This provision would resolve this problem.

(c) Issuance of Temporary National Codes

CURRENT LAW

The Secretary issues temporary national Health Care Common Procedure Coding System (HCPCS) codes under Medicare Part B that are used until permanent codes are established.

EXPLANATION OF PROVISION

Subsection (c) would require that the Secretary implement revised procedures for the issuance of temporary national HCPCS codes.

EFFECTIVE DATE

The provision would be effective not later than one year after enactment.

REASON FOR CHANGE

Coding for HCPCs under Part B is a patchwork with temporary codes allowed for some services and not for others. This would create national uniformity.

Section 734. Extension of Treatment for Certain Physician Pathology Services Under Medicare

CURRENT LAW

In general, independent laboratories cannot directly bill for the technical component of pathology services provided to Medicare beneficiaries who are inpatients or outpatients of acute care hospitals. BIPA permitted independent laboratories with existing arrangements with acute hospitals to bill Medicare separately for the technical component of pathology services provided to the hospitals' inpatients and outpatients. The arrangement between the hospital and the independent laboratory had to be in effect as of July 22, 1999. The direct payments for these services apply to services furnished during a two-year period starting on January 1, 2001 and ending December 31, 2002.

EXPLANATION OF PROVISION

Medicare would make direct payments for the technical component for these pathology services. A change in hospital ownership would not affect these direct billing arrangements.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Many hospitals do not have on-site pathology services and this provision would continue the prior arrangements.

H. TITLE VIII—MEDICARE BENEFITS ADMINISTRATION

Section 801. Establishment of Medicare Benefits Administration

CURRENT LAW

The authority for administering the Medicare program resides with the Secretary of Health and Human Services. The Secretary originally created the agency that administers the Medicare and Medicaid programs in 1977 under his administrative authority. Regulations regarding Medicare are required to be promulgated by the Secretary. The Medicare statute requires the President to appoint the Administrator of CMS (formerly known as the Health Care Financing Administration) with the advice and consent of the Senate. Title V of the U.S. Codes sets the MBA Administrator's salary at level IV of the Executive Schedule. The Medicare statute requires the CMS Administrator to appoint a Chief Actuary who reports directly to such Administrator and receives pay at the highest rate of basic pay for the Senior Executive Service.

EXPLANATION OF PROVISION

The section would amend Title XVIII to add a new Section 1809 that, under subsection (a), would establish a new Medicare Benefits Administration (MBA) within the Department of Health and Human Services.

Subsection (b) would provide for an Administrator and Deputy Administrator of the MBA. The President with the advice and consent of the Senate would appoint both for 4-year terms. If a successor did not take office at the end of the term, the Administrator would continue in office until the successor enters the office. In that event, the confirmed successor's term would be the balance of the 4-year period. The Administrator would be paid at level III of the Executive Schedule and the Deputy Administrator at level IV of the Executive Schedule. The Administrator would be responsible for the exercise of all powers and the discharge of duties of the MBA and has authority and control over all personnel. The provision would permit the Administrator to prescribe such rules and regulations as the Administrator determined necessary or appropriate to carry out the functions of MBA, subject to the Administrative Procedure Act. The Administrator would be able to establish different organizational units within the MBA except for any unit, component, or provision specifically provided for by section 1809. The Administrator may assign duties, delegate, or authorize re-delegations of authority to MBA officers and employees as needed. The Secretary shall ensure appropriate coordination between the Administrators of MBA and CMS to administer the Medicare program. The provision also would establish a position of Chief Actuary within the MBA who would be appointed by the Administrator and paid at the highest rate of basic pay for the Senior Executive Service. The Chief Actuary would exercise such duties as are appropriate for the office of Chief Actuary and in accordance with professional standards of actuarial independence.

Subsection (c) would prescribe the duties of the Administrator and administrative provisions relating to the MBA. In administering parts C, D, and E of Medicare, the Administrator would be required to negotiate, enter into, and enforce contracts with PDP and MA–EFFS sponsors. The Administrator would be required to carry out any duty provided for under Part C, D, or E, including implementation of the prescription drug discount card program and demonstration programs (carried out in whole or in part under Part C, D, or E). The provision specifically prohibits the Administrator from requiring a particular formulary or instituting a price structure for the reimbursement of covered drugs; from interfering in any way with negotiations between PDP and MA–EFFS sponsors, drug manufacturers, wholesalers, or other suppliers of covered drugs; and from otherwise interfering with the competitive nature of providing prescription drug coverage. The Administrator would be required to submit a report to Congress and the President on the administration of parts C, D, and E during the previous year by not later than March 31 of each year.

The Administrator, with the approval of the Secretary, would be permitted to hire staff to administer the activities of MBA without regard to chapter 31 of title 5 of the U.S. Code B other than sections 3110, the prohibition against officials hiring relatives, and 3112, the hiring preferences given to veterans. The Administrator would be required to employ staff with appropriate and necessary experience in negotiating contracts in the private sector. The staff of MBA would be paid without regard to chapter 51 (other than section 5101 requiring classification of positions according to certain principles) and chapter 53 (other than section 5301 relating to the principles of pay systems) of title 5 of the U.S. Code. The rate of compensation for staff of MBA would not be able to exceed level IV of the Executive Schedule. The Administrator would be limited in the number of full-time-equivalent (FTEs) employees for the MBA to the number of FTEs within CMS performing the functions being transferred at the time of enactment. The Secretary, the Administrator of MBA, and the Administrator of CMS would be required to establish an appropriate transition of responsibility to redelegate the administration of Medicare part C from CMS to MBA. The provision requires the Secretary to ensure that the Administrator of CMS transfers such information and data as the Administrator of MBA requires to carry out the duties of MBA.

Subsection (d) would require the Secretary to establish an Office of Beneficiary Assistance within MBA to coordinate Medicare beneficiary outreach and education activities, and provide Medicare benefit and appeals information to Medicare beneficiaries under parts C, D, and E.

Subsection (e) would establish the Medicare Policy Advisory Board (the Board) within the MBA to advise, consult with, and make recommendations to the Administrator regarding the administration and payment policies of parts C, D, and E. The Board would be required to report to Congress and to the Administrator of MBA such reports as the Board determines appropriate and may contain recommendations that the Board considers appropriate regarding legislative or administrative changes to improve the administration of parts C, D, and E including: increasing competition under part C, D, or E for services furnished to beneficiaries; im-

proving efforts to provide beneficiaries information and education about Medicare, parts C, D, and E, and Medicare enrollment; evaluating implementation of risk adjustment under parts C and E; and improving competition and access to plans under parts C, D, and E. The reports would be required to be published in the Federal Register. The reports would be submitted directly to Congress and no officer or agency of the government would be allowed to require the Board to submit a report for approval, comments, or review prior to submission to Congress. Not later than 90 days after a report is submitted to the Administrator, the Administrator would be required to submit to Congress and the President an analysis of the recommendations made by the Board. The analysis would be required to be published in the Federal Register.

The Board would be made up of 7 members serving three-year terms, with three members appointed by the President, two appointed by the Speaker of the House of Representatives, and two appointed by the President pro tempore of the Senate. Board members may be reappointed but may not serve for more than 8 years. The Board shall elect the Chair to serve for three years. The Board is required to meet at least three times a year and at the call of the Chair.

The Board is required to have a director who, with the approval of the Board, may appoint staff without regard to certain sections of chapter 31 of title 5 of the United States Code (which addresses authority for employment). In addition, the director and staff may be paid without regard to certain provisions of chapter 51 and 53 of title 5 which are related to classification and pay rates and pay systems B although the rate of compensation is capped at level IV of the Executive Schedule. The Board may contract with and compensate government and private agencies or persons to carry out its duties without regard to section 3709 of the Revised Statutes (41 U.S.C. (5).

Subsection (f) authorizes an appropriation of such sums as are necessary from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund (including the Prescription Drug Account) to carry out section 1808.

EFFECTIVE DATE

The provision would be effective upon enactment; however, the enrollment and eligibility functions and implementation of parts C and E would be effective January 1, 2006.

REASON FOR CHANGE

A new agency, the Medicare Benefits Administration, would provide a more flexible and contemporary structure that is citizen-centered, results-oriented, and market-based. The administration of Parts C, D, and E would be separated from the administration of other parts of Medicare to ensure appropriate conduct of those parts of Medicare involving contracts with private organizations.

Implementing the M+C program in the past, CMS's decisions have made it difficult for private plans to participate in the program. Indeed, CMS has an inherent conflict of interest in administering traditional FFS while regulating the private plans. Placing the administration of Parts C, D, and E under a new MBA would create an agency whose main responsibility is the implementation

and operation of successful private plan programs that enhance beneficiary choice.

The MBA would reshape the federal bureaucracy to better coordinate health plans and the prescription drug benefit, and replace a current system that is inefficient and outdated.

Civil service law reforms would permit the MBA to hire the best possible staff, with private sector experience in negotiating with plans. The MBA would have the ability to create a modern workforce by paying for performance, disciplining bad workers without lengthy appeals, and hiring employees more quickly. These changes would promote general government efficiency.

(c) Miscellaneous Administrative Provisions

CURRENT LAW

The Board of Trustees of the Medicare Trust Funds is composed of the Commissioner of Social Security, the Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services and two members of the public. The Administrator of the Centers for Medicare & Medicaid Services serves as the Secretary of the Board of Trustees.

Title 5 of the U.S. Code sets the Administrator's salary at level IV of the Executive Schedule.

EXPLANATION OF PROVISION

Paragraph (1) would add the Administrator of MBA as an ex officio member of the Board of Trustees of the Medicare Trust Funds.

Paragraph (2) would increase the pay level for the Administrator of CMS from level IV of the Executive Schedule to level III.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The Administrator of the MBA should be a member of the Board of Trustees to represent that part of Medicare involving contracts with private entities. The Administrator of CMS should be paid at the same level as the Administrator of the MBA.

I. TITLE IX—REGULATORY RELIEF

Subtitle A—Regulatory Reform

Section 901. Construction; Definition of Supplier

CURRENT LAW

Section 1861 of the Social Security Act contains definitions of services, institutions, and so forth under Medicare. Supplier is not explicitly defined.

EXPLANATION OF PROVISION

Nothing in this title would be construed as compromising or affecting existing legal remedies for addressing fraud or abuse, whether it be criminal prosecution, civil enforcement or administrative remedies (including the False Claims Act) or to prevent or im-

pede HHS from its efforts to eliminate waste, fraud, or abuse in Medicare. The provision also would clarify that consolidation of the Medicare administrative contractors does not consolidate the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund. The provision would also clarify that term. A supplier means a physician or other practitioner, a facility or other entity (other than a provider of services) furnishing items or services under Medicare.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The Committees are committed to extending needed regulatory relief to providers and suppliers while at the same time protecting taxpayers from waste, fraud and abuse.

Section 902. Issuance of Regulations

CURRENT LAW

The Secretary must publish a list of all manual instructions, interpretative rules, statements of policy, and guidelines that are promulgated to carry out Medicare law in the Federal Register no less frequently than every three months.

There is no explicit statutory instruction on logical outgrowth. The courts have repeatedly held that new matter in final regulations must be a logical outgrowth of the proposed rule and is an inherent aspect of notice and comment rulemaking.

EXPLANATION OF PROVISION

The provision would require the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed rule or an interim final regulation. The timeframe established would not be permitted to be longer than three years, except under extraordinary circumstances. If the Secretary were to vary the timeline he established, the provision would require him to publish a notice in the Federal Register the new timeline and an explanation of the variation. In the case of interim final regulations, the provision would require that if the Secretary did not meet his established timeframe, then the interim final regulation would not be able to continue in effect unless the Secretary published a notice of continuation of the regulation that included an explanation of why the regular timeline had not been complied with.

The provision also would require that a provision of a final regulation that is not a logical outgrowth of the proposed regulation or interim final regulation would be treated as a proposed regulation. The provision would not be able to take effect until public comment occurred and the provision published as a final regulation.

EFFECTIVE DATE

The provision regarding the establishment of regulatory timeframes would be effective upon enactment and would require the

Secretary to provide for an appropriate transition to take into account the backlog of previously published interim final regulation. The provision regarding logical outgrowth would be effective for final regulations published on or after enactment.

REASON FOR CHANGE

The volume of Medicare regulations issued by CMS can be difficult for health care providers and suppliers, particularly small providers and suppliers, to monitor. By requiring regulations to be released on a certain date, providers and suppliers would be better able to keep informed of program changes. The Secretary may stagger the notice and comment periods of regulations issued on the same day, so that the comment deadlines for these regulations do not occur simultaneously, in order to ensure that interested parties have the opportunity to comment on multiple regulations.

The collective impact provision ensures that the Department would consider the overall impact of any changes it is making on categories of providers and suppliers. If the Department determines that many changes affecting a particular category of providers or suppliers are underway, the Department should consult with representatives of that category to determine whether providers and suppliers would be better able to make the systems changes needed to accommodate those changes if all the new regulations were released simultaneously or staggered. Because of the burden implementing multiple regulations simultaneously can cause, the Secretary needs to coordinate new regulations based on an analysis of the collective impact the regulatory changes will have on any given category of provider or supplier.

Section 903. Compliance With Changes in Regulations and Policies

CURRENT LAW

No explicit statutory instruction. As a result of case law, there is a strong presumption against retroactive rulemaking. In *Bowen* v. *Georgetown University Hospital,* the Supreme Court ruled that there must be explicit statutory authority to engage in retroactive rulemaking.

EXPLANATION OF PROVISION

The provision would bar retroactive application of any substantive changes in regulation, manual instructions, interpretative rules, statements of policy, or guidelines unless the Secretary determines retroactive application is needed to comply with the statute or is in the public interest. No substantive change would go into effect until 30 days after the change is issued or published unless it would be needed to comply with statutory changes or was in the public interest. Compliance actions would be able to be taken for items and services furnished only on or after the effective date of the change. If a provider or supplier follows written guidance provided by the Secretary or a Medicare contractor when furnishing items or services or submitting a claim and the guidance is inaccurate, the provider or supplier would not be subject to sanction or repayment of overpayment (unless the inaccurate information was due to a clerical or technical operational error).

EFFECTIVE DATE

The prohibition of retroactive application of substantive changes would apply to changes issued on or after the date of enactment. The provisions affecting compliance with substantive changes would apply to compliance actions undertaken on or after the date of enactment. The reliance on guidance would take effect upon enactment but would not apply to any sanction for which notice was provided on or before the date of enactment.

REASON FOR CHANGE

This provision would ensure that Medicare's rules are not generally applied retroactively. It would also ensure providers and suppliers have sufficient time to make any changes to systems needed to comply with changes in regulations. This provision would ensure that providers and suppliers, who, in good faith, based on the information received from contractors, would not be vulnerable to recovery if it turns out that the contractor was in error. Providers should be able to rely on the directions or guidance provided by their Medicare contractors.

Section 904. Reports and Studies Relating to Regulatory Reform

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The GAO would be required to study the feasibility and appropriateness of the Secretary providing legally binding advisory opinions on appropriate interpretation and application of Medicare regulations. The report would be due to Congress one year after enactment.

The Secretary would be required to report to Congress every two years on the administration of Medicare and areas of inconsistency or conflict among various provisions under law and regulation. The report would include recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts. The first report would be due to Congress two years after enactment.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The Committees are interested in receiving additional information regarding both advisory opinions and inconsistencies in Medicare regulations.

Subtitle B—Contracting Reform

Section 911. Increased Flexibility in Medicare Administration

CURRENT LAW

The Secretary is authorized to enter into agreements with fiscal intermediaries nominated by different provider associations to

make Medicare payments for health care services furnished by institutional providers. For Medicare part B claims, the Secretary is authorized to enter into contracts only with health insurers (or carriers) to make Medicare payments to physicians, practitioners and other health care suppliers. Section 1834(a)(12) of the Act authorizes separate regional carriers for the payment of durable medical equipment (DME) claims. The Secretary is also authorized to contract for certain program safeguard activities under the Medicare Integrity Program (MIP).

Certain terms and conditions of the contracting agreements for fiscal intermediaries (FIs) and carriers are specified in the Medicare statute. Medicare regulations coupled with long-standing agency practices have further limited the way that contracts for claims administration services can be established.

Certain functions and responsibilities of the fiscal intermediaries and carriers are specified in the statute as well. The Secretary may not require that carriers or intermediaries match data obtained in its other activities with Medicare data in order to identify beneficiaries who have other insurance coverage as part of the Medicare Secondary Payer (MSP) program. With the exception of prior authorization of DME claims, an entity may not perform activities (or receive related payments) under a claims processing contract to the extent that the activities are carried out pursuant to a MIP contract. Performance standards with respect to the timeliness of reviews, fair hearings, reconsiderations and exemption decisions are established as well.

A Medicare contract with an intermediary or carrier may require any of its employees certifying or making payments provide a surety bond to the United States in an amount established by the Secretary. Neither the contractor nor the contractor's employee who certifies the amount of Medicare payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States. Neither the contractor nor the contractor's employee who disburses payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States, if such payments are based upon a voucher signed by the certifying employee.

EXPLANATION OF PROVISION

This provision would add Section 1874A to the Social Security Act and would permit the Secretary to competitively contract with any eligible entity to serve as a Medicare contractor. The provision would eliminate the distinction between Part A contractors (fiscal intermediaries) and Part B contractors (carriers) and take the separate authorities for fiscal intermediaries and carriers and merge them into a single authority for the new contractor. These new contractors would be called Medicare Administrative Contractors (MACs) and would assume all the functions of the current fiscal intermediaries and carriers: determining the amount of Medicare payments required to be made to providers and suppliers, making the payments, providing education and outreach to beneficiaries, providers and suppliers, communicating with providers and suppliers, and additional functions as are necessary.

The Secretary would be permitted to renew the MAC contracts annually for up to 5 years. All contracts would be required to be

re-competed at least every 5 years using competitive processes. Federal Acquisition Regulations (FAR) would apply to these contracts except to the extent any provisions are inconsistent with a specific Medicare requirement, including incentive contracts. The contracts would be required to contain performance requirements that would be developed by the Secretary who could consult with beneficiary, provider, and supplier organizations, would be consistent with written statements of work and would be used for evaluating contractor performance. MAC would be required to furnish the Secretary such timely information as he may require and to maintain and provide access to records the Secretary finds necessary. The Secretary could require a surety bond from the MAC or certain officers or employees as the Secretary finds appropriate. The Secretary would be prohibited from requiring that the MAC match data from other activities for Medicare secondary payer purposes.

The provision would limit liability of certifying and disbursing officers and the Medicare Administrative Contractors except in cases of reckless disregard or the intent to defraud the United States. This limitation on liability would not limit liability under the False Claims Act. The provision also establishes circumstances where contractors and their employees would be indemnified, both in the contract and as the Secretary determines appropriate.

The provision would make numerous conforming amendments as the authorities for the fiscal intermediaries and carriers are stricken.

The Secretary would be required to submit a report to Congress and the GAO by no later than October 1, 2004, that describes the plan for implementing these provisions. The GAO is required to evaluate the Secretary's plan and, within six months of receiving the plan, report on the evaluation to Congress and make any recommendations the Comptroller General believes appropriate. The Secretary is also required to report to Congress by October 1, 2008 on the status of implementing the contracting reform provisions including the number of contracts that have been competitively bid, the distribution of functions among contracts and contractors, a timeline for complete transition to full competition, and a detailed description of how the Secretary has modified oversight and management of Medicare contractors to adapt to full competition.

Competitive bidding for the MACs would be required to begin for annual contract periods that begin on or after October 1, 2011.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Medicare's current contracting represents an antiquated, inefficient, and closed system based on cozy relationships between the government, contractors and providers.

Medicare contracting is antiquated because contractors may not provide service for the entire Medicare program, or particular functions within the program; rather Fiscal Intermediaries administer claims for facilities and carriers administer claims for all other providers. It has failed to keep pace with integrated claims administration practices in the private sector.

Medicare contracting is inefficient because Medicare does not award contracts through competitive procedures, but rather on provider nomination.

Medicare contracting is closed. All but one of the contractors today have been with Medicare since the program's inception 36 years ago, and only insurers can provide contracting services.

This provision permits greater flexibility in contracting for administrative services between the Secretary and the Medicare contractors (entities that process claims under part A and part B of the Medicare program), including the flexibility to separately contract for all or parts of the contractor functions. The Secretary also may contract with a wider range of entities, so that the most efficient and effective contractor can be selected.

These amendments require the Secretary to contract competitively at least once every five years for the administration of benefits under parts A and B. In conjunction with the elimination of cost contracts, it is intended to create incentives for improved service to beneficiaries and to providers of services and suppliers.

These amendments provide a basis for a unified contracting system for the administration of parts A and B, identical to the recent Congressionally mandated structure of the Medicare Integrity Program contractors. Consolidation of contracting duties as set forth in this legislation does not constitute consolidation of the Hospital Insurance and Medical Supplementary Insurance Trust Funds, or reflect any position on that issue. In addition, the elimination of provider nomination, which hospitals have rarely been allowed to exercise in recent years, is essential for bringing full and open competition into the contracting functions of the Medicare program.

The provision establishes a basis for a unified contracting system, identical to the structure implemented for the Medicare Integrity Program contractors. It is important to note, however, that consolidation of contracting duties as set forth in this legislation does not constitute consolidation of the Hospital Insurance and Medical Supplementary Insurance Trust Funds, or reflect any position on that issue. In addition, the Secretary would have the flexibility to choose the best contractor(s) to provide telephone information on suppliers, which is intended to reduce administrative costs and improve quality. Since the carrier fair hearing requirement was eliminated in previous legislation, the requirements for the hearing are eliminated in order to conform to existing law.

Section 912. Requirements for Information Security for Medicare Administrative Contractors

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

Medicare administrative contractors (as well as fiscal intermediaries and carriers until the MACs are established) would be required to implement a contractor-wide information security program to provide information security for the operation and assets of the contractor for Medicare functions. The information security program would be required to meet certain requirements for information security programs imposed on Federal agencies under title

44 of the United States Code. Medicare administrative contractors would be required to undergo an annual independent evaluation of their information security programs. Existing contractors would be required to undergo the first independent evaluation within one year after the date the contractor begins implementing the information security program and new contractors would be required to have such a program in place before beginning the claim determination and payment activities. The results of the independent evaluations would be submitted to the Secretary and the HHS Inspector General. The Inspector General of HHS would be required to report to Congress annually on the results of the evaluations. The Secretary would be required to address the results of the evaluations in required management reports.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The increased reliance by the Federal government on the Internet and related telecommunications technologies has resulted in enhanced inter-connectivity and interdependencies associated with Federal computer systems and between federal and private computer systems. Over the past several years, this inter-connectivity or networking has resulted in increased security vulnerabilities that have put at greater risk computer systems and data that are critical to ensuring national and economic security and public health and welfare, including sensitive, non-public information that is collected and maintained by CMS and its business partners.

On May 23, 2001, the Committee on Energy and Commerce held a hearing to investigate the extent to which sensitive, non-public information related to collecting and processing Medicare claims was adequately secure on the computer networks operated by CMS and its business partners, including Medicare contractors. That investigation revealed significant weaknesses, which the agency has been working to address. Some of the computer security concerns identified include weak password management, inadequate access controls, excessive user privileges, improper network configurations, and inadequate testing of critical systems. In addition, the OIG conducted assessments of financial controls—including electronic data processing controls—at CMS and its major Medicare contractors; in every year since 1997, the OIG has identified computer security controls as a material weakness at CMS and its contractors.

Section 812 is intended to assist CMS in identifying and working with contractors to address potential security deficiencies in order to ensure that sensitive, non-public information related to the processing of Medicare claims is adequately secure from unauthorized access, misuse, or destruction.

Subtitle C—Education and Outreach

Section 921. Provider Education and Technical Assistance

(a) Coordination of Education Funding

CURRENT LAW

Medicare provider education activities are funded through the program management appropriation and through Education and Training component of the Medicare Integrity Program (MIP). Both claims processing contractors (fiscal intermediaries and carriers) and MIP contractors may undertake provider education activities.

EXPLANATION OF PROVISIONS

The provision would add Section 1889 to the Social Security Act, which would require the Secretary to coordinate the educational activities through the Medicare contractors to maximize the effectiveness of education efforts for providers and suppliers and to report to Congress with a description and evaluation of the steps taken to coordinate provider education funding.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This provision is intended to ensure that federal spending on provider education is coordinated and used as efficiently as possible to maximize the value obtained from the investment. It is not intended to change the proportion of Medicare Integrity Program funds spent on provider education.

(b) Incentives To Improve Contractor Performance

CURRENT LAW

No specific statutory provision. Since FY1996, as part of the audit required by the Chief Financial Officers Act, an annual estimate of improper payments under FFS has been established. As a recent initiative, CMS is implementing a comprehensive error rate-testing program to produce national, contractor specific, benefit category specific and provider specific paid claim error rates.

EXPLANATION OF PROVISIONS

The Secretary would be required to use specific claims payment error rates (or similar methodology) to provide incentives for contractors to implement effective education and outreach programs for providers and suppliers and would require the Comptroller General to study the adequacy of the methodology and make recommendations to the Secretary and the Secretary to report to Congress regarding how he intends to used the methodology in assessing Medicare contractor performance.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This provision would ensure that the Department monitors contractor performance for claims payment error rates, and it would identify best practices for provider education—all with the goal of reducing payment errors and helping providers and suppliers better comply with program requirements. It is the Committees' intent that, in consultation with representatives of providers and suppliers, the Secretary shall identify and encourage best practices developed by contractors for educating providers and suppliers.

(c) Provision of Access to and Prompt Responses From Medicare Administrative Contractors

CURRENT LAW

No specific statutory provision. Statutory provisions generally instruct carriers to assist providers and others who furnish services in developing procedures relating to utilization practices and to serve as a channel of communication relating information on program administration. Fiscal intermediaries are generally instructed to: (1) provide consultative services to institutions and other agencies to enable them to establish and maintain fiscal records necessary for program participation and payment, and (2) serve as a center for any information as well as a channel for communication with providers.

EXPLANATION OF PROVISIONS

The Secretary would be required to develop a strategy for communicating with beneficiaries, providers and suppliers. Medicare contractors would be required to provide responses to written inquiries that are clear, concise and accurate within 45 business days of the receipt of the inquiry. The Secretary would be required to ensure that Medicare contractors have a toll-free telephone number where beneficiaries, providers and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate Medicare information. Medicare contractors would be required to maintain a system for identifying the person supplying information to beneficiaries, providers and supplier and to monitor the accuracy, consistency, and timeliness of the information provided. The Secretary would be required to establish and make public standards to monitor the accuracy, consistency, and timeliness of written and telephone responses of Medicare contractors as well as to evaluate the contractors against these standards.

EFFECTIVE DATE

The provision would be effective October 1, 2004.

REASON FOR CHANGE

This provision is intended to improve contractor accountability to make contractors more responsive to providers and suppliers, and to increase the accuracy and reliability of the information provided in response to the questions received.

(d) Improved Provider Education and Training

CURRENT LAW

In FY2003, approximately $122 million was budget by CMS for provider education and training.

EXPLANATION OF PROVISION

The provision would authorize $25 million to be appropriated from the Medicare Trust Funds for fiscal years 2005 and 2006, and such sums as necessary for succeeding fiscal years for Medicare contractors to increase education and training activities for providers and suppliers. Medicare contractors would be required to tailor education and training activities to meet the special needs of small providers or suppliers. The provision defines a small provider as an institution with fewer than 25 full-time equivalents (FTEs) and a small supplier as one with fewer than 10 FTEs.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This provision acknowledges that contractors are being instructed to significantly improve their provider education and training efforts, and accordingly authorizes new funds to be available for those purposes.

(e) Requirement To Maintain Internet Sites

CURRENT LAW

No statutory provision. CMS and Medicare contractors currently maintain Internet sites.

EXPLANATION OF PROVISION

The provision would require that the Secretary and the Medicare contractors maintain Internet sites to answer frequently asked questions and provide published materials of the contractors beginning October 1, 2004.

EFFECTIVE DATE

The provision would be effective October 1, 2004.

REASON FOR CHANGE

This provision would facilitate greater ease of provider and supplier access to information provided by Medicare's contractors.

(f) Additional Provider Education Provisions

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The provision would bar Medicare contractors from using a record of attendance (or non-attendance) at educational activities to

select or track providers or suppliers in conducting any type of audit or prepayment review.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This provision addresses a concern raised by providers and suppliers that their participation in educational forums has been used to trigger audits. Participation in educational forums should be encouraged not discouraged.

Nothing in this section or section 1893(g) shall be construed as preventing the disclosure by a Medicare contractor of information on attendance at education activities for law enforcement purposes. Nothing in this section or section 1893(g) shall be construed as providing for the disclosure by a Medicare contractor of the claims processing screens or computer edits used for identifying claims that would be subject to review.

Section 922. Small Provider Technical Assistance Demonstration Program

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The Secretary would be required to establish a demonstration program to provide technical assistance to small providers and suppliers, when they have requested the assistance, to improve compliance with Medicare requirements. If errors are found, the Secretary would be barred from recovering any overpayments barring evidence of fraud and if the problem that is the subject of the compliance review has been satisfactorily corrected within 30 days and the problem remains corrected. A GAO study is required not later than two years after the demonstration program begins. Appropriations would be authorized for $1 million for FY 2005 and $6 million for FY 2006 to carry out the demonstration.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Many large providers and suppliers have contracts with private consulting firms to help them navigate their interactions with the Medicare program. This type of assistance can be prohibitively expensive for small providers and suppliers—but they too are required to comply with complex program rules and regulations. This provision creates a new demonstration program to facilitate small provider and supplier access to expert technical assistance. The demonstration would also test whether encouraging technical assistance on the front-end (to help providers and suppliers play by the rules) could save the program money in the long-term by promoting greater program compliance.

Section 923. Medicare Provider Ombudsman; Medicare Beneficiary Ombudsman

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

A Medicare Provider Ombudsman would be required to be appointed by the Secretary and located within the Department of Health and Human Services. The Provider Ombudsman would be required to provide confidential assistance to providers and suppliers regarding complaints, grievances, requests for information, and resolution of unclear or conflicting guidance about Medicare. The Ombudsman would submit recommendations to the Secretary regarding improving the administration of Medicare, addressing recurring patterns of confusion under Medicare, and ways to provide for an appropriate and consistent response in cases of self-identified overpayments by providers and suppliers. Such sums as necessary would be authorized to be appropriated for FY2004 and subsequent years.

A Medicare Beneficiary Ombudsman would be required to be appointed by the Secretary and located within HHS. The Beneficiary Ombudsman would be required to have expertise and experience in health care, education of, and assistance to Medicare beneficiaries. The Beneficiary Ombudsman would be required to receive complaints, grievances, and requests for information submitted by Medicare beneficiaries. The Beneficiary Ombudsman would also be required to assist beneficiaries in collecting relevant information to seek an appeal of a decision or determination made by the Secretary, a Medicare contractor, or a Medicare+Choice organization and assisting a beneficiary with any problems arising from un-enrolling in a Medicare+Choice plan. The Beneficiary Ombudsman would be required to work with state health insurance counseling programs.

Appropriations would be authorized to be appropriated in such sums, as are necessary for fiscal year 2004 and each succeeding fiscal year to carry out the ombudsmen provisions.

This provision would also require the use of 1–800–Medicare for all individuals seeking information about, or assistance with Medicare. Rather than listing individual telephone numbers for Medicare contractors in the Medicare handbook, only 1–800–Medicare would be shown. The Comptroller General would be required to study the accuracy and consistency of information provided by the 1–800–Medicare line and to assess whether the information sufficiently answers the questions of beneficiaries. The report on the study would be required to be submitted to Congress no later than one year after enactment.

EFFECTIVE DATE

The Secretary would be required to appoint both ombudsmen no later than one year from the date of enactment.

REASON FOR CHANGE

Providers are currently confronted with a morass of bureaucracy and regulation, with no clear individual to assist them. The new ombudsman would help providers navigate Medicare's complicated rules and regulations.

Medicare Provider Ombudsman shall make recommendations to the Secretary concerning how to respond to recurring patterns of confusion in the Medicare program. Such a recommendation may include calling for the suspension of the imposition of provider sanctions (except those sanctions relating to the quality of care) or where there is widespread confusion in program administration. Nothing in this section shall be construed as allowing for the suspension of provider sanctions relating to the quality of care, regardless of whether widespread confusion in the Medicare program exists.

Beneficiaries confront a morass of bureaucracy and regulation, with no clear individual to assist them. This new ombudsman would help beneficiaries navigate Medicare's complicated rules and regulations.

The Committees acknowledge that implementing these new functions would have a cost and have accordingly authorized necessary appropriations.

The beneficiary handbook currently provides a multitude of phone numbers, which is very confusing for beneficiaries, rather than a single number that can triage and transfer beneficiaries to the appropriate person or entity. This provision would promote better access to information for beneficiaries.

Section 924. Beneficiary Outreach Demonstration Program

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

Subsection (a) would require the Secretary to conduct a three-year demonstration program where Medicare specialists would provide assistance to beneficiaries in at least six local Social Security offices (two would be located in rural areas) that have a high volume of visits by Medicare beneficiaries. The Secretary would be required to evaluate the results of the demonstration regarding the feasibility and cost-effectiveness of permanently out-stationing Medicare specialists at local Social Security offices and report to Congress.

Subsection (b) would require that the Secretary establish a demonstration project to test the administrative feasibility of providing a process for Medicare beneficiaries, providers, suppliers and other individuals or entities furnishing items or services under Medicare to request and receive a determination as to whether the item or service is covered under Medicare by reasons of medical necessity, before the item or service involved is furnished to the beneficiary. The Secretary would be required to evaluate the demonstration and report to Congress by January 1, 2006.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This provision makes Medicare experts available in six Social Security Administration offices to assist beneficiaries and answer their questions. The demonstration would test whether such outsourced Medicare specialists improve beneficiary utilization, understanding of the program, and beneficiary satisfaction.

Section 925. Inclusion of Additional Information in Notices to Beneficiaries About Skilled Nursing Facility Benefits

CURRENT LAW

Although the statute requires that beneficiaries receive a statement listing the items and services for which payment has been made, there is no explicit statutory instruction that requires the notice to include information about the number of days of coverage remaining in either the hospital or skilled nursing facility (SNF) benefit or the spell of illness.

EXPLANATION OF PROVISION

The Secretary would be required to provide information about the number of days of coverage remaining under the SNF benefit and the spell of illness involved in the explanation of Medicare benefits.

EFFECTIVE DATE

The provision would apply to notices provided on and after the calendar quarter beginning more than six months after enactment.

Section 926. Information on Medicare-Certified Skilled Nursing Facilities in Hospital Discharge Plans

CURRENT LAW

The hospital discharge planning process requires evaluation of a patient's likely need for post-hospital services including hospice and home care.

EXPLANATION OF PROVISION

The Secretary would be required to make information publicly available regarding whether SNFs are participating in the Medicare program. Hospital discharge planning would be required to evaluate a patient's need for SNF care.

EFFECTIVE DATE

The provision would apply to discharge plans made on or after the date specified by the Secretary, but no later than six months after the Secretary provides information regarding SNFs that participate in the Medicare program.

Subtitle D—Appeals and Recovery

Section 931. Transfer of Responsibility for Medicare Appeals

CURRENT LAW

Denials of claims for Medicare payment may be appealed by beneficiaries (or providers who are representing the beneficiary) or in certain circumstances, providers or suppliers directly. The third level of appeal is to an Administrative Law Judge (ALJ). The Social Security Administration employs ALJs that hear Medicare cases, a legacy from the inception of the Medicare program, when Medicare was part of Social Security.

EXPLANATION OF PROVISION

The Commissioner of SSA and the Secretary would be required to develop a plan to transfer the functions of the ALJs who are responsible for hearing Medicare cases from SSA to HHS. This plan would be due to Congress no later than October 1, 2004. A GAO evaluation of the plan would be due within six months of the plan's submission. ALJ functions would be transferred no earlier than July 1, 2005 and no later than October 1, 2005.

The Secretary would be required to place the ALJs in an administrative office that is organizationally and functionally separate from the Centers for Medicare & Medicaid Services and the ALJs would be required to report to, and be under the general supervision of the Secretary. No other official within the Department would be permitted to supervise the ALJs. The Secretary would be required to provide for appropriate geographic distribution of ALJs, would have the authority to hire ALJs and support staff, and would be required to enter into arrangements with the Commissioner, as appropriate, to share office space, support staff and other resources with appropriate reimbursement.

Such sums are authorized to be appropriated as are necessary for FY2005 and each subsequent fiscal year to increase the number of ALJs, improve education and training of ALJs and to increase the staff of the Departmental Appeals Board (the final level of appeal).

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The Office of Inspector General has identified moving the functions of the Medicare Administrative Law Judges to the Department of Health and Human Services as an important priority in improving the appeals system. This provision makes that transition and increases the emphasis on providing training Administrative Law Judges and their staffs to increase their expertise in Medicare's rules and regulations. The Commissioner of SSA and the Secretary are instructed to work together on the transition plans in order to assure that the transition does not adversely affect the SSA ALJ appeals system.

The transition plan shall include information on the following:

- Workload—The number of such administrative law judges and support staff required now and in the future to hear and decide such cases in a timely manner, taking into account the

current and anticipated claims volume, appeals, number of beneficiaries, and statutory changes;

- Cost Projections—Funding levels required under this subsection to hear such cases in a timely manner;
- Transition Timetable—A timetable for the transition;
- Regulations—The establishment of specific regulations to govern the appeals process;
- Case Tracking—The development of a unified case tracking system that will facilitate the maintenance and transfer of case-specific data across both the fee-for-service and managed care components of the Medicare program;
- Feasibility of Precedential Authority—The feasibility of developing a process to give binding, precedential authority to decisions of the Departmental Appeals Board in the Department of Health and Human Services that address broad legal issues; and
- Access to Administrative Law Judges—The feasibility of filing appeals with administrative law judges electronically, and the feasibility of conducting hearings using tele- or videoconference technologies.

Section 932. Process for Expedited Access to Review

CURRENT LAW

In general, administrative appeals must be exhausted prior to judicial review.

EXPLANATION OF PROVISION

The Secretary would be required to establish a process where a provider, supplier, or a beneficiary may obtain access to judicial review when a 3-member review panel (composed of ALJs, members of the Departmental Appeals Board, or qualified individuals from qualified independent contractors designated by the Secretary) determines, within 60 days of a complete written request, that it does not have the authority to decide the question of law or regulation and where material facts are not in dispute. The decision would not be subject to review by the Secretary. Interest would be assessed on any amount in controversy and would be awarded by the reviewing court in favor of the prevailing party. This expedited access to judicial review would also be permitted for cases where the Secretary does not enter into or renew provider agreements.

Expedited review would also be established for certain remedies imposed against SNFs including denied payments and imposition of temporary management. The Secretary would be required to develop a process for reinstating approval of nurse aide training programs that have been terminated (before the end of the mandatory two-year disapproval period). The appropriation of such sums as needed for FY2005 and subsequent years would be authorized to reduce by 50 percent the average time for administrative determinations, to increase the number of ALJs and appellate staff at the DAB, and to educate these judges and their staffs on long-term care issues.

EFFECTIVE DATE

This provision would be effective for appeals filed on or after October 1, 2004.

REASON FOR CHANGE.

The provisions in 402 (a–c) on expedited access to judicial review ensure that if a review board certifies that there are no material facts in dispute and that the appeals process does not have authority to resolve the question at issue, the provider, supplier, or beneficiary may take their case to court in an expedited manner. This would facilitate more prompt resolution of challenges to the underlying validity of CMS regulations and determinations. To the extent that any part of an appeal poses a factual dispute that is being adjudicated before an administrative tribunal, this provision would not authorize the severance of the legal issues from the underlying factual dispute.

Section 933. Revisions to Medicare Appeals Process

(a) Requiring Full and Early Presentation of Evidence

CURRENT LAW

No provision. New evidence can be presented at any stage of the appeals process.

EXPLANATION OF PROVISION

The provision would require providers and suppliers to present all evidence at the reconsideration that is conducted by a QIC unless good cause precludes the introduction of the evidence.

EFFECTIVE DATE

October 1, 2004.

REASON FOR CHANGE

The Office of Inspector General identified this change as a priority to promote more expeditious resolution of appeals of denied claims. This provision requires prompt introduction of evidence relevant to a provider appeal. When deciding whether there is good cause to introduce new evidence, the adjudicator should ensure, after consideration of the totality of the circumstances that disallowing the introduction of such new evidence would unfairly prejudice the case. The totality of the circumstances may include, but is not limited to, the following: evidence is not yet available; the appellant was not represented at a lower level of appeal; the appellant was not aware of her rights; or the appellant did not understand the proceeding.

(b) Use of Patients' Medical Records

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The provision would provide for the use of beneficiaries' medical records in qualified independent contractors reconsiderations.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

In the determination of whether an item or service is reasonable and necessary for an individual, a beneficiary's medical records should be considered with other relevant information.

(c) Notice Requirements for Medicare Appeals

CURRENT LAW

No statutory provision. Determinations and denials of appeals currently include the policy, regulatory, or statutory reason for the denial and information on how to appeal the denial. The Benefits Improvement and Protection Act (BIPA) of 2000 changed the appeals process and created a new independent review (the qualified independent contractors or QICs), which has not yet been implemented.

EXPLANATION OF PROVISION

The provision would require that notice of and decisions from determinations, redeterminations, reconsiderations, ALJ appeals, and DAB appeals be written in a manner understandable to a beneficiary and that includes, as appropriate, reasons for the determination or decision and notice of the right to appeal decisions and the process for further appeal. The initial determination of a claim would also be specifically required to include: the reasons for the determination, including whether a local review policy or coverage determination was used and the procedures for obtaining additional information (including, upon request, the specific provision of the policy manual, or regulation used in making the determination). Redeterminations, the first level of appeal, would also specifically be required to include: the specific reasons for the decision; as appropriate a summary of the clinical or scientific evidence used in making the redetermination; and a description of the procedures for obtaining additional information concerning the redetermination (including, upon request, the specific provision of the policy manual, or regulation used in making the determination).

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Currently, Medicare only provides beneficiaries with a brief statement about the initial determination of her claim on the Medicare Summary Notice. This provision provides additional information to beneficiaries (or providers who appeal on their behalf) about Medicare's denial of their claim for benefits; the reasons for the denial, and the rights to further appeal so that beneficiaries can have

a clear and concise understanding of decisions affecting their medical care.

(d) Qualified Independent Contractors

CURRENT LAW

BIPA established a new and independent second level of appeal called the qualified independent contractors. BIPA called for at least 12 QICs. The QICs have not yet been implemented.

EXPLANATION OF PROVISION

The provision would clarify eligibility requirements for qualified independent contractors and their reviewer employees including medical and legal expertise, independence requirements, and the prohibition on compensation being linked to decisions rendered. The required number of qualified independent contractors would be reduced from not fewer than twelve to not fewer than four.

EFFECTIVE DATE

The provisions regarding the eligibility requirements of QICs and QIC reviews would be effective as if included in the enactment of BIPA.

REASON FOR CHANGE

The BIPA 2000 law laid out broad provisions for revision of the Medicare appeals process. These provisions strengthen the appeals process by enhancing the criteria related to the independence and expertise of the reviewers and review entities.

Section 934. Prepayment Review

CURRENT LAW

No explicit statutory instruction. Under administrative authorities, CMS has instructed the contractors to use random prepayment reviews to develop contractor-wide and program-wide error rates. Non-random payment reviews are permitted in certain circumstances laid out in instructions to the contractors.

EXPLANATION OF PROVISION

Medicare contractors would be permitted to conduct random prepayment reviews only to develop a contractor-wide or program-wide error rate or such additional circumstances as the Secretary provides for in regulations that were developed in consultation with providers and suppliers. Random prepayment review would only be permitted in accordance with standard protocol developed by the Secretary. Nonrandom payment reviews would be permitted only when there was a likelihood of sustained or high level of payment error. The Secretary would be required to issue regulations regarding the termination and termination dates of non-random prepayment review. Variation in termination dates would be permitted depending upon the differences in the circumstances triggering prepayment review.

EFFECTIVE DATE

The Secretary would be required to issue the required regulations not later than one year after enactment. The provision regarding the use of standard protocols when conducting prepayment reviews would apply to random prepayment reviews conducted on or after the date specified by the Secretary (but not later than one year after enactment). The remaining provisions would be effective one year after enactment.

REASON FOR CHANGE

These provisions build greater consistency and predictability into Medicare's rules for prepayment review, while protecting program integrity.

Section 935. Recovery of Overpayments

CURRENT LAW

No explicit statutory instruction. Under administrative authorities, CMS negotiates extended repayment plans with providers that need additional time to repay Medicare overpayments.

EXPLANATION OF PROVISION

In situations where repaying an Medicare overpayment within 30 days would be a hardship for a provider or supplier, the Secretary would be required to enter into an extended repayment plan of at least six months duration. The repayment plan would not be permitted to go beyond three years (or five years in the case of extreme hardship, as determined by the Secretary). Interest would be required to accrue on the balance through the repayment period. Hardship would be defined if, for providers that file cost reports, the aggregate amount of the overpayment exceeded 10 percent of the amount paid by Medicare to the provider for the time period covered by the most recently submitted cost report. In the case of a provider or supplier that is not required to file a cost report, hardship would be defined if the aggregate amount of the overpayment exceeded 10 percent of the amount paid under Medicare for the previous calendar year. The Secretary would be required to develop rules for the case of a provider or supplier that was not paid under Medicare during the previous year or for only a portion of the year. Any other repayment plans that a provider or supplier has with the Secretary, would not be taken into account by the Secretary in calculating hardship. If the Secretary has reason to suspect that the provider or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in Medicare or there is an indication of fraud or abuse, the Secretary would not be obligated to enter into an extended repayment plan with the provider or supplier. If a provider or supplier fails to make a payment according to the repayment plan, the Secretary would be permitted to immediately seek to offset or recover the total outstanding balance of the repayment plan, including interest.

The Secretary would be prohibited from recouping any overpayments until a reconsideration-level appeal (or a redetermination by the fiscal intermediary or carrier if the QICs are not yet in place) was decided, if a reconsideration was requested. Interest would be

required to be paid to the provider if the appeal was successful (beginning from the time the overpayment is recouped) or that interest would be required to be paid to the Secretary if the appeal was unsuccessful (and if the overpayment was not paid to the Secretary).

Extrapolation would be limited to those circumstances where there is a sustained or high level of payment error, as defined by the Secretary in regulation, or document educational intervention has failed to correct the payment error.

Medicare contractors would be permitted to request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing in the case of a provider or supplier with prior overpayments.

The Secretary would be able to use consent settlements to settle projected overpayments under certain conditions. Specifically the Secretary would be required to communicate with the provider or supplier that medical record review has indicated an overpayment exists, the nature of the problems identified, the steps needed to address the problems, and afford the provider or supplier 45 days to furnish additional information regarding the medical records for the claims reviewed. If, after reviewing the additional information an overpayment continues to exist, the Secretary would be required to provide notice and an explanation of the determination and then may offer the provider two mechanisms to resolve the overpayment: either an opportunity for a statistically valid random sample or a consent settlement (without waiving any appeal rights).

The Secretary would be required to establish a process to provide notice to certain providers and suppliers in cases where billing codes were over-utilized by members of that class in certain areas, in consultation with organizations that represent the affected provider or supplier class.

If post-payment audits were conducted, the Medicare contractor would be required to provide the provider or supplier with written notice of the intent to conduct the audit. The contractor would further be required to give the provider or supplier a full and understandable explanation of the findings of the audit and permit the development of an appropriate corrective action plan, inform the provider or supplier of appeal rights and consent settlement options, and give the provider or supplier the opportunity to provide additional information to the contractor, unless notice or findings would compromise any law enforcement activities.

The Secretary would be required to establish a standard methodology for Medicare contractors to use in selecting a sample of claims for review in cases of abnormal billing patterns.

EFFECTIVE DATE

In general, the provisions would be effective upon enactment. The limitation on extrapolation would apply to samples initiated after the date that is one year after the date of enactment. The Secretary would be required to establish the process for notice of over-utilization of billing codes not later than one year after enactment. The Secretary would be required to establish a standard methodology for selecting sample claims for abnormal billing patterns not later than one year after enactment.

REASON FOR CHANGE

These provisions build greater consistency and predictability into Medicare's rules for recovery of overpayments, while protecting program integrity.

Section 936. Provider Enrollment Process; Right of Appeal

CURRENT LAW

No explicit statutory instruction. Under administrative authorities, CMS has established provider enrollment processes in instructions to the contractors.

EXPLANATION OF PROVISION

The Secretary would be required to establish in regulation a provider enrollment process with hearing rights in the case of a denial or non-renewal. The process would be required to include deadlines for actions on applications for enrollment and enrollment renewals. The Secretary would be required to monitor the performance of the Medicare contractors in meeting the deadlines he establishes. Before changing provider enrollment forms, the Secretary would be required to consult with providers and suppliers. The provision would also establish hearing rights in cases where the applications have been denied.

EFFECTIVE DATE

The enrollment process would be required to be established within six months of enactment. The consultation process on provider enrollment forms would be required for changes in the form beginning January 1, 2004. The provision of hearing rights would apply to denials that occur one year after enactment or an earlier date specified by the Secretary.

REASON FOR CHANGE

This provision gives providers and suppliers an opportunity to appeal denials of their applications to participate in the Medicare program.

Section 937. Process for Correction of Minor Errors and Omissions on Claims without Pursuing Appeals Process

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

This provision would require the Secretary to establish a process so providers and suppliers could correct minor errors in claims that were submitted for payment.

EFFECTIVE DATE

The proposal would require that the process be developed not later than one year after enactment.

REASON FOR CHANGE

Many of the providers and suppliers who testified before the Subcommittee or contacted members directly emphasized the need to create a process in which they could correct claims that were denied because they were incomplete or contained minor errors without having to pursue a formal appeal. This provision instructs the Secretary to create such a process, which will alleviate pressure on the appeals system. The Committees would be concerned, however, if this process were to become an incentive for providers to knowingly or negligently submit incomplete information.

The Committees intend that the process for correction of minor errors and omissions on claims cover both the submission of prepayment and post-payment review claims. For example, if in the case of a home health claim, the physician has signed the plan of care and/or physician's order but has not dated it, the claim shall be returned to the home health agency and may be resubmitted by the home health agency with any incomplete or missing information without having to appeal the claim.

Section 938. Prior Determination Process for Certain Items and Services; Advance Beneficiary Notices

CURRENT LAW

Medicare law prohibits payment for items and services that are not medically reasonable and necessary for the diagnosis or treatment of an illness or an injury. Under certain circumstances, however, Medicare will pay for non-covered services that have been provided if both the beneficiary and the provider of the services did not know and could not have reasonably been expected to know that Medicare payment would not be made for these services.

A provider may be held liable for providing uncovered services, if, for example, specific requirements are published by the Medicare contractor or the provider has received a denial or reduction of payment on the same or similar service. In cases where the provider believes that the service may not be covered as reasonable and necessary, an acceptable advance notice of Medicare's possible denial of payment must be given to the patient if the provider does not want to accept financial responsibility for the service. The notice must be given in writing, in advance of providing the service; include the patient's name, date and description of service as well as reasons why the service would not be covered; and must be signed and dated by the patient to indicate that the beneficiary will assume financial liability for the service if Medicare payment is denied or reduced.

EXPLANATION OF PROVISION

The Secretary would be required to establish a process through regulation where physicians and beneficiaries can establish whether Medicare covers certain categories of items and services before such services are provided. An eligible requestor would be a physician, but only in case of items and services for which the physician is paid directly and a Medicare beneficiary who receives an advance beneficiary notice from a physician would receive direct payment for that service. The provisions would establish that: (1) such

prior determinations would be binding on the Medicare contractor, absent fraud or misrepresentation of facts, (2) the right to redetermination in the case of a denial, (3) the applicability of existing deadlines with respect to those redeterminations, (4) that contractors' advance determinations (and redeterminations) are not subject to further administrative or judicial review, and (5) an individual retains all rights to usual administrative or judicial review after receiving the service or receiving a determination that a service would not be covered. These provisions would not affect a Medicare beneficiary's right not to seek an advance determination. The prior determination process would be established in time to address such requests that are filed by 18 months of enactment. The Secretary would be required to collect data on the advance determinations and to establish a beneficiary outreach and education program. GAO is required to report on the use of the advance beneficiary notice and prior determination process within 18 months of its implementation.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The Committees believe that when there is a question of whether Medicare will cover certain care for a beneficiary, the beneficiary should have the right to find out what would be covered before getting the service and risking financial liability. Doctors also should be able to make such a request on behalf of a particular patient. This provision is particularly important for seniors and disabled individuals who tend to be risk adverse and live on fixed incomes.

Subtitle V—Miscellaneous

Section 941. Policy Development Regarding Evaluation and Management (E&M) Documentation Guidelines

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The Secretary would not be permitted to implement any new documentation guidelines for, or clinical examples of, evaluation and management (E&M) physician services unless the Secretary: (1) developed the guidelines in collaboration with practicing physicians (both generalists and specialists) and provided for an assessment of the proposed guidelines by the physician community, (2) established a plan containing specific goals, including a schedule, for improving the use of the guidelines, (3) conducted pilot projects to test modifications to the guidelines, (4) finds the guidelines have met established objectives, and (5) established and implemented an education program on the use of the guidelines with appropriate outreach. The Secretary would make changes to existing E&M guidelines to reduce paperwork burdens on physicians. The provision establishes objectives for modifications of the E&M guidelines: (1) identify clinically relevant documentation needed to code accurately and assess coding levels accurately, (2) decrease the non-

clinically pertinent documentation in the medical record, (3) increase reviewers accuracy, and (4) educate physicians and reviewers.

The pilot projects would be required to be conducted on a voluntary basis in consultation with practicing physicians (both generalists and specialists) and be of sufficient length to educate physicians and contractors on E&M guidelines. A range of different projects would be established and include at least one project: using a physician peer review method, using an alternative method based on face-to-face encounter time with the patient, in a rural area, outside a rural area, and where physicians bill under physician services in a teaching setting and non-teaching setting. The projects would examine the effect of modified E&M guidelines on different types of physician practices in terms of the cost of compliance. Data collected under these projects would not be the basis for overpayment demands or post-payment audits. This protection would apply to claims filed as part of the project, would last the duration of the project, and would last for as long as the provider participated in the project. Each pilot conducted would examine the effect of the new E&M documentation guidelines on different types of physician practices (including those with fewer than 10 full-time equivalent employees) and the costs of physician compliance including education implementation, auditing, and monitoring. The Secretary would be required to submit periodic reports to Congress on these pilot projects.

The provision would require a study of an alternative system for documenting physician claims. Specifically the Secretary would be required to study developing a simpler system for documenting claims for evaluation and management services and to consider systems other than current coding and documentation requirements. The Secretary would be required to consult with practicing physicians in designing and carrying out the study. This study would be due to Congress no later than October 1, 2005. MedPAC would be required to analyze the results of the study and report to Congress. The Secretary would also be required to study the appropriateness of coding in cases of extended office visits in which no diagnosis is made and report to Congress no later than October 1, 2005. The Secretary would be required to include in the report recommendations on how to code appropriately for these visits in a manner that takes into account the amount of time the physician spent with the patient.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This provision is designed to promote greater consultation with practicing physicians with regard to the complicated evaluation and management and coding requirements governing Medicare payment for physician services.

Section 942. Improvement in Oversight of Technology and Coverage

(a) Council for Technology and Innovation

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The Secretary would be required to establish a Council for Technology and Innovation within CMS. The council would be composed of senior CMS staff and clinicians with a chairperson designated by the Secretary who reports to the CMS Administrator. The Chairperson would serve as the Executive Coordinator for Technology and Innovation would be the single point of contact for outside groups and entities regarding Medicare coverage, coding, and payment processes. The Council would coordinate Medicare's coverage, coding, and payment processes as well as information exchange with other entities with respect to new technologies and procedures, including drug therapies.

If the National Committee on Vital and Health Statistics has not made a recommendation to the Secretary by enactment regarding implementation of the ICD–10 coding system for diagnosis and procedures, the Secretary may adopt such standards one year after the date of enactment.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

After the FDA pre-market approval, the Medicare program does a second evaluation of breakthrough technologies to determine effectiveness and cost of those technologies compared to existing technologies. The review is necessary and appropriate, but it can take months between FDA approval and the availability of new technology for Medicare beneficiaries. By coordinating FDA and CMS approval of breakthrough medical devices, where feasible, this provision is intended to facilitate a more efficient process for the coverage of certain new technology by the Medicare program.

The ICD–9 coding system was adopted in 1979, and remains in effect for diagnosis and procedure coding in hospital inpatient and outpatient settings. ICD–9 has "run out" of codes for certain new procedures. For example, no code was available for the anthrax attack in 2001. NCVHS began investigating adoption of an updated coding system—ICD–10—in 1990. ICD–10 is more clinically accurate, and has available codes for new technologies and procedures. In 1996, as part of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Congress required NCVHS to make a recommendation on adoption prior to Secretarial approval. To date, NCVHS still has not issued a recommendation.

ICD–9 has run out of codes for new technologies and procedures. ICD–10 has room for those procedures, which would improve accuracy in claims processing. Every developed country in the world except the US and Israel has adopted ICD–10 as the standard coding system because it is superior to ICD–9. Some hospitals are eager to adopt ICD–10 because ultimately they believe it would improve

efficiency. The Committee agrees, although nothing in this provision requires the Secretary to adopt the ICD–10 in any health care setting.

(b) Methods for Determining Payment Basis for New Lab Tests

CURRENT LAW

Outpatient clinical diagnostic laboratory tests are paid on the basis of area wide fee schedules. The law establishes cap on the payment amounts, which is currently set at 74 percent of the median for all fee schedules for that test. The cap is set at 100 percent of the median for tests performed after January 1, 2001 that the Secretary determines are new tests for which no limitation amount has previously been established.

EXPLANATION OF PROVISION

The Secretary would be required to establish procedures (by regulation) for determining the basis for and amount of payments for new clinical diagnostic laboratory tests. New laboratory tests would be defined as those assigned a new, or substantially revised Health Care Procedure Coding System (HCPCS) code on or after January 1, 2005. The Secretary, as part of this procedure, would be required to: (1) provide a list (on an Internet site or other appropriate venue) of tests for which payments are being established in that year, (2) publish a notice of a meeting in the Federal Register on the day the list becomes available, (3) hold the public meeting no earlier than 30 days after the notice to receive public comments and recommendations, (4) take into account the comments, recommendations and accompanying data in both proposed and final payment determinations. The Secretary would set forth the criteria for making these determinations; make public the available data considered in making such determinations; and could convene other public meetings as necessary.

EFFECTIVE DATE

Effective for codes assigned on or after January 1, 2005.

(c) GAO Study on Improvements in External Data Collection for Use in the Medicare Inpatient Payment System

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

GAO would be required to study which external data could be collected by CMS in a shorter time frame for use in calculating payments for inpatient hospital services. GAO could evaluate feasibility and appropriateness of using quarterly samples or special surveys and would include an analysis of whether other executive agencies would be better suited to collect this information. The report would be due to Congress no later than October 1, 2004.

EFFECTIVE DATE

Upon enactment.

Section 943. Treatment of Hospitals for Certain Services Under Medicare Secondary Payer (MSP) Provisions

CURRENT LAW

In certain instances when a beneficiary has other insurance coverage, Medicare becomes the secondary insurance. Medicare Secondary Payer is the Medicare program's coordination of benefits with other insurers. Section 1862(b)(6) of the Social Security Act requires an entity furnishing a Part B service to obtain information from the beneficiary on whether other insurance coverage is available.

EXPLANATION OF PROVISION

The Secretary would not require a hospital or a critical access hospital to ask questions or obtain information relating to the Medicare secondary payer provisions in the case of reference laboratory services if the same requirements are not imposed upon those provided by an independent laboratory. Reference laboratory services would be those clinical laboratory diagnostic tests and interpretations of it that are furnished without a face-to-face encounter between the beneficiary and the hospital where the hospital submits a claim for the services.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Hospitals would not have to directly contact each beneficiary on their retirement date, black lung status and other insurance information for reference laboratory services. While current law provisions for a claim containing valid insurance information are maintained, this provision is intended to reduce the amount of paperwork and regulatory burden related to the provision of these reference laboratory services by hospital-based entities.

Section 944. EMTALA Improvements

CURRENT LAW

Medicare requires participating hospitals that operate an emergency room to provide necessary screening and stabilization services to a patient in order to determine whether an emergency medical situation exists prior to asking about insurance status of the patient.

Hospitals that are found to be in violation of Emergency Medical Treatment and Active Labor Act (EMTALA) requirements may face civil monetary penalties and termination of their provider agreement. Prior to imposing a civil monetary penalty, the Secretary is required to request a peer review organization (PRO), currently called quality improvement organizations (QIOs), to assess whether the involved beneficiary had an emergency condition, which had not been stabilized and provide a report on its findings. Except in the case where a delay would jeopardize the health or safety, the Secretary provides a 60-day period for the requested PRO review.

EMTALA is enforced by general guidelines issued by CMS. Patients who present to the emergency room and request services (or another person does so on their behalf) are required to be screened and stabilized.

EXPLANATION OF PROVISIONS

Emergency room services provided to screen and stabilize a Medicare beneficiary furnished after January 1, 2004, would be evaluated as reasonable and necessary on the basis of the information available to the treating physician or practitioner at the time the services were ordered; this would include the patient's presenting symptoms or complaint and not the patient's principal diagnosis. The Secretary would not be able to consider the frequency with which the item or service was provided to the patient before or after the time of admission or visit.

The Secretary would be required to establish a procedure to notify hospitals and physicians when an EMTALA investigation is closed.

Except in the case where a delay would jeopardize the health and safety of individuals, the Secretary would be required to request a PRO review before making a compliance determination that would terminate a hospital's Medicare participation because of EMTALA violations and provide a period of 5 business days for such review. The PRO shall provide a copy of the report on its findings to the hospital or physician that is consistent with existing confidentiality requirements. This provision would apply to terminations initiated on or after enactment.

The provision also clarifies the responsibility of the hospital when the individual does not request examination or treatment for an emergency condition.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Providers have reported that some Medicare contractors are looking at final diagnoses (not presenting symptoms) in applying local medical review policies (LMRPs) that match particular tests to particular diagnoses—if a test does not match a listed diagnosis, payment is denied. Other claims are reportedly being denied based on LMRPs that set frequency limits for certain tests—if the test's use in the emergency room exceeds a frequency limit, payment is denied. In its January 2001 report entitled The Emergency Medical Treatment and Labor Act: The Enforcement Process, at the OIG recommended that CMS ensure that peer review occurs before a provider is terminated from the Medicare program for an EMTALA violation. This section implements that recommendation, making the current discretionary PRO review process mandatory in cases that involve a question of medical judgment. Finally, it clarifies CMS guidelines for persons or individuals who arrive at the emergency room for non-emergency services.

Section 945. Emergency Medical Treatment and Active Labor (EMTALA) Task Force

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The Secretary would be required to establish a 17-member technical advisory group under specified requirements to review issues related to EMTALA. The advisory group would be comprised of: the CMS Administrator; the OIG; four hospital representatives who have EMTALA experience, (including 1 person from a public hospital and two of whom have not experienced EMTALA violations); five practicing physicians with EMTALA experience; two patient representatives; two regional CMS staff involved in EMTALA investigations; one representative from a state survey organization and one from a PRO. The Secretary would select qualified individuals who are nominated by organizations representing providers and patients.

The advisory group would be required to: (1) elect a member to as chairperson, (2) schedule its first meeting at the direction of the Secretary and meet at least twice a year subsequently, (3) terminate 30 months after the date of its first meeting, and (4) be exempt from the Federal Advisory Committee Act. The advisory group would review EMTALA regulations; provide advice and recommendations to the Secretary; solicit public comments from interested parties; and disseminate information on the application of the EMTALA regulations.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

In its January 2001 report entitled The Emergency Medical Treatment and Labor Act: The Enforcement Process, the OIG recommended that CMS establish an EMTALA technical advisory group that includes all EMTALA stakeholders to help the agency resolve any emerging issues related to implementation of the law. Some of these current issues include specialists who refuse to service on call panels and inconsistencies between Stat and Federal law governing emergency medical services. In its June 2001 report entitled Emergency Care: EMTALA Implementations and Enforcement Issues, the GAO also concluded that the establishment of a technical advisory group could help CMS work with hospitals and physicians to achieve the goals of EMTALA and avoid creating unnecessary burdens for providers. This section implements the OIG recommendation, establishing a 19-member technical advisory group within HHS.

Section 946. Authorizing Use of Arrangements To Provide Core Hospice Services in Certain Circumstances

CURRENT LAW

A hospice is a public agency or private organization, which is primarily engaged in providing and making available certain care to a terminally ill Medicare beneficiary under a written plan.

EXPLANATION OF PROVISIONS

A hospice would be permitted to: (1) enter into arrangements with another hospice program to provide care in extraordinary, exigent or other non-routine circumstances, such as unanticipated high patient loads, staffing shortages due to illness, or temporary travel by a patient outside the hospice's service area, and (2) bill and be paid for the hospice care provided under these arrangements.

EFFECTIVE DATE

For hospice care provided on or after enactment.

REASON FOR CHANGE

Hospice programs would be allowed to use personnel from other hospice programs to provide services to hospice patients. The program is given the flexibility so that a hospice program could continue to serve a patient if he or she was temporarily out of the area due to travel. Otherwise, the provision of the care to the patient might be delayed by the paperwork and requirements in starting up a new service at another agency. It is the intent of Congress that the originating hospice maintains control over the billing and quality of care.

Section 947. Application of OSHA Bloodborne Pathogens Standards to Certain Hospitals

CURRENT LAW

Section 1866 establishes certain conditions of participation that providers must meet in order to participate in Medicare.

EXPLANATION OF PROVISION

Public hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 would be required to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations. A hospital that fails to comply with the requirement would be subject to a civil monetary penalty, but would not be terminated from participating in Medicare.

EFFECTIVE DATE

The provision would apply to hospitals as of July 1, 2004.

REASON FOR CHANGE

Last year, Congress enacted legislation that requires hospitals to utilize safe needles. However, that legislation only applies to non-government hospitals. Twenty-four states have similar require-

ments on public hospitals. This provision would protect the health and safety of health care workers in those facilities by requiring public hospitals in the other 26 states and the District of Columbia to comply with this important standard.

Section 948. BIPA-Related Technical Amendments and Corrections

CURRENT LAW

BIPA established an advisory process for national coverage determinations where panels of experts formed by advisory committees could forward their recommendations directly to the Secretary without prior approval of the advisory committee or the Executive Committee.

EXPLANATION OF PROVISION

The statutory reference in BIPA would be changed from the Social Security Act to the Public Health Service Act. Other BIPA references would be changed from a policy to a determinations.

EFFECTIVE DATE

The provision would be effective as if included in BIPA.

Section 949. Conforming Authority To Waive A Program Exclusion

CURRENT LAW

The Secretary is required to exclude individuals and entities from participation in Federal Health Programs that are (1) convicted of a criminal offense related to health care delivery under Medicare or under State health programs, (2) convicted of a criminal offense related to patient abuse or neglect under Federal or State law, (3) convicted of a felony relating to fraud, theft, or financial misconduct relating to a health care finance program or operated by the Federal, State or local government, or (4) convicted of a felony related to a controlled substance.

EXPLANATION OF PROVISIONS

The Administrator of a Federal health program would be permitted to waive certain 5-year exclusions if the exclusion of a sole community physician or source of specialized services in a community would impose a hardship. The mandatory exclusions that could be waived would be those related to convictions associated with program-related crimes, health care fraud and controlled substances.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The Office of Inspector General requested this technical correction.

Section 950. Treatment of Certain Dental Claims

CURRENT LAW

The Medicare benefit does not include most dental services. Some insurers may require a claim denial from Medicare before accepting the dental claim for payment review, even if Medicare does not cover the service.

EXPLANATION OF PROVISION

A group health plan providing supplemental or secondary coverage to Medicare beneficiaries would not be able to require dentists to obtain a claim denial from Medicare for non-covered dental services before paying the claim.

EFFECTIVE DATE

The provision would be effective 60 days after enactment.

REASON FOR CHANGE

The Committees are concerned about private insurers requiring dentists to submit claims to Medicare for non-covered services before making a determination for coverage under the group health plan. Because of this requirement, dentists have been forced to enroll in the Medicare program to submit claims for services that are categorically excluded from Medicare coverage. Dentists view Medicare's enrollment application process as overly burdensome, particularly in light of the fact that Medicare does not cover most dental services. This provision would alleviate the enrollment burden placed on dentists providing services clearly excluded from Medicare coverage, consistent with the overarching goal of this legislation to reduce regulatory burdens.

Section 951. Furnishing Hospitals With Information To Compute DSH Formula

CURRENT LAW

Disproportionate share hospital (DSH) payments under Medicare are calculated using a formula that includes the number of patient days for patients eligible for Medicaid.

EXPLANATION OF PROVISION

The provision would require the Secretary to arrange for the information such as number of paid or unpaid Medicaid days, and the number of dual eligibles that hospitals need to calculate the Medicare DSH payment formula.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Hospitals find it difficult to compute certain critical numbers for the purposes of Medicare DSH such as unpaid days used by Medicaid eligibles or Medicare dual eligibles. This helps ensure accuracy for hospitals and for the Trust Fund.

Section 952. Revisions to Reassignment Provisions

CURRENT LAW

Under certain circumstances, a person or entity other than the individual providing the service may receive Medicare payments.

EXPLANATION OF PROVISION

Entities, as defined by the Secretary, could receive Medicare payments for services provided by a physician or other person if the service was provided under a contractual arrangement and if the arrangement included joint and several liability (liability for several parties) for overpayment and the entities meet program integrity specifications determined by the Secretary.

EFFECTIVE DATE

The provision would be effective for payments made on or after one year after the date of enactment.

Section 953. Other Provisions

CURRENT LAW

No provisions.

EXPLANATION OF PROVISION

GAO Report on Physician Compensation. No later than six months from enactment, GAO would be required to report to Congress on the appropriateness of the updates in the conversion factor including the appropriateness of the sustainable growth rate (SGR) formula for 2002 and subsequently. The report would examine the stability and the predictability of the updates and rate as well as the alternatives for use of the SGR in the updates. No later than 12 months from enactment, GAO would be required to report to Congress on all aspects of physician compensation for Medicare services. The report would review the alternatives for the physician fee schedule.

Annual Publication of List of National Coverage Determinations. The Secretary would be required to publish an annual list of national coverage determinations made under Medicare in the previous year. Included would be information on how to get more information about the determinations. The list would be published in an appropriate annual publication that is publicly available.

GAO Report on Flexibility in Applying Home Health Conditions of Participation to Patients Who Are Not Medicare Beneficiaries. The GAO would be required to report to Congress on the implications if the Medicare conditions of participation for home health agencies were applied flexibly with respect to groups or types of patients who are not Medicare beneficiaries. The report would include an analysis of the potential impact of this flexibility on clinical operations and the recipients of such services and an analysis of methods for monitoring the quality of care provided to these recipients. The report would be due no later than six month after enactment.

OIG Report on Notices Relating to Use of Hospital Lifetime Reserve Days. The Inspector General of HHS would be required to re-

port to Congress on the extent to which hospitals provide notice to Medicare beneficiaries, in accordance with applicable requirements, before they use the 60 lifetime reserve days under the hospital benefit. The report would also include the appropriateness and feasibility of hospitals providing a notice to beneficiaries before they exhaust the lifetime reserve days. The report would be due no later than one year after enactment.

EFFECTIVE DATE

Upon enactment.

Section 954. Temporary Suspension of OASIS Requirement for Collection of Data on Non-Medicare and Non-Medicaid Claims

CURRENT LAW

Under the Conditions of Participation, home health agencies are required to complete the OASIS form on all patients.

EXPLANATION OF PROVISION

The OASIS data collected on non-Medicare or non-Medicaid patients is not collected or used by the Federal government. This provision suspends collection until the Secretary has published final regulations regarding the collection and use of this data. Moreover it requires a study of how the data is used by the agencies as well as recommendations from quality assessment experts. Agencies may continue collecting the data during the suspension.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Data mandates on the collection of data on non-Medicare and non-Medicaid patients by the Federal government should be carefully reviewed for privacy issues by the agency.

III. VOTES OF THE COMMITTEE

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the following statements are made concerning the votes of the Committee on Ways and Means in its consideration of the bill, H.R. 2473.

MOTION TO REPORT THE BILL

The bill, H.R. 2473, as amended, was ordered favorably reported by a rollcall vote of 25 yeas to 15 nays (with a quorum being present). The vote was as follows:

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Thomas	X			Mr. Rangel		X	
Mr. Crane	X			Mr. Stark		X	
Mr. Shaw	X			Mr. Matsui		X	
Mrs. Johnson	X			Mr. Levin		X	
Mr. Houghton	X			Mr. Cardin		X	
Mr. Herger	X			Mr. McDermott		X	
Mr. McCrery	X			Mr. Kleczka		X	
Mr. Camp	X			Mr. Lewis (GA)		X	

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Ramstad	X			Mr. Neal		X	
Mr. Nussle	X			Mr. McNulty		X	
Mr. Johnson	X			Mr. Jefferson		X	
Ms. Dunn	X			Mr. Tanner		X	
Mr. Collins	X			Mr. Becerra		X	
Mr. Portman	X			Mr. Doggett		X	
Mr. English	X			Mr. Pomeroy	X		
Mr. Hayworth	X			Mr. Sandlin			
Mr. Weller	X			Ms. Tubbs Jones		X	
Mr. Hulshof	X						
Mr. McInnis	X						
Mr. Lewis (KY)	X						
Mr. Foley	X						
Mr. Brady	X						
Mr. Ryan	X						
Mr. Cantor	X						

VOTES ON AMENDMENTS

An amendment in the nature of a substitute by Chairman Thomas was agreed to by a rollcall vote of 25 yeas to 15 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Thomas	X			Mr. Rangel		X	
Mr. Crane	X			Mr. Stark		X	
Mr. Shaw	X			Mr. Matsui		X	
Mrs. Johnson	X			Mr. Levin		X	
Mr. Houghton	X			Mr. Cardin		X	
Mr. Herger	X			Mr. McDermott		X	
Mr. McCrery	X			Mr. Kleczka		X	
Mr. Camp	X			Mr. Lewis (GA)		X	
Mr. Ramstad	X			Mr. Neal		X	
Mr. Nussle	X			Mr. McNulty		X	
Mr. Johnson	X			Mr. Jefferson		X	
Ms. Dunn	X			Mr. Tanner		X	
Mr. Collins	X			Mr. Becerra		X	
Mr. Portman	X			Mr. Doggett		X	
Mr. English	X			Mr. Pomeroy	X		
Mr. Hayworth	X			Mr. Sandlin			
Mr. Weller	X			Ms. Tubbs Jones		X	
Mr. Hulshof	X						
Mr. McInnis	X						
Mr. Lewis (KY)	X						
Mr. Foley	X						
Mr. Brady	X						
Mr. Ryan	X						
Mr. Cantor	X						

A rollcall vote was conducted on the following amendments to the Chairman's amendment in the nature of a substitute.

An amendment by Mr. Cardin, which would amend section 1860D–5(d) of the Social Security Act as proposed to be inserted by section 101, to require the U.S. Department of Health and Human Services to takes such steps as may be necessary to qualify and serve as a prescription drug plan sponsor and to offer a prescription drug plan that offers standard coverage throughout the United States, was defeated by a rollcall vote of 15 yeas to 23 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Thomas		X		Mr. Rangel	X		

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Crane		X		Mr. Stark	X		
Mr. Shaw				Mr. Matsui	X		
Mrs. Johnson		X		Mr. Levin	X		
Mr. Houghton		X		Mr. Cardin	X		
Mr. Herger		X		Mr. McDermott	X		
Mr. McCrery		X		Mr. Kleczka	X		
Mr. Camp		X		Mr. Lewis (GA)	X		
Mr. Ramstad		X		Mr. Neal	X		
Mr. Nussle		X		Mr. McNulty	X		
Mr. Johnson		X		Mr. Jefferson			
Ms. Dunn		X		Mr. Tanner	X		
Mr. Collins		X		Mr. Becerra	X		
Mr. Portman		X		Mr. Doggett	X		
Mr. English		X		Mr. Pomeroy	X		
Mr. Hayworth		X		Mr. Sandlin			
Mr. Weller		X		Ms. Tubbs Jones	X		
Mr. Hulshof		X					
Mr. McInnis		X					
Mr. Lewis (KY)		X					
Mr. Foley		X					
Mr. Brady		X					
Mr. Ryan		X					
Mr. Cantor		X					

An amendment by Mr. McDermott, to strike Subtitle C of Title II, eliminating the privatization of plans, was defeated by a rollcall vote of 14 yeas to 23 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Thomas		X		Mr. Rangel	X		
Mr. Crane		X		Mr. Stark	X		
Mr. Shaw				Mr. Matsui	X		
Mrs. Johnson		X		Mr. Levin	X		
Mr. Houghton		X		Mr. Cardin	X		
Mr. Herger		X		Mr. McDermott	X		
Mr. McCrery		X		Mr. Kleczka	X		
Mr. Camp		X		Mr. Lewis (GA)	X		
Mr. Ramstad		X		Mr. Neal	X		
Mr. Nussle		X		Mr. McNulty	X		
Mr. Johnson		X		Mr. Jefferson			
Ms. Dunn		X		Mr. Tanner	X		
Mr. Collins		X		Mr. Becerra	X		
Mr. Portman		X		Mr. Doggett	X		
Mr. English		X		Mr. Pomeroy	X		
Mr. Hayworth		X		Mr. Sandlin			
Mr. Weller		X		Ms. Tubbs Jones			
Mr. Hulshof		X					
Mr. McInnis		X					
Mr. Lewis (KY)		X					
Mr. Foley		X					
Mr. Brady		X					
Mr. Ryan		X					
Mr. Cantor		X					

An amendment by Mrs. Johnson, which would amend section 1848(c)(2)(H) of the Social Security Act, as proposed to be added by section 303(a)(1)(B), to direct the Secretary of Health and Human Services to expedite the process for adjusting existing CPT codes for costs associated with the administration of covered drugs, was agreed to by a rollcall vote of 32 yeas to 5 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Thomas	X			Mr. Rangel		X	
Mr. Crane	X			Mr. Stark		X	
Mr. Shaw				Mr. Matsui	X		
Mrs. Johnson	X			Mr. Levin	X		
Mr. Houghton	X			Mr. Cardin	X		
Mr. Herger	X			Mr. McDermott	X		
Mr. McCrery	X			Mr. Kleczka	X		
Mr. Camp	X			Mr. Lewis (GA)		X	
Mr. Ramstad	X			Mr. Neal		X	
Mr. Nussle	X			Mr. McNulty		X	
Mr. Johnson	X			Mr. Jefferson			
Ms. Dunn	X			Mr. Tanner	X		
Mr. Collins	X			Mr. Becerra	X		
Mr. Portman	X			Mr. Doggett	X		
Mr. English	X			Mr. Pomeroy	X		
Mr. Hayworth	X			Mr. Sandlin			
Mr. Weller	X			Ms. Tubbs Jones			
Mr. Hulshof	X						
Mr. McInnis	X						
Mr. Lewis (KY)	X						
Mr. Foley	X						
Mr. Brady	X						
Mr. Ryan	X						
Mr. Cantor	X						

An amendment by Mr. Doggett, which would amend section 1860D–3(c) of the Social Security Act as proposed to be inserted by section 101, to require each participating manufacturer of a covered outpatient drug to enter into arrangements with prescription drug plan sponsors or entities offering an MA–EFF prescription plan, was defeated by a rollcall vote of 12 yeas to 23 nays The vote was as follows:

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Thomas		X		Mr. Rangel	X		
Mr. Crane		X		Mr. Stark	X		
Mr. Shaw				Mr. Matsui	X		
Mrs. Johnson		X		Mr. Levin	X		
Mr. Houghton		X		Mr. Cardin	X		
Mr. Herger		X		Mr. McDermott	X		
Mr. McCrery		X		Mr. Kleczka	X		
Mr. Camp		X		Mr. Lewis (GA)	X		
Mr. Ramstad		X		Mr. Neal	X		
Mr. Nussle		X		Mr. McNulty	X		
Mr. Johnson		X		Mr. Jefferson			
Ms. Dunn		X		Mr. Tanner			
Mr. Collins		X		Mr. Becerra	X		
Mr. Portman		X		Mr. Doggett	X		
Mr. English		X		Mr. Pomeroy		X	
Mr. Hayworth		X		Mr. Sandlin			
Mr. Weller				Ms. Tubbs Jones			
Mr. Hulshof		X					
Mr. McInnis		X					
Mr. Lewis (KY)		X					
Mr. Foley		X					
Mr. Brady		X					
Mr. Ryan		X					
Mr. Cantor		X					

An en bloc amendment by Mr. Collins, which would add at the end of section 1851(j) of the Social Security Act, as added by section 102(a), to apply fee-for-service Medicare+Choice rules to prescription drug benefits; and as added by section 221(d), to provide the same treatment for premiums for MA private fee-for-service plans,

was agreed to by a rollcall vote of 24 yeas to 12 nays, with 2 voting present. The vote was as follows:

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Thomas	X			Mr. Rangel		X	
Mr. Crane	X			Mr. Stark		X	
Mr. Shaw	X			Mr. Matsui		X	
Mrs. Johnson	X			Mr. Levin		X	
Mr. Houghton	X			Mr. Cardin		X	
Mr. Herger	X			Mr. McDermott		X	
Mr. McCrery	X			Mr. Kleczka			X
Mr. Camp	X			Mr. Lewis (GA)		X	
Mr. Ramstad	X			Mr. Neal		X	
Mr. Nussle	X			Mr. McNulty		X	
Mr. Johnson	X			Mr. Jefferson			
Ms. Dunn	X			Mr. Tanner			
Mr. Collins	X			Mr. Becerra			X
Mr. Portman	X			Mr. Doggett		X	
Mr. English	X			Mr. Pomeroy		X	
Mr. Hayworth	X			Mr. Sandlin			
Mr. Weller	X			Ms. Tubbs Jones		X	
Mr. Hulshof	X						
Mr. McInnis	X						
Mr. Lewis (KY)	X						
Mr. Foley	X						
Mr. Brady	X						
Mr. Ryan	X						
Mr. Cantor	X						

An amendment by Messrs. Nussle and Pomeroy, which would add the following new sections at the end of Title IV: Sec. 416—Adjustment to the Medicare Inpatient Hospital PPS Wage Index to Revise the Labor-Related Share of Such Index; and Sec. 417—Medicare Incentive Payment Program Improvements for Physician Scarcity, was agreed to by a rollcall vote of 39 yeas to 0 nays, with 1 voting present. The vote was as follows:

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Thomas	X			Mr. Rangel	X		
Mr. Crane	X			Mr. Stark			X
Mr. Shaw	X			Mr. Matsui	X		
Mrs. Johnson	X			Mr. Levin	X		
Mr. Houghton	X			Mr. Cardin	X		
Mr. Herger	X			Mr. McDermott	X		
Mr. McCrery	X			Mr. Kleczka	X		
Mr. Camp	X			Mr. Lewis (GA)	X		
Mr. Ramstad	X			Mr. Neal	X		
Mr. Nussle	X			Mr. McNulty	X		
Mr. Johnson	X			Mr. Jefferson	X		
Ms. Dunn	X			Mr. Tanner	X		
Mr. Collins	X			Mr. Becerra	X		
Mr. Portman	X			Mr. Doggett	X		
Mr. English	X			Mr. Pomeroy	X		
Mr. Hayworth	X			Mr. Sandlin			
Mr. Weller	X			Ms. Tubbs Jones	X		
Mr. Hulshof	X						
Mr. McInnis	X						
Mr. Lewis (KY)	X						
Mr. Foley	X						
Mr. Brady	X						
Mr. Ryan	X						
Mr. Cantor	X						

A substitute amendment by Mr. Stark was defeated by a rollcall vote of 14 yeas to 26 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Thomas		X		Mr. Rangel	X		
Mr. Crane		X		Mr. Stark	X		
Mr. Shaw		X		Mr. Matsui	X		
Mrs. Johnson		X		Mr. Levin	X		
Mr. Houghton		X		Mr. Cardin	X		
Mr. Herger		X		Mr. McDermott	X		
Mr. McCrery		X		Mr. Kleczka	X		
Mr. Camp		X		Mr. Lewis (GA)	X		
Mr. Ramstad		X		Mr. Neal	X		
Mr. Nussle		X		Mr. McNulty	X		
Mr. Johnson		X		Mr. Jefferson	X		
Ms. Dunn		X		Mr. Tanner		X	
Mr. Collins		X		Mr. Becerra	X		
Mr. Portman		X		Mr. Doggett	X		
Mr. English		X		Mr. Pomeroy		X	
Mr. Hayworth		X		Mr. Sandlin			
Mr. Weller		X		Ms. Tubbs Jones	X		
Mr. Hulshof		X					
Mr. McInnis		X					
Mr. Lewis (KY)		X					
Mr. Foley		X					
Mr. Brady		X					
Mr. Ryan		X					
Mr. Cantor		X					

IV. BUDGET EFFECTS OF THE BILL

The Congressional Budget Office has not submitted a final score of the legislation at the time of the filing of this report (July 15, 2003).

V. OTHER MATTERS REQUIRED TO BE DISCUSSED UNDER HOUSE RULES

A. Committee Oversight Findings and Recommendations

In compliance with clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee reports that the need for this legislation was confirmed by the oversight hearings of the Subcommittee on Health. The hearings were as follows:

The Subcommittee on Health held a series of hearings on Medicare Reform during the 108th Congress to examine the implications of different proposals aimed at helping seniors gain more affordable access to prescription drugs. A list of these hearings may be found in this report in Section I. Introduction, Part C. Legislative History (Page xx).

B. Summary of General Performance Goals and Objectives

In compliance with clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee states that the primary purpose of H.R. 2473 is to create a prescription drug benefit into the Medicare program while modernizing other aspects of the program.

C. Constitutional Authority Statement

In compliance with clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, relating to constitutional Authority, the Committee states that the Committee's action in reporting the bill is derived from Article I of the Constitution, Section 8 ("The Con-

gress shall have power to lay and collect taxes, duties, imposts, and excises, to pay the debts and to provide for * * * the General Welfare of the United States * * *").

VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

Legislative Counsel has not prepared a Ramseyer at the time of the filing of this report (July 15, 2003).

VII. DISSENTING VIEWS

We oppose the Republican Medicare bill reported by the Committee on Ways and Means. This is not a bill designed to ensure that seniors and people with disabilities get a long overdue Medicare prescription drug benefit that is available and affordable to all. Instead, it is an effort by the Republican Majority to complete their ideological mission to have Medicare "wither on the vine".

Despite the legislation's paltry benefit and fundamentally flawed structure, our committee could have reported a bill supported by a strong bipartisan majority with only two simple changes that we offered as amendments. But Republicans rejected our efforts to find a compromise. This absolute refusal to negotiate reinforces our firm belief that privatizing Medicare is their real goal in this so-called reform effort.

Prescription drug coverage

This legislation has a grossly inadequate drug benefit that was designed to fit into the Republican budget, not the budget of America's elderly and disabled citizens. If the majority hadn't squandered trillions on tax breaks for the wealthy, we would have had more resources to improve this benefit.

Unlike Medicare Part B, where every beneficiary pays the same premium, the premium for prescription drug coverage would not be set in the statute. Although Republicans claim that the premium for this coverage will be $35 per person per month, that is merely a guesstimate. Premiums could be much higher and will vary in different areas of the country and even among plans in the same area. Private insurance premiums in the commercial market are rising at double-digit percentages each year, with most insurers citing prescription drugs as the primary driver. Unstable premiums translate into an unreliable benefit for senior citizens and other Medicare beneficiaries who are living on fixed incomes.

In addition, after the initial coverage limit of $2,000, beneficiaries are forced to pay 100 percent of the cost until total drug spending reaches $4,900, after which the plan will pick up the costs. This patchwork quilt of coverage doesn't exist today in any other public or private plan. Almost half of all beneficiaries—48 percent—will fall into this gap and only 10 percent will have drug needs high enough to get the catastrophic coverage on the other side of the gap. This means that a senior citizen with average drug spending in 2006 would find themselves with coverage for their medications until August, after which they would receive no coverage for the rest of the year while still paying a sizeable premium.

This legislation also would tie the level of benefits to income. The point at which catastrophic coverage would begin would be based on a beneficiary's income. People in the highest category would have no coverage from $2,000 to $13,200 in drug spending. If they

needed more than $13,200 worth of drugs, coverage would begin again. Given that wealthier beneficiaries have already paid more through the payroll taxes during their working years, this double taxation of Medicare benefits should be rejected. Even worse, however, is that this misguided policy would require the IRS and the Department of Health and Human Services (HHS) to share sensitive income data on beneficiaries for the first time. HHS would then have to give information to the plan to indicate the level of the benefit for each beneficiary, a de facto disclosure of income. It appears that beneficiaries who refuse to authorize the sharing of this information might be excluded from the drug coverage. It's an offensive invasion of privacy that undermines the social insurance nature of Medicare and it ought to be rejected.

While Republicans purport to protect those on the lower-ends of the income scale, even those provisions fall far short. Help for even the poorest seniors—those with incomes below $8,980—is contingent on meeting an assets test. This means that they will not get the extra help if they have even modest savings ($4,000 or more). Data suggest that more than one-third of otherwise eligible low-income beneficiaries would be excluded as a result of this hidden hatchet.

Republican Members of the Ways and Means Committee and the President of the United States are fond of saying that Medicare beneficiaries should get the same choices as Members of Congress do with respect to prescription drug coverage. They like to say that as a rhetorical point, but their rhetoric doesn't match the reality of this bill. As Members of Congress, we get our health insurance through the Federal Employees Health Benefits Plan like all federal employees. There isn't a single plan option in FEHBP as bad as the one they're promoting for seniors in Medicare.

We're also very concerned that the Republican Medicare bill will cause employers to drop retiree prescription drug coverage. The Congressional Budget Office informed us at the mark-up that those concerns are real. They estimate that 32% of employers who are currently providing retiree prescription drug benefits will drop that coverage if this bill becomes law as written. That needs to be fixed in this bill as well. We should be using this opportunity to reinforce the better coverage that is out there, not erode it.

While there are many other problems in this legislation, we are also particularly troubled by the fact that it does nothing to guarantee lower prices. In fact, it includes language that actually prohibits the Secretary of Health and Human Services from "interfering" in negotiations between private plans and drug companies. This is an extraordinary prohibition that affects Medicare beneficiaries and taxpayers alike. It is fiscally irresponsible.

Fundamental flaws

All of these are very serious concerns, but we would still be willing to accept this bill as a good faith effort to add a prescription drug benefit to Medicare if Republicans would accept two changes. First, the bill must be amended to include a uniform, defined prescription drug benefit that is universally available through Medicare. Second, the bill must reject proposals to privatize the program. These two changes are critical.

No real Medicare drug benefit

The lack of a uniform nationally available, defined prescription drug benefit in Medicare in the Republican bill is a fundamental flaw. The bill relies solely on private plans to provide the new prescription drug benefit. Unlike every other benefit in Medicare—doctor's visits, hospitalizations, and physical therapy as examples—a beneficiary would not have coverage through Medicare for prescription drugs. Instead, a Medicare enrollee would be "entitled" to purchase a private prescription drug plan at varying prices around the country, provided one was even available—and affordable—in their community. That is not an entitlement at all.

On top of that, we're concerned the bill won't work. Beneficiaries who want to remain in traditional Medicare would theoretically purchase new private drug-only plans; all others would get their prescription drugs through HMOs, PPOs and other managed care plans. The bill would divide the country into regions and would require that beneficiaries have the choice of two private drug plans (only one of which need be a drug-only plan) in each of those regions. But, there is no provision in the bill to account for the possibility that two plans simply won't appear in each region! It may be that no plans appear. As President Bush's Medicare Administrator, Tom Scully, has said, these drug-only plans "don't exist in nature and won't work in practice." We have yet to see any proof from the Republican authors of this program or insurance companies that these plans will materialize. In fact, Wall Street analysts, insurance companies and pharmaceutical benefit managers have cast considerable doubt on this scheme. The legislation would allow the government to try to bribe the plans to participate, but if they turned down that offer, there is no backup plan and beneficiaries would have no place to buy coverage.

Even worse, if two plans do appear, but the HMO offers a more affordable benefit than the drug-only plan, beneficiaries in traditional Medicare may be left with no option but to give up Medicare and enroll in an HMO to get prescription drug coverage. That's wrong. We repeatedly inquired about what would happen in such a situation, but failed to get any suitable answer from the Republicans.

Democratic amendments

Add a guaranteed Medicare benefit. The first key change necessary for us to support the Republican Medicare bill is to provide a guaranteed drug benefit managed by Medicare in the same way that we manage Medicare Part A (hospital services) and Medicare Part B (physician services). We can accept that private plans be allowed to compete to provide Medicare benefits, but only if beneficiaries in traditional Medicare are not disadvantaged as a result. All our amendment would do is add a stable, defined drug benefit in Medicare that is available everywhere in the country. The Republican private plans could still operate as envisioned under this program, but a Medicare option with a national, defined benefit would also be in place in every community, regardless of how many private plans were offering coverage in the area. That's the promise of Medicare today with respect to health services and it should hold true for medications as well.

Republicans shouldn't be threatened by this amendment. If the private sector truly is more efficient and able to offer better options than government-run Medicare, people will leave the traditional Medicare plan and join the private sector options developed in this Republican bill.

This is a sensible amendment that does nothing more than maintain the promise of Medicare since its inception in 1965 and carry that promise into the future. However, Republicans opposed this amendment on a strictly party line basis.

Eliminate privatization of Medicare. The second fundamental concern we have with the Republican bill is its goal to privatize Medicare. Make no mistake about it. The ultimate goal of this bill is to end Medicare's entitlement to defined benefits. Providing a drug benefit to seniors is simply the window dressing. It includes a whole scheme starting in 2010 that will end Medicare as a defined benefit universally available at a uniform price for all of America's seniors and people with disabilities. Instead, seniors' ability to get the health care they need would depend upon their ability to afford a plan that meets their needs. Beneficiaries who need or want to stay in traditional Medicare will have to pay more to do so.

Remember, Medicare was created because the private health care system would not provide affordable health insurance coverage for seniors. We shouldn't be turning back the clock to those times. But that's exactly what the Republican bill—as written—will do.

The Bipartisan Commission on the Future of Medicare already rejected this proposal. At that time, the Medicare Actuary estimated that converting Medicare to a competitive model of this nature would result in premium increases in traditional Medicare of 47%.

Increasing Medicare premiums at that rate would absolutely force seniors to leave the program—they wouldn't be able to afford to stay. They would have to go into the "competitive" side of the program and join HMOs, PPOs or other similar private plans. These private options restrict choice of physicians, hospitals and other providers and enforce limitations that don't exist in traditional Medicare. America's seniors don't want to be forced into private health plans that don't meet their needs and, more importantly, limit their choice of physician and doctor. We won't support any bill that takes away the security of Medicare. This section needs to go. Again, we offered an amendment to eliminate it. We were defeated on a party line vote.

Eliminate sweetheart deal for drug companies. This bill creates a new bureaucracy to work with the private plans. Embedded in the section establishing this new agency is a provision that actually prohibits the Secretary of Health and Human Services from "interfering" in negotiations between private plans and drug companies. This is an unprecedented restriction of authority for a government program of this magnitude. With hundreds of billions of federal dollars at stake, Republicans put their friends in the pharmaceutical industry ahead of taxpayers.

During the anthrax crisis, Secretary Thompson negotiated with the manufacturer of the antibiotic Cipro and cut prices by more than half. The VA negotiates directly for prescription drugs it pur-

chases on behalf of veterans. Even the office that is responsible for the Federal Employees Health Benefits plan does not have its hands tied in this fashion. This is an extraordinary prohibition that affects Medicare beneficiaries and taxpayers alike. We offered an amendment to delete it. But this, too, was defeated on a largely party-line vote.

The Republican bill fails senior citizens

Democrats have supported Medicare from day one—and have consistently worked to improve it. We want a prescription drug benefit added to the program. But, we won't go along with allowing the promise of a drug benefit become the Trojan Horse that ends Medicare as we know it. We are willing to work with House Republicans on a more limited benefit than we know is needed, but they have to be willing to protect the promise of Medicare. The bill reported out of our Committee fails that test, and is a bad deal for America's senior citizens and the individuals with disabilities who depend on Medicare.

C. B. RANGEL.
ROBERT T. MATSUI.
JIM MCDERMOTT.
WILLIAM J. JEFFERSON.
STEPHANIE TUBBS JONES.
SANDER LEVIN.
BEN CARDIN.
MAX SANDLIN.
PETE STARK.
MIKE MCNULTY.
JOHN TANNER.
XAVIER BECERRA.
RICHARD E. NEAL.
JERRY KLECZKA.
JOHN LEWIS.

○

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SECURITY ACT; REFERENCES TO BIPA AND SECRETARY; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Medicare Prescription Drug and Modernization Act of 2003".

(b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as otherwise specifically provided, whenever in this Act an amendment is expressed in terms of an amendment to or repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Social Security Act.

(c) BIPA; SECRETARY.—In this Act:

(1) BIPA.—The term "BIPA" means the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, as enacted into law by section 1(a)(6) of Public Law 106–554.

(2) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(d) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

SEC. 101. ESTABLISHMENT OF A MEDICARE PRESCRIPTION DRUG BENEFIT.

(a) IN GENERAL.—Title XVIII is amended—

(1) by redesignating part D as part F; and

(2) by inserting after part C the following new part:

"PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

"SEC. 1860D–1. BENEFITS; ELIGIBILITY; ENROLLMENT; AND COVERAGE PERIOD.

"(a) PROVISION OF QUALIFIED PRESCRIPTION DRUG COVERAGE THROUGH ENROLLMENT IN PLANS.—Subject to the succeeding provisions of this part, each individual who is entitled to benefits under part A or is enrolled under part B is entitled to obtain qualified prescription drug coverage (described in section 1860D–2(a)) as follows:

"(1) MEDICARE-RELATED PLANS.—

"(A) MEDICARE ADVANTAGE.—If the individual is eligible to enroll in a Medicare Advantage plan that provides qualified prescription drug coverage under section 1851(j), the individual may enroll in such plan and obtain coverage through such plan.

"(B) EFFS PLANS.—If the individual is eligible to enroll in an EFFS plan that provides qualified prescription drug coverage under part E under section 1860E–2(d), the individual may enroll in such plan and obtain coverage through such plan.

"(C) MA-EFFS PLAN; MA-EFFS RX PLAN.—For purposes of this part, the term 'MA-EFFS plan' means a Medicare Advantage plan under part C and an EFFS plan under part E and the term 'MA-EFFS Rx plan' means a MA-EFFS plan insofar as such plan provides qualified prescription drug coverage.

"(2) PRESCRIPTION DRUG PLAN.—If the individual is not enrolled in a MA-EFFS plan , the individual may enroll under this part in a prescription drug plan (as defined in section 1860D–10(a)(5)).

Such individuals shall have a choice of such plans under section 1860D–5(d).

"(b) GENERAL ELECTION PROCEDURES.—

"(1) IN GENERAL.—An individual eligible to make an election under subsection (a) may elect to enroll in a prescription drug plan under this part, or elect the option of qualified prescription drug coverage under a MA-EFFS Rx plan under part C or part E, and to change such election only in such manner and form as may be prescribed by regulations of the Administrator of the Medicare Benefits Administration (appointed under section 1809(b)) (in this part referred to as the 'Medicare Benefits Administrator') and only during an election period prescribed in or under this subsection.

"(2) ELECTION PERIODS.—

"(A) IN GENERAL.—Except as provided in this paragraph, the election periods under this subsection shall be the same as the coverage election periods under the Medicare Advantage and EFFS programs under section 1851(e), including—

"(i) annual coordinated election periods; and

"(ii) special election periods.

In applying the last sentence of section 1851(e)(4) (relating to discontinuance of an election during the first year of eligibility) under this subparagraph, in the case of an election described in such section in which the individual had elected or is provided qualified prescription drug coverage at the time of such first enrollment, the individual shall be permitted to enroll in a prescription drug plan under this part at the time of the election of coverage under the original fee-for-service plan.

"(B) INITIAL ELECTION PERIODS.—

"(i) INDIVIDUALS CURRENTLY COVERED.—In the case of an individual who is entitled to benefits under part A or enrolled under part B as of October 1, 2005, there shall be an initial election period of 6 months beginning on that date.

"(ii) INDIVIDUAL COVERED IN FUTURE.—In the case of an individual who is first entitled to benefits under part A or enrolled under part B after such date, there shall be an initial election period which is the same as the initial enrollment period under section 1837(d).

"(C) ADDITIONAL SPECIAL ELECTION PERIODS.—The Administrator shall establish special election periods—

"(i) in cases of individuals who have and involuntarily lose prescription drug coverage described in subsection (c)(2)(C);

"(ii) in cases described in section 1837(h) (relating to errors in enrollment), in the same manner as such section applies to part B;

"(iii) in the case of an individual who meets such exceptional conditions (including conditions provided under section 1851(e)(4)(D)) as the Administrator may provide; and

"(iv) in cases of individuals (as determined by the Administrator) who become eligible for prescription drug assistance under title XIX under section 1935(d).

"(3) INFORMATION ON PLANS.—Information described in section 1860D–3(b)(1) on prescription drug plans shall be made available during election periods.

"(c) GUARANTEED ISSUE; COMMUNITY RATING; AND NONDISCRIMINATION.—

"(1) GUARANTEED ISSUE.—

"(A) IN GENERAL.—An eligible individual who is eligible to elect qualified prescription drug coverage under a prescription drug plan or MA-EFFS Rx plan at a time during which elections are accepted under this part with respect to the plan shall not be denied enrollment based on any health status-related factor (described in section 2702(a)(1) of the Public Health Service Act) or any other factor.

"(B) MEDICARE ADVANTAGE LIMITATIONS PERMITTED.—The provisions of paragraphs (2) and (3) (other than subparagraph (C)(i), relating to default enrollment) of section 1851(g) (relating to priority and limitation on termination of election) shall apply to PDP sponsors under this subsection.

"(2) COMMUNITY-RATED PREMIUM.—

"(A) IN GENERAL.—In the case of an individual who enrolls under a prescription drug plan or in a MA-EFFS Rx plan during the individual's initial enrollment period under this part or maintains (as determined under subparagraph (C)) continuous prescription drug coverage since the date the individual first qualifies to elect prescription drug coverage under this part, a PDP sponsor or entity offering a prescription drug plan or MA-EFFS Rx plan and in which the individual is enrolled may not deny, limit, or condition the coverage or provision of covered prescription drug benefits or vary or increase the premium under the plan based on any health status-related factor described in section 2702(a)(1) of the Public Health Service Act or any other factor.

"(B) LATE ENROLLMENT PENALTY.—In the case of an individual who does not maintain such continuous prescription drug coverage (as described in subparagraph (C)), a PDP sponsor or an entity offering a MA-EFFS Rx plan may (notwithstanding any provision in this title) adjust the premium otherwise applicable or impose a pre-existing condition exclusion with respect to qualified prescription drug coverage in a manner that reflects additional actuarial risk involved. Such a risk shall be established through an appropriate actuarial opinion of the type described in subparagraphs (A) through (C) of section 2103(c)(4).

"(C) CONTINUOUS PRESCRIPTION DRUG COVERAGE.—An individual is considered for purposes of this part to be maintaining continuous prescription drug coverage on and after the date the individual first qualifies to elect prescription drug coverage under this part if the individual establishes that as of such date the individual is covered under any of the following prescription drug coverage and before the date that is the last day of the 63-day period that begins on the date of termination of the particular prescription drug coverage involved (regardless of whether the individual subsequently obtains any of the following prescription drug coverage):

"(i) COVERAGE UNDER PRESCRIPTION DRUG PLAN OR MA-EFFS RX PLAN.—Qualified prescription drug coverage under a prescription drug plan or under a MA-EFFS Rx plan.

"(ii) MEDICAID PRESCRIPTION DRUG COVERAGE.—Prescription drug coverage under a medicaid plan under title XIX, including through the Program of All-inclusive Care for the Elderly (PACE) under section 1934, through a social health maintenance organization (referred to in section 4104(c) of the Balanced Budget Act of 1997), or through a demonstration project under part C that demonstrates the application of capitation payment rates for frail elderly medicare beneficiaries through the use of an interdisciplinary team and through the provision of primary care services to such beneficiaries by means of such a team at the nursing facility involved.

"(iii) PRESCRIPTION DRUG COVERAGE UNDER GROUP HEALTH PLAN.—Any outpatient prescription drug coverage under a group health plan, including a health benefits plan under the Federal Employees Health Benefit Plan under chapter 89 of title 5, United States Code, and a qualified retiree prescription drug plan as defined in section 1860D–8(f)(1), but only if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

"(iv) PRESCRIPTION DRUG COVERAGE UNDER CERTAIN MEDIGAP POLICIES.—Coverage under a medicare supplemental policy under section 1882 that provides benefits for prescription drugs (whether or not such coverage conforms to the standards for packages of benefits under section 1882(p)(1)), but only if the policy was in effect on January 1, 2006, and if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

"(v) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—Coverage of prescription drugs under a State pharmaceutical assistance program, but only if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

"(vi) VETERANS' COVERAGE OF PRESCRIPTION DRUGS.—Coverage of prescription drugs for veterans under chapter 17 of title 38, United States Code, but only if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

"(D) CERTIFICATION.—For purposes of carrying out this paragraph, the certifications of the type described in sections 2701(e) of the Public Health Service Act and in section 9801(e) of the Internal Revenue Code shall also include a statement for the period of coverage of whether the individual involved had prescription drug coverage described in subparagraph (C).

"(E) DISCLOSURE.—

"(i) IN GENERAL.—Each entity that offers coverage of the type described in clause (iii), (iv), (v), or (vi) of subparagraph (C) shall provide for disclosure, consistent with standards established by the Administrator, of whether such coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

"(ii) WAIVER OF LIMITATIONS.—An individual may apply to the Administrator to waive the requirement that coverage of such type provide benefits at least equivalent to the benefits under a qualified prescription drug plan, if the individual establishes that the individual was not adequately informed that such coverage did not provide such level of benefits.

"(F) CONSTRUCTION.—Nothing in this section shall be construed as preventing the disenrollment of an individual from a prescription drug plan or a MA-EFFS Rx plan based on the termination of an election described in section 1851(g)(3), including for non-payment of premiums or for other reasons specified in subsection (d)(3), which takes into account a grace period described in section 1851(g)(3)(B)(i).

"(3) NONDISCRIMINATION.—A PDP sponsor that offers a prescription drug plan in an area designated under section 1860D–4(b)(5) shall make such plan available to all eligible individuals residing in the area without regard to their health or economic status or their place of residence within the area.

"(d) EFFECTIVE DATE OF ELECTIONS.—

"(1) IN GENERAL.—Except as provided in this section, the Administrator shall provide that elections under subsection (b) take effect at the same time as the Administrator provides that similar elections under section 1851(e) take effect under section 1851(f).

"(2) NO ELECTION EFFECTIVE BEFORE 2006.—In no case shall any election take effect before January 1, 2006.

"(3) TERMINATION.—The Administrator shall provide for the termination of an election in the case of—

"(A) termination of coverage under both part A and part B; and

"(B) termination of elections described in section 1851(g)(3) (including failure to pay required premiums).

"SEC. 1860D–2. REQUIREMENTS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.

"(a) REQUIREMENTS.—

"(1) IN GENERAL.—For purposes of this part and part C and part E, the term 'qualified prescription drug coverage' means either of the following:

"(A) STANDARD COVERAGE WITH ACCESS TO NEGOTIATED PRICES.—Standard coverage (as defined in subsection (b)) and access to negotiated prices under subsection (d).

"(B) ACTUARIALLY EQUIVALENT COVERAGE WITH ACCESS TO NEGOTIATED PRICES.—Coverage of covered outpatient drugs which meets the alternative coverage requirements of subsection (c) and access to negotiated prices

under subsection (d), but only if it is approved by the Administrator, as provided under subsection (c).

"(2) PERMITTING ADDITIONAL OUTPATIENT PRESCRIPTION DRUG COVERAGE.—

"(A) IN GENERAL.—Subject to subparagraph (B), nothing in this part shall be construed as preventing qualified prescription drug coverage from including coverage of covered outpatient drugs that exceeds the coverage required under paragraph (1), but any such additional coverage shall be limited to coverage of covered outpatient drugs.

"(B) DISAPPROVAL AUTHORITY.—The Administrator shall review the offering of qualified prescription drug coverage under this part or part C or E. If the Administrator finds, in the case of a qualified prescription drug coverage under a prescription drug plan or a MA-EFFS Rx plan, that the organization or sponsor offering the coverage is engaged in activities intended to discourage enrollment of classes of eligible medicare beneficiaries obtaining coverage through the plan on the basis of their higher likelihood of utilizing prescription drug coverage, the Administrator may terminate the contract with the sponsor or organization under this part or part C or E.

"(3) APPLICATION OF SECONDARY PAYOR PROVISIONS.—The provisions of section 1852(a)(4) shall apply under this part in the same manner as they apply under part C.

"(b) STANDARD COVERAGE.—For purposes of this part, the 'standard coverage' is coverage of covered outpatient drugs (as defined in subsection (f)) that meets the following requirements:

"(1) DEDUCTIBLE.—The coverage has an annual deductible—

"(A) for 2006, that is equal to $250; or

"(B) for a subsequent year, that is equal to the amount specified under this paragraph for the previous year increased by the percentage specified in paragraph (5) for the year involved.

Any amount determined under subparagraph (B) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

"(2) 80:20 BENEFIT STRUCTURE.—

"(A) 20 PERCENT COINSURANCE.—The coverage has cost-sharing (for costs above the annual deductible specified in paragraph (1) and up to the initial coverage limit under paragraph (3)) that is—

"(i) equal to 20 percent; or

"(ii) is actuarially equivalent (using processes established under subsection (e)) to an average expected payment of 20 percent of such costs.

"(B) USE OF TIERS.—Nothing in this part shall be construed as preventing a PDP sponsor from applying tiered copayments, so long as such tiered copayments are consistent with subparagraph (A).

"(3) INITIAL COVERAGE LIMIT.—Subject to paragraph (4), the coverage has an initial coverage limit on the maximum costs that may be recognized for payment purposes—

"(A) for 2006, that is equal to $2,000; or

"(B) for a subsequent year, that is equal to the amount specified in this paragraph for the previous year, increased by the annual percentage increase described in paragraph (5) for the year involved.

Any amount determined under subparagraph (B) that is not a multiple of $25 shall be rounded to the nearest multiple of $25.

"(4) CATASTROPHIC PROTECTION.—

"(A) IN GENERAL.—Notwithstanding paragraph (3), the coverage provides benefits with no cost-sharing after the individual has incurred costs (as described in subparagraph (C)) for covered outpatient drugs in a year equal to the annual out-of-pocket threshold specified in subparagraph (B).

"(B) ANNUAL OUT-OF-POCKET THRESHOLD.—

"(i) IN GENERAL.—For purposes of this part, the 'annual out-of-pocket threshold' specified in this subparagraph is equal to $3,500 (subject to adjustment under clause (ii) and subparagraph (D)).

"(ii) INFLATION INCREASE.—For a year after 2006, the dollar amount specified in clause (i) shall be increased by the annual percentage increase described in paragraph (5) for the year involved. Any amount determined under the previous sentence that is not a multiple of $100 shall be rounded to the nearest multiple of $100.

"(C) APPLICATION.—In applying subparagraph (A)—

"(i) incurred costs shall only include costs incurred for the annual deductible (described in paragraph (1)), cost-sharing (described in paragraph (2)), and amounts for which benefits are not provided because of the application of the initial coverage limit described in paragraph (3); and

"(ii) such costs shall be treated as incurred only if they are paid by the individual (or by another individual, such as a family member, on behalf of the individual), under section 1860D–7, under title XIX, or under a State pharmaceutical assistance program and the individual (or other individual) is not reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement (other than under such title or such program) for such costs.

"(D) ADJUSTMENT OF ANNUAL OUT-OF-POCKET THRESHOLDS.—

"(i) IN GENERAL.—For each enrollee in a prescription drug plan or in a MA-EFFS Rx plan whose adjusted gross income exceeds the income threshold as defined in clause (ii) for a year, the annual out-of-pocket threshold otherwise determined under subparagraph (B) for such year shall be increased by an amount equal to the percentage specified in clause (iii), multiplied by the lesser of—

"(I) the amount of such excess; or

"(II) the amount by which the income threshold limit exceeds the income threshold.

Any amount determined under the previous sentence that is not a multiple of $100 shall be rounded to the nearest multiple of $100.

"(ii) INCOME THRESHOLD.—For purposes of clause (i)—

"(I) IN GENERAL.—Subject to subclause (II), the term 'income threshold' means $60,000 and the term 'income threshold limit' means $200,000.

"(II) INCOME INFLATION ADJUSTMENT.—In the case of a year beginning after 2006, each of the dollar amounts in subclause (I) shall be increased by an amount equal to such dollar amount multiplied by the cost-of-living adjustment determined under section 1(f)(3) of the Internal Revenue Code of 1986 for such year, determined by substituting 'calendar year 2005' for 'calendar year 1992'. If any amount increased under the previous sentence is not a multiple of $100, such amount shall be rounded to the nearest multiple of $100.

"(iii) PERCENTAGE.—The percentage specified in this clause for a year is a fraction (expressed as a percentage) equal to—

"(I) the annual out-of-pocket threshold for a year under subparagraph (B) (determined without regard to this subparagraph), divided by

"(II) the income threshold under clause (ii) for that year.

If any percentage determined under the previous sentence that is not a multiple of 1/10th of 1 percentage point, such percentage shall be rounded to the nearest multiple of 1/10th of 1 percentage point.

"(iv) USE OF MOST RECENT RETURN INFORMATION.—For purposes of clause (i) for an enrollee for a year, except as provided in clause (v), the adjusted gross income of an individual shall be based on the most recent information disclosed to the Secretary under section 6109(l)(19) of the Internal Revenue Code of 1986 before the beginning of that year.

"(v) INDIVIDUAL ELECTION TO PRESENT MOST RECENT INFORMATION REGARDING INCOME.—The Secretary shall provide, in coordination with the Secretary of the Treasury, a procedure under which, for purposes of applying this subparagraph for a calendar year, instead of using the information described in clause (iv), an enrollee may elect to use more recent information, including information with respect to a taxable year ending in such calendar year. Such process shall—

"(I) require the enrollee to provide the Secretary with a copy of the relevant portion of the more recent return to be used under this clause;

"(II) provide for the Medicare Beneficiary Ombudsman (under section 1810) offering assistance to such enrollees in presenting such information and the toll-free number under such section being a point of contact for beneficiaries to inquire as to how to present such information;

"(III) provide for the verification of the information in such return by the Secretary of the Treasury under section 6103(l)(19) of the Internal Revenue Code of 1986; and

"(IV) provide for the payment by the Secretary (in a manner specified by the Secretary) to the enrollee of an amount equal to the excess of the benefit payments that would have been payable under the plan if the more recent return information were used, over the benefit payments that were made under the plan.

In the case of a payment under subclause (III) for an enrollee under a prescription drug plan, the PDP sponsor of the plan shall pay to the Secretary the amount so paid, less the applicable reinsurance amount that would have applied under section 1860D–8(c)(1)(B) if such payment had been treated as an allowable cost under such section. Such plan payment shall be deposited in the Treasury to the credit of the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund (under section 1841).

"(vi) DISSEMINATION OF INFORMATION ON PROCESS.—The Secretary shall provide, through the annual medicare handbook under section 1804(a), for a general description of the adjustment of annual out-of-pocket thresholds provided under this subparagraph, including the process for adjustment based upon more recent information and the confidentiality provisions of subparagraph (F), and shall provide for dissemination of a table for each year that sets forth the amount of the adjustment that is made under clause (i) based on the amount of an enrollee's adjusted gross income.

"(E) REQUESTING INFORMATION ON ENROLLEES.—

"(i) IN GENERAL.—The Secretary shall, periodically as required to carry out subparagraph (D), transmit to the Secretary of the Treasury a list of the names and TINs of enrollees in prescription drug plans (or in MA-EFFS Rx plans) and request that such Secretary disclose to the Secretary information under subparagraph (A) of section 6103(l)(19) of the Internal Revenue Code of 1986 with respect to those enrollees for a specified taxable year for application in a particular calendar year.

"(ii) DISCLOSURE TO PLAN SPONSORS.—In the case of a specified taxpayer (as defined in section 6103(l)(19)(B) of the Internal Revenue Code of 1986) who is enrolled in a prescription drug plan or in an MA-EFFS Rx plan, the Secretary shall disclose to the entity that offers the plan the annual out-of-pocket threshold applicable to such individual under subparagraph (D).

"(F) MAINTAINING CONFIDENTIALITY OF INFORMATION.—

"(i) IN GENERAL.—The amount of any increase in an annual out-of-pocket threshold under subparagraph (D) may not be disclosed by the Secretary except to a PDP sponsor or entity that offers a MA-EFFS Rx plan to the extent necessary to carry out this part.

"(ii) CRIMINAL AND CIVIL PENALTIES FOR UNAUTHORIZED DISCLOSURE.—A person who makes an unauthorized disclosure of information disclosed under section 6103(l)(19) of the Internal Revenue Code of 1986 (including disclosure of any increase in an annual out-of-pocket threshold under subparagraph (D)) shall be subject to penalty to the extent provided under—

"(I) section 7213 of such Code (relating to criminal penalty for unauthorized disclosure of information);

"(II) section 7213A of such Code (relating to criminal penalty for unauthorized inspection of returns or return information);

"(III) section 7431 of such Code (relating to civil damages for unauthorized inspection or disclosure of returns and return information);

"(IV) any other provision of the Internal Revenue Code of 1986; or

"(V) any other provision of law.

"(iii) APPLICATION OF ADDITIONAL CIVIL MONETARY PENALTY FOR UNAUTHORIZED DISCLOSURES.—In addition to any penalty otherwise provided under law, any person who makes an unauthorized disclosure of such information shall be subject to a civil monetary penalty of not to exceed $10,000 for each such unauthorized disclosure. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under section 1128A(a).

"(5) ANNUAL PERCENTAGE INCREASE.—For purposes of this part, the annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in average per capita aggregate expenditures for covered outpatient drugs in the United States for medicare beneficiaries, as determined by the Administrator for the 12-month period ending in July of the previous year.

"(c) ALTERNATIVE COVERAGE REQUIREMENTS.—A prescription drug plan or MA-EFFS Rx plan may provide a different prescription drug benefit design from the standard coverage described in subsection (b) so long as the Administrator deter-

mines (based on an actuarial analysis by the Administrator) that the following requirements are met and the plan applies for, and receives, the approval of the Administrator for such benefit design:

"(1) ASSURING AT LEAST ACTUARIALLY EQUIVALENT COVERAGE.—

"(A) ASSURING EQUIVALENT VALUE OF TOTAL COVERAGE.—The actuarial value of the total coverage (as determined under subsection (e)) is at least equal to the actuarial value (as so determined) of standard coverage.

"(B) ASSURING EQUIVALENT UNSUBSIDIZED VALUE OF COVERAGE.—The unsubsidized value of the coverage is at least equal to the unsubsidized value of standard coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage (as determined under subsection (e)) exceeds the actuarial value of the subsidy payments under section 1860D–8 with respect to such coverage.

"(C) ASSURING STANDARD PAYMENT FOR COSTS AT INITIAL COVERAGE LIMIT.—The coverage is designed, based upon an actuarially representative pattern of utilization (as determined under subsection (e)), to provide for the payment, with respect to costs incurred that are equal to the initial coverage limit under subsection (b)(3), of an amount equal to at least the product of—

"(i) the amount by which the initial coverage limit described in subsection (b)(3) exceeds the deductible described in subsection (b)(1); and

"(ii) 100 percent minus the cost-sharing percentage specified in subsection (b)(2)(A)(i).

"(2) CATASTROPHIC PROTECTION.—The coverage provides for beneficiaries the catastrophic protection described in subsection (b)(4).

"(d) ACCESS TO NEGOTIATED PRICES.—

"(1) IN GENERAL.—Under qualified prescription drug coverage offered by a PDP sponsor or an entity offering a MA-EFFS Rx plan, the sponsor or entity shall provide beneficiaries with access to negotiated prices (including applicable discounts) used for payment for covered outpatient drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of cost-sharing or an initial coverage limit (described in subsection (b)(3)). Insofar as a State elects to provide medical assistance under title XIX to a beneficiary enrolled under such title and under a prescription drug plan or MA-EFFS Rx plan for a drug based on the prices negotiated by a prescription drug plan or MA-EFFS Rx plan under this part, the requirements of section 1927 shall not apply to such drugs. The prices negotiated by a prescription drug plan under this part, by a MA-EFFS Rx plan with respect to covered outpatient drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D–8(f)(1)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B, shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).

"(2) DISCLOSURE.—The PDP sponsor or entity offering a MA-EFFS Rx plan shall disclose to the Administrator (in a manner specified by the Administrator) the extent to which discounts or rebates or other remuneration or price concessions made available to the sponsor or organization by a manufacturer are passed through to enrollees through pharmacies and other dispensers or otherwise. The provisions of section 1927(b)(3)(D) shall apply to information disclosed to the Administrator under this paragraph in the same manner as such provisions apply to information disclosed under such section.

"(3) AUDITS AND REPORTS.—To protect against fraud and abuse and to ensure proper disclosures and accounting under this part, in addition to any protections against fraud and abuse provided under section 1860D–4(b)(3)(C), the Administrator may periodically audit the financial statements and records of PDP sponsor or entities offering a MA-EFFS Rx plan.

"(e) ACTUARIAL VALUATION; DETERMINATION OF ANNUAL PERCENTAGE INCREASES.—

"(1) PROCESSES.—For purposes of this section, the Administrator shall establish processes and methods—

"(A) for determining the actuarial valuation of prescription drug coverage, including—

"(i) an actuarial valuation of standard coverage and of the reinsurance subsidy payments under section 1860D–8;

"(ii) the use of generally accepted actuarial principles and methodologies; and

"(iii) applying the same methodology for determinations of alternative coverage under subsection (c) as is used with respect to determinations of standard coverage under subsection (b); and

"(B) for determining annual percentage increases described in subsection (b)(5).

"(2) USE OF OUTSIDE ACTUARIES.—Under the processes under paragraph (1)(A), PDP sponsors and entities offering MA-EFFS Rx plans may use actuarial opinions certified by independent, qualified actuaries to establish actuarial values, but the Administrator shall determine whether such actuarial values meet the requirements under subsection (c)(1).

"(f) COVERED OUTPATIENT DRUGS DEFINED.—

"(1) IN GENERAL.—Except as provided in this subsection, for purposes of this part, the term 'covered outpatient drug' means—

"(A) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i) or (A)(ii) of section 1927(k)(2); or

"(B) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section,

and such term includes a vaccine licensed under section 351 of the Public Health Service Act and any use of a covered outpatient drug for a medically accepted indication (as defined in section 1927(k)(6)).

"(2) EXCLUSIONS.—

"(A) IN GENERAL.—Such term does not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2), other than subparagraph (E) thereof (relating to smoking cessation agents), or under section 1927(d)(3).

"(B) AVOIDANCE OF DUPLICATE COVERAGE.—A drug prescribed for an individual that would otherwise be a covered outpatient drug under this part shall not be so considered if payment for such drug is available under part A or B for an individual entitled to benefits under part A and enrolled under part B.

"(3) APPLICATION OF FORMULARY RESTRICTIONS.—A drug prescribed for an individual that would otherwise be a covered outpatient drug under this part shall not be so considered under a plan if the plan excludes the drug under a formulary and such exclusion is not successfully appealed under section 1860D–3(f)(2).

"(4) APPLICATION OF GENERAL EXCLUSION PROVISIONS.—A prescription drug plan or MA-EFFS Rx plan may exclude from qualified prescription drug coverage any covered outpatient drug—

"(A) for which payment would not be made if section 1862(a) applied to part D; or

"(B) which are not prescribed in accordance with the plan or this part.

Such exclusions are determinations subject to reconsideration and appeal pursuant to section 1860D–3(f).

"SEC. 1860D–3. BENEFICIARY PROTECTIONS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.

"(a) GUARANTEED ISSUE, COMMUNITY-RATED PREMIUMS, ACCESS TO NEGOTIATED PRICES, AND NONDISCRIMINATION.—For provisions requiring guaranteed issue, community-rated premiums, access to negotiated prices, and nondiscrimination, see sections 1860D–1(c)(1), 1860D–1(c)(2), 1860D–2(d), and 1860D–6(b), respectively.

"(b) DISSEMINATION OF INFORMATION.—

"(1) GENERAL INFORMATION.—A PDP sponsor shall disclose, in a clear, accurate, and standardized form to each enrollee with a prescription drug plan offered by the sponsor under this part at the time of enrollment and at least annually thereafter, the information described in section 1852(c)(1) relating to such plan. Such information includes the following:

"(A) Access to specific covered outpatient drugs, including access through pharmacy networks.

"(B) How any formulary used by the sponsor functions, including the drugs included in the formulary.

"(C) Co-payments and deductible requirements, including the identification of the tiered or other co-payment level applicable to each drug (or class of drugs).

"(D) Grievance and appeals procedures.

Such information shall also be made available upon request to prospective enrollees.

"(2) DISCLOSURE UPON REQUEST OF GENERAL COVERAGE, UTILIZATION, AND GRIEVANCE INFORMATION.—Upon request of an individual eligible to enroll under a prescription drug plan, the PDP sponsor shall provide the information described in section 1852(c)(2) (other than subparagraph (D)) to such individual.

"(3) RESPONSE TO BENEFICIARY QUESTIONS.—Each PDP sponsor offering a prescription drug plan shall have a mechanism for providing specific information

to enrollees upon request. The sponsor shall make available on a timely basis, through an Internet website and in writing upon request, information on specific changes in its formulary.

"(4) CLAIMS INFORMATION.—Each PDP sponsor offering a prescription drug plan must furnish to each enrollee in a form easily understandable to such enrollees an explanation of benefits (in accordance with section 1806(a) or in a comparable manner) and a notice of the benefits in relation to initial coverage limit and the annual out-of-pocket threshold applicable to such enrollee for the current year, whenever prescription drug benefits are provided under this part (except that such notice need not be provided more often than monthly).

"(c) ACCESS TO COVERED BENEFITS.—

"(1) ASSURING PHARMACY ACCESS.—

"(A) PARTICIPATION OF ANY WILLING PHARMACY.—A PDP sponsor and an entity offering a MA-EFFS Rx plan shall permit the participation of any pharmacy that meets terms and conditions that the plan has established.

"(B) DISCOUNTS ALLOWED FOR NETWORK PHARMACIES.—A prescription drug plan and a MA-EFFS Rx plan may, notwithstanding subparagraph (A), reduce coinsurance or copayments for its enrolled beneficiaries below the level otherwise provided for covered outpatient drugs dispensed through in-network pharmacies, but in no case shall such a reduction result in an increase in payments made by the Administrator under section 1860D–8 to a plan.

"(C) CONVENIENT ACCESS FOR NETWORK PHARMACIES.—The PDP sponsor of the prescription drug plan and the entity offering a MA-EFFS Rx plan shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules of the Administrator). The Administrator shall establish convenient access rules under this subparagraph that are no less favorable to enrollees than the rules for convenient access to pharmacies of the Secretary of Defense established as of June 1, 2003, for purposes of the TRICARE Retail Pharmacy (TRRx) program. Such rules shall include adequate emergency access for enrolled beneficiaries.

"(D) LEVEL PLAYING FIELD.—Such a sponsor shall permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a community pharmacy, rather than through mail order, with any differential in cost paid by such enrollees.

"(E) NOT REQUIRED TO ACCEPT INSURANCE RISK.—The terms and conditions under subparagraph (A) may not require participating pharmacies to accept insurance risk as a condition of participation.

"(2) USE OF STANDARDIZED TECHNOLOGY.—

"(A) IN GENERAL.—The PDP sponsor of a prescription drug plan and an entity offering a MA-EFFS Rx plan shall issue (and reissue, as appropriate) such a card (or other technology) that may be used by an enrollee to assure access to negotiated prices under section 1860D–2(d) for the purchase of prescription drugs for which coverage is not otherwise provided under the plan.

"(B) STANDARDS.—

"(i) DEVELOPMENT.—The Administrator shall provide for the development or utilization of uniform standards relating to a standardized format for the card or other technology referred to in subparagraph (A). Such standards shall be compatible with standards established under part C of title XI.

"(ii) APPLICATION OF ADVISORY TASK FORCE.—The advisory task force established under subsection (d)(3)(B)(ii) shall provide recommendations to the Administrator under such subsection regarding the standards developed under clause (i).

"(3) REQUIREMENTS ON DEVELOPMENT AND APPLICATION OF FORMULARIES.—If a PDP sponsor of a prescription drug plan or an entity offering a MA-EFFS Rx plan uses a formulary, the following requirements must be met:

"(A) PHARMACY AND THERAPEUTIC (P&T) COMMITTEE.—The sponsor or entity must establish a pharmacy and therapeutic committee that develops and reviews the formulary. Such committee shall include at least one practicing physician and at least one practicing pharmacist independent and free of conflict with respect to the committee both with expertise in the care of elderly or disabled persons and a majority of its members shall consist of individuals who are practicing physicians or practicing pharmacists (or both).

"(B) FORMULARY DEVELOPMENT.—In developing and reviewing the formulary, the committee shall—

"(i) base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and such other information as the committee determines to be appropriate; and

"(ii) shall take into account whether including in the formulary particular covered outpatient drugs has therapeutic advantages in terms of safety and efficacy.

"(C) INCLUSION OF DRUGS IN ALL THERAPEUTIC CATEGORIES.—The formulary must include drugs within each therapeutic category and class of covered outpatient drugs (although not necessarily for all drugs within such categories and classes). In establishing such classes, the committee shall take into account the standards published in the United States Pharmacopeia-Drug Information. The committee shall make available to the enrollees under the plan through the Internet or otherwise the bases for the exclusion of coverage of any drug from the formulary.

"(D) PROVIDER AND PATIENT EDUCATION.—The committee shall establish policies and procedures to educate and inform health care providers and enrollees concerning the formulary.

"(E) NOTICE BEFORE REMOVING DRUG FROM FORMULARY FOR CHANGING PREFERRED OR TIER STATUS OF DRUG.—Any removal of a covered outpatient drug from a formulary and any change in the preferred or tier cost-sharing status of such a drug shall take effect only after appropriate notice is made available to beneficiaries and physicians.

"(F) PERIODIC EVALUATION OF PROTOCOLS.—In connection with the formulary, a prescription drug plan shall provide for the periodic evaluation and analysis of treatment protocols and procedures.

"(G) GRIEVANCES AND APPEALS RELATING TO APPLICATION OF FORMULARIES.—For provisions relating to grievances and appeals of coverage, see subsections (e) and (f).

"(d) COST AND UTILIZATION MANAGEMENT; QUALITY ASSURANCE; MEDICATION THERAPY MANAGEMENT PROGRAM.—

"(1) IN GENERAL.—The PDP sponsor or entity offering a MA-EFFS Rx plan shall have in place, directly or through appropriate arrangements, with respect to covered outpatient drugs—

"(A) an effective cost and drug utilization management program, including medically appropriate incentives to use generic drugs and therapeutic interchange, when appropriate;

"(B) quality assurance measures and systems to reduce medical errors and adverse drug interactions, including side-effects, and improve medication use, including a medication therapy management program described in paragraph (2) and for years beginning with 2007, an electronic prescription program described in paragraph (3); and

"(C) a program to control fraud, abuse, and waste.

Nothing in this section shall be construed as impairing a PDP sponsor or entity from utilizing cost management tools (including differential payments) under all methods of operation.

"(2) MEDICATION THERAPY MANAGEMENT PROGRAM.—

"(A) IN GENERAL.—A medication therapy management program described in this paragraph is a program of drug therapy management and medication administration that may be furnished by a pharmacy provider and that is designed to assure, with respect to beneficiaries at risk for potential medication problems, such as beneficiaries with complex or chronic diseases (such as diabetes, asthma, hypertension, and congestive heart failure) or multiple prescriptions, that covered outpatient drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use and reduce the risk of adverse events, including adverse drug interactions. Such programs may distinguish between services in ambulatory and institutional settings.

"(B) ELEMENTS.—Such program may include—

"(i) enhanced beneficiary understanding to promote the appropriate use of medications by beneficiaries and to reduce the risk of potential adverse events associated with medications, through beneficiary education, counseling, case management, disease state management programs, and other appropriate means;

"(ii) increased beneficiary adherence with prescription medication regimens through medication refill reminders, special packaging, and other compliance programs and other appropriate means; and

"(iii) detection of patterns of overuse and underuse of prescription drugs.

"(C) DEVELOPMENT OF PROGRAM IN COOPERATION WITH LICENSED PHARMACISTS.—The program shall be developed in cooperation with licensed and practicing pharmacists and physicians.

"(D) CONSIDERATIONS IN PHARMACY FEES.—The PDP sponsor of a prescription drug program and an entity offering a MA-EFFS Rx plan shall take into account, in establishing fees for pharmacists and others providing services under the medication therapy management program, the resources and time used in implementing the program. Each such sponsor or entity shall disclose to the Administrator upon request the amount of any such management or dispensing fees.

"(3) ELECTRONIC PRESCRIPTION PROGRAM.—

"(A) IN GENERAL.—An electronic prescription drug program described in this paragraph is a program that includes at least the following components, consistent with uniform standards established under subparagraph (B):

"(i) ELECTRONIC TRANSMITTAL OF PRESCRIPTIONS.—Prescriptions must be written and transmitted electronically (other than by facsimile), except in emergency cases and other exceptional circumstances recognized by the Administrator.

"(ii) PROVISION OF INFORMATION TO PRESCRIBING HEALTH CARE PROFESSIONAL.—The program provides for the electronic transmittal to the prescribing health care professional of information that includes—

"(I) information (to the extent available and feasible) on the drug or drugs being prescribed for that patient and other information relating to the medical history or condition of the patient that may be relevant to the appropriate prescription for that patient;

"(II) cost-effective alternatives (if any) for the use of the drug prescribed; and

"(III) information on the drugs included in the applicable formulary.

To the extent feasible, such program shall permit the prescribing health care professional to provide (and be provided) related information on an interactive, real-time basis.

"(B) STANDARDS.—

"(i) DEVELOPMENT.—The Administrator shall provide for the development of uniform standards relating to the electronic prescription drug program described in subparagraph (A). Such standards shall be compatible with standards established under part C of title XI.

"(ii) ADVISORY TASK FORCE.—In developing such standards and the standards described in subsection (c)(2)(B)(i) the Administrator shall establish a task force that includes representatives of physicians, hospitals, pharmacies, beneficiaries, pharmacy benefit managers, individuals with expertise in information technology, and pharmacy benefit experts of the Departments of Veterans Affairs and Defense and other appropriate Federal agencies to provide recommendations to the Administrator on such standards, including recommendations relating to the following:

"(I) The range of available computerized prescribing software and hardware and their costs to develop and implement.

"(II) The extent to which such standards and systems reduce medication errors and can be readily implemented by physicians, pharmacies, and hospitals.

"(III) Efforts to develop uniform standards and a common software platform for the secure electronic communication of medication history, eligibility, benefit, and prescription information.

"(IV) Efforts to develop and promote universal connectivity and interoperability for the secure electronic exchange of such information.

"(V) The cost of implementing such systems in the range of hospital and physician office settings and pharmacies, including hardware, software, and training costs.

"(VI) Implementation issues as they relate to part C of title XI, and current Federal and State prescribing laws and regulations and their impact on implementation of computerized prescribing.

"(iii) DEADLINES.—

"(I) The Administrator shall constitute the task force under clause (ii) by not later than April 1, 2004.

"(II) Such task force shall submit recommendations to Administrator by not later than January 1, 2005.

"(III) The Administrator shall provide for the development and promulgation, by not later than January 1, 2006, of national standards relating to the electronic prescription drug program described in clause (ii). Such standards shall be issued by a standards organization accredited by the American National Standards Institute (ANSI) and shall be compatible with standards established under part C of title XI.

"(4) TREATMENT OF ACCREDITATION.—Section 1852(e)(4) (relating to treatment of accreditation) shall apply to prescription drug plans under this part with respect to the following requirements, in the same manner as they apply to plans under part C with respect to the requirements described in a clause of section 1852(e)(4)(B):

"(A) Paragraph (1) (including quality assurance), including medication therapy management program under paragraph (2).

"(B) Subsection (c)(1) (relating to access to covered benefits).

"(C) Subsection (g) (relating to confidentiality and accuracy of enrollee records).

"(5) PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS.—Each PDP sponsor and each entity offering a MA-EFFS Rx plan shall provide that each pharmacy or other dispenser that arranges for the dispensing of a covered outpatient drug shall inform the beneficiary at the time of purchase of the drug of any differential between the price of the prescribed drug to the enrollee and the price of the lowest cost available generic drug covered under the plan that is therapeutically equivalent and bioequivalent.

"(e) GRIEVANCE MECHANISM, COVERAGE DETERMINATIONS, AND RECONSIDERATIONS.—

"(1) IN GENERAL.—Each PDP sponsor shall provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the sponsor provides covered benefits) and enrollees with prescription drug plans of the sponsor under this part in accordance with section 1852(f).

"(2) APPLICATION OF COVERAGE DETERMINATION AND RECONSIDERATION PROVISIONS.—A PDP sponsor shall meet the requirements of paragraphs (1) through (3) of section 1852(g) with respect to covered benefits under the prescription drug plan it offers under this part in the same manner as such requirements apply to an organization with respect to benefits it offers under a plan under part C.

"(3) REQUEST FOR REVIEW OF TIERED FORMULARY DETERMINATIONS.—In the case of a prescription drug plan offered by a PDP sponsor or a MA-EFFS Rx plan that provides for tiered cost-sharing for drugs included within a formulary and provides lower cost-sharing for preferred drugs included within the formulary, an individual who is enrolled in the plan may request coverage of a nonpreferred drug under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both.

"(f) APPEALS.—

"(1) IN GENERAL.—Subject to paragraph (2), a PDP sponsor shall meet the requirements of paragraphs (4) and (5) of section 1852(g) with respect to drugs (including a determination related to the application of tiered cost-sharing described in subsection (e)(3)) in the same manner as such requirements apply to an organization with respect to benefits it offers under a plan under part C.

"(2) FORMULARY DETERMINATIONS.—An individual who is enrolled in a prescription drug plan offered by a PDP sponsor or in a MA-EFFS Rx plan may appeal to obtain coverage for a covered outpatient drug that is not on a formulary of the sponsor or entity offering the plan if the prescribing physician determines that the formulary drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both.

"(g) CONFIDENTIALITY AND ACCURACY OF ENROLLEE RECORDS.—A PDP sponsor that offers a prescription drug plan shall meet the requirements of section 1852(h) with respect to enrollees under the plan in the same manner as such requirements apply to an organization with respect to enrollees under part C. A PDP sponsor shall be treated as a business associate for purposes of the provisions of subpart E of part 164 of title 45, Code of Federal Regulations, adopted pursuant to the authority of the Secretary under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S. C. 1320d-2 note).

"SEC. 1860D–4. REQUIREMENTS FOR AND CONTRACTS WITH PRESCRIPTION DRUG PLAN (PDP) SPONSORS.

"(a) GENERAL REQUIREMENTS.—Each PDP sponsor of a prescription drug plan shall meet the following requirements:

"(1) LICENSURE.—Subject to subsection (c), the sponsor is organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan.

"(2) ASSUMPTION OF FINANCIAL RISK FOR UNSUBSIDIZED COVERAGE.—

"(A) IN GENERAL.—Subject to subparagraph (B) and section 1860D–5(d)(2), the entity assumes full financial risk on a prospective basis for qualified prescription drug coverage that it offers under a prescription drug plan and that is not covered under section 1860D–8.

"(B) REINSURANCE PERMITTED.—The entity may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee.

"(3) SOLVENCY FOR UNLICENSED SPONSORS.—In the case of a sponsor that is not described in paragraph (1), the sponsor shall meet solvency standards established by the Administrator under subsection (d).

"(b) CONTRACT REQUIREMENTS.—

"(1) IN GENERAL.—The Administrator shall not permit the election under section 1860D–1 of a prescription drug plan offered by a PDP sponsor under this part, and the sponsor shall not be eligible for payments under section 1860D–7 or 1860D–8, unless the Administrator has entered into a contract under this subsection with the sponsor with respect to the offering of such plan. Such a contract with a sponsor may cover more than one prescription drug plan. Such contract shall provide that the sponsor agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

"(2) NEGOTIATION REGARDING TERMS AND CONDITIONS.—The Administrator shall have the same authority to negotiate the terms and conditions of prescription drug plans under this part as the Director of the Office of Personnel Management has with respect to health benefits plans under chapter 89 of title 5, United States Code. In negotiating the terms and conditions regarding premiums for which information is submitted under section 1860D–6(a)(2), the Administrator shall take into account the subsidy payments under section 1860D–8.

"(3) INCORPORATION OF CERTAIN MEDICARE ADVANTAGE CONTRACT REQUIREMENTS.—The following provisions of section 1857 shall apply, subject to subsection (c)(5), to contracts under this section in the same manner as they apply to contracts under section 1857(a):

"(A) MINIMUM ENROLLMENT.—Paragraphs (1) and (3) of section 1857(b).

"(B) CONTRACT PERIOD AND EFFECTIVENESS.—Paragraphs (1) through (3) and (5) of section 1857(c).

"(C) PROTECTIONS AGAINST FRAUD AND BENEFICIARY PROTECTIONS.—Section 1857(d).

"(D) ADDITIONAL CONTRACT TERMS.—Section 1857(e); except that in applying section 1857(e)(2) under this part—

"(i) such section shall be applied separately to costs relating to this part (from costs under part C and part E);

"(ii) in no case shall the amount of the fee established under this subparagraph for a plan exceed 20 percent of the maximum amount of the fee that may be established under subparagraph (B) of such section; and

"(iii) no fees shall be applied under this subparagraph with respect to MA-EFFS Rx plans.

"(E) INTERMEDIATE SANCTIONS.—Section 1857(g).

"(F) PROCEDURES FOR TERMINATION.—Section 1857(h).

"(4) RULES OF APPLICATION FOR INTERMEDIATE SANCTIONS.—In applying paragraph (3)(E)—

"(A) the reference in section 1857(g)(1)(B) to section 1854 is deemed a reference to this part; and

"(B) the reference in section 1857(g)(1)(F) to section 1852(k)(2)(A)(ii) shall not be applied.

"(5) SERVICE AREA REQUIREMENT.—For purposes of this part, the Administrator shall designate at least 10 areas covering the entire United States and shall be consistent with EFFS regions established under section 1860E–1(a)(2).

"(c) WAIVER OF CERTAIN REQUIREMENTS TO EXPAND CHOICE.—

"(1) IN GENERAL.—In the case of an entity that seeks to offer a prescription drug plan in a State, the Administrator shall waive the requirement of sub-

section (a)(1) that the entity be licensed in that State if the Administrator determines, based on the application and other evidence presented to the Administrator, that any of the grounds for approval of the application described in paragraph (2) have been met.

"(2) GROUNDS FOR APPROVAL.—The grounds for approval under this paragraph are the grounds for approval described in subparagraph (B), (C), and (D) of section 1855(a)(2), and also include the application by a State of any grounds other than those required under Federal law.

"(3) APPLICATION OF WAIVER PROCEDURES.—With respect to an application for a waiver (or a waiver granted) under this subsection, the provisions of subparagraphs (E), (F), and (G) of section 1855(a)(2) shall apply.

"(4) LICENSURE DOES NOT SUBSTITUTE FOR OR CONSTITUTE CERTIFICATION.—The fact that an entity is licensed in accordance with subsection (a)(1) does not deem the entity to meet other requirements imposed under this part for a PDP sponsor.

"(5) REFERENCES TO CERTAIN PROVISIONS.—For purposes of this subsection, in applying provisions of section 1855(a)(2) under this subsection to prescription drug plans and PDP sponsors—

"(A) any reference to a waiver application under section 1855 shall be treated as a reference to a waiver application under paragraph (1); and

"(B) any reference to solvency standards shall be treated as a reference to solvency standards established under subsection (d).

"(d) SOLVENCY STANDARDS FOR NON-LICENSED SPONSORS.—

"(1) ESTABLISHMENT.—The Administrator shall establish, by not later than October 1, 2004, financial solvency and capital adequacy standards that an entity that does not meet the requirements of subsection (a)(1) must meet to qualify as a PDP sponsor under this part.

"(2) COMPLIANCE WITH STANDARDS.—Each PDP sponsor that is not licensed by a State under subsection (a)(1) and for which a waiver application has been approved under subsection (c) shall meet solvency and capital adequacy standards established under paragraph (1). The Administrator shall establish certification procedures for such PDP sponsors with respect to such solvency standards in the manner described in section 1855(c)(2).

"(e) RELATION TO STATE LAWS.—

"(1) IN GENERAL.—The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency, except as provided in subsection (d)) with respect to prescription drug plans which are offered by PDP sponsors under this part.

"(2) PROHIBITION OF STATE IMPOSITION OF PREMIUM TAXES.—No State may impose a premium tax or similar tax with respect to premiums paid to PDP sponsors for prescription drug plans under this part, or with respect to any payments made to such a sponsor by the Administrator under this part.

"SEC. 1860D–5. PROCESS FOR BENEFICIARIES TO SELECT QUALIFIED PRESCRIPTION DRUG COVERAGE.

"(a) IN GENERAL.—The Administrator shall establish a process for the selection of the prescription drug plan or MA-EFFS Rx plan through which eligible individuals elect qualified prescription drug coverage under this part.

"(b) ELEMENTS.—Such process shall include the following:

"(1) Annual, coordinated election periods, in which such individuals can change the qualifying plans through which they obtain coverage, in accordance with section 1860D–1(b)(2).

"(2) Active dissemination of information to promote an informed selection among qualifying plans based upon price, quality, and other features, in the manner described in (and in coordination with) section 1851(d), including the provision of annual comparative information, maintenance of a toll-free hotline, and the use of non-Federal entities.

"(3) Coordination of elections through filing with the entity offering a MA-EFFS Rx plan or a PDP sponsor, in the manner described in (and in coordination with) section 1851(c)(2).

"(4) Informing each enrollee before the beginning of each year of the annual out-of-pocket threshold applicable to the enrollee for that year under section 1860D–2(b)(4) at such time.

"(c) MA-EFFS RX ENROLLEE MAY ONLY OBTAIN BENEFITS THROUGH THE PLAN.—An individual who is enrolled under a MA-EFFS Rx plan may only elect to receive qualified prescription drug coverage under this part through such plan.

"(d) ASSURING ACCESS TO A CHOICE OF QUALIFIED PRESCRIPTION DRUG COVERAGE.—

"(1) CHOICE OF AT LEAST TWO PLANS IN EACH AREA.—

"(A) IN GENERAL.—The Administrator shall assure that each individual who is entitled to benefits under part A or enrolled under part B and who is residing in an area in the United States has available, consistent with subparagraph (B), a choice of enrollment in at least two qualifying plans (as defined in paragraph (5)) in the area in which the individual resides, at least one of which is a prescription drug plan.

"(B) REQUIREMENT FOR DIFFERENT PLAN SPONSORS.—The requirement in subparagraph (A) is not satisfied with respect to an area if only one PDP sponsor or one entity that offers a MA-EFFS Rx plan offers all the qualifying plans in the area.

"(2) GUARANTEEING ACCESS TO COVERAGE.—In order to assure access under paragraph (1) and consistent with paragraph (3), the Administrator may provide partial underwriting of risk for a PDP sponsor to expand the service area under an existing prescription drug plan to adjoining or additional areas or to establish such a plan (including offering such a plan on a regional or nationwide basis), but only so long as (and to the extent) necessary to assure the access guaranteed under paragraph (1).

"(3) LIMITATION ON AUTHORITY.—In exercising authority under this subsection, the Administrator—

"(A) shall not provide for the full underwriting of financial risk for any PDP sponsor; and

"(B) shall seek to maximize the assumption of financial risk by PDP sponsors or entities offering a MA-EFFS Rx plan.

"(4) REPORTS.—The Administrator shall, in each annual report to Congress under section 1809(f), include information on the exercise of authority under this subsection. The Administrator also shall include such recommendations as may be appropriate to minimize the exercise of such authority, including minimizing the assumption of financial risk.

"(5) QUALIFYING PLAN DEFINED.—For purposes of this subsection, the term 'qualifying plan' means a prescription drug plan or a MA-EFFS Rx plan.

"SEC. 1860D–6. SUBMISSION OF BIDS AND PREMIUMS.

"(a) SUBMISSION OF BIDS, PREMIUMS, AND RELATED INFORMATION.—

"(1) IN GENERAL.—Each PDP sponsor shall submit to the Administrator the information described in paragraph (2) in the same manner as information is submitted by an organization under section 1854(a)(1).

"(2) INFORMATION SUBMITTED.—The information described in this paragraph is the following:

"(A) COVERAGE PROVIDED.—Information on the qualified prescription drug coverage to be provided.

"(B) ACTUARIAL VALUE.—Information on the actuarial value of the coverage.

"(C) BID AND PREMIUM.—Information on the bid and the premium for the coverage, including an actuarial certification of—

"(i) the actuarial basis for such bid and premium;

"(ii) the portion of such bid and premium attributable to benefits in excess of standard coverage;

"(iii) the reduction in such bid resulting from the reinsurance subsidy payments provided under section 1860D–8(a)(2); and

"(iv) the reduction in such premium resulting from the direct and reinsurance subsidy payments provided under section 1860D–8.

"(D) ADDITIONAL INFORMATION.—Such other information as the Administrator may require to carry out this part.

"(3) REVIEW OF INFORMATION; NEGOTIATION AND APPROVAL OF PREMIUMS.—

"(A) IN GENERAL.—Subject to subparagraph (B), the Administrator shall review the information filed under paragraph (2) for the purpose of conducting negotiations under section 1860D–4(b)(2) (relating to using OPM-like authority under the FEHBP). The Administrator, using the information provided (including the actuarial certification under paragraph (2)(C)) shall approve the premium submitted under this subsection only if the premium accurately reflects both (i) the actuarial value of the benefits provided, and (ii) the 73 percent average subsidy provided under section 1860D–8 for the standard benefit. The Administrator shall apply actuarial principles to approval of a premium under this part in a manner similar to the manner in which those principles are applied in establishing the monthly part B premium under section 1839.

"(B) EXCEPTION.—In the case of a plan described in section 1851(a)(2)(C), the provisions of subparagraph (A) shall not apply and the provisions of paragraph (5)(B) of section 1854(a), prohibiting the review, approval, or dis-

approval of amounts described in such paragraph, shall apply to the negotiation and rejection of the monthly bid amounts and proportion referred to in subparagraph (A).

"(b) UNIFORM BID AND PREMIUM.—

"(1) IN GENERAL.—The bid and premium for a prescription drug plan under this section may not vary among enrollees in the plan in the same service area.

"(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed as preventing the imposition of a late enrollment penalty under section 1860D–1(c)(2)(B).

"(c) COLLECTION.—

"(1) BENEFICIARY'S OPTION OF PAYMENT THROUGH WITHHOLDING FROM SOCIAL SECURITY PAYMENT OR USE OF ELECTRONIC FUNDS TRANSFER MECHANISM.—In accordance with regulations, a PDP sponsor shall permit each enrollee, at the enrollee's option, to make payment of premiums under this part to the sponsor through withholding from benefit payments in the manner provided under section 1840 with respect to monthly premiums under section 1839 or through an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account) or otherwise. All premium payments that are withheld under this paragraph shall be credited to the Medicare Prescription Drug Trust Fund and shall be paid to the PDP sponsor involved.

"(2) OFFSETTING.—Reductions in premiums for coverage under parts A and B as a result of a selection of a MA-EFFS Rx plan may be used to reduce the premium otherwise imposed under paragraph (1).

"(d) ACCEPTANCE OF REFERENCE PREMIUM AMOUNT AS FULL PREMIUM FOR SUBSIDIZED LOW-INCOME INDIVIDUALS IF NO STANDARD (OR EQUIVALENT) COVERAGE IN AN AREA.—

"(1) IN GENERAL.—If there is no standard prescription drug coverage (as defined in paragraph (2)) offered in an area, in the case of an individual who is eligible for a premium subsidy under section 1860D–7 and resides in the area, the PDP sponsor of any prescription drug plan offered in the area (and any entity offering a MA-EFFS Rx plan in the area) shall accept the reference premium amount (under paragraph (3)) as payment in full for the premium charge for qualified prescription drug coverage.

"(2) STANDARD PRESCRIPTION DRUG COVERAGE DEFINED.—For purposes of this subsection, the term 'standard prescription drug coverage' means qualified prescription drug coverage that is standard coverage or that has an actuarial value equivalent to the actuarial value for standard coverage.

"(3) REFERENCE PREMIUM AMOUNT DEFINED.—For purposes of this subsection, the term 'reference premium amount' means, with respect to qualified prescription drug coverage offered under—

"(A) a prescription drug plan that—

"(i) provides standard coverage (or alternative prescription drug coverage the actuarial value is equivalent to that of standard coverage), the plan's PDP premium; or

"(ii) provides alternative prescription drug coverage the actuarial value of which is greater than that of standard coverage, the plan's PDP premium multiplied by the ratio of (I) the actuarial value of standard coverage, to (II) the actuarial value of the alternative coverage;

"(B) an EFFS plan, the EFFS monthly prescription drug beneficiary premium (as defined in section 1860E–4(a)(3)(B)); or

"(C) a Medicare Advantage, the Medicare Advantage monthly prescription drug beneficiary premium (as defined in section 1854(b)(2)(B)).

For purposes of subparagraph (A), the term 'PDP premium' means, with respect to a prescription drug plan, the premium amount for enrollment under the plan under this part (determined without regard to any low-income subsidy under section 1860D–7 or any late enrollment penalty under section 1860D–1(c)(2)(B)).

"SEC. 1860D–7. PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS.

"(a) INCOME-RELATED SUBSIDIES FOR INDIVIDUALS WITH INCOME BELOW 150 PERCENT OF FEDERAL POVERTY LEVEL.—

"(1) FULL PREMIUM SUBSIDY AND REDUCTION OF COST-SHARING FOR INDIVIDUALS WITH INCOME BELOW 135 PERCENT OF FEDERAL POVERTY LEVEL.—In the case of a subsidy eligible individual (as defined in paragraph (4)) who is determined to have income that does not exceed 135 percent of the Federal poverty level, the individual is entitled under this section—

"(A) to an income-related premium subsidy equal to 100 percent of the amount described in subsection (b)(1); and

"(B) subject to subsection (c), to the substitution for the beneficiary cost-sharing described in paragraphs (1) and (2) of section 1860D–2(b) (up to the initial coverage limit specified in paragraph (3) of such section) of amounts that do not exceed $2 for a multiple source or generic drug (as described in section 1927(k)(7)(A)) and $5 for a non-preferred drug.

"(2) SLIDING SCALE PREMIUM SUBSIDY FOR INDIVIDUALS WITH INCOME ABOVE 135, BUT BELOW 150 PERCENT, OF FEDERAL POVERTY LEVEL.—In the case of a subsidy eligible individual who is determined to have income that exceeds 135 percent, but does not exceed 150 percent, of the Federal poverty level, the individual is entitled under this section to an income-related premium subsidy determined on a linear sliding scale ranging from 100 percent of the amount described in subsection (b)(1) for individuals with incomes at 135 percent of such level to 0 percent of such amount for individuals with incomes at 150 percent of such level.

"(3) CONSTRUCTION.—Nothing in this section shall be construed as preventing a PDP sponsor or entity offering a MA-EFFS Rx plan from reducing to 0 the cost-sharing otherwise applicable to generic drugs.

"(4) DETERMINATION OF ELIGIBILITY.—

"(A) SUBSIDY ELIGIBLE INDIVIDUAL DEFINED.—For purposes of this section, subject to subparagraph (D), the term 'subsidy eligible individual' means an individual who—

"(i) is eligible to elect, and has elected, to obtain qualified prescription drug coverage under this part;

"(ii) has income below 150 percent of the Federal poverty line; and

"(iii) meets the resources requirement described in subparagraph (D)

.

"(B) DETERMINATIONS.—The determination of whether an individual residing in a State is a subsidy eligible individual and the amount of such individual's income shall be determined under the State medicaid plan for the State under section 1935(a) or by the Social Security Administration. In the case of a State that does not operate such a medicaid plan (either under title XIX or under a statewide waiver granted under section 1115), such determination shall be made under arrangements made by the Administrator. There are authorized to be appropriated to the Social Security Administration such sums as may be necessary for the determination of eligibility under this subparagraph.

"(C) INCOME DETERMINATIONS.—For purposes of applying this section—

"(i) income shall be determined in the manner described in section 1905(p)(1)(B); and

"(ii) the term 'Federal poverty line' means the official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved.

"(D) RESOURCE STANDARD APPLIED TO BE BASED ON TWICE SSI RESOURCE STANDARD.—The resource requirement of this subparagraph is that an individual's resources (as determined under section 1613 for purposes of the supplemental security income program) do not exceed—

"(i) for 2006 twice the maximum amount of resources that an individual may have and obtain benefits under that program; and

"(ii) for a subsequent year the resource limitation established under this clause for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any resource limitation established under clause (ii) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

"(E) TREATMENT OF TERRITORIAL RESIDENTS.—In the case of an individual who is not a resident of the 50 States or the District of Columbia, the individual is not eligible to be a subsidy eligible individual but may be eligible for financial assistance with prescription drug expenses under section 1935(e).

"(F) TREATMENT OF CONFORMING MEDIGAP POLICIES.—For purposes of this section, the term 'qualified prescription drug coverage' includes a medicare supplemental policy described in section 1860D–8(b)(4).

"(5) INDEXING DOLLAR AMOUNTS.—

"(A) FOR 2007.—The dollar amounts applied under paragraphs (1)(B) for 2007 shall be the dollar amounts specified in such paragraph increased by the annual percentage increase described in section 1860D–2(b)(5) for 2007.

"(B) FOR SUBSEQUENT YEARS.—The dollar amounts applied under paragraph (1)(B) for a year after 2007 shall be the amounts (under this para-

graph) applied under paragraph (1)(B) for the preceding year increased by the annual percentage increase described in section 1860D–2(b)(5) (relating to growth in medicare prescription drug costs per beneficiary) for the year involved.

"(b) PREMIUM SUBSIDY AMOUNT.—

"(1) IN GENERAL.—The premium subsidy amount described in this subsection for an individual residing in an area is the benchmark premium amount (as defined in paragraph (2)) for qualified prescription drug coverage offered by the prescription drug plan or the MA-EFFS Rx plan in which the individual is enrolled.

"(2) BENCHMARK PREMIUM AMOUNT DEFINED.—For purposes of this subsection, the term 'benchmark premium amount' means, with respect to qualified prescription drug coverage offered under—

"(A) a prescription drug plan that—

"(i) provides standard coverage (or alternative prescription drug coverage the actuarial value of which is equivalent to that of standard coverage), the premium amount for enrollment under the plan under this part (determined without regard to any subsidy under this section or any late enrollment penalty under section 1860D–1(c)(2)(B)); or

"(ii) provides alternative prescription drug coverage the actuarial value of which is greater than that of standard coverage, the premium amount described in clause (i) multiplied by the ratio of (I) the actuarial value of standard coverage, to (II) the actuarial value of the alternative coverage; or

"(B) a MA-EFFS Rx plan, the portion of the premium amount that is attributable to statutory drug benefits (described in section 1853(a)(1)(A)(ii)(II)).

"(c) RULES IN APPLYING COST-SHARING SUBSIDIES.—

"(1) IN GENERAL.—In applying subsection (a)(1)(B), nothing in this part shall be construed as preventing a plan or provider from waiving or reducing the amount of cost-sharing otherwise applicable.

"(2) LIMITATION ON CHARGES.—In the case of an individual receiving cost-sharing subsidies under subsection (a)(1)(B), the PDP sponsor or entity offering a MA-EFFS Rx plan may not charge more than $5 per prescription.

"(3) APPLICATION OF INDEXING RULES.—The provisions of subsection (a)(5) shall apply to the dollar amount specified in paragraph (2) in the same manner as they apply to the dollar amounts specified in subsections (a)(1)(B).

"(d) ADMINISTRATION OF SUBSIDY PROGRAM.—The Administrator shall provide a process whereby, in the case of an individual who is determined to be a subsidy eligible individual and who is enrolled in prescription drug plan or is enrolled in a MA-EFFS Rx plan—

"(1) the Administrator provides for a notification of the PDP sponsor or the entity offering the MA-EFFS Rx plan involved that the individual is eligible for a subsidy and the amount of the subsidy under subsection (a);

"(2) the sponsor or entity involved reduces the premiums or cost-sharing otherwise imposed by the amount of the applicable subsidy and submits to the Administrator information on the amount of such reduction; and

"(3) the Administrator periodically and on a timely basis reimburses the sponsor or entity for the amount of such reductions.

The reimbursement under paragraph (3) with respect to cost-sharing subsidies may be computed on a capitated basis, taking into account the actuarial value of the subsidies and with appropriate adjustments to reflect differences in the risks actually involved.

"(e) RELATION TO MEDICAID PROGRAM.—

"(1) IN GENERAL.—For provisions providing for eligibility determinations, and additional financing, under the medicaid program, see section 1935.

"(2) MEDICAID PROVIDING WRAP AROUND BENEFITS.—The coverage provided under this part is primary payor to benefits for prescribed drugs provided under the medicaid program under title XIX consistent with section 1935(d)(1).

"(3) COORDINATION.—The Administrator shall develop and implement a plan for the coordination of prescription drug benefits under this part with the benefits provided under the medicaid program under title XIX, with particular attention to insuring coordination of payments and prevention of fraud and abuse. In developing and implementing such plan, the Administrator shall involve the Secretary, the States, the data processing industry, pharmacists, and pharmaceutical manufacturers, and other experts.

"SEC. 1860D–8. SUBSIDIES FOR ALL MEDICARE BENEFICIARIES FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.

"(a) SUBSIDY PAYMENT.—In order to reduce premium levels applicable to qualified prescription drug coverage for all medicare beneficiaries consistent with an overall subsidy level of 73 percent, to reduce adverse selection among prescription drug plans and MA-EFFS Rx plans, and to promote the participation of PDP sponsors under this part, the Administrator shall provide in accordance with this section for payment to a qualifying entity (as defined in subsection (b)) of the following subsidies:

"(1) DIRECT SUBSIDY.—In the case of an enrollee enrolled for a month in a prescription drug plan or a MA-EFFS Rx plan, a direct subsidy equal to 43 percent of the national average monthly bid amount (computed under subsection (g)) for that month.

"(2) SUBSIDY THROUGH REINSURANCE.—In the case of an enrollee enrolled for a month in a prescription drug plan or a MA-EFFS Rx plan, the reinsurance payment amount (as defined in subsection (c)), which in the aggregate is 30 percent of the total payments made by qualifying entities for standard coverage under the respective plan, for excess costs incurred in providing qualified prescription drug coverage—

"(A) for enrollees with a prescription drug plan under this part; and

"(B) for enrollees with a MA-EFFS Rx plan.

"(3) EMPLOYER AND UNION FLEXIBILITY.—In the case of an individual who is a participant or beneficiary in a qualified retiree prescription drug plan (as defined in subsection (f)(1)) and who is not enrolled in a prescription drug plan or in a MA-EFFS Rx plan, the special subsidy payments under subsection (f)(3).

This section constitutes budget authority in advance of appropriations Acts and represents the obligation of the Administrator to provide for the payment of amounts provided under this section. In applying the percentages under paragraphs (1) and (2), there shall be taken into account under the respective paragraphs the portion of the employer and union special subsidy payments under subsection (f)(3) that reflect payments that would have been made under the respective paragraphs if such paragraphs had applied to qualified retiree prescription drug plans instead of paragraph (3).

"(b) QUALIFYING ENTITY DEFINED.—For purposes of this section, the term 'qualifying entity' means any of the following that has entered into an agreement with the Administrator to provide the Administrator with such information as may be required to carry out this section:

"(1) A PDP sponsor offering a prescription drug plan under this part.

"(2) An entity that offers a MA-EFFS Rx plan.

"(3) The sponsor of a qualified retiree prescription drug plan (as defined in subsection (f)).

"(c) REINSURANCE PAYMENT AMOUNT.—

"(1) IN GENERAL.—Subject to subsection (d)(1)(B) and paragraph (4), the reinsurance payment amount under this subsection for a qualifying covered individual (as defined in paragraph (5)) for a coverage year (as defined in subsection (h)(2)) is equal to the sum of the following:

"(A) REINSURANCE BETWEEN INITIAL REINSURANCE THRESHOLD AND THE INITIAL COVERAGE LIMIT.—For the portion of the individual's gross covered prescription drug costs (as defined in paragraph (3)) for the year that exceeds the initial reinsurance threshold specified in paragraph (4), but does not exceed the initial coverage limit specified in section 1860D–2(b)(3), an amount equal to 20 percent of the allowable costs (as defined in paragraph (2)) attributable to such gross covered prescription drug costs.

"(B) REINSURANCE ABOVE ANNUAL OUT-OF-POCKET THRESHOLD.—For the portion of the individual's gross covered prescription drug costs for the year that exceeds the annual out-of-pocket threshold specified in 1860D–2(b)(4)(B), an amount equal to 80 percent of the allowable costs attributable to such gross covered prescription drug costs.

"(2) ALLOWABLE COSTS.—For purposes of this section, the term 'allowable costs' means, with respect to gross covered prescription drug costs under a plan described in subsection (b) offered by a qualifying entity, the part of such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were standard coverage.

"(3) GROSS COVERED PRESCRIPTION DRUG COSTS.—For purposes of this section, the term 'gross covered prescription drug costs' means, with respect to an enrollee with a qualifying entity under a plan described in subsection (b) during a coverage year, the costs incurred under the plan (including costs attributable

to administrative costs) for covered prescription drugs dispensed during the year, including costs relating to the deductible, whether paid by the enrollee or under the plan, regardless of whether the coverage under the plan exceeds standard coverage and regardless of when the payment for such drugs is made.

"(4) INITIAL REINSURANCE THRESHOLD.—The initial reinsurance threshold specified in this paragraph—

"(A) for 2006, is equal to $1,000; or

"(B) for a subsequent year, is equal to the payment threshold specified in this paragraph for the previous year, increased by the annual percentage increase described in section 1860D–2(b)(5) for the year involved.

Any amount determined under subparagraph (B) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

"(5) QUALIFYING COVERED INDIVIDUAL DEFINED.—For purposes of this subsection, the term 'qualifying covered individual' means an individual who—

"(A) is enrolled with a prescription drug plan under this part; or

"(B) is enrolled with a MA-EFFS Rx plan.

"(d) ADJUSTMENT OF PAYMENTS.—

"(1) ADJUSTMENT OF REINSURANCE PAYMENTS TO ASSURE 30 PERCENT LEVEL OF SUBSIDY THROUGH REINSURANCE.—

"(A) ESTIMATION OF PAYMENTS.—The Administrator shall estimate—

"(i) the total payments to be made (without regard to this subsection) during a year under subsections (a)(2) and (c); and

"(ii) the total payments to be made by qualifying entities for standard coverage under plans described in subsection (b) during the year.

"(B) ADJUSTMENT.—The Administrator shall proportionally adjust the payments made under subsections (a)(2) and (c) for a coverage year in such manner so that the total of the payments made under such subsections (and under subsection (f)(3) insofar as such payments reflect payments that would have been made under such subsections if such subsections had applied to qualified retiree prescription drug plans instead of subsections (a)(3) and (f)(3)) for the year is equal to 30 percent of the total payments described in subparagraph (A)(ii).

"(2) RISK ADJUSTMENT FOR DIRECT SUBSIDIES.—To the extent the Administrator determines it appropriate to avoid risk selection, the payments made for direct subsidies under subsection (a)(1) are subject to adjustment based upon risk factors specified by the Administrator. Any such risk adjustment shall be designed in a manner as to not result in a change in the aggregate payments made under such subsection.

"(e) PAYMENT METHODS.—

"(1) IN GENERAL.—Payments under this section shall be based on such a method as the Administrator determines. The Administrator may establish a payment method by which interim payments of amounts under this section are made during a year based on the Administrator's best estimate of amounts that will be payable after obtaining all of the information.

"(2) SOURCE OF PAYMENTS.—Payments under this section shall be made from the Medicare Prescription Drug Trust Fund.

"(f) RULES RELATING TO QUALIFIED RETIREE PRESCRIPTION DRUG PLAN.—

"(1) DEFINITION.—For purposes of this section, the term 'qualified retiree prescription drug plan' means employment-based retiree health coverage (as defined in paragraph (4)(A)) if, with respect to an individual who is a participant or beneficiary under such coverage and is eligible to be enrolled in a prescription drug plan or a MA-EFFS Rx plan under this part, the following requirements are met:

"(A) ACTUARIAL EQUIVALENCE TO STANDARD COVERAGE.—The Administrator determines (based on an actuarial analysis by the Administrator) that coverage provides at least the same actuarial value as standard coverage. Such determination may be made on an annual basis.

"(B) AUDITS.—The sponsor (and the plan) shall maintain, and afford the Administrator access to, such records as the Administrator may require for purposes of audits and other oversight activities necessary to ensure the adequacy of prescription drug coverage and the accuracy of payments made.

"(C) PROVISION OF CERTIFICATION OF PRESCRIPTION DRUG COVERAGE.—The sponsor of the plan shall provide for issuance of certifications of the type described in section 1860D–1(c)(2)(D).

"(2) LIMITATION ON BENEFIT ELIGIBILITY.—No payment shall be provided under this section with respect to a participant or beneficiary in a qualified retiree prescription drug plan unless the individual is—

"(A) is covered under the plan; and

"(B) is eligible to obtain qualified prescription drug coverage under section 1860D–1 but did not elect such coverage under this part (either through a prescription drug plan or through a MA-EFFS Rx plan).

"(3) EMPLOYER AND UNION SPECIAL SUBSIDY AMOUNTS.—

"(A) IN GENERAL.—For purposes of subsection (a), the special subsidy payment amount under this paragraph for a qualifying covered retiree(as defined in paragraph (6)) for a coverage year (as defined in subsection (h)) enrolled in a qualifying entity described in subsection (b)(3) under a qualified retiree prescription drug plan is, for the portion of the individual's gross covered prescription drug costs for the year that exceeds the deductible amount specified in subparagraph (B), an amount equal to, subject to subparagraph (D), 28 percent of the allowable costs attributable to such gross covered prescription drug costs, but only to the extent such costs exceed the deductible under subparagraph (B) and do not exceed the cost limit under such subparagraph in the case of any such individual for the plan year.

"(B) DEDUCTIBLE AND COST LIMIT APPLICABLE.—Subject to subparagraph (C)—

"(i) the deductible under this subparagraph is equal to $250 for plan years that end in 2006; and

"(ii) the cost limit under this subparagraph is equal to $5,000 for plan years that end in 2006.

"(C) INDEXING.—The deductible and cost limit amounts specified in subparagraphs (B) for a plan year that ends after 2006 shall be adjusted in the same manner as the annual deductible under section 1860D–2(b)(1) is annually adjusted under such section.

"(D) ADJUSTMENT CONTINGENCY.—The Secretary may adjust the percentage specified in subparagraph (A) with respect to plan years that end in a year in a manner so that the aggregate expenditures in the year under this section are the same as the aggregate expenditures that would have been made under this section (taking into account the effect of any adjustment under subsection (d)(1)(B)) if paragraphs (1) and (2) of subsection (a) had applied to qualified prescription drug coverage instead of this paragraph and subsection (a)(3).

"(4) RELATED DEFINITIONS.—As used in this section:

"(A) EMPLOYMENT-BASED RETIREE HEALTH COVERAGE.—The term 'employment-based retiree health coverage' means health insurance or other coverage of health care costs for individuals eligible to enroll in a prescription drug plan or MA-EFFS Rx plan under this part (or for such individuals and their spouses and dependents) under a group health plan (including such a plan that is established or maintained under or pursuant to one or more collective bargaining agreements) based on their status as retired participants in such plan.

"(B) QUALIFYING COVERED RETIREE.—The term 'qualifying covered retiree' means an individual who is eligible to obtain qualified prescription drug coverage under section 1860D–1 but did not elect such coverage under this part (either through a prescription drug plan or through a MA-EFFS Rx plan) but is covered under a qualified retiree prescription drug plan.

"(C) SPONSOR.—The term 'sponsor' means a plan sponsor, as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974, except that, in the case of a single-employer plan (as defined in section 3(41) of such Act), such term means the employer of the plan participants if such employer has been designated as the plan sponsor in all prior summary plan descriptions and annual reports issued with respect to the plan under part 1 of subtitle B of title I of such Act.

"(5) CONSTRUCTION.—Nothing in this subsection shall be construed as—

"(A) precluding an individual who is covered under employment-based retiree health coverage from enrolling in a prescription drug plan or in a MA-EFFS plan;

"(B) precluding such employment-based retiree health coverage or an employer or other person from paying all or any portion of any premium required for coverage under such a prescription drug plan or MA-EFFS plan on behalf of such an individual; or

"(C) preventing such employment-based retiree health coverage from providing coverage for retirees—

"(i) who are covered under a qualified retiree prescription plan that is better than standard coverage; or

"(ii) who are not covered under a qualified retiree prescription plan but who are enrolled in a prescription drug plan or a MA-EFFS Rx plan, that is supplemental to the benefits provided under such prescrip-

tion drug plan or MA-EFFS Rx plan, except that any such supplemental coverage (not including payment of any premium referred to in subparagraph (B)) shall be treated as primary coverage to which section 1862(b)(2)(A)(i) is deemed to apply.

"(g) COMPUTATION OF NATIONAL AVERAGE MONTHLY BID AMOUNT.—

"(1) IN GENERAL.—For each year (beginning with 2006) the Administrator shall compute a national average monthly bid amount equal to the average of the benchmark bid amounts for each prescription drug plan and for each MA-EFFS Rx plan (as computed under paragraph (2), but excluding plans described in section 1851(a)(2)(C))) adjusted under paragraph (4) to take into account reinsurance payments.

"(2) BENCHMARK BID AMOUNT DEFINED.—For purposes of this subsection, the term 'benchmark bid amount' means, with respect to qualified prescription drug coverage offered under—

"(A) a prescription drug plan that—

"(i) provides standard coverage (or alternative prescription drug coverage the actuarial value of which is equivalent to that of standard coverage), the PDP bid; or

"(ii) provides alternative prescription drug coverage the actuarial value of which is greater than that of standard coverage, the PDP bid multiplied by the ratio of (I) the actuarial value of standard coverage, to (II) the actuarial value of the alternative coverage; or

"(B) a MA-EFFS Rx plan, the portion of the bid amount that is attributable to statutory drug benefits (described in section 1853(a)(1)(A)(ii)(II)).

For purposes of subparagraph (A), the term 'PDP bid' means, with respect to a prescription drug plan, the bid amount for enrollment under the plan under this part (determined without regard to any low-income subsidy under section 1860D–7 or any late enrollment penalty under section 1860D–1(c)(2)(B)).

"(3) WEIGHTED AVERAGE.—

"(A) IN GENERAL.—The monthly national average monthly bid amount computed under paragraph (1) shall be a weighted average, with the weight for each plan being equal to the average number of beneficiaries enrolled under such plan in the previous year.

"(B) SPECIAL RULE FOR 2006.—For purposes of applying this subsection for 2006, the Administrator shall establish procedures for determining the weighted average under subparagraph (A) for 2005.

"(4) ADJUSTMENT TO ADD BACK IN VALUE OF REINSURANCE SUBSIDIES.—The adjustment under this paragraph, to take into account reinsurance payments under subsection (c) making up 30 percent of total payments, is such an adjustment as will make the national average monthly bid amount represent represent 100 percent, instead of representing 70 percent, of average payments under this part.

"(h) COVERAGE YEAR DEFINED.—For purposes of this section, the term 'coverage year' means a calendar year in which covered outpatient drugs are dispensed if a claim for payment is made under the plan for such drugs, regardless of when the claim is paid.

"SEC. 1860D–9. MEDICARE PRESCRIPTION DRUG TRUST FUND.

"(a) IN GENERAL.—There is created on the books of the Treasury of the United States a trust fund to be known as the 'Medicare Prescription Drug Trust Fund' (in this section referred to as the 'Trust Fund'). The Trust Fund shall consist of such gifts and bequests as may be made as provided in section 201(i)(1), and such amounts as may be deposited in, or appropriated to, such fund as provided in this part. Except as otherwise provided in this section, the provisions of subsections (b) through (i) of section 1841 shall apply to the Trust Fund in the same manner as they apply to the Federal Supplementary Medical Insurance Trust Fund under such section.

"(b) PAYMENTS FROM TRUST FUND.—

"(1) IN GENERAL.—The Managing Trustee shall pay from time to time from the Trust Fund such amounts as the Administrator certifies are necessary to make—

"(A) payments under section 1860D–7 (relating to low-income subsidy payments);

"(B) payments under section 1860D–8 (relating to subsidy payments); and

"(C) payments with respect to administrative expenses under this part in accordance with section 201(g).

"(2) TRANSFERS TO MEDICAID ACCOUNT FOR INCREASED ADMINISTRATIVE COSTS.—The Managing Trustee shall transfer from time to time from the Trust Fund to the Grants to States for Medicaid account amounts the Administrator

certifies are attributable to increases in payment resulting from the application of a higher Federal matching percentage under section 1935(b).

"(c) DEPOSITS INTO TRUST FUND.—

"(1) LOW-INCOME TRANSFER.—There is hereby transferred to the Trust Fund, from amounts appropriated for Grants to States for Medicaid, amounts equivalent to the aggregate amount of the reductions in payments under section 1903(a)(1) attributable to the application of section 1935(c).

"(2) APPROPRIATIONS TO COVER GOVERNMENT CONTRIBUTIONS.—There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, to the Trust Fund, an amount equivalent to the amount of payments made from the Trust Fund under subsection (b), reduced by the amount transferred to the Trust Fund under paragraph (1).

"(d) RELATION TO SOLVENCY REQUIREMENTS.—Any provision of law that relates to the solvency of the Trust Fund under this part shall take into account the Trust Fund and amounts receivable by, or payable from, the Trust Fund.

"SEC. 1860D–10. DEFINITIONS; APPLICATION TO MEDICARE ADVANTAGE AND EFFS PROGRAMS; TREATMENT OF REFERENCES TO PROVISIONS IN PART C.

"(a) DEFINITIONS.—For purposes of this part:

"(1) COVERED OUTPATIENT DRUGS.—The term 'covered outpatient drugs' is defined in section 1860D–2(f).

"(2) INITIAL COVERAGE LIMIT.—The term 'initial coverage limit' means such limit as established under section 1860D–2(b)(3), or, in the case of coverage that is not standard coverage, the comparable limit (if any) established under the coverage.

"(3) MEDICARE PRESCRIPTION DRUG TRUST FUND.—The term 'Medicare Prescription Drug Trust Fund' means the Trust Fund created under section 1860D–9(a).

"(4) PDP SPONSOR.—The term 'PDP sponsor' means an entity that is certified under this part as meeting the requirements and standards of this part for such a sponsor.

"(5) PRESCRIPTION DRUG PLAN.—The term 'prescription drug plan' means health benefits coverage that—

"(A) is offered under a policy, contract, or plan by a PDP sponsor pursuant to, and in accordance with, a contract between the Administrator and the sponsor under section 1860D–4(b);

"(B) provides qualified prescription drug coverage; and

"(C) meets the applicable requirements of the section 1860D–3 for a prescription drug plan.

"(6) QUALIFIED PRESCRIPTION DRUG COVERAGE.—The term 'qualified prescription drug coverage' is defined in section 1860D–2(a).

"(7) STANDARD COVERAGE.—The term 'standard coverage' is defined in section 1860D–2(b).

"(b) OFFER OF QUALIFIED PRESCRIPTION DRUG COVERAGE UNDER MEDICARE ADVANTAGE AND EFFS PROGRAMS.—

"(1) AS PART OF MEDICARE ADVANTAGE PLAN.—Medicare Advantage organizations are required to offer Medicare Advantage plans that include qualified prescription drug coverage under part C pursuant to section 1851(j).

"(2) AS PART OF EFFS PLAN.—EFFS organizations are required to offer EFFS plans that include qualified prescription drug coverage under part E pursuant to section 1860E–2(d).

"(c) APPLICATION OF PART C PROVISIONS UNDER THIS PART.—For purposes of applying provisions of part C under this part with respect to a prescription drug plan and a PDP sponsor, unless otherwise provided in this part such provisions shall be applied as if—

"(1) any reference to a Medicare Advantage or other plan included a reference to a prescription drug plan;

"(2) any reference to a provider-sponsored organization included a reference to a PDP sponsor;

"(3) any reference to a contract under section 1857 included a reference to a contract under section 1860D–4(b); and

"(4) any reference to part C included a reference to this part.

"(d) REPORT ON PHARMACY SERVICES PROVIDED TO NURSING FACILITY PATIENTS.—

"(1) REVIEW.—Within 6 months after the date of the enactment of this section, the Secretary shall review the current standards of practice for pharmacy services provided to patients in nursing facilities.

"(2) EVALUATIONS AND RECOMMENDATIONS.—Specifically in the review under paragraph (1), the Secretary shall—

"(A) assess the current standards of practice, clinical services, and other service requirements generally utilized for pharmacy services in the long-term care setting;

"(B) evaluate the impact of those standards with respect to patient safety, reduction of medication errors and quality of care; and

"(C) recommend (in the Secretary's report under paragraph (3)) necessary actions and appropriate reimbursement to ensure the provision of prescription drugs to medicare beneficiaries residing in nursing facilities in a manner consistent with existing patient safety and quality of care standards under applicable State and Federal laws.

"(3) REPORT.—The Secretary shall submit a report to the Congress on the Secretary's findings and recommendations under this subsection, including a detailed description of the Secretary's plans to implement this part in a manner consistent with applicable State and Federal laws designed to protect the safety and quality of care of nursing facility patients.".

(b) ADDITIONAL CONFORMING CHANGES.—

(1) CONFORMING REFERENCES TO PREVIOUS PART D.—Any reference in law (in effect before the date of the enactment of this Act) to part D of title XVIII of the Social Security Act is deemed a reference to part F of such title (as in effect after such date).

(2) CONFORMING AMENDMENT PERMITTING WAIVER OF COST-SHARING.—Section 1128B(b)(3) (42 U.S.C. 1320a–7b(b)(3)) is amended—

(A) by striking "and" at the end of subparagraph (E);

(B) by striking the period at the end of subparagraph (F) and inserting "; and"; and

(C) by adding at the end the following new subparagraph:

"(G) the waiver or reduction of any cost-sharing imposed under part D of title XVIII.".

(3) SUBMISSION OF LEGISLATIVE PROPOSAL.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress a legislative proposal providing for such technical and conforming amendments in the law as are required by the provisions of this subtitle.

(c) STUDY ON TRANSITIONING PART B PRESCRIPTION DRUG COVERAGE.—Not later than January 1, 2005, the Medicare Benefits Administrator shall submit a report to Congress that makes recommendations regarding methods for providing benefits under part D of title XVIII of the Social Security Act for outpatient prescription drugs for which benefits are provided under part B of such title.

SEC. 102. OFFERING OF QUALIFIED PRESCRIPTION DRUG COVERAGE UNDER MEDICARE ADVANTAGE AND ENHANCED FEE-FOR-SERVICE (EFFS) PROGRAM.

(a) MEDICARE ADVANTAGE.—Section 1851 (42 U.S.C. 1395w–21) is amended by adding at the end the following new subsection:

"(j) AVAILABILITY OF PRESCRIPTION DRUG BENEFITS AND SUBSIDIES.—

"(1) OFFERING OF QUALIFIED PRESCRIPTION DRUG COVERAGE.—A Medicare Advantage organization on and after January 1, 2006—

"(A) may not offer a Medicare Advantage plan described in section 1851(a)(2)(A) in an area unless either that plan (or another Medicare Advantage plan offered by the organization in that area) includes qualified prescription drug coverage; and

"(B) may not offer the prescription drug coverage (other than that required under parts A and B) to an enrollee under a Medicare Advantage plan, unless such drug coverage is at least qualified prescription drug coverage and unless the requirements of this subsection with respect to such coverage are met.

"(2) REQUIREMENT FOR ELECTION OF PART D COVERAGE TO OBTAIN QUALIFIED PRESCRIPTION DRUG COVERAGE.—For purposes of this part, an individual who has not elected qualified prescription drug coverage under section 1860D–1(b) shall be treated as being ineligible to enroll in a Medicare Advantage plan under this part that offers such coverage.

"(3) COMPLIANCE WITH CERTAIN ADDITIONAL BENEFICIARY PROTECTIONS FOR PRESCRIPTION DRUG COVERAGE.—With respect to the offering of qualified prescription drug coverage by a Medicare Advantage organization under this part on and after January 1, 2006, the organization and plan shall meet the requirements of subsections (a) through (d) of section 1860D–3 in the same manner as they apply to a PDP sponsor and a prescription drug plan under part D and shall submit to the Administrator the information described in section 1860D–6(a)(2). The Administrator shall waive such requirements to the extent the Administrator determines that such requirements duplicate requirements otherwise applicable to the organization or plan under this part.

"(4) AVAILABILITY OF PREMIUM AND COST-SHARING SUBSIDIES.—In the case of low-income individuals who are enrolled in a Medicare Advantage plan that provides qualified prescription drug coverage, premium and cost-sharing subsidies are provided for such coverage under section 1860D–7.

"(5) AVAILABILITY OF DIRECT AND REINSURANCE SUBSIDIES TO REDUCE BIDS AND PREMIUMS.—Medicare Advantage organizations are provided direct and reinsurance subsidy payments for providing qualified prescription drug coverage under this part under section 1860D–8.

"(6) CONSOLIDATION OF DRUG AND NON-DRUG PREMIUMS.—In the case of a Medicare Advantage plan that includes qualified prescription drug coverage, with respect to an enrollee in such plan there shall be a single premium for both drug and non-drug coverage provided under the plan.

"(7) TRANSITION IN INITIAL ENROLLMENT PERIOD.—Notwithstanding any other provision of this part, the annual, coordinated election period under subsection (e)(3)(B) for 2006 shall be the 6-month period beginning with November 2005.

"(8) QUALIFIED PRESCRIPTION DRUG COVERAGE; STANDARD COVERAGE.—For purposes of this part, the terms 'qualified prescription drug coverage' and 'standard coverage' have the meanings given such terms in section 1860D–2.

"(9) SPECIAL RULES FOR PRIVATE FEE-FOR-SERVICE PLANS.— With respect to a Medicare Advantage plan described in section 1851(a)(2)(C) that offers qualified prescription drug coverage—

"(A) REQUIREMENTS REGARDING NEGOTIATED PRICES.—Subsections (a)(1) and (d)(1) of section 1860D–2 shall not be construed to require the plan to negotiate prices or discounts but shall apply to the extent the plan does so.

"(B) MODIFICATION OF PHARMACY PARTICIPATION REQUIREMENT.—If the plan provides access, without charging additional copayments, to all pharmacies without regard to whether they are participating pharmacies in a network, section 1860D-3(c)(1)(A)(iii) shall not apply to the plan.

"(C) DRUG UTILIZATION MANAGEMENT PROGRAM NOT REQUIRED.—The requirements of section 1860D-3(d)(1)(A) shall not apply to the plan.

"(D) NON-PARTICIPATING PHARMACY DISCLOSURE EXCEPTION.—If the plan provides coverage for drugs purchased from all pharmacies, without entering into contracts or agreements with pharmacies to provide drugs to enrollees covered by the plan, section 1860D-3(d)(5) shall not apply to the plan.".

(b) APPLICATION TO EFFS PLANS.—Subsection (d) of section 1860E–2, as added by section 201(a), is amended to read as follows:

"(d) AVAILABILITY OF PRESCRIPTION DRUG BENEFITS AND SUBSIDIES.—

"(1) OFFERING OF QUALIFIED PRESCRIPTION DRUG COVERAGE.—An EFFS organization—

"(A) may not offer an EFFS plan in an area unless either that plan (or another EFFS plan offered by the organization in that area) includes qualified prescription drug coverage; and

"(B) may not offer the prescription drug coverage (other than that required under parts A and B) to an enrollee under an EFFS plan, unless such drug coverage is at least qualified prescription drug coverage and unless the requirements of this subsection with respect to such coverage are met.

"(2) REQUIREMENT FOR ELECTION OF PART D COVERAGE TO OBTAIN QUALIFIED PRESCRIPTION DRUG COVERAGE.—For purposes of this part, an individual who has not elected qualified prescription drug coverage under section 1860D–1(b) shall be treated as being ineligible to enroll in an EFFS plan under this part that offers such coverage.

"(3) COMPLIANCE WITH CERTAIN ADDITIONAL BENEFICIARY PROTECTIONS FOR PRESCRIPTION DRUG COVERAGE.—With respect to the offering of qualified prescription drug coverage by an EFFS organization under this part, the organization and plan shall meet the requirements of subsections (a) through (d) of section 1860D–3 in the same manner as they apply to a PDP sponsor and a prescription drug plan under part D and shall submit to the Administrator the information described in section 1860D–6(a)(2). The Administrator shall waive such requirements to the extent the Administrator determines that such requirements duplicate requirements otherwise applicable to the organization or plan under this part.

"(4) AVAILABILITY OF PREMIUM AND COST-SHARING SUBSIDIES.—In the case of low-income individuals who are enrolled in an EFFS plan that provides qualified prescription drug coverage, premium and cost-sharing subsidies are provided for such coverage under section 1860D–7.

"(5) AVAILABILITY OF DIRECT AND REINSURANCE SUBSIDIES TO REDUCE BIDS AND PREMIUMS.—EFFS organizations are provided direct and reinsurance sub-

sidy payments for providing qualified prescription drug coverage under this part under section 1860D–8.

"(6) CONSOLIDATION OF DRUG AND NON-DRUG PREMIUMS.—In the case of an EFFS plan that includes qualified prescription drug coverage, with respect to an enrollee in such plan there shall be a single premium for both drug and non-drug coverage provided under the plan.

"(7) QUALIFIED PRESCRIPTION DRUG COVERAGE; STANDARD COVERAGE.—For purposes of this part, the terms 'qualified prescription drug coverage' and 'standard coverage' have the meanings given such terms in section 1860D–2.".

(c) CONFORMING AMENDMENTS.—Section 1851 (42 U.S.C. 1395w–21) is amended—

(1) in subsection (a)(1)—

(A) by inserting "(other than qualified prescription drug benefits)" after "benefits";

(B) by striking the period at the end of subparagraph (B) and inserting a comma; and

(C) by adding after and below subparagraph (B) the following:

"and may elect qualified prescription drug coverage in accordance with section 1860D–1."; and

(2) in subsection (g)(1), by inserting "and section 1860D–1(c)(2)(B)" after "in this subsection".

(d) EFFECTIVE DATE.—The amendments made by this section apply to coverage provided on or after January 1, 2006.

SEC. 103. MEDICAID AMENDMENTS.

(a) DETERMINATIONS OF ELIGIBILITY FOR LOW-INCOME SUBSIDIES.—

(1) REQUIREMENT.—Section 1902(a) (42 U.S.C. 1396a(a)) is amended—

(A) by striking "and" at the end of paragraph (64);

(B) by striking the period at the end of paragraph (65) and inserting "; and"; and

(C) by inserting after paragraph (65) the following new paragraph:

"(66) provide for making eligibility determinations under section 1935(a).".

(2) NEW SECTION.—Title XIX is further amended—

(A) by redesignating section 1935 as section 1936; and

(B) by inserting after section 1934 the following new section:

"SPECIAL PROVISIONS RELATING TO MEDICARE PRESCRIPTION DRUG BENEFIT

"SEC. 1935. (a) REQUIREMENT FOR MAKING ELIGIBILITY DETERMINATIONS FOR LOW-INCOME SUBSIDIES.—As a condition of its State plan under this title under section 1902(a)(66) and receipt of any Federal financial assistance under section 1903(a), a State shall—

"(1) make determinations of eligibility for premium and cost-sharing subsidies under (and in accordance with) section 1860D–7;

"(2) inform the Administrator of the Medicare Benefits Administration of such determinations in cases in which such eligibility is established; and

"(3) otherwise provide such Administrator with such information as may be required to carry out part D of title XVIII (including section 1860D–7).

"(b) PAYMENTS FOR ADDITIONAL ADMINISTRATIVE COSTS.—

"(1) IN GENERAL.—The amounts expended by a State in carrying out subsection (a) are, subject to paragraph (2), expenditures reimbursable under the appropriate paragraph of section 1903(a); except that, notwithstanding any other provision of such section, the applicable Federal matching rates with respect to such expenditures under such section shall be increased as follows (but in no case shall the rate as so increased exceed 100 percent):

"(A) For expenditures attributable to costs incurred during 2005, the otherwise applicable Federal matching rate shall be increased by 10 percent of the percentage otherwise payable (but for this subsection) by the State.

"(B)(i) For expenditures attributable to costs incurred during 2006 and each subsequent year through 2013, the otherwise applicable Federal matching rate shall be increased by the applicable percent (as defined in clause (ii)) of the percentage otherwise payable (but for this subsection) by the State.

"(ii) For purposes of clause (i), the 'applicable percent' for—

"(I) 2006 is 20 percent; or

"(II) a subsequent year is the applicable percent under this clause for the previous year increased by 10 percentage points.

"(C) For expenditures attributable to costs incurred after 2013, the otherwise applicable Federal matching rate shall be increased to 100 percent.

"(2) COORDINATION.—The State shall provide the Administrator with such information as may be necessary to properly allocate administrative expenditures

described in paragraph (1) that may otherwise be made for similar eligibility determinations.".

(b) PHASED-IN FEDERAL ASSUMPTION OF MEDICAID RESPONSIBILITY FOR PREMIUM AND COST-SHARING SUBSIDIES FOR DUALLY ELIGIBLE INDIVIDUALS.—

(1) IN GENERAL.—Section 1903(a)(1) (42 U.S.C. 1396b(a)(1)) is amended by inserting before the semicolon the following: ", reduced by the amount computed under section 1935(c)(1) for the State and the quarter".

(2) AMOUNT DESCRIBED.—Section 1935, as inserted by subsection (a)(2), is amended by adding at the end the following new subsection:

"(c) FEDERAL ASSUMPTION OF MEDICAID PRESCRIPTION DRUG COSTS FOR DUALLY-ELIGIBLE BENEFICIARIES.—

"(1) IN GENERAL.—For purposes of section 1903(a)(1), for a State that is one of the 50 States or the District of Columbia for a calendar quarter in a year (beginning with 2005) the amount computed under this subsection is equal to the product of the following:

"(A) MEDICARE SUBSIDIES.—The total amount of payments made in the quarter under section 1860D–7 (relating to premium and cost-sharing prescription drug subsidies for low-income medicare beneficiaries) that are attributable to individuals who are residents of the State and are entitled to benefits with respect to prescribed drugs under the State plan under this title (including such a plan operating under a waiver under section 1115).

"(B) STATE MATCHING RATE.—A proportion computed by subtracting from 100 percent the Federal medical assistance percentage (as defined in section 1905(b)) applicable to the State and the quarter.

"(C) PHASE-OUT PROPORTION.—The phase-out proportion (as defined in paragraph (2)) for the quarter.

"(2) PHASE-OUT PROPORTION.—For purposes of paragraph (1)(C), the 'phase-out proportion' for a calendar quarter in—

"(A) 2006 is 93-⅓ percent;

"(B) a subsequent year before 2021, is the phase-out proportion for calendar quarters in the previous year decreased by 6-⅔ percentage points; or

"(C) a year after 2020 is 0 percent.".

(c) MEDICAID PROVIDING WRAP-AROUND BENEFITS.—Section 1935, as so inserted and amended, is further amended by adding at the end the following new subsection:

"(d) ADDITIONAL PROVISIONS.—

"(1) MEDICAID AS SECONDARY PAYOR.—In the case of an individual who is entitled to qualified prescription drug coverage under a prescription drug plan under part D of title XVIII (or under a MA-EFFS Rx plan under part C or E of such title) and medical assistance for prescribed drugs under this title, medical assistance shall continue to be provided under this title (other than for copayment amounts specified in section 1860D–7(a)(1)(B), notwithstanding section 1916) for prescribed drugs to the extent payment is not made under the prescription drug plan or MA-EFFS Rx plan selected by the individual.

"(2) CONDITION.—A State may require, as a condition for the receipt of medical assistance under this title with respect to prescription drug benefits for an individual eligible to obtain qualified prescription drug coverage described in paragraph (1), that the individual elect qualified prescription drug coverage under section 1860D–1.".

(d) TREATMENT OF TERRITORIES.—

(1) IN GENERAL.—Section 1935, as so inserted and amended, is further amended—

(A) in subsection (a) in the matter preceding paragraph (1), by inserting "subject to subsection (e)" after "section 1903(a)";

(B) in subsection (c)(1), by inserting "subject to subsection (e)" after "1903(a)(1)"; and

(C) by adding at the end the following new subsection:

"(e) TREATMENT OF TERRITORIES.—

"(1) IN GENERAL.—In the case of a State, other than the 50 States and the District of Columbia—

"(A) the previous provisions of this section shall not apply to residents of such State; and

"(B) if the State establishes a plan described in paragraph (2) (for providing medical assistance with respect to the provision of prescription drugs to medicare beneficiaries), the amount otherwise determined under section 1108(f) (as increased under section 1108(g)) for the State shall be increased by the amount specified in paragraph (3).

"(2) PLAN.—The plan described in this paragraph is a plan that—

"(A) provides medical assistance with respect to the provision of covered outpatient drugs (as defined in section 1860D–2(f)) to low-income medicare beneficiaries; and

"(B) assures that additional amounts received by the State that are attributable to the operation of this subsection are used only for such assistance.

"(3) INCREASED AMOUNT.—

"(A) IN GENERAL.—The amount specified in this paragraph for a State for a year is equal to the product of—

"(i) the aggregate amount specified in subparagraph (B); and

"(ii) the amount specified in section 1108(g)(1) for that State, divided by the sum of the amounts specified in such section for all such States.

"(B) AGGREGATE AMOUNT.—The aggregate amount specified in this subparagraph for—

"(i) 2006, is equal to $25,000,000; or

"(ii) a subsequent year, is equal to the aggregate amount specified in this subparagraph for the previous year increased by annual percentage increase specified in section 1860D–2(b)(5) for the year involved.

"(4) REPORT.—The Administrator shall submit to Congress a report on the application of this subsection and may include in the report such recommendations as the Administrator deems appropriate.".

(2) CONFORMING AMENDMENT.—Section 1108(f) (42 U.S.C. 1308(f)) is amended by inserting "and section 1935(e)(1)(B)" after "Subject to subsection (g)".

(e) AMENDMENT TO BEST PRICE.—Section 1927(c)(1)(C)(i) (42 U.S.C. 1396r–8(c)(1)(C)(i)) is amended—

(1) by striking "and" at the end of subclause (III);

(2) by striking the period at the end of subclause (IV) and inserting "; and"; and

(3) by adding at the end the following new subclause:

"(V) any prices charged which are negotiated by a prescription drug plan under part D of title XVIII, by a MA-EFFS Rx plan under part C or E of such title with respect to covered outpatient drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D–8(f)(1)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title.".

SEC. 104. MEDIGAP TRANSITION.

(a) IN GENERAL.—Section 1882 (42 U.S.C. 1395ss) is amended by adding at the end the following new subsection:

"(v) COVERAGE OF PRESCRIPTION DRUGS.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, except as provided in paragraph (3) no new medicare supplemental policy that provides coverage of expenses for prescription drugs may be issued under this section on or after January 1, 2006, to an individual unless it replaces a medicare supplemental policy that was issued to that individual and that provided some coverage of expenses for prescription drugs. Nothing in this subsection shall be construed as preventing the policy holder of a medicare supplemental policy issued before January 1, 2006, from continuing to receive benefits under such policy on and after such date.

"(2) ISSUANCE OF SUBSTITUTE POLICIES FOR BENEFICIARIES ENROLLED WITH A PLAN UNDER PART D.—

"(A) IN GENERAL.—The issuer of a medicare supplemental policy—

"(i) may not deny or condition the issuance or effectiveness of a medicare supplemental policy that has a benefit package classified as 'A', 'B', 'C', 'D', 'E', 'F', or 'G' (under the standards established under subsection (p)(2)) and that is offered and is available for issuance to new enrollees by such issuer;

"(ii) may not discriminate in the pricing of such policy, because of health status, claims experience, receipt of health care, or medical condition; and

"(iii) may not impose an exclusion of benefits based on a pre-existing condition under such policy,

in the case of an individual described in subparagraph (B) who seeks to enroll under the policy not later than 63 days after the date of the termination of enrollment described in such paragraph and who submits evidence of the date of termination or disenrollment along with the application for such medicare supplemental policy.

"(B) INDIVIDUAL COVERED.—An individual described in this subparagraph is an individual who—

"(i) enrolls in a prescription drug plan under part D; and

"(ii) at the time of such enrollment was enrolled and terminates enrollment in a medicare supplemental policy which has a benefit package classified as 'H', 'I', or 'J' under the standards referred to in subparagraph (A)(i) or terminates enrollment in a policy to which such standards do not apply but which provides benefits for prescription drugs.

"(C) ENFORCEMENT.—The provisions of paragraph (4) of subsection (s) shall apply with respect to the requirements of this paragraph in the same manner as they apply to the requirements of such subsection.

"(3) NEW STANDARDS.—In applying subsection (p)(1)(E) (including permitting the NAIC to revise its model regulations in response to changes in law) with respect to the change in benefits resulting from title I of the Medicare Prescription Drug and Modernization Act of 2003, with respect to policies issued to individuals who are enrolled in a plan under part D, the changes in standards shall only provide for substituting (for the benefit packages described in paragraph (2)(B)(ii) that included coverage for prescription drugs) two benefit packages that may provide for coverage of cost-sharing (other than the prescription drug deductible) with respect to qualified prescription drug coverage under such part. The two benefit packages shall be consistent with the following:

"(A) FIRST NEW POLICY.—The policy described in this subparagraph has the following benefits, notwithstanding any other provision of this section relating to a core benefit package:

"(i) Coverage of 50 percent of the cost-sharing otherwise applicable under parts A and B, except coverage of 100 percent of any cost-sharing otherwise applicable for preventive benefits.

"(ii) No coverage of the part B deductible.

"(iii) Coverage for all hospital coinsurance for long stays (as in the current core benefit package).

"(iv) A limitation on annual out-of-pocket expenditures under parts A and B to $4,000 in 2005 (or, in a subsequent year, to such limitation for the previous year increased by an appropriate inflation adjustment specified by the Secretary).

"(B) SECOND NEW POLICY.—The policy described in this subparagraph has the same benefits as the policy described in subparagraph (A), except as follows:

"(i) Substitute '75 percent' for '50 percent' in clause (i) of such subparagraph.

"(ii) Substitute '$2,000' for '$4,000' in clause (iv) of such subparagraph.

"(4) CONSTRUCTION.—Any provision in this section or in a medicare supplemental policy relating to guaranteed renewability of coverage shall be deemed to have been met through the offering of other coverage under this subsection.".

(b) NAIC REPORT TO CONGRESS ON MEDIGAP MODERNIZATION.—The Secretary shall request the National Association of Insurance Commissioners to submit to Congress, not later than 18 months after the date of the enactment of this Act, a report that includes recommendations on the modernization of coverage under the medigap program under section 1882 of the Social Security Act (42 U.S.C. 1395ss).

SEC. 105. MEDICARE PRESCRIPTION DRUG DISCOUNT CARD ENDORSEMENT PROGRAM.

(a) IN GENERAL.—Title XVIII is amended by inserting after section 1806 the following new sections:

"MEDICARE PRESCRIPTION DRUG DISCOUNT CARD ENDORSEMENT PROGRAM

"SEC. 1807. (a) ESTABLISHMENT OF PROGRAM.—

"(1) IN GENERAL.—The Secretary (or the Medicare Benefits Administrator pursuant to section 1809(c)(3)(C)) shall establish a program to endorse prescription drug discount card programs (each such program referred to as an 'endorsed program') that meet the requirements of this section in order to provide access to prescription drug discounts for medicare beneficiaries throughout the United States. The Secretary shall make available to medicare beneficiaries information regarding endorsed programs under this section.

"(2) LIMITED PERIOD OF OPERATION.—The Secretary shall begin the program under this section as soon as possible, but in no case later than 90 days after the date of the enactment of this section. The Secretary shall provide for an appropriate transition and discontinuation of such program at the time medicare prescription drug benefits first become available under part D.

"(b) REQUIREMENTS FOR CARD ENDORSEMENT PROGRAM.—The Secretary may not endorse a prescription drug discount card program under this section unless the program meets the following requirements:

"(1) SAVINGS TO MEDICARE BENEFICIARIES.—The program passes on to medicare beneficiaries who enroll in the program discounts, rebates, and other price concessions on prescription drugs, including discounts negotiated with pharmacies and manufacturers.

"(2) PROHIBITION ON APPLICATION ONLY TO MAIL ORDER.—The program applies to drugs that are available other than solely through mail order.

"(3) BENEFICIARY SERVICES.—The program provides pharmaceutical support services, such as education and counseling, and services to prevent adverse drug interactions.

"(4) INFORMATION.—The program makes available to medicare beneficiaries through the Internet and otherwise information, including information on enrollment fees, prices charged to beneficiaries, and services offered under the program, that the Secretary identifies as being necessary to provide for informed choice by beneficiaries among endorsed programs.

"(5) DEMONSTRATED EXPERIENCE.—The program is operated directly, or through arrangements with affiliated organization, by an entity that has demonstrated experience and expertise in operating such a program or a similar program.

"(6) QUALITY ASSURANCE.—Such operating entity has in place adequate procedures for assuring quality service under the program.

"(7) ENROLLMENT FEES.—The program may charge an annual enrollment fee, but the amount of such annual fee may not exceed $30. A State may pay some or all of the fee for individuals residing in the State.

"(8) CONFIDENTIALITY PROTECTIONS.—The program implements policies and procedures to safeguard the use and disclosure of program beneficiaries' individually identifiable health information in a manner consistent with the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

"(9) PERIODIC REPORTS TO SECRETARY.—The entity operating the program shall submit to the Secretary periodic reports on performance, utilization, finances, and such other matters as the Secretary may specify.

"(10) ADDITIONAL BENEFICIARY PROTECTIONS.—The program meets such additional requirements as the Secretary identifies to protect and promote the interest of medicare beneficiaries, including requirements that ensure that beneficiaries are not charged more than the lower of the negotiated retail price or the usual and customary price.

The prices negotiated by a prescription drug discount card program endorsed under this section shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).

"(c) PROGRAM OPERATION.—The Secretary shall operate the program under this section consistent with the following:

"(1) PROMOTION OF INFORMED CHOICE.—In order to promote informed choice among endorsed prescription drug discount card programs, the Secretary shall provide for the dissemination of information which compares the prices and services of such programs in a manner coordinated with the dissemination of educational information on Medicare Advantage plans under part C.

"(2) OVERSIGHT.—The Secretary shall provide appropriate oversight to ensure compliance of endorsed programs with the requirements of this section, including verification and disclosure (upon request) of the discounts and services provided, the amount of dispensing fees recognized, and audits under section 1860D–2(d)(3).

"(3) USE OF MEDICARE TOLL-FREE NUMBER.—The Secretary shall provide through the 1-800-medicare toll free telephone number for the receipt and response to inquiries and complaints concerning the program and programs endorsed under this section.

"(4) SANCTIONS FOR ABUSIVE PRACTICES.—The Secretary may implement intermediate sanctions or may revoke the endorsement of a program in the case of a program that the Secretary determines no longer meets the requirements of this section or that has engaged in false or misleading marketing practices.

"(5) ENROLLMENT PRACTICES.—A medicare beneficiary may not be enrolled in more than one endorsed program at any time. A medicare beneficiary may change the endorsed program in which the beneficiary is enrolled, but may not make such change until the beneficiary has been enrolled in a program for a minimum period of time specified by the Secretary.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

"(e) INTERIM, FINAL REGULATORY AUTHORITY.—In order to carry out this section in a timely manner, the Secretary may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment.

"TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE PROGRAM FOR LOW-INCOME BENEFICIARIES

"SEC. 1807A. (a) PURPOSE.—The purpose of this section is to provide low-income medicare beneficiaries with incomes below 150 percent of the Federal poverty level immediate assistance in the purchase of covered outpatient prescription drugs during the period before the program under part D becomes effective.

"(b) APPROPRIATIONS.—For the purpose of carrying out this section, there is appropriated, out of any money in the Treasury not otherwise appropriated—

"(1) for fiscal year 2004, $2,000,000,000; and

"(2) for fiscal year 2005, $3,000,000,000.

"(c) ELIGIBILITY.—

"(1) IN GENERAL.—The Secretary shall establish eligibility standards consistent with this subsection.

"(2) SPECIFICS.—In no case shall an individual be eligible for assistance under this section unless the individual—

"(A) is entitled to benefits under part A or enrolled under part B;

"(B) has income that is at or below 150 percent of the Federal poverty line;

"(C) meets the resources requirement described in section 1905(p)(1)(C);

"(D) is enrolled under a prescription drug discount card program under section 1807 (or under an alternative program authorized under subsection (d)(2)); and

"(E) is not eligible for coverage of, or assistance for, outpatient prescription drugs under any of the following:

"(i) A medicaid plan under title XIX (including under any waiver approved under section 1115).

"(ii) Enrollment under a group health plan or health insurance coverage.

"(iii) Enrollment under a medicare supplemental insurance policy.

"(iv) Chapter 55 of title 10, United States Code (relating to medical and dental care for members of the uniformed services).

"(v) Chapter 17 of title 38, United States Code (relating to Veterans' medical care).

"(vi) Enrollment under a plan under chapter 89 of title 5, United States Code (relating to the Federal employees' health benefits program).

"(vii) The Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.).

"(d) FORM OF ASSISTANCE.—

"(1) IN GENERAL.—Subject to paragraph (2), the assistance under this section to an eligible individual shall be in such form as the Secretary shall specify, including the use of a debit card mechanism to pay for drugs purchased through the use of the prescription drug discount card program to eligible individuals who are enrolled in such program.

"(2) THROUGH ALTERNATIVE STATE PROGRAM.—A State may apply to the Secretary for authorization to provide the assistance under this section to an eligible individual through a State pharmaceutical assistance program or private program of pharmaceutical assistance. The Secretary shall not authorize the use of such a program unless the Secretary finds that the program—

"(A) was in existence before the date of the enactment of this section; and

"(B) is reasonably designed to provide for pharmaceutical assistance for a number of individuals, and in a scope, that is not less than the number of individuals, and minimum required amount, that would occur if the provisions of this paragraph had not applied in the State.

"(3) RELATIONSHIP TO DISCOUNTS.—The assistance provided under this section is in addition to the discount otherwise available to individuals enrolled in prescription drug discount card programs who are not eligible individuals.

"(4) LIMITATION ON ASSISTANCE.—

"(A) IN GENERAL.—The assistance under this section for an eligible individual shall be limited to assistance—

"(i) for covered outpatient drugs (as defined for purposes of part D) and for enrollment fees imposed under prescription drug discount card programs; and

"(ii) for expenses incurred—

"(I) on and after the date the individual is both enrolled in the prescription drug discount card program and determined to be an eligible individual under this section; and

"(II) before the date benefits are first available under the program under part D.

"(B) AUTHORITY.—The Secretary shall take such steps as may be necessary to assure compliance with the expenditure limitations described in subsection (b).

"(e) PAYMENT OF FEDERAL SUBSIDY TO SPONSORS.—

"(1) IN GENERAL.—Insofar as assistance is provided under this section through programs under section 1807, the Secretary shall make payment (within the amounts under subsection (b), less the administrative costs relating to determinations of eligibility) to the sponsor of the prescription drug discount card program (or to a State or other entity operating an alternative program under subsection (d)(2)) in which an eligible individual is enrolled of the amount of the assistance provided by the sponsor pursuant to this section.

"(2) PERIODIC PAYMENTS.—Payments under this subsection shall be made on a monthly or other periodic installment basis, based upon estimates of the Secretary and shall be reduced or increased to the extent of any overpayment or underpayment which the Secretary determines was made under this section for any prior period and with respect to which adjustment has not already been made under this paragraph.

"(f) DEFINITIONS.—For purposes of this section:

"(1) ELIGIBLE INDIVIDUAL.—The term 'eligible individual' means an individual who is determined by a State to be eligible for assistance under this section.

"(2) PRESCRIPTION DRUG DISCOUNT CARD PROGRAM.—The term 'prescription drug discount card program' means such a program that is endorsed under section 1807.

"(3) SPONSOR.—The term 'sponsor' means the sponsor of a prescription drug discount card program, or, in the case of an alternative program authorized under subsection (d)(2), the State or other entity operating the program.".

(b) CONFORMING AMENDMENT.—Section 1927(c)(1)(C)(i)(V) (42 U.S.C. 1396r–8(c)(1)(C)(i)(V)), as added by section 103(e), is amended by striking "or by a qualified retiree prescription drug plan (as defined in section 1860D–8(f)(1))" and inserting "by a qualified retiree prescription drug plan (as defined in section 1860D–8(f)(1)), or by a prescription drug discount card program endorsed under section 1807".

SEC. 106. DISCLOSURE OF RETURN INFORMATION FOR PURPOSES OF CARRYING OUT MEDICARE CATASTROPHIC PRESCRIPTION DRUG PROGRAM.

(a) IN GENERAL.—Subsection (l) of section 6103 of the Internal Revenue Code of 1986 (relating to disclosure of returns and return information for purposes other than tax administration) is amended by adding at the end the following new paragraph:

"(19) DISCLOSURE OF RETURN INFORMATION FOR PURPOSES OF CARRYING OUT MEDICARE CATASTROPHIC PRESCRIPTION DRUG PROGRAM.—

"(A) IN GENERAL.—The Secretary may, upon written request from the Secretary of Health and Human Services under section 1860D–2(b)(4)(E)(i) of the Social Security Act, disclose to officers and employees of the Department of Health and Human Services with respect to a specified taxpayer for the taxable year specified by the Secretary of Health and Human Services in such request—

"(i) the taxpayer identity information with respect to such taxpayer, and

"(ii) the adjusted gross income of such taxpayer for the taxable year (or, if less, the income threshold limit specified in section 1860D–2(b)(4)(D)(ii) for the calendar year specified by such Secretary in such request).

"(B) SPECIFIED TAXPAYER.—For purposes of this paragraph, the term 'specified taxpayer' means any taxpayer who—

"(i) is identified by the Secretary of Health and Human Services in the request referred to in subparagraph (A), and

"(ii) either—

"(I) has an adjusted gross income for the taxable year referred to in subparagraph (A) in excess of the income threshold specified in section 1860D–2(b)(4)(D)(ii) of such Act for the calendar year referred to in such subparagraph, or

"(II) is identified by such Secretary under subparagraph (A) as being an individual who elected to use more recent information under section 1860D–2(b)(4)(D)(v) of such Act.

"(C) JOINT RETURNS.—In the case of a joint return, the Secretary shall, for purposes of applying this paragraph, treat each spouse as a separate taxpayer having an adjusted gross income equal to one-half of the adjusted gross income determined with respect to such return.

"(D) RESTRICTION ON USE OF DISCLOSED INFORMATION.—Return information disclosed under subparagraph (A) may be used by officers and employees of the Department of Health and Human Services only for the purpose of administering the prescription drug benefit under title XVIII of the Social Security Act. Such officers and employees may disclose the annual out-of-pocket threshold which applies to an individual under such part to the entity that offers the plan referred to in section 1860D–2(b)(4)(E)(ii) of such Act in which such individual is enrolled. Such sponsor may use such information only for purposes of administering such benefit.".

(b) CONFIDENTIALITY.—Paragraph (3) of section 6103(a) of such Code is amended by striking "or (16)" and inserting "(16), or (19)".

(c) PROCEDURES AND RECORDKEEPING RELATED TO DISCLOSURES.—Subsection (p)(4) of section 6103 of such Code is amended by striking "any other person described in subsection (l)(16) or (17)" each place it appears and inserting "any other person described in subsection (l)(16), (17), or (19)".

(d) UNAUTHORIZED DISCLOSURE.—Paragraph (2) of section 7213(a) of such Code is amended by striking "or (16)" and inserting "(16), or (19)".

(e) UNAUTHORIZED INSPECTION.—Subparagraph (B) of section 7213A(a)(1) of such Code is amended by inserting "or (19)" after "subsection (l)(18)".

SEC. 107. STATE PHARMACEUTICAL ASSISTANCE TRANSITION COMMISSION.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—There is established, as of the first day of the third month beginning after the date of the enactment of this Act, a State Pharmaceutical Assistance Transition Commission (in this section referred to as the "Commission") to develop a proposal for addressing the unique transitional issues facing State pharmaceutical assistance programs, and program participants, due to the implementation of the medicare prescription drug program under part D of title XVIII of the Social Security Act.

(2) DEFINITIONS.—For purposes of this section:

(A) STATE PHARMACEUTICAL ASSISTANCE PROGRAM DEFINED.—The term "State pharmaceutical assistance program" means a program (other than the medicaid program) operated by a State (or under contract with a State) that provides as of the date of the enactment of this Act assistance to low-income medicare beneficiaries for the purchase of prescription drugs.

(B) PROGRAM PARTICIPANT.—The term "program participant" means a low-income medicare beneficiary who is a participant in a State pharmaceutical assistance program.

(b) COMPOSITION.—The Commission shall include the following:

(1) A representative of each governor of each State that the Secretary identifies as operating on a statewide basis a State pharmaceutical assistance program that provides for eligibility and benefits that are comparable or more generous than the low-income assistance eligibility and benefits offered under part D of title XVIII of the Social Security Act.

(2) Representatives from other States that the Secretary identifies have in operation other State pharmaceutical assistance programs, as appointed by the Secretary.

(3) Representatives of organizations that have an inherent interest in program participants or the program itself, as appointed by the Secretary but not to exceed the number of representatives under paragraphs (1) and (2).

(4) Representatives of Medicare Advantage organizations and other private health insurance plans, as appointed by the Secretary.

(5) The Secretary (or the Secretary's designee) and such other members as the Secretary may specify

The Secretary shall designate a member to serve as chair of the Commission and the Commission shall meet at the call of the chair.

(c) DEVELOPMENT OF PROPOSAL.—The Commission shall develop the proposal described in subsection (a) in a manner consistent with the following principles:

(1) Protection of the interests of program participants in a manner that is the least disruptive to such participants and that includes a single point of contact for enrollment and processing of benefits.

(2) Protection of the financial and flexibility interests of States so that States are not financially worse off as a result of the enactment of this title.

(3) Principles of medicare modernization provided under title II of this Act.

(d) REPORT.—By not later than January 1, 2005, the Commission shall submit to the President and the Congress a report that contains a detailed proposal (including specific legislative or administrative recommendations, if any) and such other recommendations as the Commission deems appropriate.

(e) SUPPORT.—The Secretary shall provide the Commission with the administrative support services necessary for the Commission to carry out its responsibilities under this section.

(f) TERMINATION.—The Commission shall terminate 30 days after the date of submission of the report under subsection (d).

TITLE II—MEDICARE ENHANCED FEE-FOR-SERVICE AND MEDICARE ADVANTAGE PROGRAMS; MEDICARE COMPETITION

SEC. 200. MEDICARE MODERNIZATION AND REVITALIZATION.

This title provides for—

(1) establishment of the medicare enhanced fee-for-service (EFFS) program under which medicare beneficiaries are provided access to a range of enhanced fee-for-service (EFFS) plans that may use preferred provider networks to offer an enhanced range of benefits;

(2) establishment of a Medicare Advantage program that offers improved managed care plans with coordinated care; and

(3) competitive bidding, in the style of the Federal Employees Health Benefits program (FEHBP), among enhanced fee-for-service plans and Medicare Advantage plans in order to promote greater efficiency and responsiveness to medicare beneficiaries.

Subtitle A—Medicare Enhanced Fee-for-Service Program

SEC. 201. ESTABLISHMENT OF ENHANCED FEE-FOR-SERVICE (EFFS) PROGRAM UNDER MEDICARE.

(a) IN GENERAL.—Title XVIII, as amended by section 101(a), is amended—

(1) by redesignating part E as part F; and

(2) by inserting after part D the following new part:

"PART E—ENHANCED FEE-FOR-SERVICE PROGRAM

"OFFERING OF ENHANCED FEE-FOR-SERVICE PLANS THROUGHOUT THE UNITED STATES

"SEC. 1860E–1. (a) ESTABLISHMENT OF PROGRAM.—

"(1) IN GENERAL.—The Administrator shall establish under this part beginning January 1, 2006, an enhanced fee-for-service program under which enhanced fee-for-service plans (as defined in subsection (b)) are offered to EFFS-eligible individuals (as so defined) in EFFS regions throughout the United States.

"(2) EFFS REGIONS.—For purposes of this part the Administrator shall establish EFFS regions throughout the United States by dividing the entire United States into at least 10 such regions. Before establishing such regions, the Administrator shall conduct a market survey and analysis, including an examination of current insurance markets, to determine how the regions should be established. The regions shall be established in a manner to take into consideration maximizing full access for all EFFS-eligible individuals, especially those residing in rural areas.

"(b) DEFINITIONS.—For purposes of this part:

"(1) EFFS ORGANIZATION.—The 'EFFS organization' means an entity that the Administrator certifies as meeting the requirements and standards applicable to such organization under this part.

"(2) ENHANCED FEE-FOR-SERVICE PLAN; EFFS PLAN.—The terms 'enhanced fee-for-service plan' and 'EFFS plan' mean health benefits coverage offered under a policy, contract, or plan by an EFFS organization pursuant to and in accordance with a contract pursuant to section 1860E–4(c), but only if the plan provides either fee-for-service coverage described in the following subparagraph (A) or preferred provider coverage described in the following subparagraph (B):

"(A) FEE-FOR-SERVICE COVERAGE.—The plan—

"(i) reimburses hospitals, physicians, and other providers at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk;

"(ii) does not vary such rates for such a provider based on utilization relating to such provider; and

"(iii) does not restrict the selection of providers among those who are lawfully authorized to provide the covered services and agree to accept the terms and conditions of payment established by the plan.

"(B) PREFERRED PROVIDER COVERAGE.—The plan—

"(i) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; and

"(ii) provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers.

"(3) EFFS ELIGIBLE INDIVIDUAL.—The term 'EFFS eligible individual' means an eligible individual described in section 1851(a)(3).

"(4) EFFS REGION.—The term 'EFFS region' means a region established under subsection (a)(2).

"(c) APPLICATION OF CERTAIN ELIGIBILITY, ENROLLMENT, ETC. REQUIREMENTS.—The provisions of section 1851 (other than subsection (h)(4)(A)) shall apply to EFFS plans offered by an EFFS organization in an EFFS region, including subsection (g) (relating to guaranteed issue and renewal).

"OFFERING OF ENHANCED FEE-FOR-SERVICE (EFFS) PLANS

"SEC. 1860E–2. (a) PLAN REQUIREMENTS.—No EFFS plan may be offered under this part in an EFFS region unless the requirements of this part are met with respect to the plan and EFFS organization offering the plan.

"(b) AVAILABLE TO ALL EFFS BENEFICIARIES IN THE ENTIRE REGION.—With respect to an EFFS plan offered in an EFFS region—

"(1) IN GENERAL.—The plan must be offered to all EFFS-eligible individuals residing in the region.

"(2) ASSURING ACCESS TO SERVICES.—The plan shall comply with the requirements of section 1852(d)(4).

"(c) BENEFITS.—

"(1) IN GENERAL.—Each EFFS plan shall provide to members enrolled in the plan under this part benefits, through providers and other persons that meet the applicable requirements of this title and part A of title XI—

"(A) for the items and services described in section 1852(a)(1);

"(B) that are uniform for the plan for all EFFS eligible individuals residing in the same EFFS region;

"(C) that include a single deductible applicable to benefits under parts A and B and include a catastrophic limit on out-of-pocket expenditures for such covered benefits; and

"(D) that include benefits for prescription drug coverage for each enrollee who elects under part D to be provided qualified prescription drug coverage through the plan.

"(2) DISAPPROVAL AUTHORITY.—The Administrator shall not approve a plan of an EFFS organization if the Administrator determines (pursuant to the last sentence of section 1852(b)(1)(A)) that the benefits are designed to substantially discourage enrollment by certain EFFS eligible individuals with the organization.

"(d) OUTPATIENT PRESCRIPTION DRUG COVERAGE.—For rules concerning the offering of prescription drug coverage under EFFS plans, see the amendment made by section 102(b) of the Medicare Prescription Drug and Modernization Act of 2003.

"(e) OTHER ADDITIONAL PROVISIONS.—The provisions of section 1852 (other than subsection (a)(1)) shall apply under this part to EFFS plans. For the application of chronic care improvement provisions, see the amendment made by section 722(b).

"SUBMISSION OF BIDS; BENEFICIARY SAVINGS; PAYMENT OF PLANS

"SEC. 1860E–3. (a) SUBMISSION OF BIDS.—

"(1) REQUIREMENT.—

"(A) EFFS MONTHLY BID AMOUNT.—For each year (beginning with 2006), an EFFS organization shall submit to the Administrator an EFFS monthly bid amount for each EFFS plan offered in each region. Each such bid is referred to in this section as the 'EFFS monthly bid amount'.

"(B) FORM.—Such bid amounts shall be submitted for each such plan and region in a form and manner and time specified by the Administrator, and shall include information described in paragraph (3)(A).

"(2) UNIFORM BID AMOUNTS.—Each EFFS monthly bid amount submitted under paragraph (1) by an EFFS organization under this part for an EFFS plan in an EFFS region may not vary among EFFS eligible individuals residing in the EFFS region involved.

"(3) SUBMISSION OF BID AMOUNT INFORMATION BY EFFS ORGANIZATIONS.—

"(A) INFORMATION TO BE SUBMITTED.—The information described in this subparagraph is as follows:

"(i) The EFFS monthly bid amount for provision of all items and services under this part, which amount shall be based on average costs for a typical beneficiary residing in the region, and the actuarial basis for determining such amount.

"(ii) The proportions of such bid amount that are attributable to—

"(I) the provision of statutory non-drug benefits (such portion referred to in this part as the 'unadjusted EFFS statutory non-drug monthly bid amount');

"(II) the provision of statutory prescription drug benefits; and

"(III) the provision of non-statutory benefits;

and the actuarial basis for determining such proportions.

"(iii) Such additional information as the Administrator may require to verify the actuarial bases described in clauses (i) and (ii).

"(B) STATUTORY BENEFITS DEFINED.—For purposes of this part:

"(i) The term 'statutory non-drug benefits' means benefits under section 1852(a)(1).

"(ii) The term 'statutory prescription drug benefits' means benefits under part D.

"(iii) The term 'statutory benefits' means statutory prescription drug benefits and statutory non-drug benefits.

"(C) ACCEPTANCE AND NEGOTIATION OF BID AMOUNTS.—The Administrator has the authority to negotiate regarding monthly bid amounts submitted under subparagraph (A) (and the proportion described in subparagraph (A)(ii)), and for such purpose, the Administrator has negotiation authority that the Director of the Office of Personnel Management has with respect to health benefits plans under chapter 89 of title 5, United States Code. The Administrator may reject such a bid amount or proportion if the Administrator determines that such amount or proportion is not supported by the actuarial bases provided under subparagraph (A).

"(D) CONTRACT AUTHORITY.—The Administrator may, taking into account the unadjusted EFFS statutory non-drug monthly bid amounts accepted under subparagraph (C), enter into contracts for the offering of up to 3 EFFS plans in any region.

"(b) PROVISION OF BENEFICIARY SAVINGS FOR CERTAIN PLANS.—

"(1) BENEFICIARY REBATE RULE.—

"(A) REQUIREMENT.—The EFFS plan shall provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings (if any) described in paragraph (2) applicable to the plan and year involved.

"(B) FORM OF REBATE.—A rebate required under this paragraph shall be provided—

"(i) through the crediting of the amount of the rebate towards the EFFS monthly prescription drug beneficiary premium (as defined in section 1860E–4(a)(3)(B)) and the EFFS monthly supplemental beneficiary premium (as defined in section 1860E–4(a)(3)(C));

"(ii) through a direct monthly payment (through electronic funds transfer or otherwise); or

"(iii) through other means approved by the Medicare Benefits Administrator,

or any combination thereof.

"(2) COMPUTATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—For purposes of paragraph (1)(A), the average per capita monthly savings referred to in such paragraph for an EFFS plan and year is computed as follows:

"(A) DETERMINATION OF REGION-WIDE AVERAGE RISK ADJUSTMENT.—

"(i) IN GENERAL.—The Medicare Benefits Administrator shall determine, at the same time rates are promulgated under section 1853(b)(1) (beginning with 2006), for each EFFS region the average of the risk adjustment factors described in subsection (c)(3) to be applied to enrollees under this part in that region. In the case of an EFFS region in which an EFFS plan was offered in the previous year, the Administrator may compute such average based upon risk adjustment factors applied under subsection (c)(3) in that region in a previous year.

"(ii) TREATMENT OF NEW REGIONS.—In the case of a region in which no EFFS plan was offered in the previous year, the Administrator shall estimate such average. In making such estimate, the Administrator may use average risk adjustment factors applied to comparable EFFS regions or applied on a national basis.

"(B) DETERMINATION OF RISK ADJUSTED BENCHMARK AND RISK-ADJUSTED BID.—For each EFFS plan offered in an EFFS region, the Administrator shall—

"(i) adjust the EFFS region-specific non-drug monthly benchmark amount (as defined in paragraph (3)) by the applicable average risk adjustment factor computed under subparagraph (A); and

"(ii) adjust the unadjusted EFFS statutory non-drug monthly bid amount by such applicable average risk adjustment factor.

"(C) DETERMINATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—The average per capita monthly savings described in this subparagraph is equal to the amount (if any) by which—

"(i) the risk-adjusted benchmark amount computed under subparagraph (B)(i), exceeds

"(ii) the risk-adjusted bid computed under subparagraph (B)(ii).

"(3) COMPUTATION OF EFFS REGION-SPECIFIC NON-DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of this part, the term 'EFFS region-specific non-drug monthly benchmark amount' means, with respect to an EFFS region for a month in a year, an amount equal to 1/12 of the average (weighted by number of EFFS eligible individuals in each payment area described in section 1853(d)) of the annual capitation rate as calculated under section 1853(c)(1) for that area.

"(c) PAYMENT OF PLANS BASED ON BID AMOUNTS.—

"(1) NON-DRUG BENEFITS.—Under a contract under section 1860E–4(c) and subject to section 1853(g) (as made applicable under subsection (d)), the Administrator shall make monthly payments under this subsection in advance to each EFFS organization, with respect to coverage of an individual under this part in an EFFS region for a month, in an amount determined as follows:

"(A) PLANS WITH BIDS BELOW BENCHMARK.—In the case of a plan for which there are average per capita monthly savings described in subsection (b)(2)(C), the payment under this subsection is equal to the unadjusted EFFS statutory non-drug monthly bid amount, adjusted under paragraphs (3) and (4), plus the amount of the monthly rebate computed under subsection (b)(1)(A) for that plan and year.

"(B) PLANS WITH BIDS AT OR ABOVE BENCHMARK.—In the case of a plan for which there are no average per capita monthly savings described in subsection (b)(2)(C), the payment amount under this subsection is equal to the EFFS region-specific non-drug monthly benchmark amount, adjusted under paragraphs (3) and (4).

"(2) FOR FEDERAL DRUG SUBSIDIES.—In the case in which an enrollee who elects under part D to be provided qualified prescription drug coverage through the plan, the EFFS organization offering such plan also is entitled—

"(A) to direct subsidy payment under section 1860D–8(a)(1);

"(B) to reinsurance subsidy payments under section 1860D–8(a)(2); and

"(C) to reimbursement for premium and cost-sharing reductions for low-income individuals under section 1860D–7(c)(3).

"(3) DEMOGRAPHIC RISK ADJUSTMENT, INCLUDING ADJUSTMENT FOR HEALTH STATUS.—The Administrator shall adjust under paragraph (1)(A) the unadjusted EFFS statutory non-drug monthly bid amount and under paragraph (1)(B) the EFFS region-specific non-drug monthly benchmark amount for such risk factors as age, disability status, gender, institutional status, and such other factors as the Administrator determines to be appropriate, including adjustment for health status under section 1853(a)(3) (as applied under subsection (d)), so as to ensure actuarial equivalence. The Administrator may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.

"(4) ADJUSTMENT FOR INTRA-REGIONAL GEOGRAPHIC VARIATIONS.—The Administrator shall also adjust such amounts in a manner to take into account variations in payments rates under part C among the different payment areas under such part included in each EFFS region.

"(d) APPLICATION OF ADDITIONAL PAYMENT RULES.—The provisions of section 1853 (other than subsections (a)(1)(A), (d), and (e)) shall apply to an EFFS plan under this part, except as otherwise provided in this section.

"PREMIUMS; ORGANIZATIONAL AND FINANCIAL REQUIREMENTS; ESTABLISHMENT OF STANDARDS; CONTRACTS WITH EFFS ORGANIZATIONS

"SEC. 1860E–4. (a) PREMIUMS.—

"(1) IN GENERAL.—The provisions of section 1854 (other than subsections (a)(6)(C) and (h)), including subsection (b)(5) relating to the consolidation of drug and non-drug beneficiary premiums and subsection (c) relating to uniform bids and premiums, shall apply to an EFFS plan under this part, subject to paragraph (2).

"(2) CROSS-WALK.—In applying paragraph (1), any reference in section 1854(b)(1)(A) or 1854(d) to—

"(A) a Medicare Advantage monthly basic beneficiary premium is deemed a reference to the EFFS monthly basic beneficiary premium (as defined in paragraph (3)(A));

"(B) a Medicare Advantage monthly prescription drug beneficiary premium is deemed a reference to the EFFS monthly prescription drug beneficiary premium (as defined in paragraph (3)(B)); and

"(C) a Medicare Advantage monthly supplemental beneficiary premium is deemed a reference to the EFFS monthly supplemental beneficiary premium (as defined in paragraph (3)(C)).

"(3) DEFINITIONS.—For purposes of this part:

"(A) EFFS MONTHLY BASIC BENEFICIARY PREMIUM.—The term 'EFFS monthly basic beneficiary premium' means, with respect to an EFFS plan—

"(i) described in section 1860E–3(c)(1)(A) (relating to plans providing rebates), zero; or

"(ii) described in section 1860E–3(c)(1)(B), the amount (if any) by which the unadjusted EFFS statutory non-drug monthly bid amount exceeds the EFFS region-specific non-drug monthly benchmark amount (as defined in section 1860E–3(b)(3)).

"(B) EFFS MONTHLY PRESCRIPTION DRUG BENEFICIARY PREMIUM.—The term 'EFFS monthly prescription drug beneficiary premium' means, with respect to an EFFS plan, the portion of the aggregate monthly bid amount submitted under clause (i) of section 1860E–3(a)(3)(A) for the year that is attributable under such section to the provision of statutory prescription drug benefits.

"(C) EFFS MONTHLY SUPPLEMENTAL BENEFICIARY PREMIUM.—The term 'EFFS monthly supplemental beneficiary premium' means, with respect to an EFFS plan, the portion of the aggregate monthly bid amount submitted under clause (i) of section 1860E–3(a)(3)(A) for the year that is attributable under such section to the provision of nonstatutory benefits.

"(b) ORGANIZATIONAL AND FINANCIAL REQUIREMENTS.—The provisions of section 1855 shall apply to an EFFS plan offered by an EFFS organization under this part.

"(c) CONTRACTS WITH EFFS ORGANIZATIONS.—The provisions of section 1857 shall apply to an EFFS plan offered by an EFFS organization under this part, except that any reference in such section to part C is deemed a reference to this part.".

(b) PROHIBITION ON COVERAGE UNDER MEDIGAP PLANS OF DEDUCTIBLE IMPOSED UNDER EFFS PLANS.—Section 1882 (42 U.S.C. 1395ss), as amended by section 104(a), is amended by adding at the end the following new subsection:

"(w) PROHIBITION ON COVERAGE OF DEDUCTIBLE AND CERTAIN COST-SHARING IMPOSED UNDER EFFS PLANS.—Notwithstanding any other provision of law, no medicare supplemental policy (other than the 2 benefit packages described in subsection (v)(3)) may provide for coverage of the single deductible or more than 50 percent of other cost-sharing imposed under an EFFS plan under part E.".

(c) CONFORMING PROVISIONS.—Section 1882 of the Social Security Act (42 U.S.C. 1395ss) shall be administered as if any reference to a Medicare+Choice organization offering a Medicare+Choice plan under part C of title XVIII of such Act were a reference both to a Medicare Advantage organization offering a Medicare Advantage plan under such part and an EFFS organization offering an EFFS plan under part E of such title.

Subtitle B—Medicare Advantage Program

CHAPTER 1—IMPLEMENTATION OF PROGRAM

SEC. 211. IMPLEMENTATION OF MEDICARE ADVANTAGE PROGRAM.

(a) IN GENERAL.—There is hereby established the Medicare Advantage program. The Medicare Advantage program shall consist of the program under part C of title XVIII of the Social Security Act, as amended by this title.

(b) REFERENCES.—Any reference to the program under part C of title XVIII of the Social Security Act shall be deemed a reference to the Medicare Advantage program and, with respect to such part, any reference to "Medicare+Choice" is deemed a reference to "Medicare Advantage".

SEC. 212. MEDICARE ADVANTAGE IMPROVEMENTS.

(a) EQUALIZING PAYMENTS WITH FEE-FOR-SERVICE.—

(1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C. 1395w–23(c)(1)) is amended by adding at the end the following:

"(D) BASED ON 100 PERCENT OF FEE-FOR-SERVICE COSTS.—

"(i) IN GENERAL.—For 2004, the adjusted average per capita cost for the year involved, determined under section 1876(a)(4) for the Medicare Advantage payment area for services covered under parts A and B for individuals entitled to benefits under part A and enrolled under part B who are not enrolled in a Medicare Advantage under this part for the year, but adjusted to exclude costs attributable to payments under section 1886(h).

"(ii) INCLUSION OF COSTS OF VA AND DOD MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the adjusted average per capita cost under clause (i) for a year, such cost shall be adjusted to include the Secretary's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Veterans Affairs or the Department of Defense.".

(2) CONFORMING AMENDMENT.—Such section is further amended, in the matter before subparagraph (A), by striking "or (C)" and inserting "(C), or (D)".

(b) CHANGE IN BUDGET NEUTRALITY FOR BLEND.—Section 1853(c) (42 U.S.C. 1395w–23(c)) is amended—

(1) in paragraph (1)(A), by inserting "(for a year other than 2004)" after "multiplied"; and

(2) in paragraph (5), by inserting "(other than 2004)" after "for each year".

(c) INCREASING MINIMUM PERCENTAGE INCREASE TO NATIONAL GROWTH RATE.—

(1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C. 1395w–23(c)(1)) is amended—

(A) in subparagraph (B)(iv), by striking "and each succeeding year" and inserting ", 2003, and 2004";

(B) in subparagraph (C)(iv), by striking "and each succeeding year" and inserting "and 2003"; and

(C) by adding at the end of subparagraph (C) the following new clause:

"(v) For 2004 and each succeeding year, the greater of—

"(I) 102 percent of the annual Medicare Advantage capitation rate under this paragraph for the area for the previous year; or

"(II) the annual Medicare Advantage capitation rate under this paragraph for the area for the previous year increased by the national per capita Medicare Advantage growth percentage, described in paragraph (6) for that succeeding year, but not taking into account any adjustment under paragraph (6)(C) for a year before 2004.".

(2) CONFORMING AMENDMENT.—Section 1853(c)(6)(C) (42 U.S.C. 1395w–23(c)(6)(C)) is amended by inserting before the period at the end the following: ", except that for purposes of paragraph (1)(C)(v)(II), no such adjustment shall be made for a year before 2004".

(d) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES IN CALCULATION OF MEDICARE+CHOICE PAYMENT RATES.—Section 1853(c)(3) (42 U.S.C. 1395w–23(c)(3)) is amended—

(1) in subparagraph (A), by striking "subparagraph (B)" and inserting "subparagraphs (B) and (E)", and

(2) by adding at the end the following new subparagraph:

"(E) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the area-specific Medicare+Choice capitation rate under subparagraph (A) for a year (beginning with 2004), the annual per capita rate of payment for 1997 determined under section 1876(a)(1)(C) shall be adjusted to include in the rate the Secretary's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs.".

(e) EXTENDING SPECIAL RULE FOR CERTAIN INPATIENT HOSPITAL STAYS TO REHABILITATION HOSPITALS.—

(1) IN GENERAL.—Section 1853(g) (42 U.S.C. 1395w–23(g)) is amended—

(A) by inserting "or from a rehabilitation facility (as defined in section 1886(j)(1)(A))" after "1886(d)(1)(B))"; and

(B) in paragraph (2)(B), by inserting "or section 1886(j), as the case may be," after "1886(d)".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to contract years beginning on or after January 1, 2004.

(f) MEDPAC STUDY OF AAPCC.—

(1) STUDY.—The Medicare Payment Advisory Commission shall conduct a study that assesses the method used for determining the adjusted average per capita cost (AAPCC) under section 1876(a)(4) of the Social Security Act (42 U.S.C. 1395mm(a)(4)) as applied under section 1853(c)(1)(A) of such Act (as amended by subsection (a)). Such study shall include an examination of—

(A) the bases for variation in such costs between different areas, including differences in input prices, utilization, and practice patterns;

(B) the appropriate geographic area for payment under the Medicare Advantage program under part C of title XVIII of such Act; and

(C) the accuracy of risk adjustment methods in reflecting differences in costs of providing care to different groups of beneficiaries served under such program.

(2) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study conducted under paragraph (1).

(g) REPORT ON IMPACT OF INCREASED FINANCIAL ASSISTANCE TO MEDICARE ADVANTAGE PLANS.—Not later than July 1, 2006, the Medicare Benefits Administrator shall submit to Congress a report that describes the impact of additional financing provided under this Act and other Acts (including the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and BIPA) on the availability of Medicare Advantage plans in different areas and its impact on lowering premiums and increasing benefits under such plans.

CHAPTER 2—IMPLEMENTATION OF COMPETITION PROGRAM

SEC. 221. COMPETITION PROGRAM BEGINNING IN 2006.

(a) SUBMISSION OF EFFS-LIKE BIDDING INFORMATION BEGINNING IN 2006.—Section 1854 (42 U.S.C. 1395w–24) is amended—

(1) by amending the section heading to read as follows:

"PREMIUMS AND BID AMOUNT";

(2) in subsection (a)(1)(A)—

(A) by striking "(A)" and inserting "(A)(i) if the following year is before 2006,"; and

(B) by inserting before the semicolon at the end the following: "or (ii) if the following year is 2006 or later, the information described in paragraph (3) or (6)(A) for the type of plan involved"; and

(3) by adding at the end of subsection (a) the following:

"(6) SUBMISSION OF BID AMOUNTS BY MEDICARE ADVANTAGE ORGANIZATIONS.—

"(A) INFORMATION TO BE SUBMITTED.—The information described in this subparagraph is as follows:

"(i) The monthly aggregate bid amount for provision of all items and services under this part, which amount shall be based on average costs for a typical beneficiary residing in the area, and the actuarial basis for determining such amount.

"(ii) The proportions of such bid amount that are attributable to—

"(I) the provision of statutory non-drug benefits (such portion referred to in this part as the 'unadjusted Medicare Advantage statutory non-drug monthly bid amount');

"(II) the provision of statutory prescription drug benefits; and

"(III) the provision of non-statutory benefits;

and the actuarial basis for determining such proportions.

"(iii) Such additional information as the Administrator may require to verify the actuarial bases described in clauses (i) and (ii).

"(B) STATUTORY BENEFITS DEFINED.—For purposes of this part:

"(i) The term 'statutory non-drug benefits' means benefits under section 1852(a)(1).

"(ii) The term 'statutory prescription drug benefits' means benefits under part D.

"(iii) The term 'statutory benefits' means statutory prescription drug benefits and statutory non-drug benefits.

"(C) ACCEPTANCE AND NEGOTIATION OF BID AMOUNTS.—

"(i) IN GENERAL.—Subject to clause (ii)—

"(I) the Administrator has the authority to negotiate regarding monthly bid amounts submitted under subparagraph (A) (and the proportion described in subparagraph (A)(ii)), and for such purpose and subject to such clause, the Administrator has negotiation authority that the Director of the Office of Personnel Management has with respect to health benefits plans under chapter 89 of title 5, United States Code; and

"(II) the Administrator may reject such a bid amount or proportion if the Administrator determines that such amount or proportion is not supported by the actuarial bases provided under subparagraph (A).

"(ii) EXCEPTION.—In the case of a plan described in section 1851(a)(2)(C), the provisions of clause (i) shall not apply and the provisions of paragraph (5)(B), prohibiting the review, approval, or disapproval of amounts described in such paragraph, shall apply to the negotiation and rejection of the monthly bid amounts and proportion referred to in subparagraph (A).".

(b) PROVIDING FOR BENEFICIARY SAVINGS FOR CERTAIN PLANS.—

(1) IN GENERAL.—Section 1854(b) (42 U.S.C. 1395w–24(b)) is amended—

(A) by adding at the end of paragraph (1) the following new subparagraph:

"(C) BENEFICIARY REBATE RULE.—

"(i) REQUIREMENT.—The Medicare Advantage plan shall provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings (if any) described in paragraph (3) applicable to the plan and year involved.

"(iii) FORM OF REBATE.—A rebate required under this subparagraph shall be provided—

"(I) through the crediting of the amount of the rebate towards the Medicare Advantage monthly supplementary beneficiary premium or the premium imposed for prescription drug coverage under part D;

"(II) through a direct monthly payment (through electronic funds transfer or otherwise); or

"(III) through other means approved by the Medicare Benefits Administrator,

or any combination thereof."; and

(B) by adding at the end the following new paragraphs:

"(3) COMPUTATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—For purposes of paragraph (1)(C)(i), the average per capita monthly savings referred to in such paragraph for a Medicare Advantage plan and year is computed as follows:

"(A) DETERMINATION OF STATE-WIDE AVERAGE RISK ADJUSTMENT.—

"(i) IN GENERAL.—The Medicare Benefits Administrator shall determine, at the same time rates are promulgated under section 1853(b)(1) (beginning with 2006), for each State the average of the risk adjustment factors to be applied under section 1853(a)(1)(A) to payment for enrollees in that State. In the case of a State in which a Medicare Advantage plan was offered in the previous year, the Administrator may compute such average based upon risk adjustment factors applied in that State in a previous year.

"(ii) TREATMENT OF NEW STATES.—In the case of a State in which no Medicare Advantage plan was offered in the previous year, the Administrator shall estimate such average. In making such estimate, the Administrator may use average risk adjustment factors applied to comparable States or applied on a national basis.

"(B) DETERMINATION OF RISK ADJUSTED BENCHMARK AND RISK-ADJUSTED BID.—For each Medicare Advantage plan offered in a State, the Administrator shall—

"(i) adjust the Medicare Advantage area-specific non-drug monthly benchmark amount (as defined in subsection (j)) by the applicable average risk adjustment factor computed under subparagraph (A); and

"(ii) adjust the unadjusted Medicare Advantage statutory non-drug monthly bid amount by such applicable average risk adjustment factor.

"(C) DETERMINATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—The average per capita monthly savings described in this subparagraph is equal to the amount (if any) by which—

"(i) the risk-adjusted benchmark amount computed under subparagraph (B)(i), exceeds

"(ii) the risk-adjusted bid computed under subparagraph (B)(ii).

"(D) AUTHORITY TO DETERMINE RISK ADJUSTMENT FOR AREAS OTHER THAN STATES.—The Administrator may provide for the determination and application of risk adjustment factors under this paragraph on the basis of areas other than States.

"(4) BENEFICIARY'S OPTION OF PAYMENT THROUGH WITHHOLDING FROM SOCIAL SECURITY PAYMENT OR USE OF ELECTRONIC FUNDS TRANSFER MECHANISM.—In accordance with regulations, a Medicare Advantage organization shall permit each enrollee, at the enrollee's option, to make payment of premiums under this part to the organization indirectly through withholding from benefit payments in the manner provided under section 1840 with respect to monthly premiums under section 1839 or through an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account) or otherwise. All premium payments that are withheld under this paragraph that are credited to the Federal Supplementary Medical Insurance Drug Trust Fund shall be paid to the Medicare Advantage organization involved.".

(2) PROVISION OF SINGLE CONSOLIDATED PREMIUM.—Section 1854(b) (42 U.S.C. 1395w–24(b)), as amended by paragraph (1), is further amended by adding at the end the following new paragraph:

"(5) SINGLE CONSOLIDATED PREMIUM.—In the case of an enrollee in a Medicare Advantage plan who elects under part D to be provided qualified prescription drug coverage through the plan, the Administrator shall provide a mechanism for the consolidation of the beneficiary premium amount for non-drug benefits under this part with the premium amount for prescription drug coverage under part D provided through the plan.".

(3) COMPUTATION OF MEDICARE ADVANTAGE AREA-SPECIFIC NON-DRUG BENCHMARK.—Section 1853 (42 U.S.C. 1395w–23) is amended by adding at the end the following new subsection:

"(j) COMPUTATION OF MEDICARE ADVANTAGE AREA-SPECIFIC NON-DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of this part, the term 'Medicare Advantage area-specific non-drug monthly benchmark amount' means, with respect to a Medicare Advantage payment area for a month in a year, an amount equal to 1/12 of the annual Medicare Advantage capitation rate under section 1853(c)(1) for the area for the year.".

(c) PAYMENT OF PLANS BASED ON BID AMOUNTS.—

(1) IN GENERAL.—Section 1853(a)(1)(A) (42 U.S.C. 1395w–23) is amended by striking "in an amount" and all that follows and inserting the following: "in an amount determined as follows:

"(i) PAYMENT BEFORE 2006.—For years before 2006, the payment amount shall be equal to 1/12 of the annual Medicare Advantage capitation rate (as calculated under subsection (c)(1)) with respect to that individual for that area, reduced by the amount of any reduction elected under section 1854(f)(1)(E) and adjusted under clause (iv).

"(ii) PAYMENT FOR STATUTORY NON-DRUG BENEFITS BEGINNING WITH 2006.—For years beginning with 2006—

"(I) PLANS WITH BIDS BELOW BENCHMARK.—In the case of a plan for which there are average per capita monthly savings described in section 1854(b)(3)(C), the payment under this subsection is equal to the unadjusted Medicare Advantage statutory non-drug monthly bid amount, adjusted under clause (iv), plus the amount of the monthly rebate computed under section 1854(b)(1)(C)(i) for that plan and year.

"(II) PLANS WITH BIDS AT OR ABOVE BENCHMARK.—In the case of a plan for which there are no average per capita monthly savings described in section 1854(b)(3)(C), the payment amount under this subsection is equal to the Medicare Advantage area-specific non-drug monthly benchmark amount, adjusted under clause (iv).

"(iii) FOR FEDERAL DRUG SUBSIDIES.—In the case in which an enrollee who elects under part D to be provided qualified prescription drug coverage through the plan, the Medicare Advantage organization offering such plan also is entitled—

"(I) to direct subsidy payment under section 1860D–8(a)(1);

"(II) to reinsurance subsidy payments under section 1860D–8(a)(2); and

"(III) to reimbursement for premium and cost-sharing reductions for low-income individuals under section 1860D–7(c)(3).

"(iv) DEMOGRAPHIC ADJUSTMENT, INCLUDING ADJUSTMENT FOR HEALTH STATUS.—The Administrator shall adjust the payment amount under clause (i), the unadjusted Medicare Advantage statutory non-drug monthly bid amount under clause (ii)(I), and the Medicare Advantage area-specific non-drug monthly benchmark amount under clause (ii)(II) for such risk factors as age, disability status, gender, institutional status, and such other factors as the Administrator determines to be appropriate, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence. The Administrator may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.".

(d) CONFORMING AMENDMENTS.—

(1) PROTECTION AGAINST BENEFICIARY SELECTION.—Section 1852(b)(1)(A) (42 U.S.C. 1395w–22(b)(1)(A)) is amended by adding at the end the following: "The Administrator shall not approve a plan of an organization if the Administrator determines that the benefits are designed to substantially discourage enrollment by certain Medicare Advantage eligible individuals with the organization.".

(2) CONFORMING AMENDMENT TO PREMIUM TERMINOLOGY.—Section 1854(b)(2) (42 U.S.C. 1395w–24(b)(2)) is amended by redesignating subparagraph (C) as subparagraph (D) and by striking subparagraphs (A) and (B) and inserting the following:

"(A) MEDICARE ADVANTAGE MONTHLY BASIC BENEFICIARY PREMIUM.—The term 'Medicare Advantage monthly basic beneficiary premium' means, with respect to a Medicare Advantage plan—

"(i) described in section 1853(a)(1)(A)(ii)(I) (relating to plans providing rebates), zero; or

"(ii) described in section 1853(a)(1)(A)(ii)(II), the amount (if any) by which the unadjusted Medicare Advantage statutory non-drug monthly bid amount exceeds the Medicare Advantage area-specific non-drug monthly benchmark amount.

"(B) MEDICARE ADVANTAGE MONTHLY PRESCRIPTION DRUG BENEFICIARY PREMIUM.—The term 'Medicare Advantage monthly prescription drug beneficiary premium' means, with respect to a Medicare Advantage plan, that portion of the bid amount submitted under clause (i) of subsection (a)(6)(A) for the year that is attributable under such section to the provision of statutory prescription drug benefits.

"(C) MEDICARE ADVANTAGE MONTHLY SUPPLEMENTAL BENEFICIARY PREMIUM.—The term 'Medicare Advantage monthly supplemental beneficiary premium' means, with respect to a Medicare Advantage plan, the portion of the aggregate monthly bid amount submitted under clause (i) of subsection (a)(6)(A) for the year that is attributable under such section to the provision of nonstatutory benefits.".

(3) REQUIREMENT FOR UNIFORM PREMIUM AND BID AMOUNTS.—Section 1854(c) (42 U.S.C. 1395w–24(c)) is amended to read as follows:

"(c) UNIFORM PREMIUM AND BID AMOUNTS.—The Medicare Advantage monthly bid amount submitted under subsection (a)(6), the Medicare Advantage monthly basic, prescription drug, and supplemental beneficiary premiums, and the Medicare Advantage monthly MSA premium charged under subsection (b) of a Medicare Advantage organization under this part may not vary among individuals enrolled in the plan.".

(4) PERMITTING BENEFICIARY REBATES.—

(A) Section 1851(h)(4)(A) (42 U.S.C. 1395w–21(h)(4)(A)) is amended by inserting "except as provided under section 1854(b)(1)(C)" after "or otherwise".

(B) Section 1854(d) (42 U.S.C. 1395w–24(d)) is amended by inserting ", except as provided under subsection (b)(1)(C)," after "and may not provide".

(5) OTHER CONFORMING AMENDMENTS RELATING TO BIDS.—Section 1854 (42 U.S.C. 1395w–24) is amended—

(A) in the heading of subsection (a), by inserting "AND BID AMOUNTS" after "PREMIUMS"; and

(B) in subsection (a)(5)(A), by inserting "paragraphs (2), (3), and (4) of" after "filed under".

(e) ADDITIONAL CONFORMING AMENDMENTS.—

(1) ANNUAL DETERMINATION AND ANNOUNCEMENT OF CERTAIN FACTORS.—Section 1853(b)(1) (42 U.S.C. 1395w–23(b)(1)) is amended by striking "the respective calendar year" and all that follows and inserting the following: "the calendar year concerned with respect to each Medicare Advantage payment area, the following:

"(A) PRE-COMPETITION INFORMATION.—For years before 2006, the following:

"(i) MEDICARE ADVANTAGE CAPITATION RATES.—The annual Medicare Advantage capitation rate for each Medicare Advantage payment area for the year.

"(ii) ADJUSTMENT FACTORS.—The risk and other factors to be used in adjusting such rates under subsection (a)(1)(A) for payments for months in that year.

"(B) COMPETITION INFORMATION.—For years beginning with 2006, the following:

"(i) BENCHMARK.—The Medicare Advantage area-specific non-drug benchmark under section 1853(j).

"(ii) ADJUSTMENT FACTORS.—The adjustment factors applied under section 1853(a)(1)(A)(iv) (relating to demographic adjustment), section 1853(a)(1)(B) (relating to adjustment for end-stage renal disease), and section 1853(a)(3) (relating to health status adjustment).".

(2) REPEAL OF PROVISIONS RELATING TO ADJUSTED COMMUNITY RATE (ACR).—

(A) IN GENERAL.—Subsections (e) and (f) of section 1854 (42 U.S.C. 1395w–24) are repealed.

(B) CONFORMING AMENDMENTS.—(i) Section 1839(a)(2) (42 U.S.C. 1395r(a)(2)) is amended by striking ", and to reflect" and all that follows and inserting a period.

(ii) Section 1852(a)(1) (42 U.S.C. 1395w–22(a)(1)) is amended by striking "title XI" and all that follows and inserting the following: "title XI those items and services (other than hospice care) for which benefits are available under parts A and B to individuals residing in the area served by the plan.".

(iii) Section 1857(d)(1) (42 U.S.C. 1395w–27(d)(1)) is amended by striking ", costs, and computation of the adjusted community rate" and inserting "and costs".

(f) REFERENCES UNDER PART E.—Section 1859 (42 U.S.C. 1395w–29) is amended by adding at the end the following new subsection:

"(f) APPLICATION UNDER PART E.—In the case of any reference under part E to a requirement or provision of this part in the relation to an EFFS plan or organization under such part, except as otherwise specified any such requirement or provision shall be applied to such organization or plan in the same manner as such requirement or provision applies to a Medicare Advantage private fee-for-service plan (and the Medicare Advantage organization that offers such plan) under this part.".

(g) EFFECTIVE DATE.—The amendments made by this section shall apply to payments and premiums for months beginning with January 2006.

CHAPTER 3—ADDITIONAL REFORMS

SEC. 231. MAKING PERMANENT CHANGE IN MEDICARE ADVANTAGE REPORTING DEADLINES AND ANNUAL, COORDINATED ELECTION PERIOD.

(a) CHANGE IN REPORTING DEADLINE.—Section 1854(a)(1) (42 U.S.C. 1395w–24(a)(1)), as amended by section 532(b)(1) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, is amended by striking "2002, 2003, and 2004 (or July 1 of each other year)" and inserting "2002 and each subsequent year".

(b) DELAY IN ANNUAL, COORDINATED ELECTION PERIOD.—Section 1851(e)(3)(B) (42 U.S.C. 1395w–21(e)(3)(B)), as amended by section 532(c)(1)(A) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, is amended—

(1) by striking "and after 2005"; and

(2) by striking ", 2004, and 2005" and inserting "and any subsequent year".

(c) ANNUAL ANNOUNCEMENT OF PAYMENT RATES.—Section 1853(b)(1) (42 U.S.C. 1395w–23(b)(1)), as amended by section 532(d)(1) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, is amended—

(1) by striking "and after 2005"; and

(2) by striking "and 2005" and inserting "and each subsequent year".

(d) REQUIRING PROVISION OF AVAILABLE INFORMATION COMPARING PLAN OPTIONS.—The first sentence of section 1851(d)(2)(A)(ii) (42 U.S.C. 1395w–21(d)(2)(A)(ii)) is amended by inserting before the period the following: "to the extent

such information is available at the time of preparation of materials for the mailing".

SEC. 232. AVOIDING DUPLICATIVE STATE REGULATION.

(a) IN GENERAL.—Section 1856(b)(3) (42 U.S.C. 1395w–26(b)(3)) is amended to read as follows:

"(3) RELATION TO STATE LAWS.—The standards established under this subsection shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to Medicare Advantage plans which are offered by Medicare Advantage organizations under this part.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act.

SEC. 233. SPECIALIZED MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS BENEFICIARIES.

(a) TREATMENT AS COORDINATED CARE PLAN.—Section 1851(a)(2)(A) (42 U.S.C. 1395w–21(a)(2)(A)) is amended by adding at the end the following new sentence: "Specialized Medicare Advantage plans for special needs beneficiaries (as defined in section 1859(b)(4)) may be any type of coordinated care plan.".

(b) SPECIALIZED MEDICARE ADVANTAGE PLAN FOR SPECIAL NEEDS BENEFICIARIES DEFINED.—Section 1859(b) (42 U.S.C. 1395w–29(b)) is amended by adding at the end the following new paragraph:

"(4) SPECIALIZED MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—

"(A) IN GENERAL.—The term 'specialized Medicare Advantage plan for special needs beneficiaries' means a Medicare Advantage plan that exclusively serves special needs beneficiaries (as defined in subparagraph (B)).

"(B) SPECIAL NEEDS BENEFICIARY.—The term 'special needs beneficiary' means a Medicare Advantage eligible individual who—

"(i) is institutionalized (as defined by the Secretary);

"(ii) is entitled to medical assistance under a State plan under title XIX; or

"(iii) meets such requirements as the Secretary may determine would benefit from enrollment in such a specialized Medicare Advantage plan described in subparagraph (A) for individuals with severe or disabling chronic conditions.".

(c) RESTRICTION ON ENROLLMENT PERMITTED.—Section 1859 (42 U.S.C. 1395w–29) is amended by adding at the end the following new subsection:

"(f) RESTRICTION ON ENROLLMENT FOR SPECIALIZED MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—In the case of a specialized Medicare Advantage plan (as defined in subsection (b)(4)), notwithstanding any other provision of this part and in accordance with regulations of the Secretary and for periods before January 1, 2007, the plan may restrict the enrollment of individuals under the plan to individuals who are within one or more classes of special needs beneficiaries.".

(d) REPORT TO CONGRESS.—Not later than December 31, 2005, the Medicare Benefits Administrator shall submit to Congress a report that assesses the impact of specialized Medicare Advantage plans for special needs beneficiaries on the cost and quality of services provided to enrollees. Such report shall include an assessment of the costs and savings to the medicare program as a result of amendments made by subsections (a), (b), and (c).

(e) EFFECTIVE DATES.—

(1) IN GENERAL.—The amendments made by subsections (a), (b), and (c) shall take effect upon the date of the enactment of this Act.

(2) DEADLINE FOR ISSUANCE OF REQUIREMENTS FOR SPECIAL NEEDS BENEFICIARIES; TRANSITION.—No later than 6 months after the date of the enactment of this Act, the Secretary shall issue interim final regulations to establish requirements for special needs beneficiaries under section 1859(b)(4)(B)(iii) of the Social Security Act, as added by subsection (b).

SEC. 234. MEDICARE MSAS.

(a) EXEMPTION FROM REPORTING ENROLLEE ENCOUNTER DATA.—

(1) IN GENERAL.—Section 1852(e)(1) (42 U.S.C. 1395w–22(e)(1)) is amended by inserting "(other than MSA plans)" after "plans".

(2) CONFORMING AMENDMENTS.—Section 1852 (42 U.S.C. 1395w–22) is amended—

(A) in subsection (c)(1)(I), by inserting before the period at the end the following: "if required under such section"; and

(B) in subparagraphs (A) and (B) of subsection (e)(2), by striking ", a non-network MSA plan," and ", NON-NETWORK MSA PLANS," each place it appears.

(b) MAKING PROGRAM PERMANENT AND ELIMINATING CAP.—Section 1851(b)(4) (42 U.S.C. 1395w–21(b)(4)) is amended—

(1) in the heading, by striking "ON A DEMONSTRATION BASIS";

(2) by striking the first sentence of subparagraph (A); and

(3) by striking the second sentence of subparagraph (C).

(c) APPLYING LIMITATIONS ON BALANCE BILLING.—Section 1852(k)(1) (42 U.S.C. 1395w–22(k)(1)) is amended by inserting "or with an organization offering a MSA plan" after "section 1851(a)(2)(A)".

(d) ADDITIONAL AMENDMENT.—Section 1851(e)(5)(A) (42 U.S.C. 1395w–21(e)(5)(A)) is amended—

(1) by adding "or" at the end of clause (i);

(2) by striking ", or" at the end of clause (ii) and inserting a semicolon; and

(3) by striking clause (iii).

SEC. 235. EXTENSION OF REASONABLE COST CONTRACTS.

Subparagraph (C) of section 1876(h)(5) (42 U.S.C. 1395mm(h)(5)) is amended to read as follows:

"(C)(i) Subject to clause (ii), may be extended or renewed under this subsection indefinitely.

"(ii) For any period beginning on or after January 1, 2008, a reasonable cost reimbursement contract under this subsection may not be extended or renewed for a service area insofar as such area, during the entire previous year, was within the service area of 2 or more plans which were coordinated care Medicare Advantage plans under part C or 2 or more enhanced fee-for-service plans under part E and each of which plan for that previous year for the area involved meets the following minimum enrollment requirements:

"(I) With respect to any portion of the area involved that is within a Metropolitan Statistical Area with a population of more than 250,000 and counties contiguous to such Metropolitan Statistical Area, 5,000 individuals.

"(II) With respect to any other portion of such area, 1,500 individuals.".

SEC. 236. EXTENSION OF MUNICIPAL HEALTH SERVICE DEMONSTRATION PROJECTS.

Section 9215(a) of the Consolidated Omnibus Budget Reconciliation Act of 1985 (42 U.S.C. 1395b–1 note), as amended by section 6135 of the Omnibus Budget Reconciliation Act of 1989, section 13557 of the Omnibus Budget Reconciliation Act of 1993, section 4017 of BBA, section 534 of BBRA (113 Stat. 1501A–390), and section 633 of BIPA, is amended by striking "December 31, 2004" and inserting "December 31, 2009".

Subtitle C—Application of FEHBP-Style Competitive Reforms

SEC. 241. APPLICATION OF FEHBP-STYLE COMPETITIVE REFORM BEGINNING IN 2010.

(a) IDENTIFICATION OF COMPETITIVE EFFS REGIONS; COMPUTATION OF COMPETITIVE EFFS NON-DRUG BENCHMARKS UNDER EFFS PROGRAM.—

(1) IN GENERAL.—Section 1860E–3, as added by section 201(a), is amended by adding at the end the following new subsection:

"(e) APPLICATION OF COMPETITION.—

"(1) DETERMINATION OF COMPETITIVE EFFS REGIONS.—

"(A) IN GENERAL.—For purposes of this part, the term 'competitive EFFS region' means, for a year beginning with 2010, an EFFS region that the Administrator finds—

"(i) there will be offered in the region during the annual, coordinated election period under section 1851(e)(3)(B) (as applied under section 1860E–1(c)) before the beginning of the year at least 2 EFFS plans (in addition to the fee-for-service program under parts A and B), each offered by a different EFFS organization and each of which met the minimum enrollment requirements of paragraph (1) of section 1857(b) (as applied without regard to paragraph (3) thereof) as of March of the previous year; and

"(ii) during March of the previous year at least the percentage specified in subparagraph (C) of the number of EFFS eligible individuals who reside in the region were enrolled in an EFFS plan.

"(B) PERCENTAGE SPECIFIED.—

"(i) IN GENERAL.—For purposes of subparagraph (A), subject to clause (ii), the percentage specified in this subparagraph for a year is equal the lesser of 20 percent or to the sum of—

"(I) the percentage, as estimated by the Administrator, of EFFS eligible individuals in the United States who are enrolled in EFFS plans during March of the previous year; and

"(II) the percentage, as estimated by the Administrator, of Medicare Advantage eligible individuals in the United States who are enrolled in Medicare Advantage plans during March of the previous year.

"(ii) EXCEPTION.—In the case of an EFFS region that was a competitive EFFS region for the previous year, the Medicare Benefits Administrator may continue to treat the region as meeting the requirement of subparagraph (A)(ii) if the region would meet such requirement but for a de minimis reduction below the percentage specified in clause (i).

"(2) COMPETITIVE EFFS NON-DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of this part, the term 'competitive EFFS non-drug monthly benchmark amount' means, with respect to an EFFS region for a month in a year and subject to paragraph (8), the sum of the 2 components described in paragraph (3) for the region and year. The Administrator shall compute such benchmark amount for each competitive EFFS region before the beginning of each annual, coordinated election period under section 1851(e)(3)(B) for each year (beginning with 2010) in which it is designated as such a region.

"(3) 2 COMPONENTS.—For purposes of paragraph (2), the 2 components described in this paragraph for an EFFS region and a year are the following:

"(A) EFFS COMPONENT.—The product of the following:

"(i) WEIGHTED AVERAGE OF PLAN BIDS IN REGION.—The weighted average of the EFFS plan bids for the region and year (as determined under paragraph (4)(A)).

"(ii) NON-FFS MARKET SHARE.—1 minus the fee-for-service market share percentage determined under paragraph (5) for the region and the year.

"(B) FEE-FOR-SERVICE COMPONENT.—The product of the following:

"(i) FEE-FOR-SERVICE REGION-SPECIFIC NON-DRUG AMOUNT.—The fee-for-service region-specific non-drug amount (as defined in paragraph (6)) for the region and year.

"(ii) FEE-FOR-SERVICE MARKET SHARE.—The fee-for-service market share percentage (determined under paragraph (5)) for the region and the year.

"(4) DETERMINATION OF WEIGHTED AVERAGE EFFS PLAN BIDS FOR A REGION.—

"(A) IN GENERAL.—For purposes of paragraph (3)(A)(i), the weighted average of EFFS plan bids for an EFFS region and a year is the sum of the following products for EFFS plans described in subparagraph (C) in the region and year:

"(i) UNADJUSTED EFFS STATUTORY NON-DRUG MONTHLY BID AMOUNT.—The unadjusted EFFS statutory non-drug monthly bid amount (as defined in subsection (a)(3)(A)(ii)(I)) for the region and year.

"(ii) PLAN'S SHARE OF EFFS ENROLLMENT IN REGION.—The number of individuals described in subparagraph (B), divided by the total number of such individuals for all EFFS plans described in subparagraph (C) for that region and year.

"(B) COUNTING OF INDIVIDUALS.—The Administrator shall count, for each EFFS plan described in subparagraph (C) for an EFFS region and year, the number of individuals who reside in the region and who were enrolled under such plan under this part during March of the previous year.

"(C) EXCLUSION OF PLANS NOT OFFERED IN PREVIOUS YEAR.—For an EFFS region and year, the EFFS plans described in this subparagraph are plans that are offered in the region and year and were offered in the region in March of the previous year.

"(5) COMPUTATION OF FEE-FOR-SERVICE MARKET SHARE PERCENTAGE.—The Administrator shall determine, for a year and an EFFS region, the proportion (in this subsection referred to as the 'fee-for-service market share percentage') of the EFFS eligible individuals who are residents of the region during March of the previous year, of such individuals who were not enrolled in an EFFS plan or in a Medicare Advantage plan (or, if greater, such proportion determined for individuals nationally).

"(6) FEE-FOR-SERVICE REGION-SPECIFIC NON-DRUG AMOUNT.—

"(A) IN GENERAL.—For purposes of paragraph (3)(B)(i) and section 1839(h)(2)(A), subject to subparagraph (B), the term 'fee-for-service region-specific non-drug amount' means, for a competitive EFFS region and a year, the adjusted average per capita cost for the year involved, determined under section 1876(a)(4) for such region for services covered under parts A

and B for individuals entitled to benefits under part A and enrolled under this part who are not enrolled in an EFFS plan under part E or a Medicare Advantage plan under part C for the year, but adjusted to exclude costs attributable to payments under section 1886(h).

"(B) INCLUSION OF COSTS OF VA AND DOD MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the adjusted average per capita cost under subparagraph (A) for a year, such cost shall be adjusted to include the Administrator's estimate, on a per capita basis, of the amount of additional payments that would have been made in the region involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Veterans Affairs or the Department of Defense.

"(7) APPLICATION OF COMPETITION.—In the case of an EFFS region that is a competitive EFFS region for a year, for purposes of applying subsections (b) and (c)(1) and section 1860E–4(a), any reference to an EFFS region-specific non-drug monthly benchmark amount shall be treated as a reference to the competitive EFFS non-drug monthly benchmark amount under paragraph (2) for the region and year.

"(8) PHASE-IN OF BENCHMARK FOR EACH REGION.—

"(A) USE OF BLENDED BENCHMARK.—In the case of a region that has not been a competitive EFFS region for each of the previous 4 years, the competitive EFFS non-drug monthly benchmark amount shall be equal to the sum of the following:

"(i) NEW COMPETITIVE COMPONENT.—The product of—

"(I) the weighted average phase-in proportion for that area and year, as specified in subparagraph (B); and

"(II) the competitive EFFS non-drug monthly benchmark amount for the region and year, determined under paragraph (2) without regard to this paragraph.

"(ii) OLD COMPETITIVE COMPONENT.—The product of—

"(I) 1 minus the weighted average phase-in proportion for that region and year; and

"(II) the EFFS region-specific non-drug benchmark amount for the region and the year.

"(B) COMPUTATION OF WEIGHTED AVERAGE PHASE-IN PROPORTION.—For purposes of this paragraph, the 'weighted average phase-in proportion' for an EFFS region for a year shall be determined as follows:

"(i) FIRST YEAR (AND REGION NOT COMPETITIVE REGION IN PREVIOUS YEAR).—If the area was not a competitive EFFS region in the previous year, the weighted average phase-in proportion for the region for the year is equal to ⅕.

"(ii) COMPETITIVE REGION IN PREVIOUS YEAR.—If the region was a competitive EFFS region in the previous year, the weighted average phase-in proportion for the region for the year is equal to the weighted average phase-in proportion determined under this subparagraph for the region for the previous year plus ⅕, but in no case more than 1.".

(2) CONFORMING AMENDMENTS.—

(A) Such section 1860E–3 is further amended—

(i) in subsection (b), by adding at the end the following new paragraph:

"(4) APPLICATION IN COMPETITIVE REGIONS.—For special rules applying this subsection in competitive EFFS regions, see subsection (e)(7).";

(ii) in subsection (c)(1), by inserting "and subsection (e)(7)" after "(as made applicable under subsection (d))"; and

(iii) in subsection (d) , by striking "and (e)" and inserting "(e), and (k) ".

(B) Section 1860E–4(a)(1), as inserted by section 201(a)(2), is amended by inserting ", except as provided in section 1860E–3(e)(7)" after "paragraph (2)".

(b) IDENTIFICATION OF COMPETITIVE MEDICARE ADVANTAGE AREAS; APPLICATION OF COMPETITIVE MEDICARE ADVANTAGE NON-DRUG BENCHMARKS UNDER MEDICARE ADVANTAGE PROGRAM.—

(1) IN GENERAL.—Section 1853, as amended by section 221(b)(3), is amended by adding at the end the following new subsection:

"(k) APPLICATION OF COMPETITION.—

"(1) DETERMINATION OF COMPETITIVE MEDICARE ADVANTAGE AREAS.—

"(A) IN GENERAL.—For purposes of this part, the terms 'competitive Medicare Advantage area' and 'CMA area' mean, for a year beginning with 2010, an area (which is a metropolitan statistical area or other area with a sub-

stantial number of Medicare Advantage enrollees) that the Administrator finds—

"(i) there will be offered during the annual, coordinated election period under section 1851(e)(3)(B) under this part before the beginning of the year at least 2 Medicare Advantage plans (in addition to the fee-for-service program under parts A and B), each offered by a different Medicare Advantage organization and each of which met the minimum enrollment requirements of paragraph (1) of section 1857(b) (as applied without regard to paragraph (3) thereof) as of March of the previous year with respect to the area; and

"(ii) during March of the previous year at least the percentage specified in subparagraph (B) of the number of Medicare Advantage eligible individuals who reside in the area were enrolled in a Medicare Advantage plan.

"(B) PERCENTAGE SPECIFIED.—

"(i) IN GENERAL.—For purposes of subparagraph (A), subject to clause (ii), the percentage specified in this subparagraph for a year is equal the lesser of 20 percent or to the sum of—

"(I) the percentage, as estimated by the Administrator, of EFFS eligible individuals in the United States who are enrolled in EFFS plans during March of the previous year; and

"(II) the percentage, as estimated by the Administrator, of Medicare Advantage eligible individuals in the United States who are enrolled in Medicare Advantage plans during March of the previous year.

"(ii) EXCEPTION.—In the case of an area that was a competitive area for the previous year, the Medicare Benefits Administrator may continue to treat the area as meeting the requirement of subparagraph (A)(ii) if the area would meet such requirement but for a de minimis reduction below the percentage specified in clause (i).

"(2) COMPETITIVE MEDICARE ADVANTAGE NON-DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of this part, the term 'competitive Medicare Advantage non-drug monthly benchmark amount' means, with respect to a competitive Medicare Advantage area for a month in a year subject to paragraph (8), the sum of the 2 components described in paragraph (3) for the area and year. The Administrator shall compute such benchmark amount for each competitive Medicare Advantage area before the beginning of each annual, coordinated election period under section 1851(e)(3)(B) for each year (beginning with 2010) in which it is designated as such an area.

"(3) 2 COMPONENTS.—For purposes of paragraph (2), the 2 components described in this paragraph for a competitive Medicare Advantage area and a year are the following:

"(A) MEDICARE ADVANTAGE COMPONENT.—The product of the following:

"(i) WEIGHTED AVERAGE OF MEDICARE ADVANTAGE PLAN BIDS IN AREA.—The weighted average of the plan bids for the area and year (as determined under paragraph (4)(A)).

"(ii) NON-FFS MARKET SHARE.—1 minus the fee-for-service market share percentage, determined under paragraph (5) for the area and year.

"(B) FEE-FOR-SERVICE COMPONENT.—The product of the following:

"(i) FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG AMOUNT.—The fee-for-service area-specific non-drug amount (as defined in paragraph (6)) for the area and year.

"(ii) FEE-FOR-SERVICE MARKET SHARE.—The fee-for-service market share percentage, determined under paragraph (5) for the area and year.

"(4) DETERMINATION OF WEIGHTED AVERAGE MEDICARE ADVANTAGE BIDS FOR AN AREA.—

"(A) IN GENERAL.—For purposes of paragraph (3)(A)(i), the weighted average of plan bids for an area and a year is the sum of the following products for Medicare Advantage plans described in subparagraph (C) in the area and year:

"(i) MONTHLY MEDICARE ADVANTAGE STATUTORY NON-DRUG BID AMOUNT.—The unadjusted Medicare Advantage statutory non-drug monthly bid amount.

"(ii) PLAN'S SHARE OF MEDICARE ADVANTAGE ENROLLMENT IN AREA.—The number of individuals described in subparagraph (B), divided by the total number of such individuals for all Medicare Advantage plans described in subparagraph (C) for that area and year.

"(B) COUNTING OF INDIVIDUALS.—The Administrator shall count, for each Medicare Advantage plan described in subparagraph (C) for an area and year, the number of individuals who reside in the area and who were enrolled under such plan under this part during March of the previous year.

"(C) EXCLUSION OF PLANS NOT OFFERED IN PREVIOUS YEAR.—For an area and year, the Medicare Advantage plans described in this subparagraph are plans described in the first sentence of section 1851(a)(2)(A) that are offered in the area and year and were offered in the area in March of the previous year.

"(5) COMPUTATION OF FEE-FOR-SERVICE MARKET SHARE PERCENTAGE.—The Administrator shall determine, for a year and a competitive Medicare Advantage area, the proportion (in this subsection referred to as the 'fee-for-service market share percentage') of Medicare Advantage eligible individuals residing in the area who during March of the previous year were not enrolled in a Medicare Advantage plan or in an EFFS plan (or, if greater, such proportion determined for individuals nationally).

"(6) FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG AMOUNT.—

"(A) IN GENERAL.—For purposes of paragraph (3)(B)(i) and section 1839(h)(1)(A), subject to subparagraph (B), the term 'fee-for-service area-specific non-drug amount' means, for a competitive Medicare Advantage area and a year, the adjusted average per capita cost for the year involved, determined under section 1876(a)(4) for such area for services covered under parts A and B for individuals entitled to benefits under part A and enrolled under this part who are not enrolled in a Medicare Advantage plan under part C or an EFFS plan under part E for the year, but adjusted to exclude costs attributable to payments under section 1886(h).

"(B) INCLUSION OF COSTS OF VA AND DOD MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the adjusted average per capita cost under subparagraph (A) for a year, such cost shall be adjusted to include the Administrator's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Veterans Affairs or the Department of Defense.

"(7) APPLICATION OF COMPETITION.—In the case of an area that is a competitive Medicare Advantage area for a year, for purposes of applying subsection (a)(1)(A)(ii) and sections 1854(b)(2)(A)(ii) and 1854(b)(3)(B)(i), any reference to a Medicare Advantage area-specific non-drug monthly benchmark amount shall be treated as a reference to the competitive Medicare Advantage non-drug monthly benchmark amount under paragraph (2) for the area and year.

"(8) PHASE-IN OF BENCHMARK FOR EACH AREA.—

"(A) USE OF BLENDED BENCHMARK.—In the case of an area that has not been a competitive Medicare Advantage area for each of the previous 4 years, the competitive Medicare Advantage non-drug monthly benchmark amount shall be equal to the sum of the following:

"(i) NEW COMPETITIVE COMPONENT.—The product of—

"(I) the weighted average phase-in proportion for that area and year, as specified in subparagraph (B); and

"(II) the competitive Medicare Advantage non-drug monthly benchmark amount for the area and year, determined under paragraph (2) without regard to this paragraph.

"(ii) OLD COMPETITIVE COMPONENT.—The product of—

"(I) 1 minus the weighted average phase-in proportion for that area and year; and

"(II) the Medicare Advantage area-wide non-drug benchmark amount for the area and the year.

"(B) COMPUTATION OF WEIGHTED AVERAGE PHASE-IN PROPORTION.—For purposes of this paragraph, the 'weighted average phase-in proportion' for a Medicare Advantage payment area for a year shall be determined as follows:

"(i) FIRST YEAR (AND AREA NOT COMPETITIVE AREA IN PREVIOUS YEAR).—If the area was not a Medicare Advantage competitive area in the previous year, the weighted average phase-in proportion for the area for the year is equal to ⅕.

"(ii) COMPETITIVE AREA IN PREVIOUS YEAR.—If the area was a competitive Medicare Advantage area in the previous year, the weighted average phase-in proportion for the area for the year is equal to the weighted average phase-in proportion determined under this subpara-

graph for the area for the previous year plus ⅕, but in no case more than 1.

"(C) MEDICARE ADVANTAGE AREA-WIDE NON-DRUG BENCHMARK AMOUNT.—For purposes of subparagraph (A)(ii)(II), the term 'Medicare Advantage area-wide non-drug benchmark amount' means, for an area and year, the weighted average of the amounts described in section 1853(j) for Medicare Advantage payment area or areas included in the area (based on the number of traditional fee-for-service enrollees in such payment area or areas) and year.".

(2) APPLICATION.—Section 1854 (42 U.S.C. 1395w–24) is amended—

(A) in subsection (b)(1)(C)(i), as added by section 221(b)(1)(A), by striking "(i) REQUIREMENT.—The" and inserting "(i) REQUIREMENT FOR NON-COMPETITIVE AREAS.—In the case of a Medicare Advantage payment area that is not a competitive Medicare Advantage area designated under section 1853(k)(1), the";

(B) in subsection (b)(1)(C), as so added, by inserting after clause (i) the following new clause:

"(ii) REQUIREMENT FOR COMPETITIVE MEDICARE ADVANTAGE AREAS.—In the case of a Medicare Advantage payment area that is designated as a competitive Medicare Advantage area under section 1853(k)(1), if there are average per capita monthly savings described in paragraph (6) for a Medicare Advantage plan and year, the Medicare Advantage plan shall provide to the enrollee a monthly rebate equal to 75 percent of such savings."; and

(C) by adding at the end of subsection (b), as amended by sections 221(b)(1)(B) and 221(b)(2), the following new paragraph:

"(6) COMPUTATION OF AVERAGE PER CAPITA MONTHLY SAVINGS FOR COMPETITIVE MEDICARE ADVANTAGE AREAS.—For purposes of paragraph (1)(C)(ii), the average per capita monthly savings referred to in such paragraph for a Medicare Advantage plan and year shall be computed in the same manner as the average per capita monthly savings is computed under paragraph (3) except that the reference to the Medicare Advantage area-specific non-drug monthly benchmark amount in paragraph (3)(B)(i) (or to the benchmark amount as adjusted under paragraph (3)(C)(i)) is deemed to be a reference to the competitive Medicare Advantage non-drug monthly benchmark amount (or such amount as adjusted in the manner described in paragraph (3)(B)(i)).".

(3) ADDITIONAL CONFORMING AMENDMENTS.—

(A) PAYMENT OF PLANS.—Section 1853(a)(1)(A)(ii), as amended by section 221(c)(1), is amended—

(i) in subclauses (I) and (II), by inserting "(or, insofar as such payment area is a competitive Medicare Advantage area, described in section 1854(b)(6))" after "section 1854(b)(3)(C)"; and

(ii) in subclause (II), by inserting "(or, insofar as such payment area is a competitive Medicare Advantage area, the competitive Medicare Advantage non-drug monthly benchmark amount)" after "Medicare Advantage area-specific non-drug monthly benchmark amount"; and

(B) DISCLOSURE OF INFORMATION.—Section 1853(b)(1)(B), as amended by section 221(e)(1), is amended to read as follows:

"(B) COMPETITION INFORMATION.—For years beginning with 2006, the following:

"(i) BENCHMARKS.—The Medicare Advantage area-specific non-drug benchmark under section 1853(j) and, if applicable, the competitive Medicare Advantage non-drug benchmark under section 1853(k)(2), for the year and competitive Medicare Advantage area involved and the national fee-for-service market share percentage for the area and year.

"(ii) ADJUSTMENT FACTORS.—The adjustment factors applied under section 1853(a)(1)(A)(iv) (relating to demographic adjustment), section 1853(a)(1)(B) (relating to adjustment for end-stage renal disease), and section 1853(a)(3) (relating to health status adjustment).

"(iii) CERTAIN BENCHMARKS AND AMOUNTS.—In the case of a competitive Medicare Advantage area, the Medicare Advantage area-wide non-drug benchmark amount (as defined in subsection (k)(8)(C)) and the fee-for-service area-specific non-drug amount (as defined in section 1853(k)(6)) for the area.

"(iv) INDIVIDUALS.—The number of individuals counted under subsection (k)(4)(B) and enrolled in each Medicare Advantage plan in the area.".

(C) DEFINITION OF MONTHLY BASIC PREMIUM.—Section 1854(b)(2)(A)(ii), as amended by section 221(d)(2), is amended by inserting "(or, in the case of

a competitive Medicare Advantage area, the competitive Medicare Advantage non-drug monthly benchmark amount or, in applying this paragraph under part E in the case of a competitive EFFS region, the competitive EFFS non-drug monthly benchmark amount)" after "benchmark amount".

(c) PREMIUM ADJUSTMENT.—

(1) IN GENERAL.—Section 1839 (42 U.S.C. 1395r) is amended by adding at the end the following new subsection:

"(h)(1)(A) In the case of an individual who resides in a competitive Medicare Advantage area under section 1853(k)(1) (regardless of whether such area is in a competitive EFFS region under section 1860E–3(e)) and who is not enrolled in a Medicare Advantage plan under part C or in an EFFS plan under part E, the monthly premium otherwise applied under this part (determined without regard to subsections (b) and (f) or any adjustment under this subsection) shall be adjusted as follows: If the fee-for-service area-specific non-drug amount (as defined in section 1853(k)(6)) for the competitive Medicare Advantage area in which the individual resides for a month—

"(i) does not exceed the competitive Medicare Advantage non-drug benchmark (as determined under paragraph (2) of section 1853(k), without regard to paragraph (8) thereof) for such area, the amount of the premium for the individual for the month shall be reduced by an amount equal to the product of the adjustment factor under subparagraph (C) and 75 percent of the amount by which such competitive benchmark exceeds such fee-for-service area-specific non-drug amount; or

"(ii) exceeds such competitive Medicare Advantage non-drug benchmark, the amount of the premium for the individual for the month shall be adjusted to ensure, subject to subparagraph (B), that—

"(I) the sum of the amount of the adjusted premium and the competitive Medicare Advantage non-drug benchmark for the area, is equal to

"(II) the sum of the unadjusted premium plus amount of the fee-for-service area-specific non-drug amount for the area.

"(B) In no case shall the actual amount of an adjustment under subparagraph (A)(ii) exceed the product of the adjustment factor under subparagraph (C) and the amount of the adjustment otherwise computed under subparagraph (A)(ii) without regard to this subparagraph.

"(C) The adjustment factor under this subparagraph for an area for a year is equal to—

"(i) the number of consecutive years (in the 5-year period ending with the year involved) in which such area was a competitive Medicare Advantage area; divided by

"(ii) 5.

"(2)(A) In the case of an individual who resides in an area that is within a competitive EFFS region under section 1860E–3(e) but is not within a competitive Medicare Advantage area under section 1853(k)(1) and who is not enrolled in a Medicare Advantage plan under part C or in an EFFS plan under part E, the monthly premium otherwise applied under this part (determined without regard to subsections (b) and (f) or any adjustment under this subsection) shall be adjusted as follows: If the fee-for-service region-specific non-drug amount (as defined in section 1860E–3(e)(6)) for a region for a month—

"(i) does not exceed the competitive EFFS non-drug monthly benchmark amount (as determined under paragraph (2) of section 1860E–3(e), without regard to paragraph (8) thereof) for such region, the amount of the premium for the individual for the month shall be reduced by an amount equal to the product of the adjustment factor under subparagraph (C) and 75 percent of the amount by which such competitive benchmark amount exceeds such fee-for-service region-specific non-drug benchmark amount; or

"(ii) exceeds such competitive EFFS non-drug monthly benchmark amount, the amount of the premium for the individual for the month shall be adjusted to ensure, subject to subparagraph (B), that—

"(I) the sum of the amount of the adjusted premium and the competitive EFFS non-drug monthly benchmark amount for the region, is equal to

"(II) the sum of the unadjusted premium plus the amount of the EFFS region-specific non-drug monthly bidfor the region.

"(B) In no case shall the actual amount of an adjustment under subparagraph (A)(ii) exceed the product of the adjustment factor under subparagraph (C) and the amount of the adjustment otherwise computed under subparagraph (A)(ii) without regard to this subparagraph.

"(C) The adjustment factor under this subparagraph for an EFFS region for a year is equal to—

"(i) the number of consecutive years (in the 5-year period ending with the year involved) in which such region was a competitive EFFS region; divided by

"(ii) 5.

"(3) Nothing in this subsection shall be construed as preventing a reduction under paragraph (1)(A) or paragraph (2)(A) in the premium otherwise applicable under this part to zero or from requiring the provision of a rebate to the extent such premium would otherwise be required to be less than zero.

"(4) The adjustment in the premium under this subsection shall be effected in such manner as the Medicare Benefits Administrator determines appropriate.

"(5) In order to carry out this subsection (insofar as it is effected through the manner of collection of premiums under 1840(a)), the Medicare Benefits Administrator shall transmit to the Commissioner of Social Security—

"(A) at the beginning of each year, the name, social security account number, and the amount of the adjustment (if any) under this subsection for each individual enrolled under this part for each month during the year; and

"(B) periodically throughout the year, information to update the information previously transmitted under this paragraph for the year.".

(2) CONFORMING AMENDMENT.—Section 1844(c) (42 U.S.C. 1395w(c)) is amended by inserting "and without regard to any premium adjustment effected under section 1839(h)" before the period at the end.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect on January 1, 2010.

TITLE III—COMBATTING WASTE, FRAUD, AND ABUSE

SEC. 301. MEDICARE SECONDARY PAYOR (MSP) PROVISIONS.

(a) TECHNICAL AMENDMENT CONCERNING SECRETARY'S AUTHORITY TO MAKE CONDITIONAL PAYMENT WHEN CERTAIN PRIMARY PLANS DO NOT PAY PROMPTLY.—

(1) IN GENERAL.—Section 1862(b)(2) (42 U.S.C. 1395y(b)(2)) is amended—

(A) in subparagraph (A)(ii), by striking "promptly (as determined in accordance with regulations)";

(B) in subparagraph (B)—

(i) by redesignating clauses (i) through (iii) as clauses (ii) through (iv), respectively; and

(ii) by inserting before clause (ii), as so redesignated, the following new clause:

"(i) AUTHORITY TO MAKE CONDITIONAL PAYMENT.—The Secretary may make payment under this title with respect to an item or service if a primary plan described in subparagraph (A)(ii) has not made or cannot reasonably be expected to make payment with respect to such item or service promptly (as determined in accordance with regulations). Any such payment by the Secretary shall be conditioned on reimbursement to the appropriate Trust Fund in accordance with the succeeding provisions of this subsection.".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall be effective as if included in the enactment of title III of the Medicare and Medicaid Budget Reconciliation Amendments of 1984 (Public Law 98-369).

(b) CLARIFYING AMENDMENTS TO CONDITIONAL PAYMENT PROVISIONS.—Section 1862(b)(2) (42 U.S.C. 1395y(b)(2)) is further amended—

(1) in subparagraph (A), in the matter following clause (ii), by inserting the following sentence at the end: "An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.";

(2) in subparagraph (B)(ii), as redesignated by subsection (a)(2)(B)—

(A) by striking the first sentence and inserting the following: "A primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment made by the Secretary under this title with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service. A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means."; and

(B) in the final sentence, by striking "on the date such notice or other information is received" and inserting "on the date notice of, or information related to, a primary plan's responsibility for such payment or other information is received"; and

(3) in subparagraph (B)(iii), , as redesignated by subsection (a)(2)(B), by striking the first sentence and inserting the following: "In order to recover payment made under this title for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity.".

(c) CLERICAL AMENDMENTS.—Section 1862(b) (42 U.S.C. 1395y(b)) is amended—

(1) in paragraph (1)(A), by moving the indentation of clauses (ii) through (v) 2 ems to the left; and

(2) in paragraph (3)(A), by striking "such" before "paragraphs".

SEC. 302. COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES.

(a) IN GENERAL.—Section 1847 (42 U.S.C. 1395w–3) is amended to read as follows:

"COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES

"SEC. 1847. (a) ESTABLISHMENT OF COMPETITIVE ACQUISITION PROGRAMS.—

"(1) IMPLEMENTATION OF PROGRAMS.—

"(A) IN GENERAL.—The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.

"(B) PHASED-IN IMPLEMENTATION.—The programs shall be phased-in—

"(i) among competitive acquisition areas over a period of not longer than 3 years in a manner so that the competition under the programs occurs in—

"(I) at least ⅓ of such areas in 2005; and

"(II) at least ⅔ of such areas in 2006; and

"(ii) among items and services in a manner such that the programs apply to the highest cost and highest volume items and services first.

"(C) WAIVER OF CERTAIN PROVISIONS.—In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

"(2) ITEMS AND SERVICES DESCRIBED.—The items and services referred to in paragraph (1) are the following:

"(A) DURABLE MEDICAL EQUIPMENT AND MEDICAL SUPPLIES.—Covered items (as defined in section 1834(a)(13)) for which payment is otherwise made under section 1834(a), including items used in infusion and drugs and supplies used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act.

"(B) OTHER EQUIPMENT AND SUPPLIES.—Items, equipment, and supplies (as described in section 1842(s)(2)(D) other than enteral nutrients).

"(C) OFF-THE-SHELF ORTHOTICS.—Orthotics (described in section 1861(s)(9)) for which payment is otherwise made under section 1834(h) which require minimal self-adjustment for appropriate use and does not require expertise in trimming, bending, molding, assembling, or customizing to fit to the patient.

"(3) EXCEPTION AUTHORITY.—In carrying out the programs under this section, the Secretary may exempt—

"(A) rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service; and

"(B) items and services for which the application of competitive acquisition is not likely to result in significant savings.

"(4) SPECIAL RULE FOR CERTAIN RENTED ITEMS OF DURABLE MEDICAL EQUIPMENT.—In the case of a covered item for which payment is made on a rental

basis under section 1834(a), the Secretary shall establish a process by which rental agreements for the covered items entered into before the application of the competitive acquisition program under this section for the item may be continued notwithstanding this section. In the case of any such continuation, the supplier involved shall provide for appropriate servicing and replacement, as required under section 1834(a).

"(5) PHYSICIAN AUTHORIZATION.—The Secretary may establish a process under which a physician may prescribe a particular brand or mode of delivery of an item or service if the item or service involved is clinically more appropriate than other similar items or services.

"(6) APPLICATION.—For each competitive acquisition area in which the program is implemented under this subsection with respect to items and services, the payment basis determined under the competition conducted under subsection (b) shall be substituted for the payment basis otherwise applied under section 1834(a).

"(b) PROGRAM REQUIREMENTS.—

"(1) IN GENERAL.—The Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services.

"(2) CONDITIONS FOR AWARDING CONTRACT.—

"(A) IN GENERAL.—The Secretary may not award a contract to any entity under the competition conducted in an competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

"(i) The entity meets quality and financial standards specified by the Secretary or developed by the Program Advisory and Oversight Committee established under subsection (c).

"(ii) The total amounts to be paid under the contract (including costs associated with the administration of the contract) are expected to be less than the total amounts that would otherwise be paid.

"(iii) Beneficiary access to a choice of multiple suppliers in the area is maintained.

"(iv) Beneficiary liability is limited to 20 percent of the applicable contract award price, except in such cases where a supplier has furnished an upgraded item and has executed an advanced beneficiary notice.

"(B) DEVELOPMENT OF QUALITY STANDARDS FOR DME PRODUCTS.—

"(i) IN GENERAL.—The quality standards specified under subparagraph (A)(i) shall not be less than the quality standards that would otherwise apply if this section did not apply and shall include consumer services standards. Not later than July 1, 2004, the Secretary shall establish new quality standards for products subject to competitive acquisition under this section. Such standards shall be applied prospectively and shall be published on the website of the Department of Health and Human Services.

"(ii) CONSULTATION WITH PROGRAM ADVISORY AND OVERSIGHT COMMITTEE.—The Secretary shall consult with the Program Advisory and Oversight Committee (established under subsection (c)) to review (and advise the Secretary concerning) the quality standards referred to in clause (i).

"(3) CONTENTS OF CONTRACT.—

"(A) IN GENERAL.—A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify.

"(B) TERM OF CONTRACTS.—The Secretary shall recompete contracts under this section not less often than once every 3 years.

"(4) LIMIT ON NUMBER OF CONTRACTORS.—

"(A) IN GENERAL.—The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts. In awarding contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of beneficiaries for such items or services in the geographic area covered under the contract on a timely basis.

"(B) MULTIPLE WINNERS.—The Secretary shall award contracts to multiple entities submitting bids in each area for an item or service.

"(5) PAYMENT.—Payment under this part for competitively priced items and services described in subsection (a)(2) shall be based on the bids submitted and accepted under this section for such items and services.

"(6) PARTICIPATING CONTRACTORS.—Payment shall not be made for items and services described in subsection (a)(2) furnished by a contractor and for which competition is conducted under this section unless—

"(A) the contractor has submitted a bid for such items and services under this section; and

"(B) the Secretary has awarded a contract to the contractor for such items and services under this section.

In this section, the term 'bid' means a request for a proposal for an item or service that includes the cost of the item or service, and where appropriate, any services that are attendant to the provision of the item or service.

"(7) CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary shall consider the similarity of the clinical efficiency and value of specific codes and products, including products that may provide a therapeutic advantage to beneficiaries, before delineating the categories and products that will be subject to bidding.

"(8) AUTHORITY TO CONTRACT FOR EDUCATION, MONITORING, OUTREACH AND COMPLAINT SERVICES.—The Secretary may enter into a contract with an appropriate entity to address complaints from beneficiaries who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such beneficiaries and monitoring quality of services with respect to the program.

"(c) PROGRAM ADVISORY AND OVERSIGHT COMMITTEE.—

"(1) ESTABLISHMENT.—There is established a Program Advisory and Oversight Committee (hereinafter in this section referred to as the 'Committee').

"(2) MEMBERSHIP; TERMS.—The Committee shall consist of such members as the Secretary may appoint who shall serve for such term as the Secretary may specify.

"(3) DUTIES.—

"(A) TECHNICAL ASSISTANCE.—The Committee shall provide advice and technical assistance to the Secretary with respect to the following functions:

"(i) The implementation of the program under this section.

"(ii) The establishment of requirements for collection of data.

"(iii) The development of proposals for efficient interaction among manufacturers and distributors of the items and services and providers and beneficiaries.

"(B) ADDITIONAL DUTIES.—The Committee shall perform such additional functions to assist the Secretary in carrying out this section as the Secretary may specify.

"(4) INAPPLICABILITY OF FACA.—The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply.

"(d) ANNUAL REPORTS.—The Secretary shall submit to Congress an annual management report on the programs under this section. Each such report shall include information on savings, reductions in beneficiary cost-sharing, access to and quality of items and services, and beneficiary satisfaction.

"(e) DEMONSTRATION PROJECT FOR CLINICAL LABORATORY SERVICES.—

"(1) IN GENERAL.—The Secretary shall conduct a demonstration project on the application of competitive acquisition under this section to clinical diagnostic laboratory tests—

"(A) for which payment is otherwise made under section 1833(h) or 1834(d)(1) (relating to colorectal cancer screening tests); and

"(B) which are furnished by entities that did not have a face-to-face encounter with the individual.

"(2) TERMS AND CONDITIONS.—Such project shall be under the same conditions as are applicable to items and services described in subsection (a)(2).

"(3) REPORT.—The Secretary shall submit to Congress—

"(A) an initial report on the project not later than December 31, 2005; and

"(B) such progress and final reports on the project after such date as the Secretary determines appropriate.".

(b) CONFORMING AMENDMENTS.—

(1) DURABLE MEDICAL EQUIPMENT; ELIMINATION OF INHERENT REASONABLENESS AUTHORITY.—Section 1834(a) (42 U.S.C. 1395m(a)) is amended—

(A) in paragraph (1)(B), by striking "The payment basis" and inserting "Subject to subparagraph (E)(i), the payment basis";

(B) in paragraph (1)(C), by striking "This subsection" and inserting "Subject to subparagraph (E)(ii), this subsection";

(C) by adding at the end of paragraph (1) the following new subparagraph:

"(E) APPLICATION OF COMPETITIVE ACQUISITION; ELIMINATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of covered items and services that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)—

"(i) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and

"(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847 and in the case of such adjustment, paragraph (10)(B) shall not be applied."; and

(D) in paragraph (10)(B), by inserting "in an area and with respect to covered items and services for which the Secretary does not make a payment amount adjustment under paragraph (1)(E)" after "under this subsection".

(2) OFF-THE-SHELF ORTHOTICS; ELIMINATION OF INHERENT REASONABLENESS AUTHORITY.—Section 1834(h) (42 U.S.C. 1395m(h)) is amended—

(A) in paragraph (1)(B), by striking "and (E)" and inserting ", (E) , and (H)(i)";

(B) in paragraph (1)(D), by striking "This subsection" and inserting "Subject to subparagraph (H)(ii), this subsection";

(C) by adding at the end of paragraph (1) the following new subparagraph:

"(H) APPLICATION OF COMPETITIVE ACQUISITION TO ORTHOTICS; ELIMINATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of orthotics described in paragraph (2)(B) of section 1847(a) that are included in a competitive acquisition program in a competitive acquisition area under such section—

"(i) the payment basis under this subsection for such orthotics furnished in such area shall be the payment basis determined under such competitive acquisition program; and

"(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.".

(c) REPORT ON ACTIVITIES OF SUPPLIERS.—The Secretary shall conduct a study to determine the extent to which (if any) suppliers of covered items of durable medical equipment that are subject to the competitive acquisition program under section 1847 of the Social Security Act, as amended by subsection (a), are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability.

SEC. 303. COMPETITIVE ACQUISITION OF COVERED OUTPATIENT DRUGS AND BIOLOGICALS.

(a) ADJUSTMENT TO PHYSICIAN FEE SCHEDULE.—

(1) ADJUSTMENT IN PRACTICE EXPENSE RELATIVE VALUE UNITS.—Section 1848(c)(2) (42 U.S.C. 1395w–4(c)(2)) is amended—

(A) in subparagraph (B)—

(i) in clause (ii)(II), by striking "The adjustments" and inserting "Subject to clause (iv), the adjustments"; and

(ii) by adding at the end of subparagraph (B), the following new clause:

"(iv) EXCEPTION TO BUDGET NEUTRALITY.—The additional expenditures attributable to clauses (ii) and (iii) of subparagraph (H) shall not be taken into account in applying clause (ii)(II) for 2005."; and

(B) by adding at the end the following new subparagraph:

"(H) ADJUSTMENTS IN PRACTICE EXPENSE RELATIVE VALUE UNITS FOR 2004.—

"(i) IN GENERAL.—As part of the annual process of establishing the physician fee schedule under subsection (b) for 2004, the Secretary shall increase the practice expense relative value units for 2004 consistent with clauses (ii) and (iii).

"(ii) USE OF SUPPLEMENTAL SURVEY DATA.—For 2004 for any specialty that submitted survey data that included expenses for the administration of drugs and biologicals for which payment is made under section 1842(o) (or section 1847A), the Secretary shall use such supplemental

survey data in carrying out this subparagraph insofar as they are collected and provided by entities and organizations consistent with the criteria established by the Secretary pursuant to section 212(a) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and insofar as such data are submitted to the Secretary by the date of the enactment of this subparagraph.

"(iii) EXPEDITING CONSIDERATION OF CPT CODES FOR AFFECTED PHYSICIAN SPECIALTIES.—The Secretary shall, in cooperation with representatives of physician specialities affected by section 1847A, take such actions as are necessary to expedite considerations of CPT codes, or expand the ability to appropriately bill for physicians' services under existing CPT codes, for costs associated with the administration of covered outpatient drugs. The Secretary shall consult with representatives of advisory physician groups in expediting such considerations.

"(iv) SUBSEQUENT, BUDGET NEUTRAL ADJUSTMENTS PERMITTED.—Nothing in this subparagraph shall be construed as preventing the Secretary from providing for adjustments in practice expense relative value units under (and consistent with) subparagraph (B) for years after 2004.

"(v) CONSULTATION.—Before publishing the notice of proposed rulemaking to carry out this subparagraph, the Secretary shall consult with the Comptroller General of the United States and with groups representing the physician specialties involved.

"(vi) TREATMENT AS CHANGE IN LAW AND REGULATION IN SUSTAINABLE GROWTH RATE DETERMINATION.—The enactment of subparagraph (B)(iv) and this subparagraph shall be treated as a change in law for purposes of applying subsection (f)(2)(D).".

(2) PROHIBITION OF ADMINISTRATIVE AND JUDICIAL REVIEW.—Section 1848(i)(1) (42 U.S.C. 1395w–4(i)(1)) is amended—

(A) by striking "and" at the end of subparagraph (D);

(B) by striking the period at the end of subparagraph (E) and inserting ", and"; and

(C) by adding at the end the following new subparagraph:

"(F) adjustments in practice expense relative value units for 2005 under subsection (c)(2)(H).".

(3) TREATMENT OF OTHER SERVICES CURRENTLY IN THE NON-PHYSICIAN WORK POOL.—The Secretary shall make adjustments to the non-physician work pool methodology (as such term is used in the regulations promulgated by the Secretary in the Federal Register as of December 31, 2002) for determination of practice expense relative value units under the physician fee schedule described in section 1848(c)(2)(C)(ii) of the Social Security Act so that the practice expense relative value units for services determined under such methodology are not disproportionately reduced relative to the practice expense relative value units of other services not determined under such non-physician work pool methodology, as the result of amendments made by paragraph (1).

(4) SUBMISSION OF PRACTICE EXPENSE SURVEY DATA.—Any physician specialty may submit survey data related to practice expenses to the Secretary through Decmeber 31, 2004. Nothing in this paragraph shall be construed as waiving the application of budget neutrality under section 1848 of the Social Security Act.

(b) PAYMENT BASED ON COMPETITION.—Title XVIII is amended by inserting after section 1847 (42 U.S.C. 1395w–3), as amended by section 302, the following new sections:

"COMPETITIVE ACQUISITION OF COVERED OUTPATIENT DRUGS AND BIOLOGICALS

"SEC. 1847A. (a) IMPLEMENTATION OF COMPETITIVE ACQUISITION.—

"(1) IMPLEMENTATION OF PROGRAM.—

"(A) IN GENERAL.—The Secretary shall establish and implement a competitive acquisition program under which—

"(i) competitive acquisition areas are established throughout the United States for contract award purposes for acquisition of and payment for categories of covered outpatient drugs and biologicals (as defined in paragraph (2)) under this part; and

"(ii) each physician who does not elect section 1847B to apply makes an annual selection, under paragraph (5) of the contractor through which drugs and biologicals within a category of drugs and biologicals will be acquired and delivered to the physician under this part.

"(B) IMPLEMENTATION.—The Secretary shall implement the program so that the program applies to—

"(i) the oncology category beginning in 2005; and

"(ii) the non-oncology category beginning in 2006.

This section shall not apply in the case of a physician who elects section 1847B to apply.

"(C) WAIVER OF CERTAIN PROVISIONS.—In order to promote competition, efficient service, and product quality, in carrying out the program the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

"(D) EXCLUSION AUTHORITY.—The Secretary may exclude covered outpatient drugs and biologicals (including a class of such drugs and biologicals) from the competitive bidding system under this section if the drugs or biologicals (or class) are not appropriate for competitive bidding due to low volume of utilization by beneficiaries under this part or a unique mode or method of delivery or similar reasons.

"(2) COVERED OUTPATIENT DRUGS AND BIOLOGICALS, CATEGORIES, PROGRAM DEFINED.—For purposes of this section—

"(A) COVERED OUTPATIENT DRUGS AND BIOLOGICALS DEFINED.—The term 'covered outpatient drugs and biologicals' means drugs and biologicals to which section 1842(o) applies and which are not covered under section 1847 (relating to competitive acquisition for items of durable medical equipment). Such term does not include the following:

"(i) Blood clotting factors.

"(ii) Drugs and biologicals furnished to individuals in connection with the treatment of end stage renal disease.

"(iii) Radiopharmaceuticals.

"(B) 2 CATEGORIES.—Each of the following shall be a separate category of covered outpatient drugs and biologicals, as identified by the Secretary:

"(i) ONCOLOGY CATEGORY.—A category (in this section referred to as the 'oncology category') consisting of those covered outpatient drugs and biologicals that, as determined by the Secretary, are typically primarily billed by oncologists or are otherwise used to treat cancer.

"(ii) NON-ONCOLOGY CATEGORIES.—Such numbers of categories (in this section referred to as the 'non-oncology categories') consisting of covered outpatient drugs and biologicals not described in clause (i), and appropriate subcategories of such drugs and biologicals as the Secretary may specify.

"(C) PROGRAM.—The term 'program' means the competitive acquisition program under this section.

"(D) COMPETITIVE ACQUISITION AREA; AREA.—The terms 'competitive acquisition area' and 'area' mean an appropriate geographic region established by the Secretary under the program.

"(E) CONTRACTOR.—The term 'contractor' means an entity that has entered into a contract with the Secretary under this section.

"(3) APPLICATION OF PROGRAM PAYMENT METHODOLOGY.—With respect to covered outpatient drugs and biologicals which are supplied under the program in an area and which are prescribed by a physician who has not elected section 1847B to apply—

"(A) the claim for such drugs and biologicals shall be submitted by the contractor that supplied the drugs and biologicals;

"(B) collection of amounts of any deductible and coinsurance applicable with respect to such drugs and biologicals shall be the responsibility of such contractor and shall not be collected unless the drug or biological is administered to the beneficiary involved; and

"(C) the payment under this section (and related coinsurance amounts) for such drugs and biologicals—

"(i) shall be made only to such contractor;

"(ii) shall be conditioned upon the administration of such drugs and biologicals; and

"(iii) shall be based on the average of the bid prices for such drugs and biologicals in the area, as computed under subsection (d).

The Secretary shall provide a process for recoupment in the case in which payment is made for drugs and biologicals which were billed at the time of dispensing but which were not actually administered.

"(4) CONTRACT REQUIRED.—

"(A) IN GENERAL.—Payment may not be made under this part for covered outpatient drugs and biologicals prescribed by a physician who has not

elected section 1847B to apply within a category and a competitive acquisition area with respect to which the program applies unless—

"(i) the drugs or biologicals are supplied by a contractor with a contract under this section for such category of drugs and biologicals and area; and

"(ii) the physician has elected such contractor under paragraph (5) for such category and area.

"(B) PHYSICIAN CHOICE.—Subparagraph (A) shall not apply for a category of drugs for an area if the physician prescribing the covered outpatient drug in such category and area has elected to apply section 1847B instead of this section.

"(5) CONTRACTOR SELECTION PROCESS.—

"(A) IN GENERAL.—The Secretary shall provide a process for the selection of a contractor, on an annual basis and in such exigent circumstances as the Secretary may provide and with respect to each category of covered outpatient drugs and biologicals for an area, by physicians prescribing such drugs and biologicals in the area of the contractor under this section that will supply the drugs and biologicals within that category and area. Such selection shall also include the election described in section 1847B(a).

"(B) INFORMATION ON CONTRACTORS.—The Secretary shall make available to physicians on an ongoing basis, through a directory posted on the Department's Internet website or otherwise and upon request, a list of the contractors under this section in the different competitive acquisition areas.

"(C) SELECTING PHYSICIAN DEFINED.—For purposes of this section, the term 'selecting physician' means, with respect to a contractor and category and competitive acquisition area, a physician who has not elected section 1847B to apply and has selected to apply under this section such contractor for such category and area.

"(b) PROGRAM REQUIREMENTS.—

"(1) CONTRACT FOR COVERED OUTPATIENT DRUGS AND BIOLOGICALS.—The Secretary shall conduct a competition among entities for the acquisition of a covered outpatient drug or biological within each HCPCS code within each category for each competitive acquisition area.

"(2) CONDITIONS FOR AWARDING CONTRACT.—

"(A) IN GENERAL.—The Secretary may not award a contract to any entity under the competition conducted in a competitive acquisition area pursuant to paragraph (1) with respect to the acquisition of covered outpatient drugs and biologicals within a category unless the Secretary finds that the entity meets all of the following with respect to the contract period involved:

"(i) CAPACITY TO SUPPLY COVERED OUTPATIENT DRUG OR BIOLOGICAL WITHIN CATEGORY.—

"(I) IN GENERAL.—The entity has sufficient arrangements to acquire and to deliver covered outpatient drugs and biologicals within such category in the area specified in the contract at the bid price specified in the contract for all physicians that may elect such entity.

"(II) SHIPMENT METHODOLOGY.—The entity has arrangements in effect for the shipment at least 5 days each week of covered outpatient drugs and biologicals under the contract and for the timely delivery (including for emergency situations) of such drugs and biologicals in the area under the contract.

"(ii) QUALITY, SERVICE, FINANCIAL PERFORMANCE AND SOLVENCY STANDARDS.—The entity meets quality, service, financial performance, and solvency standards specified by the Secretary, including—

"(I) the establishment of procedures for the prompt response and resolution of physician and beneficiary complaints and inquiries regarding the shipment of covered outpatient drugs and biologicals; and

"(II) a grievance process for the resolution of disputes.

"(B) ADDITIONAL CONSIDERATIONS.—The Secretary may refuse to award a contract under this section, and may terminate such a contract, with an entity based upon—

"(i) the suspension or revocation, by the Federal Government or a State government, of the entity's license for the distribution of drugs or biologicals (including controlled substances); or

"(ii) the exclusion of the entity under section 1128 from participation under this title.

"(C) APPLICATION OF MEDICARE PROVIDER OMBUDSMAN.—For provision providing for a program-wide Medicare Provider Ombudsman to review

complaints, see section 1868(b), as added by section 923 of the Medicare Prescription Drug and Modernization Act of 2003.

"(3) AWARDING MULTIPLE CONTRACTS FOR A CATEGORY AND AREA.—In order to provide a choice of at least 2 contractors in each competitive acquisition area for a category of drugs and biologicals, the Secretary may limit (but not below 2) the number of qualified entities that are awarded such contracts for any category and area. The Secretary shall select among qualified entities based on the following:

"(A) The bid prices for covered outpatient drugs and biologicals within the category and area.

"(B) Bid price for distribution of such drugs and biologicals.

"(C) Ability to ensure product integrity.

"(D) Customer service.

"(E) Past experience in the distribution of drugs and biologicals, including controlled substances.

"(F) Such other factors as the Secretary may specify.

"(4) TERMS OF CONTRACTS.—

"(A) IN GENERAL.—A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify consistent with this section.

"(B) PERIOD OF CONTRACTS.—A contract under this section shall be for a term of 2 years, but may be terminated by the Secretary or the entity with appropriate, advance notice.

"(C) INTEGRITY OF DRUG AND BIOLOGICAL DISTRIBUTION SYSTEM.—The Secretary—

"(i) shall require that for all drug and biological products distributed by a contractor under this section be acquired directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer; and

"(ii) may require, in the case of such products that are particularly susceptible to counterfeit or diversion, that the contractor comply with such additional product integrity safeguards as may be determined to be necessary.

"(D) IMPLEMENTATION OF ANTI-COUNTERFEITING, QUALITY, SAFETY, AND RECORD KEEPING REQUIREMENTS.—The Secretary shall require each contractor to implement (through its officers, agents, representatives, and employees) requirements relating to the storage and handling of covered outpatient drugs and biologicals and for the establishment and maintenance of distribution records for such drugs and biologicals. A contract under this section may include requirements relating to the following:

"(i) Secure facilities.

"(ii) Safe and appropriate storage of drugs and biologicals.

"(iii) Examination of drugs and biologicals received and dispensed.

"(iv) Disposition of damaged and outdated drugs and biologicals.

"(v) Record keeping and written policies and procedures.

"(vi) Compliance personnel.

"(E) COMPLIANCE WITH CODE OF CONDUCT AND FRAUD AND ABUSE RULES.—Under the contract—

"(i) the contractor shall comply with a code of conduct, specified or recognized by the Secretary, that includes standards relating to conflicts of interest; and

"(ii) the contractor shall comply with all applicable provisions relating to prevention of fraud and abuse, including compliance with applicable guidelines of the Department of Justice and the Inspector General of the Department of Health and Human Services.

"(F) DIRECT DELIVERY OF DRUGS AND BIOLOGICALS TO PHYSICIANS.—Under the contract the contractor shall only supply covered outpatient drugs and biologicals directly to the selecting physicians and not directly to beneficiaries, except under circumstances and settings where a beneficiary currently receives a drug or biological in the beneficiary's home or other nonphysician office setting as the Secretary may provide. The contractor shall not deliver drugs and biologicals to a selecting physician except upon receipt of a prescription for such drugs and biologicals, and such necessary data as may be required by the Secretary to carry out this section. This section does not require a physician to submit a prescription for each individual treatment and does not change the physician's flexibility in terms of writing a prescription for drugs for a single treatment or a course of treatment.

"(5) PERMITTING ACCESS TO DRUGS AND BIOLOGICALS.—The Secretary shall establish rules under this section under which drugs and biologicals which are acquired through a contractor under this section may be used to resupply inventories of such drugs and biologicals which are administered consistent with safe drug practices and with adequate safeguards against fraud and abuse. The previous sentence shall apply—

"(A) in cases in which the drugs or biologicals are immediately required;

"(B) in cases in which the physician could not have reasonably anticipated the immediate requirement for the drugs or biologicals;

"(C) in cases in which the contractor could not deliver to the physician the drugs or biologicals in a timely manner; and

"(D) in emergency situations.

"(6) CONSTRUCTION.—Nothing in this section shall be construed as waiving applicable State requirements relating to licensing of pharmacies.

"(c) BIDDING PROCESS.—

"(1) IN GENERAL.—In awarding a contract for a category of drugs and biologicals in an area under the program, the Secretary shall consider with respect to each entity seeking to be awarded a contract the prices bid to acquire and supply the covered outpatient drugs and biologicals for that category and area and the other factors referred to in subsection (b)(3).

"(2) PRICES BID.—The prices bid by an entity under paragraph (1) shall be the prices in effect and available for the supply of contracted drugs and biologicals in the area through the entity for the contract period.

"(3) REJECTION OF CONTRACT OFFER.—The Secretary shall reject the contract offer of an entity with respect to a category of drugs and biologicals for an area if the Secretary estimates that the prices bid, in the aggregate on average, would exceed 120 percent of the average sales price (as determined under section 1847B).

"(4) BIDDING ON A NATIONAL OR REGIONAL BASIS.—Nothing in this section shall be construed as precluding a bidder from bidding for contracts in all areas of the United States or as requiring a bidder to submit a bid for all areas of the United States.

"(5) UNIFORMITY OF BIDS WITHIN AREA.—The amount of the bid submitted under a contract offer for any covered outpatient drug or biological for an area shall be the same for that drug or biological for all portions of that area.

"(6) CONFIDENTIALITY OF BIDS.—The provisions of subparagraph (D) of section 1927(b)(3) shall apply to a bid submitted in a contract offer for a covered outpatient drug or biological under this section in the same manner as it applies to information disclosed under such section, except that any reference—

"(A) in that subparagraph to a 'manufacturer or wholesaler' is deemed a reference to a 'bidder' under this section;

"(B) in that section to 'prices charged for drugs' is deemed a reference to a 'bid' submitted under this section; and

"(C) in clause (i) of that section to 'this section', is deemed a reference to 'part B of title XVIII'.

"(7) INCLUSION OF COSTS.—The bid price submitted in a contract offer for a covered outpatient drug or biological shall—

"(A) include all costs related to the delivery of the drug or biological to the selecting physician (or other point of delivery); and

"(B) include the costs of dispensing (including shipping) of such drug or biological and management fees, but shall not include any costs related to the administration of the drug or biological, or wastage, spillage, or spoilage.

"(8) PRICE ADJUSTMENTS DURING CONTRACT PERIOD; DISCLOSURE OF COSTS.—Each contract awarded shall provide for—

"(A) disclosure to the Secretary the contractor's reasonable, net acquisition costs for periods specified by the Secretary, not more often than quarterly, of the contract; and

"(B) appropriate price adjustments over the period of the contract to reflect significant increases or decreases in a contractor's reasonable, net acquisition costs, as so disclosed.

"(d) COMPUTATION OF AVERAGE BID PRICES FOR A CATEGORY AND AREA.—

"(1) IN GENERAL.—For each year or other contract period for each covered outpatient drug or biological and area with respect to which a competition is conducted under the program, the Secretary shall compute an area average of the bid prices submitted, in contract offers accepted for the category and area, for that year or other contract period.

"(2) SPECIAL RULES.—The Secretary shall establish rules regarding the use under this section of the alternative payment amount provided under section

1847B to the use of a price for specific covered outpatient drugs and biologicals in the following cases:

"(A) NEW DRUGS AND BIOLOGICALS.—A covered outpatient drug or biological for which an average bid price has not been previously determined.

"(B) OTHER CASES.—Such other exceptional cases as the Secretary may specify in regulations.

Such alternative payment amount shall be based upon actual market price information and in no case shall it exceed the average sales price (as determined under section 1847B).

"(e) COINSURANCE.—

"(1) IN GENERAL.—Coinsurance under this part with respect to a covered outpatient drug or biological for which payment is payable under this section shall be based on 20 percent of the payment basis under this section.

"(2) COLLECTION.—Such coinsurance shall be collected by the contractor that supplies the drug or biological involved and, subject to subsection (a)(3)(B), in the same manner as coinsurance is collected for durable medical equipment under this part.

"(f) SPECIAL PAYMENT RULES.—

"(1) IN GENERAL.—The Secretary may not provide for an adjustment to reimbursement for covered outpatient drugs and biologicals unless adjustments to the practice expense payment adjustment are made on the basis of supplemental surveys under section 1848(c)(2)(H)(ii) of the Social Security Act, as added by subsection (a)(1)(B).

"(B) USE IN EXCLUSION CASES.—If the Secretary excludes a drug or biological (or class of drugs or biologicals) under subsection (a)(1)(D), the Secretary may provide for reimbursement to be made under this part for such drugs and biologicals (or class) using the payment methodology under section 1847B or other market based pricing system.

"(2) COORDINATION RULES.—The provisions of section 1842(h)(3) shall apply to a contractor with respect to covered outpatients drugs and biologicals supplied by that contractor in the same manner as they apply to a participating supplier. In order to administer this section, the Secretary may condition payment under this part to a person for the administration of a drug or biological supplied under this section upon person's provision of information on such administration.

"(3) APPLICATION OF REQUIREMENT FOR ASSIGNMENT.—For provision requiring assignment of claims for covered outpatient drugs and biologicals, see section 1842(o)(3).

"(4) PROTECTION FOR BENEFICIARY IN CASE OF MEDICAL NECESSITY DENIAL.—For protection of beneficiaries against liability in the case of medical necessity determinations, see section 1842(b)(3)(B)(ii)(III).

"(5) PHYSICIAN ROLE IN APPEALS PROCESS.—The Secretary shall establish a procedure under which a physician who prescribes a drug or biological for which payment is made under this section has appeal rights that are similar to those provided to a physician who prescribes durable medical equipment or a laboratory test.

"(g) ADVISORY COMMITTEE.—The Secretary shall establish an advisory committee that includes representatives of parties affected by the program under this section, including physicians, specialty pharmacies, distributors, manufacturers, and beneficiaries. The committee shall advise the Secretary on issues relating to the effective implementation of this section.

"(h) ANNUAL REPORTS.—The Secretary shall submit to Congress an annual report in each of 2004, 2005, and 2006, on the program. Each such report shall include information on savings, reductions in cost-sharing, access to covered outpatient drugs and biologicals, the range of choices of contractors available to providers, and beneficiary and provider satisfaction.

"OPTIONAL USE OF AVERAGE SALES PRICE PAYMENT METHODOLOGY

"SEC. 1847B. (a) IN GENERAL.—In connection with the election made by a physician under section 1847A(a)(5), the physician may elect to apply this section to the payment for covered outpatient drugs instead of the payment methodology under section 1847A. For purposes of this section, the term 'covered outpatient drug' has the meaning given such term in section 1847A(a)(2)(A).

"(b) COMPUTATION OF PAYMENT AMOUNT.—

"(1) IN GENERAL.—If this section applies with respect to a covered outpatient drug, the amount payable for the drug (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance—

"(A) in the case of a multiple source drug (as defined in subsection (c)(6)(C)), the amount determined under paragraph (3); or

"(B) in the case of a single source drug (as defined in subsection (c)(6)(D)), the amount determined under paragraph (4).

"(2) SPECIFICATION OF UNIT.—

"(A) SPECIFICATION BY MANUFACTURER.—The manufacturer of a covered outpatient drug shall specify the unit associated with each National Drug Code as part of the submission of data under section 1927(b)(3)(A)(iii).

"(B) UNIT DEFINED.—In this section, the term 'unit' means, with respect to a covered outpatient drug, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids.

"(3) MULTIPLE SOURCE DRUG.—For all drug products included within the same multiple source drug, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1927(b)(3)(A)(iii) computed as follows:

"(A) Compute the sum of the products (for each national drug code assigned to such drug products) of—

"(i) the manufacturer's average sales price (as defined in subsection (c)); and

"(ii) the total number of units specified under paragraph (2) sold, as reported under section 1927(b)(3)(A)(iii).

"(B) Divide the sum computed under subparagraph (A) by the sum of the total number of units under subparagraph (A)(ii) for all national drug codes assigned to such drug products.

"(4) SINGLE SOURCE DRUG.—The amount specified in this paragraph for a single source drug is the lesser of the following:

"(A) MANUFACTURER'S AVERAGE SALES PRICE.—The manufacturer's average sales price for a national drug code, as computed using the methodology applied under paragraph (3).

"(B) WHOLESALE ACQUISITION COST (WAC).—The wholesale acquisition cost (as defined in subsection (c)(6)(B)) reported for the single source drug.

"(5) BASIS FOR DETERMINATION.—The payment amount shall be determined under this subsection based on information reported under subsection (e) and without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

"(c) MANUFACTURER'S AVERAGE SALES PRICE.—

"(1) IN GENERAL.—For purposes of this subsection, subject to paragraphs (2) and (3), the manufacturer's 'average sales price' means, of a covered outpatient drug for a NDC code for a calendar quarter for a manufacturer for a unit—

"(A) the manufacturer's total sales (as defined by the Secretary in regulations for purposes of section 1927(c)(1)) in the United States for such drug in the calendar quarter; divided by

"(B) the total number of such units of such drug sold by the manufacturer in such quarter.

"(2) CERTAIN SALES EXEMPTED FROM COMPUTATION.—In calculating the manufacturer's average sales price under this subsection, the following sales shall be excluded:

"(A) SALES EXEMPT FROM BEST PRICE.—Sales exempt from the inclusion in the determination of 'best price' under section 1927(c)(1)(C)(i).

"(B) SALES AT NOMINAL CHARGE.—Such other sales as the Secretary identifies by regulation as sales to an entity that are nominal in price or do not reflect a market price paid by an entity to which payment is made under this section.

"(3) SALE PRICE NET OF DISCOUNTS.—In calculating the manufacturer's average sales price under this subsection, such price shall be determined taking into account volume discounts, prompt pay discounts, cash discounts, the free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927), that result in a reduction of the cost to the purchaser. A rebate to a payor or other entity that does not take title to a covered outpatient drug shall not be taken into account in determining such price unless the manufacturer has an agreement with the payor or other entity under which the purchaser's price for the drug is reduced as a consequence of such rebate.

"(4) AUTHORITY TO DISREGARD AVERAGE SALES PRICE DURING FIRST QUARTER OF SALES.—In the case of a covered outpatient drug during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug is not sufficiently available from the manufacturer to compute an average sales price for the drug, the Secretary may determine the amount payable

under this section for the drug without considering the manufacturer's average sales price of that manufacturer for that drug.

"(5) FREQUENCY OF DETERMINATIONS.—

"(A) IN GENERAL ON A QUARTERLY BASIS.—The manufacturer's average sales price, for a covered outpatient drug of a manufacturer, shall be determined by such manufacturer under this subsection on a quarterly basis. In making such determination insofar as there is a lag in the reporting of the information on rebates and chargebacks under paragraph (3) so that adequate data are not available on a timely basis, the manufacturer shall apply a methodology established by the Secretary based on a 12-month rolling average for the manufacturer to estimate costs attributable to rebates and chargebacks.

"(B) UPDATES IN RATES.—The payment rates under subsection (b)(1) and (b)(2)(A) shall be updated by the Secretary on a quarterly basis and shall be applied based upon the manufacturer's average sales price determined for the most recent calendar quarter.

"(C) USE OF CONTRACTORS; IMPLEMENTATION.—The Secretary may use a carrier, fiscal intermediary, or other contractor to determine the payment amount under subsection (b). Notwithstanding any other provision of law, the Secretary may implement, by program memorandum or otherwise, any of the provisions of this section.

"(6) DEFINITIONS AND OTHER RULES.—In this section:

"(A) MANUFACTURER.—The term 'manufacturer' means, with respect to a covered outpatient drug, the manufacturer (as defined in section 1927(k)(5)) whose national drug code appears on such drug.

"(ii) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' means, with respect to a covered outpatient drug, the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug pricing data.

"(C) MULTIPLE SOURCE DRUG.—The term 'multiple source drug' means, for a calendar quarter, a covered outpatient drug for which there are 2 or more drug products which—

"(i) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations'),

"(ii) except as provided in subparagraph (E), are pharmaceutically equivalent and bioequivalent, as determined under subparagraph (F) and as determined by the Food and Drug Administration, and

"(iii) are sold or marketed in the United States during the quarter.

"(D) SINGLE SOURCE DRUG.—The term 'single source drug' means a covered outpatient drug which is not a multiple source drug and which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application, or which is a biological.

"(E) EXCEPTION FROM PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVALENCE REQUIREMENT.—Subparagraph (C)(ii) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (C)(i), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (F).

"(F) DETERMINATION OF PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVALENCE.—For purposes of this paragraph—

"(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; and

"(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence.

"(G) INCLUSION OF VACCINES.—In applying provisions of section 1927 under this section, 'other than a vaccine' is deemed deleted from section 1927(k)(2)(B).

"(d) MONITORING PRICE INFORMATION.—

"(1) IN GENERAL.—The Secretary shall monitor available pricing information, including information on average sales price and average manufacturer price.

"(2) RESPONSE TO SIGNIFICANT DISCREPANCIES.—

"(A) REPORT TO CONGRESS.—If the Secretary finds that there are significant discrepancies among such prices and that the manufacturer's average sales price does not reflect a broad-based market price or a reasonable approximation of the acquisition cost of the covered outpatient drug involved to purchasers reimbursed under this section, the Secretary shall submit to Congress a report.

"(B) CONFIDENTIALITY OF INFORMATION REPORTED.—Consistent with requirements relating to maintaining the confidentiality of information reported on manufacturer's average prices under section 1927(b)(3)(D), such report shall include details regarding such discrepancies and recommendations on how to best address such discrepancies. Such report shall not disclose average manufacturer prices or average sales prices.

"(C) RECOMMENDATIONS.—Such recommendations may include other changes in payment methodology.

"(D) AUTHORITY TO MODIFY PAYMENT METHODOLOGY BY RULE.—Upon submission of such report, the Secretary may commence a rulemaking to change such percent or payment methodologies under paragraph (1)(D) and (2) as applied to the covered outpatient drug involved under this section.

"(3) RESPONSE TO PUBLIC HEALTH EMERGENCY.—In the case of a public health emergency under section 319 of the Public Health Service Act in which there is a documented inability to access covered outpatient drugs, and a concomitant increase in the price, of a drug which is not reflected in the manufacturer's average sales price for one or more quarters, the Secretary may use the wholesale acquisition cost (or other reasonable measure of drug price) instead of the manufacturer's average sales price for such quarters and for subsequent quarters until the price and availability of the drug has stabilized and is substantially reflected in the applicable manufacturer's average sales price.

"(4) ANNUAL REPORT TO CONGRESS.—The Secretary shall submit to the Committees on Energy and Commerce and Ways and Means of the House of Representatives and the Committee on Finance of the Senate an annual report on the operation of this section. Such report shall be submitted in coordination with the submission of reports under section 1927(i). Such report shall include information on the following:

"(A) Trends in average sales price under subsection (b).

"(B) Administrative costs associated with compliance with this section.

"(C) Total value of payments made under this section.

"(D) Comparison of the average manufacturer price as applied under section 1927 for a covered outpatient drug with the manufacturer's average sales price for the drug under this section.

"(e) REPORTS ON PRICING INFORMATION.—

"(1) REFERENCE TO REPORTING REQUIREMENT ON AVERAGE SALES PRICE.—For requirements for reporting the manufacturer's average sales price (and, if required to make payment, the manufacturer's wholesale acquisition cost) for the covered outpatient drug, see section 1927(b)(3).

"(2) MEDPAC REVIEW.—The Medicare Payment Advisory Commission shall periodically review the payment methodology established under this section and submit to Congress such recommendations on such methodology as it deems appropriate as part of its annual reports to Congress.

"(3) CONSTRUCTION.—Nothing in this subsection shall be construed as authorizing the Secretary to review for purposes of this section information reported only under section 1927(b)(3).

"(f) RESTRICTION ON ADMINISTRATIVE AND JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations of manufacturer's average sales price under subsection (c).".

(c) CONTINUATION OF PAYMENT METHODOLOGY FOR RADIOPHARMACEUTICALS.—Nothing in the amendments made by this section shall be construed as changing the payment methodology under part B of title XVIII of the Social Security Act for radiopharmaceuticals, including the use by carriers of invoice pricing methodology.

(d) CONFORMING AMENDMENTS.—

(1) IN GENERAL.—Section 1842(o) (42 U.S.C. 1395u(o)) is amended—

(A) in paragraph (1), by inserting ", subject to section 1847A and 1847B," before "the amount payable for the drug or biological"; and

(B) by adding at the end of paragraph (2) the following: "This paragraph shall not apply in the case of payment under section 1847A or 1847B.".

(2) NO CHANGE IN COVERAGE BASIS.—Section 1861(s)(2)(A) (42 U.S.C. 1395x(s)(2)(A)) is amended by inserting "(or would have been so included but for the application of section 1847A or 1847B)" after "included in the physicians' bills".

(3) PAYMENT.—Section 1833(a)(1)(S) (42 U.S.C. 1395l(a)(1)(S)) is amended by inserting "(or, if applicable, under section 1847A or 1847B)" after "1842(o)".

(4) CONSOLIDATED REPORTING OF PRICING INFORMATION.—Section 1927 (42 U.S.C. 1396r–8) is amended—

(A) in subsection (a)(1), by inserting "or under part B of title XVIII" after "section 1903(a)";

(B) in subsection (b)(3)(A)—

(i) in clause (i), by striking "and" at the end;

(ii) in clause (ii), by striking the period and inserting "; and"; and

(iii) by adding at the end the following new clause:

"(iii) for calendar quarters beginning on or after April 1, 2004, in conjunction with reporting required under clause (i) and by national drug code (NDC)—

"(I) the manufacturer's average sales price (as defined in section 1847B(c)) and the total number of units specified under section 1847B(b)(2)(A);

"(II) if required to make payment under section 1847B, the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section; and

"(III) information on those sales that were made at a nominal price or otherwise described in section 1847B(c)(2)(B), which information is subject to audit by the Inspector General of the Department of Health and Human Services;

for a covered outpatient drug for which payment is made under section 1847B.";

(C) in subsection (b)(3)(B)—

(i) in the heading, by inserting "AND MANUFACTURER'S AVERAGE SALES PRICE" after "PRICE"; and

(ii) by inserting "and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment" after "manufacturer prices"; and

(D) in subsection (b)(3)(D)(i), by inserting "and section 1847B" after "this section".

(e) GAO STUDY.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to assess the impact of the amendments made by this section on the delivery of services, including their impact on—

(A) beneficiary access to drugs and biologicals for which payment is made under part B of title XVIII of the Social Security Act; and

(B) the site of delivery of such services.

(2) REPORT.—Not later than 2 years after the year in which the amendment made by subsection (a)(1) first takes effect, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).

(f) MEDPAC RECOMMENDATIONS ON BLOOD CLOTTING FACTORS.—The Medicare Payment Advisory Commission shall submit to Congress, in its annual report in 2004, specific recommendations regarding a payment amount (or amounts) for blood clotting factors and its administration under the medicare program.

(g) ESTABLISHMENT OF PHARMACEUTICAL MANAGEMENT FEE WHERE DRUGS PROVIDED THROUGH A CONTRACTOR.—Section 1848(a) (42 U.S.C. 1395w–4(a)) is amended by adding at the end the following new paragraph:

"(5) RECOGNITION OF PHARMACEUTICAL MANAGEMENT FEE IN CERTAIN CASES.—In establishing the fee schedule under this section, the Secretary shall provide for a separate payment with respect to physicians' services consisting of the unique administrative and management costs associated with covered drugs and biologicals which are furnished to physicians through a contractor under section 1847A (compared with such costs if such drugs and biologicals were acquired directly by such physicians).".

SEC. 304. DEMONSTRATION PROJECT FOR USE OF RECOVERY AUDIT CONTRACTORS.

(a) IN GENERAL.—The Secretary of Health and Human Services shall conduct a demonstration project under this section (in this section referred to as the "project") to demonstrate the use of recovery audit contractors under the Medicare Integrity Program in identifying underpayments and overpayments and recouping overpayments under the medicare program for services for which payment is made under part A or part B of title XVIII of the Social Security Act. Under the project—

(1) payment may be made to such a contractor on a contingent basis;

(2) a percentage of the amount recovered may be retained by the Secretary and shall be available to the program management account of the Centers for Medicare & Medicaid Services; and

(3) the Secretary shall examine the efficacy of such use with respect to duplicative payments, accuracy of coding, and other payment policies in which inaccurate payments arise.

(b) SCOPE AND DURATION.—

(1) SCOPE.—The project shall cover at least 2 States that are among the States with—

(A) the highest per capita utilization rates of medicare services, and

(B) at least 3 contractors.

(2) DURATION.—The project shall last for not longer than 3 years.

(c) WAIVER.—The Secretary of Health and Human Services shall waive such provisions of title XVIII of the Social Security Act as may be necessary to provide for payment for services under the project in accordance with subsection (a).

(d) QUALIFICATIONS OF CONTRACTORS.—

(1) IN GENERAL.—The Secretary shall enter into a recovery audit contract under this section with an entity only if the entity has staff that has the appropriate clinical knowledge of and experience with the payment rules and regulations under the medicare program or the entity has or will contract with another entity that has such knowledgeable and experienced staff.

(2) INELIGIBILITY OF CERTAIN CONTRACTORS.—The Secretary may not enter into a recovery audit contract under this section with an entity to the extent that the entity is a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h), a carrier under section 1842 of such Act (42 U.S.C. 1395u), or a Medicare Administrative Contractor under section 1874A of such Act.

(3) PREFERENCE FOR ENTITIES WITH DEMONSTRATED PROFICIENCY WITH PRIVATE INSURERS.—In awarding contracts to recovery audit contractors under this section, the Secretary shall give preference to those risk entities that the Secretary determines have demonstrated more than 3 years direct management experience and a proficiency in recovery audits with private insurers or under the medicaid program under title XIX of such Act.

(e) CONSTRUCTION RELATING TO CONDUCT OF INVESTIGATION OF FRAUD.—A recovery of an overpayment to a provider by a recovery audit contractor shall not be construed to prohibit the Secretary or the Attorney General from investigating and prosecuting, if appropriate, allegations of fraud or abuse arising from such overpayment.

(f) REPORT.—The Secretary of Health and Human Services shall submit to Congress a report on the project not later than 6 months after the date of its completion. Such reports shall include information on the impact of the project on savings to the medicare program and recommendations on the cost-effectiveness of extending or expanding the project.

TITLE IV—RURAL HEALTH CARE IMPROVEMENTS

SEC. 401. ENHANCED DISPROPORTIONATE SHARE HOSPITAL (DSH) TREATMENT FOR RURAL HOSPITALS AND URBAN HOSPITALS WITH FEWER THAN 100 BEDS.

(a) DOUBLING THE CAP.—

(1) IN GENERAL.—Section 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is amended by adding at the end the following new clause:

"(xiv)(I) In the case of discharges in a fiscal year beginning on or after October 1, 2003, subject to subclause (II), there shall be substituted for the disproportionate share adjustment percentage otherwise determined under clause (iv) (other than subclause (I)) or under clause (viii), (x), (xi), (xii), or (xiii), the disproportionate share adjustment percentage determined under clause (vii) (relating to large, urban hospitals).

"(II) Under subclause (I), the disproportionate share adjustment percentage shall not exceed 10 percent for a hospital that is not classified as a rural referral center under subparagraph (C).".

(2) CONFORMING AMENDMENTS.—Section 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is amended—

(A) in each of subclauses (II), (III), (IV), (V), and (VI) of clause (iv), by inserting "subject to clause (xiv) and" before "for discharges occurring";

(B) in clause (viii), by striking "The formula" and inserting "Subject to clause (xiv), the formula"; and

(C) in each of clauses (x), (xi), (xii), and (xiii), by striking "For purposes" and inserting "Subject to clause (xiv), for purposes".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to discharges occurring on or after October 1, 2003.

SEC. 402. IMMEDIATE ESTABLISHMENT OF UNIFORM STANDARDIZED AMOUNT IN RURAL AND SMALL URBAN AREAS.

(a) IN GENERAL.—Section 1886(d)(3)(A) (42 U.S.C. 1395ww(d)(3)(A)) is amended—

(1) in clause (iv), by inserting "and ending on or before September 30, 2003," after "October 1, 1995,"; and

(2) by redesignating clauses (v) and (vi) as clauses (vii) and (viii), respectively, and inserting after clause (iv) the following new clauses:

"(v) For discharges occurring in the fiscal year beginning on October 1, 2003, the average standardized amount for hospitals located in areas other than a large urban area shall be equal to the average standardized amount for hospitals located in a large urban area.".

(b) CONFORMING AMENDMENTS.—

(1) COMPUTING DRG-SPECIFIC RATES.—Section 1886(d)(3)(D) (42 U.S.C. 1395ww(d)(3)(D)) is amended—

(A) in the heading, by striking "IN DIFFERENT AREAS";

(B) in the matter preceding clause (i), by striking ", each of";

(C) in clause (i)—

(i) in the matter preceding subclause (I), by inserting "for fiscal years before fiscal year 2004," before "for hospitals"; and

(ii) in subclause (II), by striking "and" after the semicolon at the end;

(D) in clause (ii)—

(i) in the matter preceding subclause (I), by inserting "for fiscal years before fiscal year 2004," before "for hospitals"; and

(ii) in subclause (II), by striking the period at the end and inserting "; and"; and

(E) by adding at the end the following new clause:

"(iii) for a fiscal year beginning after fiscal year 2003, for hospitals located in all areas, to the product of—

"(I) the applicable standardized amount (computed under subparagraph (A)), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C) for the fiscal year; and

"(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.".

(2) TECHNICAL CONFORMING SUNSET.—Section 1886(d)(3) (42 U.S.C. 1395ww(d)(3)) is amended—

(A) in the matter preceding subparagraph (A), by inserting ", for fiscal years before fiscal year 1997," before "a regional adjusted DRG prospective payment rate"; and

(B) in subparagraph (D), in the matter preceding clause (i), by inserting ", for fiscal years before fiscal year 1997," before "a regional DRG prospective payment rate for each region,".

SEC. 403. ESTABLISHMENT OF ESSENTIAL RURAL HOSPITAL CLASSIFICATION.

(a) CLASSIFICATION.—Section 1861(mm) (42 U.S.C. 1395x(mm)) is amended—

(1) in the heading by adding "ESSENTIAL RURAL HOSPITALS" at the end; and

(2) by adding at the end the following new paragraphs:

"(4)(A) The term 'essential rural hospital' means a subsection (d) hospital (as defined in section 1886(d)(1)(B)) that is located in a rural area (as defined for purposes of section 1886(d)), has more than 25 licensed acute care inpatient beds, has applied to the Secretary for classification as such a hospital, and with respect to which the Secretary has determined that the closure of the hospital would significantly diminish the ability of medicare beneficiaries to obtain essential health care services.

"(B) The determination under subparagraph (A) shall be based on the following criteria:

"(i) HIGH PROPORTION OF MEDICARE BENEFICIARIES RECEIVING CARE FROM HOSPITAL.—(I) A high percentage of such beneficiaries residing in the area of the hospital who are hospitalized (during the most recent year for which complete data are available) receive basic inpatient medical care at the hospital.

"(II) For a hospital with more than 200 licensed beds, a high percentage of such beneficiaries residing in such area who are hospitalized (during such recent year) receive specialized surgical inpatient care at the hospital.

"(III) Almost all physicians described in section 1861(r)(1) in such area have privileges at the hospital and provide their inpatient services primarily at the hospital.

"(ii) SIGNIFICANT ADVERSE IMPACT IN ABSENCE OF HOSPITAL.—If the hospital were to close—

"(I) there would be a significant amount of time needed for residents to reach emergency treatment, resulting in a potential significant harm to beneficiaries with critical illnesses or injuries;

"(II) there would be an inability in the community to stablize emergency cases for transfers to another acute care setting, resulting in a potential for significant harm to medicare beneficiaries; and

"(III) any other nearby hospital lacks the physical and clinical capacity to take over the hospital's typical admissions.

"(C) In making such determination, the Secretary may also consider the following:

"(i) Free-standing ambulatory surgery centers, office-based oncology care, and imaging center services are insufficient in the hospital's area to handle the outpatient care of the hospital.

"(ii) Beneficiaries in nearby areas would be adversely affected if the hospital were to close as the hospital provides specialized knowledge and services to a network of smaller hospitals and critical access hospitals.

"(iii) Medicare beneficiaries would have difficulty in accessing care if the hospital were to close as the hospital provides significant subsidies to support ambulatory care in local clinics, including mental health clinics and to support post acute care.

"(iv) The hospital has a committment to provide graduate medical education in a rural area.

"(C) QUALITY CARE.—The hospital inpatient score for quality of care is not less than the median hospital score for qualify of care for hospitals in the State, as established under standards of the utilization and quality control peer review organization under part B of title XI or other quality standards recognized by the Secretary.

A hospital classified as an essential rural hospital may not change such classification and a hospital so classified shall not be treated as a sole community hospital, medicare dependent hospital, or rural referral center for purposes of section 1886.".

(b) PAYMENT BASED ON 102 PERCENT OF ALLOWED COSTS.—

(1) INPATIENT HOSPITAL SERVICES.—Section 1886(d) (42 U.S.C. 1395ww(d)) is amended by adding at the end the following:

"(11) In the case of a hospital classified as an essential rural hospital under section 1861(mm)(4) for a cost reporting period, the payment under this subsection for inpatient hospital services for discharges occurring during the period shall be based on 102 percent of the reasonable costs for such services. Nothing in this paragraph shall be construed as affecting the application or amount of deductibles or copayments otherwise applicable to such services under part A or as waiving any requirement for billing for such services.".

(2) HOSPITAL OUTPATIENT SERVICES.—Section 1833(t)(13) (42 U.S.C. 1395l(t)(13)) is amended by adding at the end the following new subparagraph:

"(B) SPECIAL RULE FOR ESSENTIAL RURAL HOSPITALS.—In the case of a hospital classified as an essential rural hospital under section 1861(mm)(4) for a cost reporting period, the payment under this subsection for covered OPD services during the period shall be based on 102 percent of the reasonable costs for such services. Nothing in this subparagraph shall be construed as affecting the application or amount of deductibles or copayments otherwise applicable to such services under this part or as waiving any requirement for billing for such services.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to cost reporting periods beginning on or after October 1, 2004.

SEC. 404. MORE FREQUENT UPDATE IN WEIGHTS USED IN HOSPITAL MARKET BASKET.

(a) MORE FREQUENT UPDATES IN WEIGHTS.—After revising the weights used in the hospital market basket under section 1886(b)(3)(B)(iii) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(iii)) to reflect the most current data available, the Secretary shall establish a frequency for revising such weights, including the labor share, in such market basket to reflect the most current data available more frequently than once every 5 years.

(b) REPORT.—Not later than October 1, 2004, the Secretary shall submit a report to Congress on the frequency established under subsection (a), including an explanation of the reasons for, and options considered, in determining such frequency.

SEC. 405. IMPROVEMENTS TO CRITICAL ACCESS HOSPITAL PROGRAM.

(a) INCREASE IN PAYMENT AMOUNTS.—

(1) IN GENERAL.—Sections 1814(l), 1834(g)(1), and 1883(a)(3) (42 U.S.C. 1395f(l); 1395m(g)(1); 42 U.S.C. 1395tt(a)(3)) are each amended by inserting "equal to 102 percent of" before "the reasonable costs".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to payments for services furnished during cost reporting periods beginning on or after October 1, 2003.

(b) COVERAGE OF COSTS FOR CERTAIN EMERGENCY ROOM ON-CALL PROVIDERS.—

(1) IN GENERAL.—Section 1834(g)(5) (42 U.S.C. 1395m(g)(5)) is amended—

(A) in the heading—

(i) by inserting "CERTAIN" before "EMERGENCY"; and

(ii) by striking "PHYSICIANS" and inserting "PROVIDERS";

(B) by striking "emergency room physicians who are on-call (as defined by the Secretary)" and inserting "physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on-call (as defined by the Secretary) to provide emergency services"; and

(C) by striking "physicians' services" and inserting "services covered under this title".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply with respect to costs incurred for services provided on or after January 1, 2004.

(c) MODIFICATION OF THE ISOLATION TEST FOR COST-BASED CAH AMBULANCE SERVICES.—

(1) IN GENERAL.—Section 1834(l)(8) (42 U.S.C. 1395m(l)), as added by section 205(a) of BIPA (114 Stat. 2763A–482), is amended by adding at the end the following: "The limitation described in the matter following subparagraph (B) in the previous sentence shall not apply if the ambulance services are furnished by such a provider or supplier of ambulance services who is a first responder to emergencies (as determined by the Secretary).".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to ambulances services furnished on or after the first cost reporting period that begins after the date of the enactment of this Act.

(d) REINSTATEMENT OF PERIODIC INTERIM PAYMENT (PIP).—

(1) IN GENERAL.—Section 1815(e)(2) (42 U.S.C. 1395g(e)(2)) is amended—

(A) in the matter before subparagraph (A), by inserting ", in the cases described in subparagraphs (A) through (D)" after "1986"; and

(B) by striking "and" at the end of subparagraph (C);

(C) by adding "and" at the end of subparagraph (D); and

(D) by inserting after subparagraph (D) the following new subparagraph:

"(E) inpatient critical access hospital services;".

(2) DEVELOPMENT OF ALTERNATIVE METHODS OF PERIODIC INTERIM PAYMENTS.—With respect to periodic interim payments to critical access hospitals for inpatient critical access hospital services under section 1815(e)(2)(E) of the Social Security Act, as added by paragraph (1), the Secretary shall develop alternative methods for such payments that are based on expenditures of the hospital.

(3) REINSTATEMENT OF PIP.—The amendments made by paragraph (1) shall apply to payments made on or after January 1, 2004.

(e) CONDITION FOR APPLICATION OF SPECIAL PHYSICIAN PAYMENT ADJUSTMENT.—

(1) IN GENERAL.—Section 1834(g)(2) (42 U.S.C. 1395m(g)(2)) is amended by adding after and below subparagraph (B) the following:

"The Secretary may not require, as a condition for applying subparagraph (B) with respect to a critical access hospital, that each physician providing professional services in the hospital must assign billing rights with respect to such services, except that such subparagraph shall not apply to those physicians who have not assigned such billing rights.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall be effective as if included in the enactment of section 403(d) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (113 Stat. 1501A–371).

(f) FLEXIBILITY IN BED LIMITATION FOR HOSPITALS.—Section 1820 (42 U.S.C. 1395i–4) is amended—

(1) in subsection (c)(2)(B)(iii), by inserting "subject to paragraph (3)" after "(iii) provides";

(2) by adding at the end of subsection (c) the following new paragraph:

"(3) INCREASE IN MAXIMUM NUMBER OF BEDS FOR HOSPITALS WITH STRONG SEASONAL CENSUS FLUCTUATIONS.—

"(A) IN GENERAL.—Subject to subparagraph (C), in the case of a hospital that demonstrates that it meets the standards established under subparagraph (B) and has not made the election described in subsection (f)(2)(A), the bed limitations otherwise applicable under paragraph (2)(B)(iii) and subsection (f) shall be increased by 5 beds.

"(B) STANDARDS.—The Secretary shall specify standards for determining whether a critical access hospital has sufficiently strong seasonal variations

in patient admissions to justify the increase in bed limitation provided under subparagraph (A).''; and

(3) in subsection (f)—

(A) by inserting ''(1)'' after ''(f)''; and

(B) by adding at the end the following new paragraph:

''(2)(A) A hospital may elect to treat the reference in paragraph (1) to '15 beds' as a reference to '25 beds', but only if no more than 10 beds in the hospital are at any time used for non-acute care services. A hospital that makes such an election is not eligible for the increase provided under subsection (c)(3)(A).

''(B) The limitations in numbers of beds under the first sentence of paragraph (1) are subject to adjustment under subsection (c)(3).''.

(4) EFFECTIVE DATE.—The amendments made by this subsection shall apply to designations made before, on, or after January 1, 2004.

(g) ADDITIONAL 5-YEAR PERIOD OF FUNDING FOR GRANT PROGRAM.—

(1) IN GENERAL.—Section 1820(g) (42 U.S.C. 1395i–4(g)) is amended by adding at the end the following new paragraph:

''(4) FUNDING.—

''(A) IN GENERAL.—Subject to subparagraph (B), payment for grants made under this subsection during fiscal years 2004 through 2008 shall be made from the Federal Hospital Insurance Trust Fund.

''(B) ANNUAL AGGREGATE LIMITATION.—In no case may the amount of payment provided for under subparagraph (A) for a fiscal year exceed $25,000,000.''.

(2) CONFORMING AMENDMENT.—Section 1820 (42 U.S.C. 1395i–4) is amended by striking subsection (j).

SEC. 406. REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.

(a) IN GENERAL.—Section 1886(h)(4) (42 U.S.C. 1395ww(h)(4)) is amended—

(1) in subparagraph (F)(i), by inserting ''subject to subparagraph (I),'' after ''October 1, 1997,'';

(2) in subparagraph (H)(i), by inserting ''subject to subparagraph (I),'' after ''subparagraphs (F) and (G),''; and

(3) by adding at the end the following new subparagraph:

''(I) REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.—

''(i) REDUCTION IN LIMIT BASED ON UNUSED POSITIONS.—

''(I) IN GENERAL.—If a hospital's resident level (as defined in clause (iii)(I)) is less than the otherwise applicable resident limit (as defined in clause (iii)(II)) for each of the reference periods (as defined in subclause (II)), effective for cost reporting periods beginning on or after January 1, 2004, the otherwise applicable resident limit shall be reduced by 75 percent of the difference between such limit and the reference resident level specified in subclause (III) (or subclause (IV) if applicable).

''(II) REFERENCE PERIODS DEFINED.—In this clause, the term 'reference periods' means, for a hospital, the 3 most recent consecutive cost reporting periods of the hospital for which cost reports have been settled (or, if not, submitted) on or before September 30, 2002.

''(III) REFERENCE RESIDENT LEVEL.—Subject to subclause (IV), the reference resident level specified in this subclause for a hospital is the highest resident level for the hospital during any of the reference periods.

''(IV) ADJUSTMENT PROCESS.—Upon the timely request of a hospital, the Secretary may adjust the reference resident level for a hospital to be the resident level for the hospital for the cost reporting period that includes July 1, 2003.

''(V) AFFILIATION.—With respect to hospitals which are members of the same affiliated group (as defined by the Secretary under subparagraph (H)(ii)), the provisions of this section shall be applied with respect to such an affiliated group by deeming the affiliated group to be a single hospital.

''(ii) REDISTRIBUTION.—

''(I) IN GENERAL.—The Secretary is authorized to increase the otherwise applicable resident limits for hospitals by an aggregate number estimated by the Secretary that does not exceed the aggregate reduction in such limits attributable to clause (i) (without taking into account any adjustment under subclause (IV) of such clause).

''(II) EFFECTIVE DATE.—No increase under subclause (I) shall be permitted or taken into account for a hospital for any portion of a

cost reporting period that occurs before July 1, 2004, or before the date of the hospital's application for an increase under this clause. No such increase shall be permitted for a hospital unless the hospital has applied to the Secretary for such increase by December 31, 2005.

"(III) CONSIDERATIONS IN REDISTRIBUTION.—In determining for which hospitals the increase in the otherwise applicable resident limit is provided under subclause (I), the Secretary shall take into account the need for such an increase by specialty and location involved, consistent with subclause (IV).

"(IV) PRIORITY FOR RURAL AND SMALL URBAN AREAS.—In determining for which hospitals and residency training programs an increase in the otherwise applicable resident limit is provided under subclause (I), the Secretary shall first distribute the increase to programs of hospitals located in rural areas or in urban areas that are not large urban areas (as defined for purposes of subsection (d)) on a first-come-first-served basis (as determined by the Secretary) based on a demonstration that the hospital will fill the positions made available under this clause and not to exceed an increase of 25 full-time equivalent positions with respect to any hospital.

"(V) APPLICATION OF LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—With respect to additional residency positions in a hospital attributable to the increase provided under this clause, notwithstanding any other provision of this subsection, the approved FTE resident amount is deemed to be equal to the locality adjusted national average per resident amount computed under subparagraph (E) for that hospital.

"(VI) CONSTRUCTION.—Nothing in this clause shall be construed as permitting the redistribution of reductions in residency positions attributable to voluntary reduction programs under paragraph (6) or as affecting the ability of a hospital to establish new medical residency training programs under subparagraph (H).

"(iii) RESIDENT LEVEL AND LIMIT DEFINED.—In this subparagraph:

"(I) RESIDENT LEVEL.—The term 'resident level' means, with respect to a hospital, the total number of full-time equivalent residents, before the application of weighting factors (as determined under this paragraph), in the fields of allopathic and osteopathic medicine for the hospital.

"(II) OTHERWISE APPLICABLE RESIDENT LIMIT.—The term 'otherwise applicable resident limit' means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) on the resident level for the hospital determined without regard to this subparagraph.".

(b) CONFORMING AMENDMENT TO IME.—Section 1886(d)(5)(B)(v) (42 U.S.C. 1395ww(d)(5)(B)(v)) is amended by adding at the end the following: "The provisions of subparagraph (I) of subsection (h)(4) shall apply with respect to the first sentece of this clause in the same manner as it applies with respect to subparagraph (F) of such subsection.".

(c) REPORT ON EXTENSION OF APPLICATIONS UNDER REDISTRIBUTION PROGRAM.—Not later than July 1, 2005, the Secretary shall submit to Congress a report containing recommendations regarding whether to extend the deadline for applications for an increase in resident limits under section 1886(h)(4)(I)(ii)(II) of the Social Security Act (as added by subsection (a)).

SEC. 407. TWO-YEAR EXTENSION OF HOLD HARMLESS PROVISIONS FOR SMALL RURAL HOSPITALS AND SOLE COMMUNITY HOSPITALS UNDER PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES.

(a) HOLD HARMLESS PROVISIONS.—

(1) IN GENERAL.—Section 1833(t)(7)(D)(i) (42 U.S.C. 1395l(t)(7)(D)(i)) is amended—

(A) in the heading, by striking "SMALL" and inserting "CERTAIN";

(B) by inserting "or a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) located in a rural area" after "100 beds"; and

(C) by striking "2004" and inserting "2006".

(2) EFFECTIVE DATE.—The amendment made by subsection (a)(2) shall apply with respect to payment for OPD services furnished on and after January 1, 2004.

(b) STUDY; ADJUSTMENT.—

(1) STUDY.—The Secretary shall conduct a study to determine if, under the prospective payment system for hospital outpatient department services under

section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)), costs incurred by rural providers of services by ambulatory payment classification groups (APCs) exceed those costs incurred by urban providers of services.

(2) ADJUSTMENT.—Insofar as the Secretary determines under paragraph (1) that costs incurred by rural providers exceed those costs incurred by urban providers of services, the Secretary shall provide for an appropriate adjustment under such section 1833(t) to reflect those higher costs by January 1, 2005.

SEC. 408. EXCLUSION OF CERTAIN RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES FROM THE PROSPECTIVE PAYMENT SYSTEM FOR SKILLED NURSING FACILITIES.

(a) IN GENERAL.—Section 1888(e)(2)(A) (42 U.S.C. 1395yy(e)(2)(A)) is amended—

(1) in clause (i)(II), by striking "clauses (ii) and (iii)" and inserting "clauses (ii), (iii), and (iv)"; and

(2) by adding at the end the following new clause:

"(iv) EXCLUSION OF CERTAIN RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES.—Services described in this clause are—

"(I) rural health clinic services (as defined in paragraph (1) of section 1861(aa)); and

"(II) Federally qualified health center services (as defined in paragraph (3) of such section);

that would be described in clause (ii) if such services were not furnished by an individual affiliated with a rural health clinic or a Federally qualified health center.".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to services furnished on or after January 1, 2004.

SEC. 409. RECOGNITION OF ATTENDING NURSE PRACTITIONERS AS ATTENDING PHYSICIANS TO SERVE HOSPICE PATIENTS.

(a) IN GENERAL.—Section 1861(dd)(3)(B) (42 U.S.C. 1395x(dd)(3)(B)) is amended by inserting "or nurse practitioner (as defined in subsection (aa)(5))" after "the physician (as defined in subsection (r)(1))".

(b) PROHIBITION ON NURSE PRACTITIONER CERTIFYING NEED FOR HOSPICE.—Section 1814(a)(7)(A)(i)(I) (42 U.S.C. 1395f(a)(7)(A)(i)(I)) is amended by inserting "(which for purposes of this subparagraph does not include a nurse practitioner)" after "attending physician (as defined in section 1861(dd)(3)(B))".

SEC. 410. IMPROVEMENT IN PAYMENTS TO RETAIN EMERGENCY CAPACITY FOR AMBULANCE SERVICES IN RURAL AREAS.

Section 1834(l) (42 U.S.C. 1395m(l)) is amended—

(1) by redesignating paragraph (8), as added by section 221(a) of BIPA (114 Stat. 2763A–486), as paragraph (9); and

(2) by adding at the end the following new paragraph:

"(10) ASSISTANCE FOR RURAL PROVIDERS FURNISHING SERVICES IN LOW MEDICARE POPULATION DENSITY AREAS.—

"(A) IN GENERAL.—In the case of ground ambulance services furnished on or after January 1, 2004, for which the transportation originates in a qualified rural area (as defined in subparagraph (B)), the Secretary shall provide for an increase in the base rate of the fee schedule for mileage for a trip established under this subsection. In establishing such increase, the Secretary shall, based on the relationship of cost and volume, estimate the average increase in cost per trip for such services as compared with the cost per trip for the average ambulance service.

"(B) QUALIFIED RURAL AREA DEFINED.—For purposes of subparagraph (A), the term 'qualified rural area' is a rural area (as defined in section 1886(d)(2)(D)) with a population density of medicare beneficiaries residing in the area that is in the lowest quartile of all rural county populations.".

SEC. 411. TWO-YEAR INCREASE FOR HOME HEALTH SERVICES FURNISHED IN A RURAL AREA.

(a) IN GENERAL.—In the case of home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act (42 U.S.C. 1395ww(d)(2)(D))) during 2004 and 2005, the Secretary shall increase the payment amount otherwise made under section 1895 of such Act (42 U.S.C. 1395fff) for such services by 5 percent.

(b) WAIVING BUDGET NEUTRALITY.—The Secretary shall not reduce the standard prospective payment amount (or amounts) under section 1895 of the Social Security Act (42 U.S.C. 1395fff) applicable to home health services furnished during a period to offset the increase in payments resulting from the application of subsection (a).

SEC. 412. PROVIDING SAFE HARBOR FOR CERTAIN COLLABORATIVE EFFORTS THAT BENEFIT MEDICALLY UNDERSERVED POPULATIONS.

(a) IN GENERAL.—Section 1128B(b)(3) (42 U.S.C. 1320a–7(b)(3)), as amended by section 101(b)(2), is amended—

(1) in subparagraph (F), by striking "and" after the semicolon at the end;

(2) in subparagraph (G), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following new subparagraph:

"(H) any remuneration between a public or nonprofit private health center entity described under clause (i) or (ii) of section 1905(l)(2)(B) and any individual or entity providing goods, items, services, donations or loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity.".

(b) RULEMAKING FOR EXCEPTION FOR HEALTH CENTER ENTITY ARRANGEMENTS.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the "Secretary") shall establish, on an expedited basis, standards relating to the exception described in section 1128B(b)(3)(H) of the Social Security Act, as added by subsection (a), for health center entity arrangements to the antikickback penalties.

(B) FACTORS TO CONSIDER.—The Secretary shall consider the following factors, among others, in establishing standards relating to the exception for health center entity arrangements under subparagraph (A):

(i) Whether the arrangement between the health center entity and the other party results in savings of Federal grant funds or increased revenues to the health center entity.

(ii) Whether the arrangement between the health center entity and the other party restricts or limits a patient's freedom of choice.

(iii) Whether the arrangement between the health center entity and the other party protects a health care professional's independent medical judgment regarding medically appropriate treatment.

The Secretary may also include other standards and criteria that are consistent with the intent of Congress in enacting the exception established under this section.

(2) INTERIM FINAL EFFECT.—No later than 180 days after the date of enactment of this Act, the Secretary shall publish a rule in the Federal Register consistent with the factors under paragraph (1)(B). Such rule shall be effective and final immediately on an interim basis, subject to such change and revision, after public notice and opportunity (for a period of not more than 60 days) for public comment, as is consistent with this subsection.

SEC. 413. GAO STUDY OF GEOGRAPHIC DIFFERENCES IN PAYMENTS FOR PHYSICIANS' SERVICES.

(a) STUDY.—The Comptroller General of the United States shall conduct a study of differences in payment amounts under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for physicians' services in different geographic areas. Such study shall include—

(1) an assessment of the validity of the geographic adjustment factors used for each component of the fee schedule;

(2) an evaluation of the measures used for such adjustment, including the frequency of revisions; and

(3) an evaluation of the methods used to determine professional liability insurance costs used in computing the malpractice component, including a review of increases in professional liability insurance premiums and variation in such increases by State and physician specialty and methods used to update the geographic cost of practice index and relative weights for the malpractice component.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subsection (a). The report shall include recommendations regarding the use of more current data in computing geographic cost of practice indices as well as the use of data directly representative of physicians' costs (rather than proxy measures of such costs).

SEC. 414. TREATMENT OF MISSING COST REPORTING PERIODS FOR SOLE COMMUNITY HOSPITALS.

(a) IN GENERAL.—Section 1886(b)(3)(I) (42 U.S.C. 1395ww(b)(3)(I)) is amended by adding at the end the following new clause:

"(iii) In no case shall a hospital be denied treatment as a sole community hospital or payment (on the basis of a target rate as such as a hospital) because data are unavailable for any cost reporting period due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances, so long as data for at least one applicable base cost reporting period is available.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to cost reporting periods beginning on or after January 1, 2004.

SEC. 415. EXTENSION OF TELEMEDICINE DEMONSTRATION PROJECT.

Section 4207 of Balanced Budget Act of 1997 (Public Law 105–33) is amended—

(1) in subsection (a)(4), by striking "4-year" and inserting "8-year"; and

(2) in subsection (d)(3), by striking "$30,000,000" and inserting "$60,000,000".

SEC. 416. ADJUSTMENT TO THE MEDICARE INPATIENT HOSPITAL PPS WAGE INDEX TO REVISE THE LABOR-RELATED SHARE OF SUCH INDEX.

(a) IN GENERAL.—Section 1886(d)(3)(E) (42 U.S.C. 1395ww(d)(3)(E)) is amended—

(1) by striking "WAGE LEVELS.—The Secretary" and inserting "WAGE LEVELS.—

"(i) IN GENERAL.—Except as provided in clause (ii), the Secretary"; and

(2) by adding at the end the following new clause:

"(ii) ALTERNATIVE PROPORTION TO BE ADJUSTED BEGINNING IN FISCAL YEAR 2004.—

"(I) IN GENERAL.—Except as provided in subclause (II), for discharges occurring on or after October 1, 2003, the Secretary shall substitute the '62 percent' for the proportion described in the first sentence of clause (i).

"(II) HOLD HARMLESS FOR CERTAIN HOSPITALS.—If the application of subclause (I) would result in lower payments to a hospital than would otherwise be made, then this subparagraph shall be applied as if this clause had not been enacted.".

(b) WAIVING BUDGET NEUTRALITY.—Section 1886(d)(3)(E) (42 U.S.C. 1395ww(d)(3)(E)), as amended by subsection (a), is amended by adding at the end of clause (i) the following new sentence: "The Secretary shall apply the previous sentence for any period as if the amendments made by section 402(a) of the Medicare Prescription Drug and Modernization Act of 2003 had not been enacted.".

SEC. 417. MEDICARE INCENTIVE PAYMENT PROGRAM IMPROVEMENTS FOR PHYSICIAN SCARCITY.

(a) ADDITIONAL BONUS PAYMENT FOR CERTAIN PHYSICIAN SCARCITY AREAS.—

(1) IN GENERAL.—Section 1833 (42 U.S.C. 1395*l*) is amended by adding at the end the following new subsection:

"(u) INCENTIVE PAYMENTS FOR PHYSICIAN SCARCITY AREAS.—

"(1) IN GENERAL.—In the case of physicians' services furnished in a year—

"(A) by a primary care physician in a primary care scarcity county (identified under paragraph (4)); or

"(B) by a physician who is not a primary care physician in a specialist care scarcity county (as so identified),

in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid an amount equal to 5 percent of the payment amount for the service under this part.

"(2) DETERMINATION OF RATIOS OF PHYSICIANS TO MEDICARE BENEFICIARIES IN AREA.—Based upon available data, the Secretary shall periodically determine, for each county or equivalent area in the United States, the following:

"(A) NUMBER OF PHYSICIANS PRACTICING IN THE AREA.—The number of physicians who furnish physicians' services in the active practice of medicine or osteopathy in that county or area, other than physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services. Of such number, the number of such physicians who are—

"(i) primary care physicians; or

"(ii) physicians who are not primary care physicians.

"(B) NUMBER OF MEDICARE BENEFICIARIES RESIDING IN THE AREA.—The number of individuals who are residing in the county and are entitled to benefits under part A or enrolled under this part, or both.

"(C) DETERMINATION OF RATIOS.—

"(i) PRIMARY CARE RATIO.—The ratio (in this paragraph referred to as the 'primary care ratio') of the number of primary care physicians (de-

termined under subparagraph (A)(i)), to number of medicare beneficiaries determined under subparagraph (B).

"(ii) SPECIALIST CARE RATIO.—The ratio (in this paragraph referred to as the 'specialist care ratio') of the number of other physicians (determined under subparagraph (A)(ii)), to number of medicare beneficiaries determined under subparagraph (B).

"(3) RANKING OF COUNTIES.—The Secretary shall rank each such county or area based separately on its primary care ratio and its specialist care ratio.

"(4) IDENTIFICATION OF COUNTIES.—The Secretary shall identify—

"(A) those counties and areas (in this paragraph referred to as 'primary care scarcity counties') with the lowest primary care ratios that represent, if each such county or area were weighted by the number of medicare beneficiaries determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the medicare beneficiaries determined under such paragraph; and

"(B) those counties and areas (in this subsection referred to as 'specialist care scarcity counties') with the lowest specialist care ratios that represent, if each such county or area were weighted by the number of medicare beneficiaries determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the medicare beneficiaries determined under such paragraph.

There is no administrative or judicial review respecting the identification of a county or area or the assignment of a specialty of any physician under this paragraph.

"(5) RURAL CENSUS TRACKS.—To the extent feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725) as an equivalent area for purposes of qualifying as a primary care scarcity county or specialist care scarcity county under this subsection.

"(6) PHYSICIAN DEFINED.—For purposes of this paragraph, the term 'physician' means a physician described in section 1861(r)(1) and the term 'primary care physician' means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

"(7) PUBLICATION OF LIST OF COUNTIES.—In carrying out this subsection for a year, the Secretary shall include, as part of the proposed and final rule to implement the physician fee schedule under section 1848 for the year, a list of all areas which will qualify as a primary care scarcity county or specialist care scarcity county under this subsection for the year involved.".

(2) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to physicians' services furnished or after January 1, 2004.

(b) IMPROVEMENT TO MEDICARE INCENTIVE PAYMENT PROGRAM.—

(1) IN GENERAL.—Section 1833(m) (42 U.S.C. 1395*l*(m)) is amended—

(A) by inserting "(1)" after "(m)"; and

(B) by adding at the end the following new paragraphs:

"(2) The Secretary shall establish procedures under which the Secretary, and not the physician furnishing the service, is responsible for determining when a payment is required to be made under paragraph (1).

"(3) In carrying out paragraph (1) for a year, the Secretary shall include, as part of the proposed and final rule to implement the physician fee schedule under section 1848 for the year, a list of all areas which will qualify as a health professional shortage area under paragraph (1) for the year involved.".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to physicians' services furnished or after January 1, 2004.

TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

SEC. 501. REVISION OF ACUTE CARE HOSPITAL PAYMENT UPDATES.

Section 1886(b)(3)(B)(i) (42 U.S.C. 1395ww(b)(3)(B)(i)) is amended—

(1) by striking "and" at the end of subclause (XVIII);

(2) by striking subclause (XIX); and

(3) by inserting after subclause (XVIII) the following new subclauses:

"(XIX) for each of fiscal years 2004 through 2006, the market basket percentage increase minus 0.4 percentage points for hospitals in all areas; and

"(XX) for fiscal year 2007 and each subsequent fiscal year, the market basket percentage increase for hospitals in all areas.".

SEC. 502. RECOGNITION OF NEW MEDICAL TECHNOLOGIES UNDER INPATIENT HOSPITAL PPS.

(a) IMPROVING TIMELINESS OF DATA COLLECTION.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is amended by adding at the end the following new clause:

"(vii) Under the mechanism under this subparagraph, the Secretary shall provide for the addition of new diagnosis and procedure codes in April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) under this subsection until the fiscal year that begins after such date.".

(b) ELIGIBILITY STANDARD FOR TECHNOLOGY OUTLIERS.—

(1) MINIMUM PERIOD FOR RECOGNITION OF NEW TECHNOLOGIES.—Section 1886(d)(5)(K)(vi) (42 U.S.C. 1395ww(d)(5)(K)(vi)) is amended—

(A) by inserting "(I)" after "(vi)"; and

(B) by adding at the end the following new subclause:

"(II) Under such criteria, a service or technology shall not be denied treatment as a new service or technology on the basis of the period of time in which the service or technology has been in use if such period ends before the end of the 2-to-3-year period that begins on the effective date of implementation of a code under ICD–9–CM (or a successor coding methodology) that enables the identification of specific discharges in which the service or technology has been used.".

(2) ADJUSTMENT OF THRESHOLD.—Section 1886(d)(5)(K)(ii)(I) (42 U.S.C. 1395ww(d)(5)(K)(ii)(I)) is amended by inserting "(applying a threshold specified by the Secretary that is 75 percent of one standard deviation for the diagnosis-related group involved)" after "is inadequate".

(3) CRITERION FOR SUBSTANTIAL IMPROVEMENT.—Section 1886(d)(5)(K)(vi) (42 U.S.C. 1395ww(d)(5)(K)(vi)), as amended by paragraph (1), is further amended by adding at the end the following subclause:

"(III) The Secretary shall by regulation provide for further clarification of the criteria applied to determine whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of beneficiaries. Under such criteria, in determining whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of beneficiaries, the Secretary shall deem a service or technology as meeting such requirement if the service or technology is a drug or biological that is designated under section 506 of the Federal Food, Drug, and Cosmetic Act, approved under section 314.510 or 601.41 of title 21, Code of Federal Regulations, or designated for priority review when the marketing application for such drug or biological was filed or is a medical device for which an exemption has been granted under section 520(m) of such Act, or for which priority review has been provided under section 515(d)(5) of such Act. Nothing in this subclause shall be construed as effecting the authority of the Secretary to determine whether items and services are medically necessary and appropriate under section 1862(a)(1).".

(4) PROCESS FOR PUBLIC INPUT.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)), as amended by paragraph (1), is amended—

(A) in clause (i), by adding at the end the following: "Such mechanism shall be modified to meet the requirements of clause (viii).."; and

(B) by adding at the end the following new clause:

"(viii) The mechanism established pursuant to clause (i) shall be adjusted to provide, before publication of a proposed rule, for public input regarding whether a new service or technology not described in the second sentence of clause (vi)(III) represents an advance in medical technology that substantially improves the diagnosis or treatment of beneficiaries as follows:

"(I) The Secretary shall make public and periodically update a list of all the services and technologies for which an application for additional payment under this subparagraph is pending.

"(II) The Secretary shall accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial improvement.

"(III) The Secretary shall provide for a meeting at which organizations representing hospitals, physicians, medicare beneficiaries, manufacturers, and any other interested party may present comments, recommendations, and data to the clinical staff of the Centers for Medicare & Medicaid Services before publication of a notice of proposed rulemaking regarding whether service or technology represents a substantial improvement.".

(c) PREFERENCE FOR USE OF DRG ADJUSTMENT.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is further amended by adding at the end the following new clause:

"(ix) Before establishing any add-on payment under this subparagraph with respect to a new technology, the Secretary shall seek to identify one or more diagnosis-related groups associated with such technology, based on similar clinical or anatomical characteristics and the cost of the technology. Within such groups the Secretary shall assign an eligible new technology into a diagnosis-related group where the average costs of care most closely approximate the costs of care of using the new technology. In such case, the new technology would no longer meet the threshold of exceeding 75 percent of the standard deviation for the diagnosis-related group involved under clause (ii)(I). No add-on payment under this subparagraph shall be made with respect to such new technology and this clause shall not affect the application of paragraph (4)(C)(iii).".

(d) IMPROVEMENT IN PAYMENT FOR NEW TECHNOLOGY.—Section 1886(d)(5)(K)(ii)(III) (42 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by inserting after "the estimated average cost of such service or technology" the following: "(based on the marginal rate applied to costs under subparagraph (A))".

(e) ESTABLISHMENT OF NEW FUNDING FOR HOSPITAL INPATIENT TECHNOLOGY.—Section 1886(d)(5)(K)(ii)(III) (42 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by striking "subject to paragraph (4)(C)(iii),".

(f) EFFECTIVE DATE.—

(1) IN GENERAL.—The Secretary shall implement the amendments made by this section so that they apply to classification for fiscal years beginning with fiscal year 2005.

(2) RECONSIDERATIONS OF APPLICATIONS FOR FISCAL YEAR 2003 THAT ARE DENIED.—In the case of an application for a classification of a medical service or technology as a new medical service or technology under section 1886(d)(5)(K) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)) that was filed for fiscal year 2004 and that is denied—

(A) the Secretary shall automatically reconsider the application as an application for fiscal year 2005 under the amendments made by this section; and

(B) the maximum time period otherwise permitted for such classification of the service or technology shall be extended by 12 months.

SEC. 503. INCREASE IN FEDERAL RATE FOR HOSPITALS IN PUERTO RICO.

Section 1886(d)(9) (42 U.S.C. 1395ww(d)(9)) is amended—

(1) in subparagraph (A)—

(A) in clause (i), by striking "for discharges beginning on or after October 1, 1997, 50 percent (and for discharges between October 1, 1987, and September 30, 1997, 75 percent)" and inserting "the applicable Puerto Rico percentage (specified in subparagraph (E))"; and

(B) in clause (ii), by striking "for discharges beginning in a fiscal year beginning on or after October 1, 1997, 50 percent (and for discharges between October 1, 1987, and September 30, 1997, 25 percent)" and inserting "the applicable Federal percentage (specified in subparagraph (E))"; and

(2) by adding at the end the following new subparagraph:

"(E) For purposes of subparagraph (A), for discharges occurring—

"(i) on or after October 1, 1987, and before October 1, 1997, the applicable Puerto Rico percentage is 75 percent and the applicable Federal percentage is 25 percent;

"(ii) on or after October 1, 1997, and before October 1, 2003, the applicable Puerto Rico percentage is 50 percent and the applicable Federal percentage is 50 percent;

"(iii) during fiscal year 2004, the applicable Puerto Rico percentage is 41 percent and the applicable Federal percentage is 59 percent;

"(iv) during fiscal year 2005, the applicable Puerto Rico percentage is 33 percent and the applicable Federal percentage is 67 percent; and

"(v) on or after October 1, 2005, the applicable Puerto Rico percentage is 25 percent and the applicable Federal percentage is 75 percent.".

SEC. 504. WAGE INDEX ADJUSTMENT RECLASSIFICATION REFORM .

(a) IN GENERAL.—Section 1886(d) (42 U.S.C. 1395ww(d)) is amended by adding at the end the following:

"(11)(A) In order to recognize commuting patterns among Metropolitan Statistical Areas and between such Areas and rural areas, the Secretary shall establish a process, upon application of a subsection (d) hospital that establishes that it is a qualifying hospital described in subparagraph (B), for an increase of the wage index applied under paragraph (3)(E) for the hospital in the amount computed under subparagraph (D).

"(B) A qualifying hospital described in this subparagraph is a subsection (d) hospital—

"(i) the average wages of which exceed the average wages for the area in which the hospital is located; and

"(ii) which has at least 10 percent of its employees who reside in one or more higher wage index areas.

"(C) For purposes of this paragraph, the term 'higher wage index area' means, with respect to a hospital, an area with a wage index that exceeds that of the area in which the hospital is located.

"(D) The increase in the wage index under subparagraph (A) for a hospital shall be equal to the percentage of the employees of the hospital that resides in any higher wage index area multiplied by the sum of the products, for each higher wage index area of—

"(i) the difference between (I) the wage index for such area, and (II) the wage index of the area in which the hospital is located (before the application of this paragraph); and

"(ii) the number of employees of the hospital that reside in such higher wage index area divided by the total number of such employees that reside in all high wage index areas.

"(E) The process under this paragraph shall be based upon the process used by the Medicare Geographic Classification Review Board under paragraph (10) with respect to data submitted by hospitals to the Board on the location of residence of hospital employees and wages under the applicable schedule established for geographic reclassification.

"(F) A reclassification under this paragraph shall be effective for a period of 3 fiscal years, except that the Secretary shall establish procedures under which a subsection (d) hospital may elect to terminate such reclassification before the end of such period.

"(G) A hospital that is reclassified under this paragraph for a period is not eligible for reclassification under paragraphs (8) or (10) during that period.

"(H) Any increase in a wage index under this paragraph for a hospital shall not be taken into account for purposes of—

"(i) computing the wage index for the area in which the hospital is located or any other area; or

"(ii) applying any budget neutrality adjustment with respect to such index under paragraph (8)(D).".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall first apply to the wage index for cost reporting period beginning on or after October 1, 2004.

SEC. 505. MEDPAC REPORT ON SPECIALTY HOSPITALS.

(a) MEDPAC STUDY.—The Medicare Payment Advisory Commission shall conduct a study of specialty hospitals compared with other similar general acute care hospitals under the medicare program. Such study shall examine—

(1) whether there are excessive self-referrals;

(2) quality of care furnished;

(3) the impact of specialty hospitals on such general acute care hospitals; and

(4) differences in the scope of services, medicaid utilization, and uncompensated care furnished.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under subsection (a), and shall include any recommendations for legislation or administrative change as the Secretary determines appropriate.

Subtitle B—Other Provisions

SEC. 511. PAYMENT FOR COVERED SKILLED NURSING FACILITY SERVICES.

(a) ADJUSTMENT TO RUGS FOR AIDS RESIDENTS.—Paragraph (12) of section 1888(e) (42 U.S.C. 1395yy(e)) is amended to read as follows:

"(12) ADJUSTMENT FOR RESIDENTS WITH AIDS.—

"(A) IN GENERAL.—Subject to subparagraph (B), in the case of a resident of a skilled nursing facility who is afflicted with acquired immune deficiency syndrome (AIDS), the per diem amount of payment otherwise applicable shall be increased by 128 percent to reflect increased costs associated with such residents.

"(B) SUNSET.—Subparagraph (A) shall not apply on and after such date as the Secretary certifies that there is an appropriate adjustment in the case mix under paragraph (4)(G)(i) to compensate for the increased costs associated with residents described in such subparagraph.".

(b) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to services furnished on or after October 1, 2003.

SEC. 512. COVERAGE OF HOSPICE CONSULTATION SERVICES.

(a) COVERAGE OF HOSPICE CONSULTATION SERVICES.—Section 1812(a) (42 U.S.C. 1395d(a)) is amended—

(1) by striking "and" at the end of paragraph (3);

(2) by striking the period at the end of paragraph (4) and inserting "; and"; and

(3) by inserting after paragraph (4) the following new paragraph:

"(5) for individuals who are terminally ill, have not made an election under subsection (d)(1), and have not previously received services under this paragraph, services that are furnished by a physician who is either the medical director or an employee of a hospice program and that consist of—

"(A) an evaluation of the individual's need for pain and symptom management;

"(B) counseling the individual with respect to end-of-life issues and care options; and

"(C) advising the individual regarding advanced care planning.".

(b) PAYMENT.—Section 1814(i) (42 U.S.C. l395f(i)) is amended by adding at the end the following new paragraph:

"(4) The amount paid to a hospice program with respect to the services under section 1812(a)(5) for which payment may be made under this part shall be equal to an amount equivalent to the amount established for an office or other outpatient visit for evaluation and management associated with presenting problems of moderate severity under the fee schedule established under section 1848(b), other than the portion of such amount attributable to the practice expense component.".

(c) CONFORMING AMENDMENT.—Section 1861(dd)(2)(A)(i) (42 U.S.C. 1395x(dd)(2)(A)(i)) is amended by inserting before the comma at the end the following: "and services described in section 1812(a)(5)".

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to services provided by a hospice program on or after January 1, 2004.

TITLE VI—PROVISIONS RELATING TO PART B

Subtitle A—Physicians' Services

SEC. 601. REVISION OF UPDATES FOR PHYSICIANS' SERVICES.

(a) UPDATE FOR 2004 AND 2005.—

(1) IN GENERAL.—Section 1848(d) (42 U.S.C. 1395w–4(d)) is amended by adding at the end the following new paragraph:

"(5) UPDATE FOR 2004 AND 2005.—The update to the single conversion factor established in paragraph (1)(C) for each of 2004 and 2005 shall be not less than 1.5 percent.".

(2) CONFORMING AMENDMENT.—Paragraph (4)(B) of such section is amended, in the matter before clause (i), by inserting "and paragraph (5)" after "subparagraph (D)".

(3) NOT TREATED AS CHANGE IN LAW AND REGULATION IN SUSTAINABLE GROWTH RATE DETERMINATION.—The amendments made by this subsection shall not be treated as a change in law for purposes of applying section 1848(f)(2)(D) of the Social Security Act (42 U.S.C. 1395w–4(f)(2)(D)).

(b) USE OF 10-YEAR ROLLING AVERAGE IN COMPUTING GROSS DOMESTIC PRODUCT.—

(1) IN GENERAL.—Section 1848(f)(2)(C) (42 U.S.C. 1395w–4(f)(2)(C)) is amended—

(A) by striking "projected" and inserting "annual average"; and

(B) by striking "from the previous applicable period to the applicable period involved" and inserting "during the 10-year period ending with the applicable period involved".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to computations of the sustainable growth rate for years beginning with 2003.

SEC. 602. STUDIES ON ACCESS TO PHYSICIANS' SERVICES.

(a) GAO STUDY ON BENEFICIARY ACCESS TO PHYSICIANS' SERVICES.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on access of medicare beneficiaries to physicians' services under the medicare program. The study shall include—

(A) an assessment of the use by beneficiaries of such services through an analysis of claims submitted by physicians for such services under part B of the medicare program;

(B) an examination of changes in the use by beneficiaries of physicians' services over time;

(C) an examination of the extent to which physicians are not accepting new medicare beneficiaries as patients.

(2) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1). The report shall include a determination whether—

(A) data from claims submitted by physicians under part B of the medicare program indicate potential access problems for medicare beneficiaries in certain geographic areas; and

(B) access by medicare beneficiaries to physicians' services may have improved, remained constant, or deteriorated over time.

(b) STUDY AND REPORT ON SUPPLY OF PHYSICIANS.—

(1) STUDY.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct a study on the adequacy of the supply of physicians (including specialists) in the United States and the factors that affect such supply.

(2) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of this section, the Secretary shall submit to Congress a report on the results of the study described in paragraph (1), including any recommendations for legislation.

(c) GAO STUDY OF MEDICARE PAYMENT FOR INHALATION THERAPY.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to examine the adequacy of current reimbursements for inhalation therapy under the medicare program.

(2) REPORT.—Not later than May 1, 2004, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).

SEC. 603. MEDPAC REPORT ON PAYMENT FOR PHYSICIANS' SERVICES.

(a) PRACTICE EXPENSE COMPONENT.—Not later than 1 year after the date of the enactment of this Act, the Medicare Payment Advisory Commission shall submit to Congress a report on the effect of refinements to the practice expense component of payments for physicians' services, after the transition to a full resource-based payment system in 2002, under section 1848 of the Social Security Act (42 U.S.C. 1395w–4). Such report shall examine the following matters by physician specialty:

(1) The effect of such refinements on payment for physicians' services.

(2) The interaction of the practice expense component with other components of and adjustments to payment for physicians' services under such section.

(3) The appropriateness of the amount of compensation by reason of such refinements.

(4) The effect of such refinements on access to care by medicare beneficiaries to physicians' services.

(5) The effect of such refinements on physician participation under the medicare program.

(b) VOLUME OF PHYSICIAN SERVICES.—The Medicare Payment Advisory Commission shall submit to Congress a report on the extent to which increases in the volume of physicians' services under part B of the medicare program are a result of care that improves the health and well-being of medicare beneficiaries. The study shall include the following:

(1) An analysis of recent and historic growth in the components that the Secretary includes under the sustainable growth rate (under section 1848(f) of the Social Security Act).

(2) An examination of the relative growth of volume in physician services between medicare beneficiaries and other populations.

(3) An analysis of the degree to which new technology, including coverage determinations of the Centers for Medicare & Medicaid Services, has affected the volume of physicians' services.

(4) An examination of the impact on volume of demographic changes.

(5) An examination of shifts in the site of service of services that influence the number and intensity of services furnished in physicians' offices and the extent to which changes in reimbursement rates to other providers have affected these changes.

(6) An evaluation of the extent to which the Centers for Medicare & Medicaid Services takes into account the impact of law and regulations on the sustainable growth rate.

Subtitle B—Preventive Services

SEC. 611. COVERAGE OF AN INITIAL PREVENTIVE PHYSICAL EXAMINATION.

(a) COVERAGE.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)) is amended—

(1) in subparagraph (U), by striking "and" at the end;

(2) in subparagraph (V), by inserting "and" at the end; and

(3) by adding at the end the following new subparagraph:

"(W) an initial preventive physical examination (as defined in subsection (ww));".

(b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

"Initial Preventive Physical Examination

"(ww) The term 'initial preventive physical examination' means physicians' services consisting of a physical examination with the goal of health promotion and disease detection and includes items and services (excluding clinical laboratory tests), as determined by the Secretary, consistent with the recommendations of the United States Preventive Services Task Force.".

(c) WAIVER OF DEDUCTIBLE AND COINSURANCE.—

(1) DEDUCTIBLE.—The first sentence of section 1833(b) (42 U.S.C. 1395l(b)) is amended—

(A) by striking "and" before "(6)", and

(B) by inserting before the period at the end the following: ", and (7) such deductible shall not apply with respect to an initial preventive physical examination (as defined in section 1861(ww))".

(2) COINSURANCE.—Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)) is amended—

(A) in clause (N), by inserting "(or 100 percent in the case of an initial preventive physical examination, as defined in section 1861(ww))" after "80 percent"; and

(B) in clause (O), by inserting "(or 100 percent in the case of an initial preventive physical examination, as defined in section 1861(ww))" after "80 percent".

(d) PAYMENT AS PHYSICIANS' SERVICES.—Section 1848(j)(3) (42 U.S.C. 1395w–4(j)(3)) is amended by inserting "(2)(W)," after "(2)(S),".

(e) OTHER CONFORMING AMENDMENTS.—Section 1862(a) (42 U.S.C. 1395y(a)) is amended—

(1) in paragraph (1)—

(A) by striking "and" at the end of subparagraph (H);

(B) by striking the semicolon at the end of subparagraph (I) and inserting ", and"; and

(C) by adding at the end the following new subparagraph:

"(J) in the case of an initial preventive physical examination, which is performed not later than 6 months after the date the individual's first coverage period begins under part B;"; and

(2) in paragraph (7), by striking "or (H)" and inserting "(H), or (J)".

(f) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2004, but only for individuals whose coverage period begins on or after such date.

SEC. 612. COVERAGE OF CHOLESTEROL AND BLOOD LIPID SCREENING.

(a) COVERAGE.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)), as amended by section 611(a), is amended—

(1) in subparagraph (V), by striking "and" at the end;

(2) in subparagraph (W), by inserting "and" at the end; and

(3) by adding at the end the following new subparagraph:

"(X) cholesterol and other blood lipid screening tests (as defined in subsection (XX));".

(b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C. 1395x), as amended by section 611(b), is amended by adding at the end the following new subsection:

"Cholesterol and Other Blood Lipid Screening Test

"(xx)(1) The term 'cholesterol and other blood lipid screening test' means diagnostic testing of cholesterol and other lipid levels of the blood for the purpose of early detection of abnormal cholesterol and other lipid levels.

"(2) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency and type of cholesterol and other blood lipid

screening tests, except that such frequency may not be more often than once every 2 years.".

(c) FREQUENCY.—Section 1862(a)(1) (42 U.S.C. 1395y(a)(1)), as amended by section 611(e), is amended—

(1) by striking "and" at the end of subparagraph (I);

(2) by striking the semicolon at the end of subparagraph (J) and inserting "; and"; and

(3) by adding at the end the following new subparagraph:

"(K) in the case of a cholesterol and other blood lipid screening test (as defined in section 1861(xx)(1)), which is performed more frequently than is covered under section 1861(xx)(2).".

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to tests furnished on or after January 1, 2005.

SEC. 613. WAIVER OF DEDUCTIBLE FOR COLORECTAL CANCER SCREENING TESTS.

(a) IN GENERAL.—The first sentence of section 1833(b) (42 U.S.C. 1395*l*(b)), as amended by section 611(c)(1), is amended—

(1) by striking "and" before "(7)"; and

(2) by inserting before the period at the end the following: ", and (8) such deductible shall not apply with respect to colorectal cancer screening tests (as described in section 1861(pp)(1))".

(b) CONFORMING AMENDMENTS.—Paragraphs (2)(C)(ii) and (3)(C)(ii) of section 1834(d) (42 U.S.C. 1395m(d)) are each amended—

(1) by striking "DEDUCTIBLE AND" in the heading; and

(2) in subclause (I), by striking "deductible or" each place it appears.

(c) EFFECTIVE DATE.—The amendment made by this section shall apply to items and services furnished on or after Janaury 1, 2004.

SEC. 614. IMPROVED PAYMENT FOR CERTAIN MAMMOGRAPHY SERVICES.

(a) EXCLUSION FROM OPD FEE SCHEDULE.—Section 1833(t)(1)(B)(iv) (42 U.S.C. 1395l(t)(1)(B)(iv)) is amended by inserting before the period at the end the following: "and does not include screening mammography (as defined in section 1861(jj)) and unilateral and bilateral diagnostic mammography".

(b) ADJUSTMENT TO TECHNICAL COMPONENT.—For diagnostic mammography performed on or after January 1, 2004, for which payment is made under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4), the Secretary, based on the most recent cost data available, shall provide for an appropriate adjustment in the payment amount for the technical component of the diagnostic mammography.

(c) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to mammography performed on or after January 1, 2004.

Subtitle C—Other Services

SEC. 621. HOSPITAL OUTPATIENT DEPARTMENT (HOPD) PAYMENT REFORM.

(a) PAYMENT FOR DRUGS.—

(1) MODIFICATION OF AMBULATORY PAYMENT CLASSIFICATION (APC) GROUPS.—Section 1833(t) (42 U.S.C. 1395l(t)) is amended—

(A) by redesignating paragraph (13) as paragraph (14); and

(B) by inserting after paragraph (12) the following new paragraph:

"(13) DRUG APC PAYMENT RATES.—

"(A) IN GENERAL.—With respect to payment for covered OPD services that includes a specified covered outpatient drug (defined in subparagraph (B)), the amount provided for payment for such drug under the payment system under this subsection for services furnished in—

"(i) 2004, 2005, or 2006, shall in no case—

"(I) exceed 95 percent of the average wholesale price for the drug; or

"(II) be less than the transition percentage (under subparagraph (C)) of the average wholesale price for the drug; or

"(ii) a subsequent year, shall be equal to the average price for the drug for that area and year established under the competitive acquisition program under section 1847A as calculated and applied by the Secretary for purposes of this paragraph.

"(B) SPECIFIED COVERED OUTPATIENT DRUG DEFINED.—

"(i) IN GENERAL.—In this paragraph, the term 'specified covered outpatient drug' means, subject to clause (ii), a covered outpatient drug (as defined in 1927(k)(2), that is—

"(I) a radiopharmaceutical; or

"(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

"(ii) EXCEPTION.—Such term does not include—

"(I) a drug for which payment is first made on or after January 1, 2003, under paragraph (6); or

"(II) a drug for a which a temporary HCPCS code has not been assigned.

"(C) TRANSITION TOWARDS HISTORICAL AVERAGE ACQUISITION COST.—The transition percentage under this subparagraph for drugs furnished in a year is determined in accordance with the following table:

For the year—	The transition percentage for— Single source drugs are—	Innovator multiple source drugs are—	Generic drugs are—
2004	83%	81.5%	46%
2005	77%	75%	46%
2006	71%	68%	46%

"(D) PAYMENT FOR NEW DRUGS UNTIL TEMPORARY HCPCS CODE ASSIGNED.—With respect to payment for covered OPD services that includes a covered outpatient drug (as defined in 1927(k)) for a which a temporary HCPCS code has not been assigned, the amount provided for payment for such drug under the payment system under this subsection shall be equal to 95 percent of the average wholesale price for the drug.

"(E) CLASSES OF DRUGS.—For purposes of this paragraph, each of the following shall be treated as a separate class of drugs:

"(i) SOLE SOURCE DRUGS.—A sole source drug which for purposes of this paragraph means a drug or biological that is not a multiple source drug (as defined in subclauses (I) and (II) of section 1927(k)(7)(A)(i)) and is not a drug approved under an abbreviated new drug application under section 355(j) of the Federal Food, Drug, and Cosmetic Act.

"(ii) INNOVATOR MULTIPLE SOURCE DRUGS.—Innovator multiple source drugs (as defined in section 1927(k)(7)(A)(ii)).

"(iii) NONINNOVATOR MULTIPLE SOURCE DRUGS.—Noninnovator multiple source drugs (as defined in section 1927(k)(7)(A)(iii)).

"(F) INAPPLICABILITY OF EXPENDITURES IN DETERMINING CONVERSION FACTORS.—Additional expenditures resulting from this paragraph and paragraph (14)(C) in a year shall not be taken into account in establishing the conversion factor for that year.".

(2) REDUCTION IN THRESHOLD FOR SEPARATE APCS FOR DRUGS.—Section 1833(t)(14), as redesignated by paragraph (1)(A), is amended by adding at the end the following new subparagraph:

"(B) THRESHOLD FOR ESTABLISHMENT OF SEPARATE APCS FOR DRUGS.—The Secretary shall reduce the threshold for the establishment of separate ambulatory procedure classification groups (APCs) with respect to drugs to $50 per administration.".

(3) EXCLUSION OF SEPARATE DRUG APCS FROM OUTLIER PAYMENTS.—Section 1833(t)(5) is amended by adding at the end the following new subparagraph:

"(E) EXCLUSION OF SEPARATE DRUG APCS FROM OUTLIER PAYMENTS.—No additional payment shall be made under subparagraph (A) in the case of ambulatory procedure codes established separately for drugs.".

(4) PAYMENT FOR PASS THROUGH DRUGS.—Clause (i) of section 1833(t)(6)(D) (42 U.S.C. 1395l(t)(6)(D)) is amended by inserting after "under section 1842(o)" the following: "(or if the drug is covered under a competitive acquisition contract under section 1847A for an area, an amount determined by the Secretary equal to the average price for the drug for that area and year established under such section as calculated and applied by the Secretary for purposes of this paragraph)".

(5) EFFECTIVE DATE.—The amendments made by this subsection shall apply to services furnished on or after January 1, 2004.

(b) SPECIAL PAYMENT FOR BRACHYTHERAPY.—

(1) IN GENERAL.—Section 1833(t)(14), as so redesignated and amended by subsection (a)(2), is amended by adding at the end the following new subparagraph:

"(C) PAYMENT FOR DEVICES OF BRACHYTHERAPY AT CHARGES ADJUSTED TO COST.—Notwithstanding the preceding provisions of this subsection, for a device of brachytherapy furnished on or after January 1, 2004, and before January 1, 2007, the payment basis for the device under this subsection shall be equal to the hospital's charges for each device furnished, adjusted to cost.".

(2) SPECIFICATION OF GROUPS FOR BRACHYTHERAPY DEVICES.—Section 1833(t)(2) (42 U.S.C. 1395l(t)(2) is amended—

(A) in subparagraph (F), by striking "and" at the end;

(B) in subparagraph (G), by striking the period at the end and inserting "; and"; and

(C) by adding at the end the following new subparagraph:

"(H) with respect to devices of brachytherapy, the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices.".

(3) GAO REPORT.—The Comptroller General of the United States shall conduct a study to determine appropriate payment amounts under section 1833(t)(13)(B) of the Social Security Act, as added by paragraph (1), for devices of brachytherapy. Not later than January 1, 2005, the Comptroller General shall submit to Congress and the Secretary a report on the study conducted under this paragraph, and shall include specific recommendations for appropriate payments for such devices.

(c) APPLICATION OF FUNCTIONAL EQUIVALENCE TEST.—

(1) IN GENERAL.—Section 1833(t)(6) (42 U.S.C. 1395l(t)(6)) is amended by adding at the end the following new subparagraph:

"(F) LIMITATION ON APPLICATION OF FUNCTIONAL EQUIVALENCE STANDARD.—The Secretary may not apply a 'functional equivalence' payment standard (including such standard promulgated on November 1, 2002) or any other similar standard in order to deem a particular drug or biological to be identical to or similar to another drug or biological with respect to its mechanism of action or clinical effect to deny pass-through status to new drugs or biologics or to remove such status of an existing eligible drug or biologic under this paragraph unless—

"(i) the Secretary develops by regulation (after providing notice and a period for public comment) criteria for the application of such standard; and

"(ii) such criteria provide for coordination with the Federal Food and Drug Administration and require scientific studies that show the clinical relationship between the drugs or biologicals treated as functionally equivalent.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to the application of a functional equivalence standard to a drug or biological on or after the date of the enactment of this Act, unless such application was being made to such drug or biological prior to June 13, 2003.

(d) HOSPITAL ACQUISITION COST STUDY.—

(1) IN GENERAL.—The Secretary shall conduct a study on the costs incurred by hospitals in acquiring covered outpatient drugs for which payment is made under section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)).

(2) DRUGS COVERED.—The study in paragraph (1) shall not include those drugs for which the acquisition costs is less than $50 per administration.

(3) REPRESENTATIVE SAMPLE OF HOSPITALS.—In conducting the study under paragraph (1), the Secretary shall collect data from a statistically valid sample of hospitals with an urban/rural stratification.

(4) REPORT.—Not later than January 1, 2006, the Secretary shall submit to Congress a report on the study conducted under paragraph (1), and shall include recommendations with respect to the following:

(A) Whether the study should be repeated, and if so, how frequently.

(B) Whether the study produced useful data on hospital acquisition cost.

(C) Whether data produced in the study is appropriate for use in making adjustments to payments for drugs and biologicals under section 1847A of the Social Security Act.

(D) Whether separate estimates can made of overhead costs, including handing and administering costs for drugs.

SEC. 622. PAYMENT FOR AMBULANCE SERVICES.

(a) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—Section 1834(l) (42 U.S.C. 1395m(l)), as amended by section 410(a), is amended—

(1) in paragraph (2)(E), by inserting "consistent with paragraph (11)" after "in an efficient and fair manner"; and

(2) by adding at the end the following new paragraph:

"(11) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—In carrying out the phase-in under paragraph (2)(E) for each level of service furnished in a year, the portion of the payment amount that is based on the fee schedule shall not be less than the following blended rate of the fee schedule under paragraph (1) and of a regional fee schedule for the region involved:

"(A) For 2004, the blended rate shall be based 20 percent on the fee schedule under paragraph (1) and 80 percent on the regional fee schedule.

"(B) For 2005, the blended rate shall be based 40 percent on the fee schedule under paragraph (1) and 60 percent on the regional fee schedule.

"(C) For 2006, the blended rate shall be based 60 percent on the fee schedule under paragraph (1) and 40 percent on the regional fee schedule.

"(D) For 2007, 2008, and 2009, the blended rate shall be based 80 percent on the fee schedule under paragraph (1) and 20 percent on the regional fee schedule.

"(E) For 2010 and each succeeding year, the blended rate shall be based 100 percent on the fee schedule under paragraph (1).

For purposes of this paragraph, the Secretary shall establish a regional fee schedule for each of the 9 Census divisions using the methodology (used in establishing the fee schedule under paragraph (1)) to calculate a regional conversion factor and a regional mileage payment rate and using the same payment adjustments and the same relative value units as used in the fee schedule under such paragraph.".

(b) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG TRIPS.—Section 1834(l), as amended by subsection (a), is further amended by adding at the end the following new paragraph:

"(12) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG TRIPS.—In the case of ground ambulance services furnished on or after January 1, 2004, and before January 1, 2009, regardless of where the transportation originates, the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 50 miles the per mile rate otherwise established shall be increased by ¼ of the payment per mile otherwise applicable to such miles.".

(c) GAO REPORT ON COSTS AND ACCESS.—Not later than December 31, 2005, the Comptroller General of the United States shall submit to Congress an initial report on how costs differ among the types of ambulance providers and on access, supply, and quality of ambulance services in those regions and States that have a reduction in payment under the medicare ambulance fee schedule (under section 1834(l) of the Social Security Act, as amended by this section). Not later than December 31, 2007, the Comptroller General shall submit to Congress a final report on such access and supply.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to ambulance services furnished on or after January 1, 2004.

SEC. 623. RENAL DIALYSIS SERVICES.

(a) DEMONSTRATION OF ALTERNATIVE DELIVERY MODELS.—

(1) USE OF ADVISORY BOARD.—In carrying out the demonstration project relating to improving care for people with end-stage renal disease through alternative delivery models (as published in the Federal Register of June 4, 2003), the Secretary shall establish an advisory board comprised of representatives described in paragraph (2) to provide advice and recommendations with respect to the establishment and operation of such demonstration project.

(2) REPRESENTATIVES.—Representatives referred to in paragraph (1) include representatives of the following:

(A) Patient organizations.

(B) Clinicians.

(C) The medicare payment advisory commission, established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6).

(D) The National Kidney Foundation.

(E) The National Institute of Diabetes and Digestive and Kidney Diseases of National Institutes of Health.

(F) End-stage renal disease networks.

(G) Medicare contractors to monitor quality of care.

(I) providers of services and renal dialysis facilities furnishing end-stage renal disease services.

(J) Economists.

(K) Researchers.

(b) RESTORING COMPOSITE RATE EXCEPTIONS FOR PEDIATRIC FACILITIES.—

(1) IN GENERAL.—Section 422(a)(2) of BIPA is amended—

(A) in subparagraph (A), by striking "and (C)" and inserting ", (C), and (D)";

(B) in subparagraph (B), by striking "In the case" and inserting "Subject to subparagraph (D), in the case"; and

(C) by adding at the end the following new subparagraph:

"(D) INAPPLICABILITY TO PEDIATRIC FACILITIES.—Subparagraphs (A) and (B) shall not apply, as of October 1, 2002, to pediatric facilities that do not have an exception rate described in subparagraph (C) in effect on such date. For purposes of this subparagraph, the term 'pediatric facility' means a renal facility at least 50 percent of whose patients are individuals under 18 years of age.".

(2) CONFORMING AMENDMENT.—The fourth sentence of section 1881(b)(7) (42 U.S.C. 1395rr(b)(7)), as amended by subsection (b), is further amended by striking "Until" and inserting "Subject to section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, and until".

(c) INCREASE IN RENAL DIALYSIS COMPOSITE RATE FOR SERVICES FURNISHED IN 2004.—Notwithstanding any other provision of law, with respect to payment under part B of title XVIII of the Social Security Act for renal dialysis services furnished in 2004, the composite payment rate otherwise established under section 1881(b)(7) of such Act (42 U.S.C. 1395rr(b)(7)) shall be increased by 1.6 percent.

SEC. 624. ONE-YEAR MORATORIUM ON THERAPY CAPS; PROVISIONS RELATING TO REPORTS.

(a) 1-YEAR MORATORIUM ON THERAPY CAPS.—Section 1833(g)(4) (42 U.S.C. 1395l(g)(4)) is amended by striking "and 2002" and inserting "2002, and 2004".

(b) PROMPT SUBMISSION OF OVERDUE REPORTS ON PAYMENT AND UTILIZATION OF OUTPATIENT THERAPY SERVICES.—Not later than December 31, 2003, the Secretary shall submit to Congress the reports required under section 4541(d)(2) of the Balanced Budget Act of 1997 (relating to alternatives to a single annual dollar cap on outpatient therapy) and under section 221(d) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (relating to utilization patterns for outpatient therapy).

(c) IDENTIFICATION OF CONDITIONS AND DISEASES JUSTIFYING WAIVER OF THERAPY CAP.—

(1) STUDY.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to identify conditions or diseases that should justify conducting an assessment of the need to waive the therapy caps under section 1833(g)(4) of the Social Security Act (42 U.S.C. 1395l(g)(4)).

(2) REPORTS TO CONGRESS.—

(A) PRELIMINARY REPORT.—Not later than July 1, 2004, the Secretary shall submit to Congress a preliminary report on the conditions and diseases identified under paragraph (1).

(B) FINAL REPORT.—Not later than September 1, 2004, the Secretary shall submit to Congress a final report on such conditions and diseases.

(C) RECOMMENDATIONS.—Not later than October 1, 2004, the Secretary shall submit to Congress a recommendation of criteria, with respect to such conditions and disease, under which a waiver of the therapy caps would apply.

(d) GAO STUDY OF PATIENT ACCESS TO PHYSICAL THERAPIST SERVICES.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on access to physical therapist services in States authorizing such services without a physician referral and in States that require such a physician referral. The study shall—

(A) examine the use of and referral patterns for physical therapist services for patients age 50 and older in States that authorize such services without a physician referral and in States that require such a physician referral;

(B) examine the use of and referral patterns for physical therapist services for patients who are medicare beneficiaries;

(C) examine the potential effect of prohibiting a physician from referring patients to physical therapy services owned by the physician and provided in the physician's office;

(D) examine the delivery of physical therapists' services within the facilities of Department of Defense; and

(E) analyze the potential impact on medicare beneficiaries and on expenditures under the medicare program of eliminating the need for a physician referral and physician certification for physical therapist services under the medicare program.

(2) REPORT.—The Comptroller General shall submit to Congress a report on the study conducted under paragraph (1) by not later than 1 year after the date of the enactment of this Act.

SEC. 625. ADJUSTMENT TO PAYMENTS FOR SERVICES FURNISHED IN AMBULATORY SURGICAL CENTERS.

Section 1833(i)(2)(C) (42 U.S.C. 1395l(i)(2)(C)) is amended in the last sentence by inserting "and each of fiscal years 2004 through 2008" after "In each of the fiscal years 1998 through 2002".

SEC. 626. PAYMENT FOR CERTAIN SHOES AND INSERTS UNDER THE FEE SCHEDULE FOR ORTHOTICS AND PROSTHETICS.

(a) IN GENERAL.—Section 1833(o) (42 U.S.C. 1395l(o)) is amended—

(1) in paragraph (1), by striking "no more than the limits established under paragraph (2)" and inserting "no more than the amount of payment applicable under paragraph (2)"; and

(2) in paragraph (2), to read as follows:

"(2)(A) Except as provided by the Secretary under subparagraphs (B) and (C), the amount of payment under this paragraph for custom molded shoes, extra depth shoes, and inserts shall be the amount determined for such items by the Secretary under section 1834(h).

"(B) The Secretary or a carrier may establish payment amounts for shoes and inserts that are lower than the amount established under section 1834(h) if the Secretary finds that shoes and inserts of an appropriate quality are readily available at or below the amount established under such section.

"(C) In accordance with procedures established by the Secretary, an individual entitled to benefits with respect to shoes described in section 1861(s)(12) may substitute modification of such shoes instead of obtaining one (or more, as specified by the Secretary) pair of inserts (other than the original pair of inserts with respect to such shoes). In such case, the Secretary shall substitute, for the payment amount established under section 1834(h), a payment amount that the Secretary estimates will assure that there is no net increase in expenditures under this subsection as a result of this subparagraph.".

(b) CONFORMING AMENDMENTS.—(1) Section 1834(h)(4)(C) (42 U.S.C. 1395m(h)(4)(C)) is amended by inserting "(and includes shoes described in section 1861(s)(12))" after "in section 1861(s)(9)".

(2) Section 1842(s)(2) (42 U.S.C. 1395u(s)(2)) is amended by striking subparagraph (C).

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to items furnished on or after January 1, 2004.

SEC. 627. WAIVER OF PART B LATE ENROLLMENT PENALTY FOR CERTAIN MILITARY RETIREES; SPECIAL ENROLLMENT PERIOD.

(a) WAIVER OF PENALTY.—

(1) IN GENERAL.—Section 1839(b) (42 U.S.C. 1395r(b)) is amended by adding at the end the following new sentence: "No increase in the premium shall be effected for a month in the case of an individual who is 65 years of age or older, who enrolls under this part during 2001, 2002, 2003, or 2004 and who demonstrates to the Secretary before December 31, 2004, that the individual is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code). The Secretary of Health and Human Services shall consult with the Secretary of Defense in identifying individuals described in the previous sentence.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to premiums for months beginning with January 2004. The Secretary of Health and Human Services shall establish a method for providing rebates of premium penalties paid for months on or after January 2004 for which a penalty does not apply under such amendment but for which a penalty was previously collected.

(b) MEDICARE PART B SPECIAL ENROLLMENT PERIOD.—

(1) IN GENERAL.—In the case of any individual who, as of the date of the enactment of this Act, is 65 years of age or older, is eligible to enroll but is not enrolled under part B of title XVIII of the Social Security Act, and is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code), the Secretary of Health and Human Services shall provide for a special enrollment period during which the individual may enroll under such part. Such period

shall begin as soon as possible after the date of the enactment of this Act and shall end on December 31, 2004.

(2) COVERAGE PERIOD.—In the case of an individual who enrolls during the special enrollment period provided under paragraph (1), the coverage period under part B of title XVIII of the Social Security Act shall begin on the first day of the month following the month in which the individual enrolls.

SEC. 628. PART B DEDUCTIBLE.

Section 1833(b) (42 U.S.C. 1395l(b)) is amended—

(1) by striking "1991 and" and inserting "1991,"; and

(2) by striking "and subsequent years" and inserting "and each subsequent year through 2003, and for a subsequent year after 2003 the amount of such deductible for the previous year increased by the annual percentage increase in the monthly actuarial rate under section 1839(a)(1) ending with such subsequent year (rounded to the nearest $1)".

SEC. 629. EXTENSION OF COVERAGE OF INTRAVENOUS IMMUNE GLOBULIN (IVIG) FOR THE TREATMENT OF PRIMARY IMMUNE DEFICIENCY DISEASES IN THE HOME.

(a) IN GENERAL.—Section 1861 (42 U.S.C. 1395x), as amended by sections 611(a) and 612(a) is amended—

(1) in subsection (s)(2)—

(A) by striking "and" at the end of subparagraph (W);

(B) by adding "and" at the end of subparagraph (X); and

(C) by adding at the end the following new subparagraph:

"(Y) intravenous immune globulin for the treatment of primary immune deficiency diseases in the home (as defined in subsection (yy));"; and

(2) by adding at the end the following new subsection:

"Intravenous Immune Globulin

"(yy) The term 'intravenous immune globulin' means an approved pooled plasma derivative for the treatment in the patient's home of a patient with a diagnosed primary immune deficiency disease, but not including items or services related to the administration of the derivative, if a physician determines administration of the derivative in the patient's home is medically appropriate.".

(b) PAYMENT AS A DRUG OR BIOLOGICAL.—Section 1833(a)(1)(S) (42 U.S.C. 1395l(a)(1)(S)) is amended by inserting "(including intravenous immune globulin (as defined in section 1861(yy)))" after "with respect to drugs and biologicals".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to items furnished administered on or after January 1, 2004.

TITLE VII—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

SEC. 701. UPDATE IN HOME HEALTH SERVICES.

(a) CHANGE TO CALENDER YEAR UPDATE.—

(1) IN GENERAL.—Section 1895(b) (42 U.S.C. 1395fff(b)(3)) is amended—

(A) in paragraph (3)(B)(i)—

(i) by striking "each fiscal year (beginning with fiscal year 2002)" and inserting "fiscal year 2002 and for fiscal year 2003 and for each subsequent year (beginning with 2004)"; and

(ii) by inserting "or year" after "the fiscal year";

(B) in paragraph (3)(B)(ii)(II), by striking "any subsequent fiscal year" and inserting "2004 and any subsequent year";

(C) in paragraph (3)(B)(iii), by inserting "or year" after "fiscal year" each place it appears;

(D) in paragraph (3)(B)(iv)—

(i) by inserting "or year" after "fiscal year" each place it appears; and

(ii) by inserting "or years" after "fiscal years"; and

(E) in paragraph (5), by inserting "or year" after "fiscal year".

(2) TRANSITION RULE.—The standard prospective payment amount (or amounts) under section 1895(b)(3) of the Social Security Act for the calendar quarter beginning on October 1, 2003, shall be such amount (or amounts) for the previous calendar quarter.

(b) CHANGES IN UPDATES FOR 2004, 2005, AND 2006.—Section 1895(b)(3)(B)(ii) (42 U.S.C. 1395fff(b)(3)(B)(ii)), as amended by subsection (a)(1)(B), is amended—

(1) by striking "or" at the end of subclause (I);
(2) by redesignating subclause (II) as subclause (III);
(3) in subclause (III), as so redesignated, by striking "2004" and inserting "2007"; and
(4) by inserting after subclause (I) the following new subclause:

"(II) each of 2004, 2005, and 2006 the home health market basket percentage increase minus 0.4 percentage points; or".

SEC. 702. ESTABLISHMENT OF REDUCED COPAYMENT FOR A HOME HEALTH SERVICE EPISODE OF CARE FOR CERTAIN BENEFICIARIES.

(a) PART A.—

(1) IN GENERAL.—Section 1813(a) (42 U.S.C. 1395e(a)) is amended by adding at the end the following new paragraph:

"(5)(A)(i) Subject to clause (ii), the amount payable for home health services furnished to the individual under this title for each episode of care beginning in a year (beginning with 2004) shall be reduced by a copayment equal to the copayment amount specified in subparagraph (B)(ii) for such year.

"(ii) The copayment under clause (i) shall not apply—

"(I) in the case of an individual who has been determined to be entitled to medical assistance under section 1902(a)(10)(A) or 1902(a)(10)(C) or to be a qualified medicare beneficiary (as defined in section 1905(p)(1)), a specified low-income medicare beneficiary described in section 1902(a)(10)(E)(iii), or a qualifying individual described in section 1902(a)(10)(E)(iv)(I); and

"(II) in the case of an episode of care which consists of 4 or fewer visits.

"(B)(i) The Secretary shall estimate, before the beginning of each year (beginning with 2004), the national average payment under this title per episode for home health services projected for the year involved.

"(ii) For each year the copayment amount under this clause is equal to 1.5 percent of the national average payment estimated for the year involved under clause (i). Any amount determined under the preceding sentence which is not a multiple of $5 shall be rounded to the nearest multiple of $5.

"(iii) There shall be no administrative or judicial review under section 1869, 1878, or otherwise of the estimation of average payment under clause (i).".

(2) TIMELY IMPLEMENTATION.—Unless the Secretary of Health and Human Services otherwise provides on a timely basis, the copayment amount specified under section 1813(a)(5)(B)(ii) of the Social Security Act (as added by paragraph (1)) for 2004 shall be deemed to be $40.

(b) CONFORMING PROVISIONS.—

(1) Section 1833(a)(2)(A) (42 U.S.C. 1395l(a)(2)(A)) is amended by inserting "less the copayment amount applicable under section 1813(a)(5)" after "1895".

(2) Section 1866(a)(2)(A)(i) (42 U.S.C. 1395cc(a)(2)(A)(i)) is amended—

(A) by striking "or coinsurance" and inserting ", coinsurance, or copayment"; and

(B) by striking "or (a)(4)" and inserting "(a)(4), or (a)(5)".

SEC. 703. MEDPAC STUDY ON MEDICARE MARGINS OF HOME HEALTH AGENCIES.

(a) STUDY.—The Medicare Payment Advisory Commission shall conduct a study of payment margins of home health agencies under the home health prospective payment system under section 1895 of the Social Security Act (42 U.S.C. 1395fff). Such study shall examine whether systematic differences in payment margins are related to differences in case mix (as measured by home health resource groups (HHRGs)) among such agencies. The study shall use the partial or full-year cost reports filed by home health agencies.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study under subsection (a).

Subtitle B—Direct Graduate Medical Education

SEC. 711. EXTENSION OF UPDATE LIMITATION ON HIGH COST PROGRAMS.

Section 1886(h)(2)(D)(iv) (42 U.S.C. 1395ww(h)(2)(D)(iv)) is amended—

(1) in subclause (I)—

(A) by inserting "AND 2004 THROUGH 2013" after "AND 2002"; and

(B) by inserting "or during the period beginning with fiscal year 2004 and ending with fiscal year 2013" after "during fiscal year 2001 or fiscal year 2002"; and

(2) in subclause (II)—

(A) by striking "fiscal year 2004, or fiscal year 2005," and

(B) by striking "For a" and inserting "For the".

Subtitle C—Chronic Care Improvement

SEC. 721. VOLUNTARY CHRONIC CARE IMPROVEMENT UNDER TRADITIONAL FEE-FOR-SERVICE.

Title XVIII, as amended by section 105(a), is amended by inserting after section 1807 the following new section:

"CHRONIC CARE IMPROVEMENT

"SEC. 1808. (a) IN GENERAL.—

"(1) IN GENERAL.—The Secretary shall establish a process for providing chronic care improvement programs in each CCIA region for medicare beneficiaries who are not enrolled under part C or E and who have certain chronic conditions, such as congestive heart failure, diabetes, chronic obstructive pulmonary disease (COPD), stroke, or other disease as identified by the Secretary as appropriate for chronic care improvement. Such a process shall begin to be implemented no later than 1 year after the date of the enactment of this section.

"(2) TERMINOLOGY.—For purposes of this section:

"(A) CCIA REGION.—The term 'CCIA region' means a chronic care improvement administrative region delineated under subsection (b)(2).

"(B) CHRONIC CARE IMPROVEMENT PROGRAM.—The terms 'chronic care improvement program' and 'program' means such a program provided by a contractor under this section.

"(C) CONTRACTOR.—The term 'contractor' means an entity with a contract to provide a chronic care improvement program in a CCIA region under this section.

"(D) INDIVIDUAL PLAN.—The term 'individual plan' means a chronic care improvement plan established under subsection (c)(5) for an individual.

"(3) CONSTRUCTION.—Nothing in this section shall be construed as expanding the amount, duration, or scope of benefits under this title.

"(b) COMPETITIVE BIDDING PROCESS.—

"(1) IN GENERAL.—Under this section the Secretary shall award contracts to qualified entities for chronic care improvement programs for each CCIA region under this section through a competitive bidding process.

"(2) PROCESS.—Under such process—

"(A) the Secretary shall delineate the United States into multiple chronic care improvement administrative regions; and

"(B) the Secretary shall select at least 2 winning bidders in each CCIA region on the basis of the ability of each bidder to carry out a chronic care improvement program in accordance with this section, in order to achieve improved health and financial outcomes.

"(3) ELIGIBLE CONTRACTOR.—A contractor may be a disease improvement organization, health insurer, provider organization, a group of physicians, or any other legal entity that the Secretary determines appropriate.

"(c) CHRONIC CARE IMPROVEMENT PROGRAMS.—

"(1) IN GENERAL.—Each contract under this section shall provide for the operation of a chronic care improvement program by a contractor in a CCIA region consistent with this subsection.

"(2) IDENTIFICATION OF PROSPECTIVE PROGRAM PARTICIPANTS.—Each contractor shall have a method for identifying medicare beneficiaries in the region to whom it will offer services under its program. The contractor shall identify such beneficiaries through claims or other data and other means permitted consistent with applicable disclosure provisions.

"(3) INITIAL CONTACT BY SECRETARY.—The Secretary shall communicate with each beneficiary identified under paragraph (2) as a prospective participant in one or more programs concerning participation in a program. Such communication may be made by the Secretary (or on behalf of the Secretary) and shall include information on the following:

"(A) A description of the advantages to the beneficiary in participating in a program.

"(B) Notification that the contractor offering a program may contact the beneficiary directly concerning such participation.

"(C) Notification that participation in a program is voluntary.

"(D) A description of the method for the beneficiary to select the single program in which the beneficiary wishes to participate and for declining to

participate and a method for obtaining additional information concerning such participation.

"(4) PARTICIPATION.—A medicare beneficiary may participate in only one program under this section and may terminate participation at any time in a manner specified by the Secretary.

"(5) INDIVIDUAL CHRONIC CARE IMPROVEMENT PLANS.—

"(A) IN GENERAL.—For each beneficiary participating in a program of a contractor under this section, the contractor shall develop with the beneficiary an individualized, goal-oriented chronic care improvement plan.

"(B) ELEMENTS OF INDIVIDUAL PLAN.—Each individual plan developed under subparagraph (A) shall include a single point of contact to coordinate care and the following, as appropriate:

"(i) Self-improvement education for the beneficiary and support education for health care providers, primary caregivers, and family members.

"(ii) Coordination of health care services, such as application of a prescription drug regimen and home health services.

"(iii) Collaboration with physicians and other providers to enhance communication of relevant clinical information.

"(iv) The use of monitoring technologies that enable patient guidance through the exchange of pertinent clinical information, such as vital signs, symptomatic information, and health self-assessment.

"(v) The provision of information about hospice care, pain and palliative care, and end-of-life care.

"(C) CONTRACTOR RESPONSIBILITIES.—In establishing and carrying out individual plans under a program, a contractor shall, directly or through subcontractors—

"(i) guide participants in managing their health, including all their co-morbidities, and in performing activities as specified under the elements of the plan;

"(ii) use decision support tools such as evidence-based practice guidelines or other criteria as determined by the Secretary; and

"(iii) develop a clinical information database to track and monitor each participant across settings and to evaluate outcomes.

"(6) ADDITIONAL REQUIREMENTS.—The Secretary may establish additional requirements for programs and contractors under this section.

"(7) ACCREDITATION.—The Secretary may provide that programs that are accredited by qualified organizations may be deemed to meet such requirements under this section as the Secretary may specify.

"(c) CONTRACT TERMS.—

"(1) IN GENERAL.—A contract under this section shall contain such terms and conditions as the Secretary may specify consistent with this section. The Secretary may not enter into a contract with an entity under this section unless the entity meets such clinical, quality improvement, financial, and other requirements as the Secretary deems to be appropriate for the population to be served.

"(2) USE OF SUBCONTRACTORS PERMITTED.—A contractor may carry out a program directly or through contracts with subcontractors.

"(3) BUDGET NEUTRAL PAYMENT CONDITION.—In entering into a contract with an entity under this subsection, the Secretary shall establish payment rates that assure that there will be no net aggregate increase in payments under this title over any period of 3 years or longer, as agreed to by the Secretary. Under this section, the Secretary shall assure that medicare program outlays plus administrative expenses (that would not have been paid under this title without implementation of this section), including contractor fees, shall not exceed the expenditures that would have been incurred under this title for a comparable population in the absence of the program under this section for the 3-year contract period.

"(4) AT RISK RELATIONSHIP.—For purposes of section 1128B(b)(3)(F), a contract under this section shall be treated as a risk-sharing arrangement referred to in such section.

"(5) PERFORMANCE STANDARDS.—Payment to contractors under this section shall be subject to the contractor's meeting of clinical and financial performance standards set by the Secretary.

"(6) CONTRACTOR OUTCOMES REPORT.—Each contractor offering a program shall monitor and report to the Secretary, in a manner specified by the Secretary, the quality of care and efficacy of such program in terms of—

"(A) process measures, such as reductions in errors of treatment and rehospitalization rates;

"(B) beneficiary and provider satisfaction;
"(C) health outcomes; and
"(D) financial outcomes.

"(7) PHASED IN IMPLEMENTATION.—Nothing in this section shall be construed as preventing the Secretary from phasing in the implementation of programs.

"(d) BIANNUAL OUTCOMES REPORTS.—The Secretary shall submit to the Congress biannual reports on the implementation of this section. Each such report shall include information on—

"(1) the scope of implementation (in terms of both regions and chronic conditions);
"(2) program design; and
"(3) improvements in health outcomes and financial efficiencies that result from such implementation.

"(e) CLINICAL TRIALS.—The Secretary shall conduct randomized clinical trials, that compare program participants with medicare beneficiaries who are offered, but decline, to participate, in order to assess the potential of programs to—

"(1) reduce costs under this title; and
"(2) improve health outcomes under this title.

"(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary, in appropriate part from the Hospital Insurance Trust Fund and the Supplementary Medical Insurance Trust Fund, such sums as may be necessary to provide for contracts with chronic care improvement programs under this section.

"(g) LIMITATION ON FUNDING.—In no case shall the funding under this section exceed $100,000,000 over a period of 3 years.".

SEC. 722. CHRONIC CARE IMPROVEMENT UNDER MEDICARE ADVANTAGE AND ENHANCED FEE-FOR-SERVICE PROGRAMS.

(a) UNDER MEDICARE ADVANTAGE PROGRAM.—Section 1852 (42 U.S.C. 1395w–22) is amended—

(1) by amending subsection (e) to read as follows:

"(e) IMPLEMENTATION OF CHRONIC CARE IMPROVEMENT PROGRAMS FOR BENEFICIARIES WITH MULTIPLE OR SUFFICIENTLY SEVERE CHRONIC CONDITIONS.—

"(1) IN GENERAL.—Each Medicare Advantage organization with respect to each Medicare Advantage plan it offers shall have in effect, for enrollees with multiple or sufficiently severe chronic conditions, a chronic care improvement program that is designed to manage the needs of such enrollees and that meets the requirements of this subsection.

"(2) ENROLLEE WITH MULTIPLE OR SUFFICIENTLY SEVERE CHRONIC CONDITIONS.—For purposes of this subsection, the term 'enrollee with multiple or sufficiently severe chronic conditions' means, with respect to an enrollee in a Medicare Advantage plan of a Medicare Advantage organization, an enrollee in the plan who has one or more chronic conditions, such as congestive heart failure, diabetes, COPD, stroke, or other disease as identified by the organization as appropriate for chronic care improvement.

"(3) GENERAL REQUIREMENTS.—

"(A) IN GENERAL.—Each chronic care improvement program under this subsection shall be conducted consistent with this subsection.

"(B) IDENTIFICATION OF ENROLLEES.—Each such program shall have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions that meet the organization's criteria for participation under the program.

"(C) DEVELOPMENT OF PLANS.—For an enrollee identified under subparagraph (B) for participation in a program, the program shall develop, with the enrollee's consent, an individualized, goal-oriented chronic care improvement plan for chronic care improvement.

"(D) ELEMENTS OF PLANS.—Each chronic care improvement plan developed under subparagraph (C) shall include a single point of contact to coordinate care and the following, as appropriate:

"(i) Self-improvement education for the enrollee and support education for health care providers, primary caregivers, and family members.

"(ii) Coordination of health care services, such as application of a prescription drug regimen and home health services.

"(iii) Collaboration with physicians and other providers to enhance communication of relevant clinical information.

"(iv) The use of monitoring technologies that enable patient guidance through the exchange of pertinent clinical information, such as vital signs, symptomatic information, and health self-assessment.

"(v) The provision of information about hospice care, pain and palliative care, and end-of-life care.

"(E) ORGANIZATION RESPONSIBILITIES.—In establishing and carrying out chronic care improvement plans for participants under this paragraph, a Medicare Advantage organization shall, directly or through subcontractors—

"(i) guide participants in managing their health, including all their co-morbidities, and in performing the activities as specified under the elements of the plan;

"(ii) use decision support tools such as evidence-based practice guidelines or other criteria as determined by the Secretary; and

"(iii) develop a clinical information database to track and monitor each participant across settings and to evaluate outcomes.

"(3) ADDITIONAL REQUIREMENTS.—The Secretary may establish additional requirements for chronic care improvement programs under this section.

"(4) ACCREDITATION.—The Secretary may provide that chronic care improvement programs that are accredited by qualified organizations may be deemed to meet such requirements under this subsection as the Secretary may specify.

"(5) OUTCOMES REPORT.—Each Medicare Advantage organization with respect to its chronic care improvement program under this subsection shall monitor and report to the Secretary information on the quality of care and efficacy of such program as the Secretary may require."; and

(2) by amending subparagraph (I) of subsection (c)(1) to read as follows:

"(I) CHRONIC CARE IMPROVEMENT PROGRAM.—A description of the organization's chronic care improvement program under subsection (e).".

(b) APPLICATION UNDER ENHANCED FEE-FOR-SERVICE PROGRAM.—Section 1860E–2(c)(3), as inserted by section 201(a), is amended by inserting ", including subsection (e) (relating to implementation of chronic care improvement programs)" after "The provisions of section 1852".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply for contract years beginning on or after 1 year after the date of the enactment of this Act.

SEC. 723. INSTITUTE OF MEDICINE REPORT.

(a) STUDY.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall contract with the Institute of Medicine of the National Academy of Sciences to conduct a study of the barriers to effective integrated care improvement for medicare beneficiaries with multiple or severe chronic conditions across settings and over time and to submit a report under subsection (b).

(2) SPECIFIC ITEMS.—The study shall examine the statutory and regulatory barriers to coordinating care across settings for medicare beneficiaries in transition from one setting to another (such as between hospital, nursing facility, home health, hospice, and home). The study shall specifically identify the following:

(A) Clinical, financial, or administrative requirements in the medicare program that present barriers to effective, seamless transitions across care settings.

(B) Policies that impede the establishment of administrative and clinical information systems to track health status, utilization, cost, and quality data across settings.

(C) State-level requirements that may present barriers to better care for medicare beneficiaries.

(3) CONSULTATION.—The study under this subsection shall be conducted in consultation with experts in the field of chronic care, consumers, and family caregivers, working to integrate care delivery and create more seamless transitions across settings and over time.

(b) REPORT.—The report under this subsection shall be submitted to the Secretary and Congress not later than 18 months after the date of the enactment of this Act.

SEC. 724. MEDPAC REPORT.

(a) EVALUATION.—shall conduct an evaluation that includes a description of the status of the implementation of chronic care improvement programs under section 1808 of the Social Security Act, the quality of health care services provided to individuals in such program, the health status of the participants of such program, and the cost savings attributed to implementation of such program.

(b) REPORT.—Not later than 2 years after the date of implementation of such chronic care improvement programs, the Commission shall submit a report on such evaluation.

Subtitle D—Other Provisions

SEC. 731. MODIFICATIONS TO MEDICARE PAYMENT ADVISORY COMMISSION (MEDPAC).

(a) EXAMINATION OF BUDGET CONSEQUENCES.—Section 1805(b) (42 U.S.C. 1395b–6(b)) is amended by adding at the end the following new paragraph:

"(8) EXAMINATION OF BUDGET CONSEQUENCES.—Before making any recommendations, the Commission shall examine the budget consequences of such recommendations, directly or through consultation with appropriate expert entities.".

(b) CONSIDERATION OF EFFICIENT PROVISION OF SERVICES.—Section 1805(b)(2)(B)(i) (42 U.S.C. 1395b–6(b)(2)(B)(i)) is amended by inserting "the efficient provision of" after "expenditures for".

(c) APPLICATION OF DISCLOSURE REQUIREMENTS.—

(1) IN GENERAL.—Section 1805(c)(2)(D) (42 U.S.C. 1395b–6(c)(2)(D)) is amended by adding at the end the following: "Members of the Commission shall be treated as employees of the Congress for purposes of applying title I of the Ethics in Government Act of 1978 (Public Law 95-521).".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on January 1, 2004.

(d) ADDITIONAL REPORTS.—

(1) DATA NEEDS AND SOURCES.—The Medicare Payment Advisory Commission shall conduct a study, and submit a report to Congress by not later than June 1, 2004, on the need for current data, and sources of current data available, to determine the solvency and financial circumstances of hospitals and other medicare providers of services. The Commission shall examine data on uncompensated care, as well as the share of uncompensated care accounted for by the expenses for treating illegal aliens.

(2) USE OF TAX-RELATED RETURNS.—Using return information provided under Form 990 of the Internal Revenue Service, the Commission shall submit to Congress, by not later than June 1, 2004, a report on the following:

(A) Investments, endowments, and fundraising of hospitals participating under the medicare program and related foundations.

(B) Access to capital financing for private and for not-for-profit hospitals.

SEC. 732. DEMONSTRATION PROJECT FOR MEDICAL ADULT DAY CARE SERVICES.

(a) ESTABLISHMENT.—Subject to the succeeding provisions of this section, the Secretary of Health and Human Services shall establish a demonstration project (in this section referred to as the "demonstration project") under which the Secretary shall, as part of a plan of an episode of care for home health services established for a medicare beneficiary, permit a home health agency, directly or under arrangements with a medical adult day care facility, to provide medical adult day care services as a substitute for a portion of home health services that would otherwise be provided in the beneficiary's home.

(b) PAYMENT.—

(1) IN GENERAL.—The amount of payment for an episode of care for home health services, a portion of which consists of substitute medical adult day care services, under the demonstration project shall be made at a rate equal to 95 percent of the amount that would otherwise apply for such home health services under section 1895 of the Social Security Act (42 u.s.c. 1395fff). In no case may a home health agency, or a medical adult day care facility under arrangements with a home health agency, separately charge a beneficiary for medical adult day care services furnished under the plan of care.

(2) BUDGET NEUTRALITY FOR DEMONSTRATION PROJECT.—Notwithstanding any other provision of law, the Secretary shall provide for an appropriate reduction in the aggregate amount of additional payments made under section 1895 of the Social Security Act (42 U.S.C. 1395fff) to reflect any increase in amounts expended from the Trust Funds as a result of the demonstration project conducted under this section.

(c) DEMONSTRATION PROJECT SITES.—The project established under this section shall be conducted in not more than 5 States selected by the Secretary that license or certify providers of services that furnish medical adult day care services.

(d) DURATION.—The Secretary shall conduct the demonstration project for a period of 3 years.

(e) VOLUNTARY PARTICIPATION.—Participation of medicare beneficiaries in the demonstration project shall be voluntary. The total number of such beneficiaries that may participate in the project at any given time may not exceed 15,000.

(f) PREFERENCE IN SELECTING AGENCIES.—In selecting home health agencies to participate under the demonstration project, the Secretary shall give preference to

those agencies that are currently licensed or certified through common ownership and control to furnish medical adult day care services.

(g) WAIVER AUTHORITY.—The Secretary may waive such requirements of title XVIII of the Social Security Act as may be necessary for the purposes of carrying out the demonstration project, other than waiving the requirement that an individual be homebound in order to be eligible for benefits for home health services.

(h) EVALUATION AND REPORT.—The Secretary shall conduct an evaluation of the clinical and cost effectiveness of the demonstration project. Not later 30 months after the commencement of the project, the Secretary shall submit to Congress a report on the evaluation, and shall include in the report the following:

(1) An analysis of the patient outcomes and costs of furnishing care to the medicare beneficiaries participating in the project as compared to such outcomes and costs to beneficiaries receiving only home health services for the same health conditions.

(2) Such recommendations regarding the extension, expansion, or termination of the project as the Secretary determines appropriate.

(i) DEFINITIONS.—In this section:

(1) HOME HEALTH AGENCY.—The term "home health agency" has the meaning given such term in section 1861(o) of the Social Security Act (42 U.S.C. 1395x(o)).

(2) MEDICAL ADULT DAY CARE FACILITY.—The term "medical adult day care facility" means a facility that—

(A) has been licensed or certified by a State to furnish medical adult day care services in the State for a continuous 2-year period;

(B) is engaged in providing skilled nursing services and other therapeutic services directly or under arrangement with a home health agency;

(C) meets such standards established by the Secretary to assure quality of care and such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the facility; and

(D) provides medical adult day care services.

(3) MEDICAL ADULT DAY CARE SERVICES.—The term "medical adult day care services" means—

(A) home health service items and services described in paragraphs (1) through (7) of section 1861(m) furnished in a medical adult day care facility;

(B) a program of supervised activities furnished in a group setting in the facility that—

(i) meet such criteria as the Secretary determines appropriate; and

(ii) is designed to promote physical and mental health of the individuals; and

(C) such other services as the Secretary may specify.

(4) MEDICARE BENEFICIARY.—The term "medicare beneficiary" means an individual entitled to benefits under part A of this title, enrolled under part B of this title, or both.

SEC. 733. IMPROVEMENTS IN NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS TO RESPOND TO CHANGES IN TECHNOLOGY.

(a) NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS.—

(1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended—

(A) in the third sentence of subsection (a) by inserting "consistent with subsection (k)" after "the Secretary shall ensure"; and

(B) by adding at the end the following new subsection:

"(k) NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS.—

"(1) CRITERIA AND EVIDENCE USED IN MAKING NATIONAL COVERAGE DETERMINATIONS.—The Secretary shall make available to the public the criteria the Secretary uses in making national coverage determinations, including how evidence to demonstrate that a procedure or device is reasonable and necessary is considered.

"(2) TIMEFRAME FOR DECISIONS ON REQUESTS FOR NATIONAL COVERAGE DETERMINATIONS.—In the case of a request for a national coverage determination that—

"(A) does not require a technology assessment from an outside entity or deliberation from the Medicare Coverage Advisory Committee, the decision on the request shall be made not later than 6 months after the date of the request; or

"(B) requires such an assessment or deliberation and in which a clinical trial is not requested, the decision on the request shall be made not later than 12 months after the date of the request.

"(3) PROCESS FOR PUBLIC COMMENT IN NATIONAL COVERAGE DETERMINATIONS.—At the end of the 6-month period that begins on the date a request for a national coverage determination is made, the Secretary shall—

"(A) make a draft of proposed decision on the request available to the public through the Medicare Internet site of the Department of Health and Human Services or other appropriate means;

"(B) provide a 30-day period for public comment on such draft;

"(C) make a final decision on the request within 60 days of the conclusion of the 30-day period referred to under subparagraph (B);

"(D) include in such final decision summaries of the public comments received and responses thereto;

"(E) make available to the public the clinical evidence and other data used in making such a decision when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and

"(F) in the case of a decision to grant the coverage determination, assign a temporary or permanent code during the 60-day period referred to in subparagraph (C).

"(4) CONSULTATION WITH OUTSIDE EXPERTS IN CERTAIN NATIONAL COVERAGE DETERMINATIONS.—With respect to a request for a national coverage determination for which there is not a review by the Medicare Coverage Advisory Committee, the Secretary shall consult with appropriate outside clinical experts.

"(5) LOCAL COVERAGE DETERMINATION PROCESS.—With respect to local coverage determinations made on or after January 1, 2004—

"(A) PLAN TO PROMOTE CONSISTENCY OF COVERAGE DETERMINATIONS.—The Secretary shall develop a plan to evaluate new local coverage determinations to determine which determinations should be adopted nationally and to what extent greater consistency can be achieved among local coverage determinations.

"(B) CONSULTATION.—The Secretary shall require the fiscal intermediaries or carriers providing services within the same area to consult on all new local coverage determinations within the area.

"(C) DISSEMINATION OF INFORMATION.—The Secretary should serve as a center to disseminate information on local coverage determinations among fiscal intermediaries and carriers to reduce duplication of effort.

"(6) NATIONAL AND LOCAL COVERAGE DETERMINATION DEFINED.—For purposes of this subsection, the terms 'national coverage determination' and 'local coverage determination' have the meaning given such terms in paragraphs (1)(B) and (2)(B), respectively, of section 1869(f).".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to national and local coverage determinations as of January 1, 2004.

(b) MEDICARE COVERAGE OF ROUTINE COSTS ASSOCIATED WITH CERTAIN CLINICAL TRIALS.—

(1) IN GENERAL.—With respect to the coverage of routine costs of care for beneficiaries participating in a qualifying clinical trial, as set forth on the date of the enactment of this Act in National Coverage Determination 30-1 of the Medicare Coverage Issues Manual, the Secretary shall deem clinical trials conducted in accordance with an investigational device exemption approved under section 520(g) of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 360j(g)) to be automatically qualified for such coverage.

(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as authorizing or requiring the Secretary to modify the regulations set forth on the date of the enactment of this Act at subpart B of part 405 of title 42, Code of Federal Regulations, or subpart A of part 411 of such title, relating to coverage of, and payment for, a medical device that is the subject of an investigational device exemption by the Food and Drug Administration (except as may be necessary to implement paragraph (1)).

(3) EFFECTIVE DATE.—This subsection shall apply to clinical trials begun before, on, or after the date of the enactment of this Act and to items and services furnished on or after such date.

(c) ISSUANCE OF TEMPORARY NATIONAL CODES.—Not later than January 1, 2004, the Secretary shall implement revised procedures for the issuance of temporary national HCPCS codes under part B of title XVIII of the Social Security Act.

SEC. 734. TREATMENT OF CERTAIN PHYSICIAN PATHOLOGY SERVICES.

(a) IN GENERAL.—Section 1848(i) (42 U.S.C. 1395w–4(i)) is amended by adding at the end the following new paragraph:

"(4) TREATMENT OF CERTAIN INPATIENT PHYSICIAN PATHOLOGY SERVICES.—

"(A) IN GENERAL.—With respect to services furnished on or after January 1, 2001, and before January 1, 2006, if an independent laboratory furnishes

the technical component of a physician pathology service to a fee-for-service medicare beneficiary who is an inpatient or outpatient of a covered hospital, the Secretary shall treat such component as a service for which payment shall be made to the laboratory under this section and not as an inpatient hospital service for which payment is made to the hospital under section 1886(d) or as a hospital outpatient service for which payment is made to the hospital under section 1833(t).

"(B) DEFINITIONS.—In this paragraph:

"(i) COVERED HOSPITAL.—

"(I) IN GENERAL.—The term 'covered hospital' means, with respect to an inpatient or outpatient, a hospital that had an arrangement with an independent laboratory that was in effect as of July 22, 1999, under which a laboratory furnished the technical component of physician pathology services to fee-for-service medicare beneficiaries who were hospital inpatients or outpatients, respectively, and submitted claims for payment for such component to a carrier with a contract under section 1842 and not to the hospital.

"(II) CHANGE IN OWNERSHIP DOES NOT AFFECT DETERMINATION.—A change in ownership with respect to a hospital on or after the date referred to in subclause (I) shall not affect the determination of whether such hospital is a covered hospital for purposes of such subclause.

"(ii) FEE-FOR-SERVICE MEDICARE BENEFICIARY.—The term 'fee-for-service medicare beneficiary' means an individual who is entitled to benefits under part A, or enrolled under this part, or both, but is not enrolled in any of the following:

"(I) A Medicare+Choice plan under part C.

"(II) A plan offered by an eligible organization under section 1876.

"(III) A program of all-inclusive care for the elderly (PACE) under section 1894.

"(IV) A social health maintenance organization (SHMO) demonstration project established under section 4018(b) of the Omnibus Budget Reconciliation Act of 1987 (Public Law 100–203).".

(b) CONFORMING AMENDMENT.—Section 542 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (114 Stat. 2763A–550), as enacted into law by section 1(a)(6) of Public Law 106–554, is repealed.

(c) EFFECTIVE DATES.—The amendments made by this section shall take effect as if included in the enactment of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Appendix F, 114 Stat. 2763A–463), as enacted into law by section 1(a)(6) of Public Law 106–554.

TITLE VIII—MEDICARE BENEFITS ADMINISTRATION

SEC. 801. ESTABLISHMENT OF MEDICARE BENEFITS ADMINISTRATION.

(a) IN GENERAL.—Title XVIII (42 U.S.C. 1395 et seq.), as amended by sections 105 and 721, is amended by inserting after 1808 the following new section:

"MEDICARE BENEFITS ADMINISTRATION

"SEC. 1809. (a) ESTABLISHMENT.—There is established within the Department of Health and Human Services an agency to be known as the Medicare Benefits Administration.

"(b) ADMINISTRATOR; DEPUTY ADMINISTRATOR; CHIEF ACTUARY.—

"(1) ADMINISTRATOR.—

"(A) IN GENERAL.—The Medicare Benefits Administration shall be headed by an administrator to be known as the 'Medicare Benefits Administrator' (in this section referred to as the 'Administrator') who shall be appointed by the President, by and with the advice and consent of the Senate. The Administrator shall be in direct line of authority to the Secretary.

"(B) COMPENSATION.—The Administrator shall be paid at the rate of basic pay payable for level III of the Executive Schedule under section 5314 of title 5, United States Code.

"(C) TERM OF OFFICE.—The Administrator shall be appointed for a term of 4 years. In any case in which a successor does not take office at the end of an Administrator's term of office, that Administrator may continue in office until the entry upon office of such a successor. An Administrator ap-

pointed to a term of office after the commencement of such term may serve under such appointment only for the remainder of such term.

"(D) GENERAL AUTHORITY.—The Administrator shall be responsible for the exercise of all powers and the discharge of all duties of the Administration, and shall have authority and control over all personnel and activities thereof.

"(E) RULEMAKING AUTHORITY.—The Administrator may prescribe such rules and regulations as the Administrator determines necessary or appropriate to carry out the functions of the Administration. The regulations prescribed by the Administrator shall be subject to the rulemaking procedures established under section 553 of title 5, United States Code. The Administrator shall provide for the issuance of new regulations to carry out parts C, D, and E.

"(F) AUTHORITY TO ESTABLISH ORGANIZATIONAL UNITS.—The Administrator may establish, alter, consolidate, or discontinue such organizational units or components within the Administration as the Administrator considers necessary or appropriate, except as specified in this section.

"(G) AUTHORITY TO DELEGATE.—The Administrator may assign duties, and delegate, or authorize successive redelegations of, authority to act and to render decisions, to such officers and employees of the Administration as the Administrator may find necessary. Within the limitations of such delegations, redelegations, or assignments, all official acts and decisions of such officers and employees shall have the same force and effect as though performed or rendered by the Administrator.

"(2) DEPUTY ADMINISTRATOR.—

"(A) IN GENERAL.—There shall be a Deputy Administrator of the Medicare Benefits Administration who shall be appointed by the President, by and with the advice and consent of the Senate.

"(B) COMPENSATION.—The Deputy Administrator shall be paid at the rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

"(C) TERM OF OFFICE.—The Deputy Administrator shall be appointed for a term of 4 years. In any case in which a successor does not take office at the end of a Deputy Administrator's term of office, such Deputy Administrator may continue in office until the entry upon office of such a successor. A Deputy Administrator appointed to a term of office after the commencement of such term may serve under such appointment only for the remainder of such term.

"(D) DUTIES.—The Deputy Administrator shall perform such duties and exercise such powers as the Administrator shall from time to time assign or delegate. The Deputy Administrator shall be Acting Administrator of the Administration during the absence or disability of the Administrator and, unless the President designates another officer of the Government as Acting Administrator, in the event of a vacancy in the office of the Administrator.

"(3) CHIEF ACTUARY.—

"(A) IN GENERAL.—There is established in the Administration the position of Chief Actuary. The Chief Actuary shall be appointed by, and in direct line of authority to, the Administrator of such Administration. The Chief Actuary shall be appointed from among individuals who have demonstrated, by their education and experience, superior expertise in the actuarial sciences. The Chief Actuary may be removed only for cause.

"(B) COMPENSATION.—The Chief Actuary shall be compensated at the highest rate of basic pay for the Senior Executive Service under section 5382(b) of title 5, United States Code.

"(C) DUTIES.—The Chief Actuary shall exercise such duties as are appropriate for the office of the Chief Actuary and in accordance with professional standards of actuarial independence.

"(4) SECRETARIAL COORDINATION OF PROGRAM ADMINISTRATION.—The Secretary shall ensure appropriate coordination between the Administrator and the Administrator of the Centers for Medicare & Medicaid Services in carrying out the programs under this title.

"(c) DUTIES; ADMINISTRATIVE PROVISIONS.—

"(1) DUTIES.—

"(A) GENERAL DUTIES.—The Administrator shall carry out parts C, D, and E, including—

"(i) negotiating, entering into, and enforcing, contracts with plans for the offering of Medicare Advantage plans under part C and EFFS plans under part E, including the offering of qualified prescription drug coverage under such plans; and

"(ii) negotiating, entering into, and enforcing, contracts with PDP sponsors for the offering of prescription drug plans under part D.

"(B) OTHER DUTIES.—The Administrator shall carry out any duty provided for under part C, part D, or part E, including demonstration projects carried out in part or in whole under such parts, the programs of all-inclusive care for the elderly (PACE program) under section 1894, the social health maintenance organization (SHMO) demonstration projects (referred to in section 4104(c) of the Balanced Budget Act of 1997), medicare cost contractors under section 1876(h), and through a Medicare Advantage project that demonstrates the application of capitation payment rates for frail elderly medicare beneficiaries through the use of a interdisciplinary team and through the provision of primary care services to such beneficiaries by means of such a team at the nursing facility involved).

"(C) PRESCRIPTION DRUG CARD.—The Administrator shall carry out section 1807 (relating to the medicare prescription drug discount card endorsement program).

"(D) NONINTERFERENCE.—In carrying out its duties with respect to the provision of qualified prescription drug coverage to beneficiaries under this title, the Administrator may not—

"(i) require a particular formulary or institute a price structure for the reimbursement of covered outpatient drugs;

"(ii) interfere in any way with negotiations between PDP sponsors and Medicare Advantage organizations and EFFS organizations and drug manufacturers, wholesalers, or other suppliers of covered outpatient drugs; and

"(iii) otherwise interfere with the competitive nature of providing such coverage through such sponsors and organizations.

"(E) ANNUAL REPORTS.—Not later March 31 of each year, the Administrator shall submit to Congress and the President a report on the administration of parts C, D, and E during the previous fiscal year.

"(2) STAFF.—

"(A) IN GENERAL.—The Administrator, with the approval of the Secretary, may employ, without regard to chapter 31 of title 5, United States Code, other than sections 3102 through 3108, 3110 through 3113, 3136m and 3151, such officers and employees as are necessary to administer the activities to be carried out through the Medicare Benefits Administration. The Administrator shall employ staff with appropriate and necessary expertise in negotiating contracts in the private sector.

"(B) FLEXIBILITY WITH RESPECT TO COMPENSATION.—

"(i) IN GENERAL.—The staff of the Medicare Benefits Administration shall, subject to clause (ii), be paid without regard to the provisions of chapter 51 (other than section 5101) and chapter 53 (other than section 5301) of such title (relating to classification and schedule pay rates).

"(ii) MAXIMUM RATE.—In no case may the rate of compensation determined under clause (i) exceed the rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

"(C) LIMITATION ON FULL-TIME EQUIVALENT STAFFING FOR CURRENT CMS FUNCTIONS BEING TRANSFERRED.—The Administrator may not employ under this paragraph a number of full-time equivalent employees, to carry out functions that were previously conducted by the Centers for Medicare & Medicaid Services and that are conducted by the Administrator by reason of this section, that exceeds the number of such full-time equivalent employees authorized to be employed by the Centers for Medicare & Medicaid Services to conduct such functions as of the date of the enactment of this Act.

"(3) REDELEGATION OF CERTAIN FUNCTIONS OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES.—

"(A) IN GENERAL.—The Secretary, the Administrator, and the Administrator of the Centers for Medicare & Medicaid Services shall establish an appropriate transition of responsibility in order to redelegate the administration of part C from the Secretary and the Administrator of the Centers for Medicare & Medicaid Services to the Administrator as is appropriate to carry out the purposes of this section.

"(B) TRANSFER OF DATA AND INFORMATION.—The Secretary shall ensure that the Administrator of the Centers for Medicare & Medicaid Services transfers to the Administrator of the Medicare Benefits Administration such information and data in the possession of the Administrator of the Centers for Medicare & Medicaid Services as the Administrator of the

Medicare Benefits Administration requires to carry out the duties described in paragraph (1).

"(C) CONSTRUCTION.—Insofar as a responsibility of the Secretary or the Administrator of the Centers for Medicare & Medicaid Services is redelegated to the Administrator under this section, any reference to the Secretary or the Administrator of the Centers for Medicare & Medicaid Services in this title or title XI with respect to such responsibility is deemed to be a reference to the Administrator.

"(d) OFFICE OF BENEFICIARY ASSISTANCE.—

"(1) ESTABLISHMENT.—The Secretary shall establish within the Medicare Benefits Administration an Office of Beneficiary Assistance to coordinate functions relating to outreach and education of medicare beneficiaries under this title, including the functions described in paragraph (2). The Office shall be separate operating division within the Administration.

"(2) DISSEMINATION OF INFORMATION ON BENEFITS AND APPEALS RIGHTS.—

"(A) DISSEMINATION OF BENEFITS INFORMATION.—The Office of Beneficiary Assistance shall disseminate, directly or through contract, to medicare beneficiaries, by mail, by posting on the Internet site of the Medicare Benefits Administration and through a toll-free telephone number, information with respect to the following:

"(i) Benefits, and limitations on payment (including cost-sharing, stop-loss provisions, and formulary restrictions) under parts C, D, and E.

"(ii) Benefits, and limitations on payment under parts A and B, including information on medicare supplemental policies under section 1882.

Such information shall be presented in a manner so that medicare beneficiaries may compare benefits under parts A, B, D, and medicare supplemental policies with benefits under Medicare Advantage plans under part C and EFFS plans under part E.

"(B) DISSEMINATION OF APPEALS RIGHTS INFORMATION.—The Office of Beneficiary Assistance shall disseminate to medicare beneficiaries in the manner provided under subparagraph (A) a description of procedural rights (including grievance and appeals procedures) of beneficiaries under the original medicare fee-for-service program under parts A and B, the Medicare Advantage program under part C, the Voluntary Prescription Drug Benefit Program under part D, and the Enhanced Fee-for-Service program under part E.

"(e) MEDICARE POLICY ADVISORY BOARD.—

"(1) ESTABLISHMENT.—There is established within the Medicare Benefits Administration the Medicare Policy Advisory Board (in this section referred to the 'Board'). The Board shall advise, consult with, and make recommendations to the Administrator of the Medicare Benefits Administration with respect to the administration of parts C, D, and E, including the review of payment policies under such parts.

"(2) REPORTS.—

"(A) IN GENERAL.—With respect to matters of the administration of parts C, D, and E the Board shall submit to Congress and to the Administrator of the Medicare Benefits Administration such reports as the Board determines appropriate. Each such report may contain such recommendations as the Board determines appropriate for legislative or administrative changes to improve the administration of such parts, including the topics described in subparagraph (B). Each such report shall be published in the Federal Register.

"(B) TOPICS DESCRIBED.—Reports required under subparagraph (A) may include the following topics:

"(i) FOSTERING COMPETITION.—Recommendations or proposals to increase competition under parts C, D, and E for services furnished to medicare beneficiaries.

"(ii) EDUCATION AND ENROLLMENT.—Recommendations for the improvement to efforts to provide medicare beneficiaries information and education on the program under this title, and specifically parts C, D, and E, and the program for enrollment under the title.

"(iii) IMPLEMENTATION OF RISK-ADJUSTMENT.—Evaluation of the implementation under section 1853(a)(3)(C) of the risk adjustment methodology to payment rates under that section to Medicare Advantage organizations offering Medicare Advantage plans (and the corresponding payment provisions under part E) that accounts for variations in per

capita costs based on health status, geography, and other demographic factors.

"(iv) RURAL ACCESS.—Recommendations to improve competition and access to plans under parts C, D, and E in rural areas.

"(C) MAINTAINING INDEPENDENCE OF BOARD.—The Board shall directly submit to Congress reports required under subparagraph (A). No officer or agency of the United States may require the Board to submit to any officer or agency of the United States for approval, comments, or review, prior to the submission to Congress of such reports.

"(3) DUTY OF ADMINISTRATOR OF MEDICARE BENEFITS ADMINISTRATION.—With respect to any report submitted by the Board under paragraph (2)(A), not later than 90 days after the report is submitted, the Administrator of the Medicare Benefits Administration shall submit to Congress and the President an analysis of recommendations made by the Board in such report. Each such analysis shall be published in the Federal Register.

"(4) MEMBERSHIP.—

"(A) APPOINTMENT.—Subject to the succeeding provisions of this paragraph, the Board shall consist of seven members to be appointed as follows:

"(i) Three members shall be appointed by the President.

"(ii) Two members shall be appointed by the Speaker of the House of Representatives, with the advice of the chairmen and the ranking minority members of the Committees on Ways and Means and on Energy and Commerce of the House of Representatives.

"(iii) Two members shall be appointed by the President pro tempore of the Senate with the advice of the chairman and the ranking minority member of the Senate Committee on Finance.

"(B) QUALIFICATIONS.—The members shall be chosen on the basis of their integrity, impartiality, and good judgment, and shall be individuals who are, by reason of their education and experience in health care benefits management, exceptionally qualified to perform the duties of members of the Board.

"(C) PROHIBITION ON INCLUSION OF FEDERAL EMPLOYEES.—No officer or employee of the United States may serve as a member of the Board.

"(5) COMPENSATION.—Members of the Board shall receive, for each day (including travel time) they are engaged in the performance of the functions of the board, compensation at rates not to exceed the daily equivalent to the annual rate in effect for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

"(6) TERMS OF OFFICE.—

"(A) IN GENERAL.—The term of office of members of the Board shall be 3 years.

"(B) TERMS OF INITIAL APPOINTEES.—As designated by the President at the time of appointment, of the members first appointed—

"(i) one shall be appointed for a term of 1 year;

"(ii) three shall be appointed for terms of 2 years; and

"(iii) three shall be appointed for terms of 3 years.

"(C) REAPPOINTMENTS.—Any person appointed as a member of the Board may not serve for more than 8 years.

"(D) VACANCY.—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office. A vacancy in the Board shall be filled in the manner in which the original appointment was made.

"(7) CHAIR.—The Chair of the Board shall be elected by the members. The term of office of the Chair shall be 3 years.

"(8) MEETINGS.—The Board shall meet at the call of the Chair, but in no event less than three times during each fiscal year.

"(9) DIRECTOR AND STAFF.—

"(A) APPOINTMENT OF DIRECTOR.—The Board shall have a Director who shall be appointed by the Chair.

"(B) IN GENERAL.—With the approval of the Board, the Director may appoint, without regard to chapter 31 of title 5, United States Code, such additional personnel as the Director considers appropriate.

"(C) FLEXIBILITY WITH RESPECT TO COMPENSATION.—

"(i) IN GENERAL.—The Director and staff of the Board shall, subject to clause (ii), be paid without regard to the provisions of chapter 51 and chapter 53 of such title (relating to classification and schedule pay rates).

"(ii) MAXIMUM RATE.—In no case may the rate of compensation determined under clause (i) exceed the rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

"(D) ASSISTANCE FROM THE ADMINISTRATOR OF THE MEDICARE BENEFITS ADMINISTRATION.—The Administrator of the Medicare Benefits Administration shall make available to the Board such information and other assistance as it may require to carry out its functions.

"(10) CONTRACT AUTHORITY.—The Board may contract with and compensate government and private agencies or persons to carry out its duties under this subsection, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

"(f) FUNDING.—There is authorized to be appropriated, in appropriate part from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund (including the Medicare Prescription Drug Account), such sums as are necessary to carry out this section.".

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act.

(2) DUTIES WITH RESPECT TO ELIGIBILITY DETERMINATIONS AND ENROLLMENT.—The Administrator of the Medicare Benefits Administration shall carry out enrollment under title XVIII of the Social Security Act, make eligibility determinations under such title, and carry out parts C and E of such title for years beginning or after January 1, 2006.

(3) TRANSITION.—Before the date the Administrator of the Medicare Benefits Administration is appointed and assumes responsibilities under this section and section 1807 of the Social Security Act, the Secretary of Health and Human Services shall provide for the conduct of any responsibilities of such Administrator that are otherwise provided under law.

(c) MISCELLANEOUS ADMINISTRATIVE PROVISIONS.—

(1) ADMINISTRATOR AS MEMBER OF THE BOARD OF TRUSTEES OF THE MEDICARE TRUST FUNDS.—Section 1817(b) and section 1841(b) (42 U.S.C. 1395i(b), 1395t(b)) are each amended by striking "and the Secretary of Health and Human Services, all ex officio," and inserting "the Secretary of Health and Human Services, and the Administrator of the Medicare Benefits Administration, all ex officio,".

(2) INCREASE IN GRADE TO EXECUTIVE LEVEL III FOR THE ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES; LEVEL FOR MEDICARE BENEFITS ADMINISTRATOR.—

(A) IN GENERAL.—Section 5314 of title 5, United States Code, by adding at the end the following:

"Administrator of the Centers for Medicare & Medicaid Services.

"Administrator of the Medicare Benefits Administration.".

(B) CONFORMING AMENDMENT.—Section 5315 of such title is amended by striking "Administrator of the Health Care Financing Administration.".

(C) EFFECTIVE DATE.—The amendments made by this paragraph take effect on January 1, 2004.

TITLE IX—REGULATORY REDUCTION AND CONTRACTING REFORM

Subtitle A—Regulatory Reform

SEC. 901. CONSTRUCTION; DEFINITION OF SUPPLIER.

(a) CONSTRUCTION.—Nothing in this title shall be construed—

(1) to compromise or affect existing legal remedies for addressing fraud or abuse, whether it be criminal prosecution, civil enforcement, or administrative remedies, including under sections 3729 through 3733 of title 31, United States Code (known as the False Claims Act); or

(2) to prevent or impede the Department of Health and Human Services in any way from its ongoing efforts to eliminate waste, fraud, and abuse in the medicare program.

Furthermore, the consolidation of medicare administrative contracting set forth in this Act does not constitute consolidation of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund or reflect any position on that issue.

(b) DEFINITION OF SUPPLIER.—Section 1861 (42 U.S.C. 1395x) is amended by inserting after subsection (c) the following new subsection:

"Supplier

"(d) The term 'supplier' means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.".

SEC. 902. ISSUANCE OF REGULATIONS.

(a) REGULAR TIMELINE FOR PUBLICATION OF FINAL RULES.—

(1) IN GENERAL.—Section 1871(a) (42 U.S.C. 1395hh(a)) is amended by adding at the end the following new paragraph:

"(3)(A) The Secretary, in consultation with the Director of the Office of Management and Budget, shall establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation.

"(B) Such timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but shall not be longer than 3 years except under exceptional circumstances. If the Secretary intends to vary such timeline with respect to the publication of a final regulation, the Secretary shall cause to have published in the Federal Register notice of the different timeline by not later than the timeline previously established with respect to such regulation. Such notice shall include a brief explanation of the justification for such variation.

"(C) In the case of interim final regulations, upon the expiration of the regular timeline established under this paragraph for the publication of a final regulation after opportunity for public comment, the interim final regulation shall not continue in effect unless the Secretary publishes (at the end of the regular timeline and, if applicable, at the end of each succeeding 1-year period) a notice of continuation of the regulation that includes an explanation of why the regular timeline (and any subsequent 1-year extension) was not complied with. If such a notice is published, the regular timeline (or such timeline as previously extended under this paragraph) for publication of the final regulation shall be treated as having been extended for 1 additional year.

"(D) The Secretary shall annually submit to Congress a report that describes the instances in which the Secretary failed to publish a final regulation within the applicable regular timeline under this paragraph and that provides an explanation for such failures.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act. The Secretary shall provide for an appropriate transition to take into account the backlog of previously published interim final regulations.

(b) LIMITATIONS ON NEW MATTER IN FINAL REGULATIONS.—

(1) IN GENERAL.—Section 1871(a) (42 U.S.C. 1395hh(a)), as amended by subsection (a), is amended by adding at the end the following new paragraph:

"(4) If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to final regulations published on or after the date of the enactment of this Act.

SEC. 903. COMPLIANCE WITH CHANGES IN REGULATIONS AND POLICIES.

(a) NO RETROACTIVE APPLICATION OF SUBSTANTIVE CHANGES.—

(1) IN GENERAL.—Section 1871 (42 U.S.C. 1395hh), as amended by section 902(a), is amended by adding at the end the following new subsection:

"(e)(1)(A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this title shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that—

"(i) such retroactive application is necessary to comply with statutory requirements; or

"(ii) failure to apply the change retroactively would be contrary to the public interest.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to substantive changes issued on or after the date of the enactment of this Act.

(b) TIMELINE FOR COMPLIANCE WITH SUBSTANTIVE CHANGES AFTER NOTICE.—

(1) IN GENERAL.—Section 1871(e)(1), as added by subsection (a), is amended by adding at the end the following:

"(B)(i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be, the substantive change.

"(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.

"(C) No action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to compliance actions undertaken on or after the date of the enactment of this Act.

(c) RELIANCE ON GUIDANCE.—

(1) IN GENERAL.—Section 1871(e), as added by subsection (a), is further amended by adding at the end the following new paragraph:

"(2)(A) If—

"(i) a provider of services or supplier follows the written guidance (which may be transmitted electronically) provided by the Secretary or by a medicare contractor (as defined in section 1889(g)) acting within the scope of the contractor's contract authority, with respect to the furnishing of items or services and submission of a claim for benefits for such items or services with respect to such provider or supplier;

"(ii) the Secretary determines that the provider of services or supplier has accurately presented the circumstances relating to such items, services, and claim to the contractor in writing; and

"(iii) the guidance was in error;

the provider of services or supplier shall not be subject to any sanction (including any penalty or requirement for repayment of any amount) if the provider of services or supplier reasonably relied on such guidance.

"(B) Subparagraph (A) shall not be construed as preventing the recoupment or repayment (without any additional penalty) relating to an overpayment insofar as the overpayment was solely the result of a clerical or technical operational error.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act but shall not apply to any sanction for which notice was provided on or before the date of the enactment of this Act.

SEC. 904. REPORTS AND STUDIES RELATING TO REGULATORY REFORM.

(a) GAO STUDY ON ADVISORY OPINION AUTHORITY.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to determine the feasibility and appropriateness of establishing in the Secretary authority to provide legally binding advisory opinions on appropriate interpretation and application of regulations to carry out the medicare program under title XVIII of the Social Security Act. Such study shall examine the appropriate timeframe for issuing such advisory opinions, as well as the need for additional staff and funding to provide such opinions.

(2) REPORT.—The Comptroller General shall submit to Congress a report on the study conducted under paragraph (1) by not later than one year after the date of the enactment of this Act.

(b) REPORT ON LEGAL AND REGULATORY INCONSISTENCIES.—Section 1871 (42 U.S.C. 1395hh), as amended by section 2(a), is amended by adding at the end the following new subsection:

"(f)(1) Not later than 2 years after the date of the enactment of this subsection, and every 2 years thereafter, the Secretary shall submit to Congress a report with respect to the administration of this title and areas of inconsistency or conflict among the various provisions under law and regulation.

"(2) In preparing a report under paragraph (1), the Secretary shall collect—

"(A) information from individuals entitled to benefits under part A or enrolled under part B, or both, providers of services, and suppliers and from the Medicare Beneficiary Ombudsman and the Medicare Provider Ombudsman with respect to such areas of inconsistency and conflict; and

"(B) information from medicare contractors that tracks the nature of written and telephone inquiries.

"(3) A report under paragraph (1) shall include a description of efforts by the Secretary to reduce such inconsistency or conflicts, and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.".

Subtitle B—Contracting Reform

SEC. 911. INCREASED FLEXIBILITY IN MEDICARE ADMINISTRATION.

(a) CONSOLIDATION AND FLEXIBILITY IN MEDICARE ADMINISTRATION.—

(1) IN GENERAL.—Title XVIII is amended by inserting after section 1874 the following new section:

"CONTRACTS WITH MEDICARE ADMINISTRATIVE CONTRACTORS

"SEC. 1874A. (a) AUTHORITY.—

"(1) AUTHORITY TO ENTER INTO CONTRACTS.—The Secretary may enter into contracts with any eligible entity to serve as a medicare administrative contractor with respect to the performance of any or all of the functions described in paragraph (4) or parts of those functions (or, to the extent provided in a contract, to secure performance thereof by other entities).

"(2) ELIGIBILITY OF ENTITIES.—An entity is eligible to enter into a contract with respect to the performance of a particular function described in paragraph (4) only if—

"(A) the entity has demonstrated capability to carry out such function;

"(B) the entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement;

"(C) the entity has sufficient assets to financially support the performance of such function; and

"(D) the entity meets such other requirements as the Secretary may impose.

"(3) MEDICARE ADMINISTRATIVE CONTRACTOR DEFINED.—For purposes of this title and title XI—

"(A) IN GENERAL.—The term 'medicare administrative contractor' means an agency, organization, or other person with a contract under this section.

"(B) APPROPRIATE MEDICARE ADMINISTRATIVE CONTRACTOR.—With respect to the performance of a particular function in relation to an individual entitled to benefits under part A or enrolled under part B, or both, a specific provider of services or supplier (or class of such providers of services or suppliers), the 'appropriate' medicare administrative contractor is the medicare administrative contractor that has a contract under this section with respect to the performance of that function in relation to that individual, provider of services or supplier or class of provider of services or supplier.

"(4) FUNCTIONS DESCRIBED.—The functions referred to in paragraphs (1) and (2) are payment functions, provider services functions, and functions relating to services furnished to individuals entitled to benefits under part A or enrolled under part B, or both, as follows:

"(A) DETERMINATION OF PAYMENT AMOUNTS.—Determining (subject to the provisions of section 1878 and to such review by the Secretary as may be provided for by the contracts) the amount of the payments required pursuant to this title to be made to providers of services, suppliers and individuals.

"(B) MAKING PAYMENTS.—Making payments described in subparagraph (A) (including receipt, disbursement, and accounting for funds in making such payments).

"(C) BENEFICIARY EDUCATION AND ASSISTANCE.—Providing education and outreach to individuals entitled to benefits under part A or enrolled under part B, or both, and providing assistance to those individuals with specific issues, concerns or problems.

"(D) PROVIDER CONSULTATIVE SERVICES.—Providing consultative services to institutions, agencies, and other persons to enable them to establish and maintain fiscal records necessary for purposes of this title and otherwise to qualify as providers of services or suppliers.

"(E) COMMUNICATION WITH PROVIDERS.—Communicating to providers of services and suppliers any information or instructions furnished to the medicare administrative contractor by the Secretary, and facilitating communication between such providers and suppliers and the Secretary.

"(F) PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.—Performing the functions relating to provider education, training, and technical assistance.

"(G) ADDITIONAL FUNCTIONS.—Performing such other functions as are necessary to carry out the purposes of this title.

"(5) RELATIONSHIP TO MIP CONTRACTS.—

"(A) NONDUPLICATION OF DUTIES.—In entering into contracts under this section, the Secretary shall assure that functions of medicare administrative contractors in carrying out activities under parts A and B do not duplicate activities carried out under the Medicare Integrity Program under section 1893. The previous sentence shall not apply with respect to the activity described in section 1893(b)(5) (relating to prior authorization of certain items of durable medical equipment under section 1834(a)(15)).

"(B) CONSTRUCTION.—An entity shall not be treated as a medicare administrative contractor merely by reason of having entered into a contract with the Secretary under section 1893.

"(6) APPLICATION OF FEDERAL ACQUISITION REGULATION.—Except to the extent inconsistent with a specific requirement of this title, the Federal Acquisition Regulation applies to contracts under this title.

"(b) CONTRACTING REQUIREMENTS.—

"(1) USE OF COMPETITIVE PROCEDURES.—

"(A) IN GENERAL.—Except as provided in laws with general applicability to Federal acquisition and procurement or in subparagraph (B), the Secretary shall use competitive procedures when entering into contracts with medicare administrative contractors under this section, taking into account performance quality as well as price and other factors.

"(B) RENEWAL OF CONTRACTS.—The Secretary may renew a contract with a medicare administrative contractor under this section from term to term without regard to section 5 of title 41, United States Code, or any other provision of law requiring competition, if the medicare administrative contractor has met or exceeded the performance requirements applicable with respect to the contract and contractor, except that the Secretary shall provide for the application of competitive procedures under such a contract not less frequently than once every five years.

"(C) TRANSFER OF FUNCTIONS.—The Secretary may transfer functions among medicare administrative contractors consistent with the provisions of this paragraph. The Secretary shall ensure that performance quality is considered in such transfers. The Secretary shall provide public notice (whether in the Federal Register or otherwise) of any such transfer (including a description of the functions so transferred, a description of the providers of services and suppliers affected by such transfer, and contact information for the contractors involved).

"(D) INCENTIVES FOR QUALITY.—The Secretary shall provide incentives for medicare administrative contractors to provide quality service and to promote efficiency.

"(2) COMPLIANCE WITH REQUIREMENTS.—No contract under this section shall be entered into with any medicare administrative contractor unless the Secretary finds that such medicare administrative contractor will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial responsibility, legal authority, quality of services provided, and other matters as the Secretary finds pertinent.

"(3) PERFORMANCE REQUIREMENTS.—

"(A) DEVELOPMENT OF SPECIFIC PERFORMANCE REQUIREMENTS.—In developing contract performance requirements, the Secretary shall develop performance requirements applicable to functions described in subsection (a)(4).

"(B) CONSULTATION.— In developing such requirements, the Secretary may consult with providers of services and suppliers, organizations representing individuals entitled to benefits under part A or enrolled under part B, or both, and organizations and agencies performing functions necessary to carry out the purposes of this section with respect to such performance requirements.

"(C) INCLUSION IN CONTRACTS.—All contractor performance requirements shall be set forth in the contract between the Secretary and the appropriate medicare administrative contractor. Such performance requirements—

"(i) shall reflect the performance requirements developed under subparagraph (A), but may include additional performance requirements;

"(ii) shall be used for evaluating contractor performance under the contract; and

"(iii) shall be consistent with the written statement of work provided under the contract.

"(4) INFORMATION REQUIREMENTS.—The Secretary shall not enter into a contract with a medicare administrative contractor under this section unless the contractor agrees—

"(A) to furnish to the Secretary such timely information and reports as the Secretary may find necessary in performing his functions under this title; and

"(B) to maintain such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of the information and reports under subparagraph (A) and otherwise to carry out the purposes of this title.

"(5) SURETY BOND.—A contract with a medicare administrative contractor under this section may require the medicare administrative contractor, and any of its officers or employees certifying payments or disbursing funds pursuant to the contract, or otherwise participating in carrying out the contract, to give surety bond to the United States in such amount as the Secretary may deem appropriate.

"(c) TERMS AND CONDITIONS.—

"(1) IN GENERAL.—A contract with any medicare administrative contractor under this section may contain such terms and conditions as the Secretary finds necessary or appropriate and may provide for advances of funds to the medicare administrative contractor for the making of payments by it under subsection (a)(4)(B).

"(2) PROHIBITION ON MANDATES FOR CERTAIN DATA COLLECTION.—The Secretary may not require, as a condition of entering into, or renewing, a contract under this section, that the medicare administrative contractor match data obtained other than in its activities under this title with data used in the administration of this title for purposes of identifying situations in which the provisions of section 1862(b) may apply.

"(d) LIMITATION ON LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTORS AND CERTAIN OFFICERS.—

"(1) CERTIFYING OFFICER.—No individual designated pursuant to a contract under this section as a certifying officer shall, in the absence of the reckless disregard of the individual's obligations or the intent by that individual to defraud the United States, be liable with respect to any payments certified by the individual under this section.

"(2) DISBURSING OFFICER.—No disbursing officer shall, in the absence of the reckless disregard of the officer's obligations or the intent by that officer to defraud the United States, be liable with respect to any payment by such officer under this section if it was based upon an authorization (which meets the applicable requirements for such internal controls established by the Comptroller General) of a certifying officer designated as provided in paragraph (1) of this subsection.

"(3) LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTOR.—

"(A) IN GENERAL.—No medicare administrative contractor shall be liable to the United States for a payment by a certifying or disbursing officer unless, in connection with such payment, the medicare administrative contractor acted with reckless disregard of its obligations under its medicare administrative contract or with intent to defraud the United States.

"(B) RELATIONSHIP TO FALSE CLAIMS ACT.—Nothing in this subsection shall be construed to limit liability for conduct that would constitute a violation of sections 3729 through 3731 of title 31, United States Code (commonly known as the 'False Claims Act').

"(4) INDEMNIFICATION BY SECRETARY.—

"(A) IN GENERAL.—Subject to subparagraphs (B) and (D), in the case of a medicare administrative contractor (or a person who is a director, officer, or employee of such a contractor or who is engaged by the contractor to participate directly in the claims administration process) who is made a party to any judicial or administrative proceeding arising from or relating directly to the claims administration process under this title, the Secretary may, to the extent the Secretary determines to be appropriate and as specified in the contract with the contractor, indemnify the contractor and such persons.

"(B) CONDITIONS.—The Secretary may not provide indemnification under subparagraph (A) insofar as the liability for such costs arises directly from conduct that is determined by the judicial proceeding or by the Secretary to be criminal in nature, fraudulent, or grossly negligent. If indemnification is provided by the Secretary with respect to a contractor before a deter-

mination that such costs arose directly from such conduct, the contractor shall reimburse the Secretary for costs of indemnification.

"(C) SCOPE OF INDEMNIFICATION.—Indemnification by the Secretary under subparagraph (A) may include payment of judgments, settlements (subject to subparagraph (D)), awards, and costs (including reasonable legal expenses).

"(D) WRITTEN APPROVAL FOR SETTLEMENTS.—A contractor or other person described in subparagraph (A) may not propose to negotiate a settlement or compromise of a proceeding described in such subparagraph without the prior written approval of the Secretary to negotiate such settlement or compromise. Any indemnification under subparagraph (A) with respect to amounts paid under a settlement or compromise of a proceeding described in such subparagraph are conditioned upon prior written approval by the Secretary of the final settlement or compromise.

"(E) CONSTRUCTION.—Nothing in this paragraph shall be construed—

"(i) to change any common law immunity that may be available to a medicare administrative contractor or person described in subparagraph (A); or

"(ii) to permit the payment of costs not otherwise allowable, reasonable, or allocable under the Federal Acquisition Regulations.".

(2) CONSIDERATION OF INCORPORATION OF CURRENT LAW STANDARDS.—In developing contract performance requirements under section 1874A(b) of the Social Security Act, as inserted by paragraph (1), the Secretary shall consider inclusion of the performance standards described in sections 1816(f)(2) of such Act (relating to timely processing of reconsiderations and applications for exemptions) and section 1842(b)(2)(B) of such Act (relating to timely review of determinations and fair hearing requests), as such sections were in effect before the date of the enactment of this Act.

(b) CONFORMING AMENDMENTS TO SECTION 1816 (RELATING TO FISCAL INTERMEDIARIES).—Section 1816 (42 U.S.C. 1395h) is amended as follows:

(1) The heading is amended to read as follows:

"PROVISIONS RELATING TO THE ADMINISTRATION OF PART A".

(2) Subsection (a) is amended to read as follows:

"(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.".

(3) Subsection (b) is repealed.

(4) Subsection (c) is amended—

(A) by striking paragraph (1); and

(B) in each of paragraphs (2)(A) and (3)(A), by striking "agreement under this section" and inserting "contract under section 1874A that provides for making payments under this part".

(5) Subsections (d) through (i) are repealed.

(6) Subsections (j) and (k) are each amended—

(A) by striking "An agreement with an agency or organization under this section" and inserting "A contract with a medicare administrative contractor under section 1874A with respect to the administration of this part"; and

(B) by striking "such agency or organization" and inserting "such medicare administrative contractor" each place it appears.

(7) Subsection (l) is repealed.

(c) CONFORMING AMENDMENTS TO SECTION 1842 (RELATING TO CARRIERS).—Section 1842 (42 U.S.C. 1395u) is amended as follows:

(1) The heading is amended to read as follows:

"PROVISIONS RELATING TO THE ADMINISTRATION OF PART B".

(2) Subsection (a) is amended to read as follows:

"(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.".

(3) Subsection (b) is amended—

(A) by striking paragraph (1);

(B) in paragraph (2)—

(i) by striking subparagraphs (A) and (B);

(ii) in subparagraph (C), by striking "carriers" and inserting "medicare administrative contractors"; and

(iii) by striking subparagraphs (D) and (E);

(C) in paragraph (3)—

(i) in the matter before subparagraph (A), by striking "Each such contract shall provide that the carrier" and inserting "The Secretary";

(ii) by striking "will" the first place it appears in each of subparagraphs (A), (B), (F), (G), (H), and (L) and inserting "shall";

(iii) in subparagraph (B), in the matter before clause (i), by striking "to the policyholders and subscribers of the carrier" and inserting "to the policyholders and subscribers of the medicare administrative contractor";

(iv) by striking subparagraphs (C), (D), and (E);

(v) in subparagraph (H)—

(I) by striking "if it makes determinations or payments with respect to physicians' services," in the matter preceding clause (i); and

(II) by striking "carrier" and inserting "medicare administrative contractor" in clause (i);

(vi) by striking subparagraph (I);

(vii) in subparagraph (L), by striking the semicolon and inserting a period;

(viii) in the first sentence, after subparagraph (L), by striking "and shall contain" and all that follows through the period; and

(ix) in the seventh sentence, by inserting "medicare administrative contractor," after "carrier,"; and

(D) by striking paragraph (5);

(E) in paragraph (6)(D)(iv), by striking "carrier" and inserting "medicare administrative contractor"; and

(F) in paragraph (7), by striking "the carrier" and inserting "the Secretary" each place it appears.

(4) Subsection (c) is amended—

(A) by striking paragraph (1);

(B) in paragraph (2)(A), by striking "contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B)," and inserting "contract under section 1874A that provides for making payments under this part";

(C) in paragraph (3)(A), by striking "subsection (a)(1)(B)" and inserting "section 1874A(a)(3)(B)";

(D) in paragraph (4), in the matter preceding subparagraph (A), by striking "carrier" and inserting "medicare administrative contractor"; and

(E) by striking paragraphs (5) and (6).

(5) Subsections (d), (e), and (f) are repealed.

(6) Subsection (g) is amended by striking "carrier or carriers" and inserting "medicare administrative contractor or contractors".

(7) Subsection (h) is amended—

(A) in paragraph (2)—

(i) by striking "Each carrier having an agreement with the Secretary under subsection (a)" and inserting "The Secretary"; and

(ii) by striking "Each such carrier" and inserting "The Secretary";

(B) in paragraph (3)(A)—

(i) by striking "a carrier having an agreement with the Secretary under subsection (a)" and inserting "medicare administrative contractor having a contract under section 1874A that provides for making payments under this part"; and

(ii) by striking "such carrier" and inserting "such contractor";

(C) in paragraph (3)(B)—

(i) by striking "a carrier" and inserting "a medicare administrative contractor" each place it appears; and

(ii) by striking "the carrier" and inserting "the contractor" each place it appears; and

(D) in paragraphs (5)(A) and (5)(B)(iii), by striking "carriers" and inserting "medicare administrative contractors" each place it appears.

(8) Subsection (l) is amended—

(A) in paragraph (1)(A)(iii), by striking "carrier" and inserting "medicare administrative contractor"; and

(B) in paragraph (2), by striking "carrier" and inserting "medicare administrative contractor".

(9) Subsection (p)(3)(A) is amended by striking "carrier" and inserting "medicare administrative contractor".

(10) Subsection (q)(1)(A) is amended by striking "carrier".

(d) EFFECTIVE DATE; TRANSITION RULE.—

(1) EFFECTIVE DATE.—

(A) IN GENERAL.—Except as otherwise provided in this subsection, the amendments made by this section shall take effect on October 1, 2005, and the Secretary is authorized to take such steps before such date as may be necessary to implement such amendments on a timely basis.

(B) CONSTRUCTION FOR CURRENT CONTRACTS.—Such amendments shall not apply to contracts in effect before the date specified under subparagraph (A) that continue to retain the terms and conditions in effect on such date (except as otherwise provided under this Act, other than under this section) until such date as the contract is let out for competitive bidding under such amendments.

(C) DEADLINE FOR COMPETITIVE BIDDING.—The Secretary shall provide for the letting by competitive bidding of all contracts for functions of medicare administrative contractors for annual contract periods that begin on or after October 1, 2010.

(D) WAIVER OF PROVIDER NOMINATION PROVISIONS DURING TRANSITION.—During the period beginning on the date of the enactment of this Act and before the date specified under subparagraph (A), the Secretary may enter into new agreements under section 1816 of the Social Security Act (42 U.S.C. 1395h) without regard to any of the provider nomination provisions of such section.

(2) GENERAL TRANSITION RULES.—The Secretary shall take such steps, consistent with paragraph (1)(B) and (1)(C), as are necessary to provide for an appropriate transition from contracts under section 1816 and section 1842 of the Social Security Act (42 U.S.C. 1395h, 1395u) to contracts under section 1874A, as added by subsection (a)(1).

(3) AUTHORIZING CONTINUATION OF MIP FUNCTIONS UNDER CURRENT CONTRACTS AND AGREEMENTS AND UNDER ROLLOVER CONTRACTS.—The provisions contained in the exception in section 1893(d)(2) of the Social Security Act (42 U.S.C. 1395ddd(d)(2)) shall continue to apply notwithstanding the amendments made by this section, and any reference in such provisions to an agreement or contract shall be deemed to include a contract under section 1874A of such Act, as inserted by subsection (a)(1), that continues the activities referred to in such provisions.

(e) REFERENCES.—On and after the effective date provided under subsection (d)(1), any reference to a fiscal intermediary or carrier under title XI or XVIII of the Social Security Act (or any regulation, manual instruction, interpretative rule, statement of policy, or guideline issued to carry out such titles) shall be deemed a reference to a medicare administrative contractor (as provided under section 1874A of the Social Security Act).

(f) REPORTS ON IMPLEMENTATION.—

(1) PLAN FOR IMPLEMENTATION.—By not later than October 1, 2004, the Secretary shall submit a report to Congress and the Comptroller General of the United States that describes the plan for implementation of the amendments made by this section. The Comptroller General shall conduct an evaluation of such plan and shall submit to Congress, not later than 6 months after the date the report is received, a report on such evaluation and shall include in such report such recommendations as the Comptroller General deems appropriate.

(2) STATUS OF IMPLEMENTATION.—The Secretary shall submit a report to Congress not later than October 1, 2008, that describes the status of implementation of such amendments and that includes a description of the following:

(A) The number of contracts that have been competitively bid as of such date.

(B) The distribution of functions among contracts and contractors.

(C) A timeline for complete transition to full competition.

(D) A detailed description of how the Secretary has modified oversight and management of medicare contractors to adapt to full competition.

SEC. 912. REQUIREMENTS FOR INFORMATION SECURITY FOR MEDICARE ADMINISTRATIVE CONTRACTORS.

(a) IN GENERAL.—Section 1874A, as added by section 911(a)(1), is amended by adding at the end the following new subsection:

"(e) REQUIREMENTS FOR INFORMATION SECURITY.—

"(1) DEVELOPMENT OF INFORMATION SECURITY PROGRAM.—A medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall implement a contractor-wide information security program to provide information security for the operation and assets of the contractor with respect to such functions under this title. An information security program under this paragraph shall meet the requirements for information security programs imposed on Federal agencies under paragraphs (1) through (8) of section 3544(b)

of title 44, United States Code (other than the requirements under paragraphs (2)(D)(i), (5)(A), and (5)(B) of such section).

"(2) INDEPENDENT AUDITS.—

"(A) PERFORMANCE OF ANNUAL EVALUATIONS.—Each year a medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall undergo an evaluation of the information security of the contractor with respect to such functions under this title. The evaluation shall—

"(i) be performed by an entity that meets such requirements for independence as the Inspector General of the Department of Health and Human Services may establish; and

"(ii) test the effectiveness of information security control techniques of an appropriate subset of the contractor's information systems (as defined in section 3502(8) of title 44, United States Code) relating to such functions under this title and an assessment of compliance with the requirements of this subsection and related information security policies, procedures, standards and guidelines, including policies and procedures as may be prescribed by the Director of the Office of Management and Budget and applicable information security standards promulgated under section 11331 of title 40, United States Code.

"(B) DEADLINE FOR INITIAL EVALUATION.—

"(i) NEW CONTRACTORS.—In the case of a medicare administrative contractor covered by this subsection that has not previously performed the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) as a fiscal intermediary or carrier under section 1816 or 1842, the first independent evaluation conducted pursuant subparagraph (A) shall be completed prior to commencing such functions.

"(ii) OTHER CONTRACTORS.—In the case of a medicare administrative contractor covered by this subsection that is not described in clause (i), the first independent evaluation conducted pursuant subparagraph (A) shall be completed within 1 year after the date the contractor commences functions referred to in clause (i) under this section.

"(C) REPORTS ON EVALUATIONS.—

"(i) TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.—The results of independent evaluations under subparagraph (A) shall be submitted promptly to the Inspector General of the Department of Health and Human Services and to the Secretary.

"(ii) TO CONGRESS.—The Inspector General of Department of Health and Human Services shall submit to Congress annual reports on the results of such evaluations, including assessments of the scope and sufficiency of such evaluations.

"(iii) AGENCY REPORTING.—The Secretary shall address the results of such evaluations in reports required under section 3544(c) of title 44, United States Code.".

(b) APPLICATION OF REQUIREMENTS TO FISCAL INTERMEDIARIES AND CARRIERS.—

(1) IN GENERAL.—The provisions of section 1874A(e)(2) of the Social Security Act (other than subparagraph (B)), as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(2) DEADLINE FOR INITIAL EVALUATION.—In the case of such a fiscal intermediary or carrier with an agreement or contract under such respective section in effect as of the date of the enactment of this Act, the first evaluation under section 1874A(e)(2)(A) of the Social Security Act (as added by subsection (a)), pursuant to paragraph (1), shall be completed (and a report on the evaluation submitted to the Secretary) by not later than 1 year after such date.

Subtitle C—Education and Outreach

SEC. 921. PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.

(a) COORDINATION OF EDUCATION FUNDING.—

(1) IN GENERAL.—Title XVIII is amended by inserting after section 1888 the following new section:

"PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

"SEC. 1889. (a) COORDINATION OF EDUCATION FUNDING.—The Secretary shall coordinate the educational activities provided through medicare contractors (as defined in subsection (g), including under section 1893) in order to maximize the effectiveness of Federal education efforts for providers of services and suppliers.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act.

(3) REPORT.—Not later than October 1, 2004, the Secretary shall submit to Congress a report that includes a description and evaluation of the steps taken to coordinate the funding of provider education under section 1889(a) of the Social Security Act, as added by paragraph (1).

(b) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE.—

(1) IN GENERAL.—Section 1874A, as added by section 911(a)(1) and as amended by section 912(a), is amended by adding at the end the following new subsection:

"(f) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE IN PROVIDER EDUCATION AND OUTREACH.—The Secretary shall use specific claims payment error rates or similar methodology of medicare administrative contractors in the processing or reviewing of medicare claims in order to give such contractors an incentive to implement effective education and outreach programs for providers of services and suppliers.".

(2) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(f) of the Social Security Act, as added by paragraph (1), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(3) GAO REPORT ON ADEQUACY OF METHODOLOGY.—Not later than October 1, 2004, the Comptroller General of the United States shall submit to Congress and to the Secretary a report on the adequacy of the methodology under section 1874A(f) of the Social Security Act, as added by paragraph (1), and shall include in the report such recommendations as the Comptroller General determines appropriate with respect to the methodology.

(4) REPORT ON USE OF METHODOLOGY IN ASSESSING CONTRACTOR PERFORMANCE.—Not later than October 1, 2004, the Secretary shall submit to Congress a report that describes how the Secretary intends to use such methodology in assessing medicare contractor performance in implementing effective education and outreach programs, including whether to use such methodology as a basis for performance bonuses. The report shall include an analysis of the sources of identified errors and potential changes in systems of contractors and rules of the Secretary that could reduce claims error rates.

(c) PROVISION OF ACCESS TO AND PROMPT RESPONSES FROM MEDICARE ADMINISTRATIVE CONTRACTORS.—

(1) IN GENERAL.—Section 1874A, as added by section 911(a)(1) and as amended by section 912(a) and subsection (b), is further amended by adding at the end the following new subsection:

"(g) COMMUNICATIONS WITH BENEFICIARIES, PROVIDERS OF SERVICES AND SUPPLIERS.—

"(1) COMMUNICATION STRATEGY.—The Secretary shall develop a strategy for communications with individuals entitled to benefits under part A or enrolled under part B, or both, and with providers of services and suppliers under this title.

"(2) RESPONSE TO WRITTEN INQUIRIES.—Each medicare administrative contractor shall, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, provide general written responses (which may be through electronic transmission) in a clear, concise, and accurate manner to inquiries of providers of services, suppliers and individuals entitled to benefits under part A or enrolled under part B, or both, concerning the programs under this title within 45 business days of the date of receipt of such inquiries.

"(3) RESPONSE TO TOLL-FREE LINES.—The Secretary shall ensure that each medicare administrative contractor shall provide, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, a toll-free telephone number at which such individuals, providers of services

and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate information under this title.

"(4) MONITORING OF CONTRACTOR RESPONSES.—

"(A) IN GENERAL.—Each medicare administrative contractor shall, consistent with standards developed by the Secretary under subparagraph (B)—

"(i) maintain a system for identifying who provides the information referred to in paragraphs (2) and (3); and

"(ii) monitor the accuracy, consistency, and timeliness of the information so provided.

"(B) DEVELOPMENT OF STANDARDS.—

"(i) IN GENERAL.—The Secretary shall establish and make public standards to monitor the accuracy, consistency, and timeliness of the information provided in response to written and telephone inquiries under this subsection. Such standards shall be consistent with the performance requirements established under subsection (b)(3).

"(ii) EVALUATION.—In conducting evaluations of individual medicare administrative contractors, the Secretary shall take into account the results of the monitoring conducted under subparagraph (A) taking into account as performance requirements the standards established under clause (i). The Secretary shall, in consultation with organizations representing providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, establish standards relating to the accuracy, consistency, and timeliness of the information so provided.

"(C) DIRECT MONITORING.—Nothing in this paragraph shall be construed as preventing the Secretary from directly monitoring the accuracy, consistency, and timeliness of the information so provided.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect October 1, 2004.

(3) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(g) of the Social Security Act, as added by paragraph (1), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(d) IMPROVED PROVIDER EDUCATION AND TRAINING.—

(1) IN GENERAL.—Section 1889, as added by subsection (a), is amended by adding at the end the following new subsections:

"(b) ENHANCED EDUCATION AND TRAINING.—

"(1) ADDITIONAL RESOURCES.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) $25,000,000 for each of fiscal years 2005 and 2006 and such sums as may be necessary for succeeding fiscal years.

"(2) USE.—The funds made available under paragraph (1) shall be used to increase the conduct by medicare contractors of education and training of providers of services and suppliers regarding billing, coding, and other appropriate items and may also be used to improve the accuracy, consistency, and timeliness of contractor responses.

"(c) TAILORING EDUCATION AND TRAINING ACTIVITIES FOR SMALL PROVIDERS OR SUPPLIERS.—

"(1) IN GENERAL.—Insofar as a medicare contractor conducts education and training activities, it shall tailor such activities to meet the special needs of small providers of services or suppliers (as defined in paragraph (2)).

"(2) SMALL PROVIDER OF SERVICES OR SUPPLIER.—In this subsection, the term 'small provider of services or supplier' means—

"(A) a provider of services with fewer than 25 full-time-equivalent employees; or

"(B) a supplier with fewer than 10 full-time-equivalent employees.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on October 1, 2004.

(e) REQUIREMENT TO MAINTAIN INTERNET SITES.—

(1) IN GENERAL.—Section 1889, as added by subsection (a) and as amended by subsection (d), is further amended by adding at the end the following new subsection:

"(d) INTERNET SITES; FAQS.—The Secretary, and each medicare contractor insofar as it provides services (including claims processing) for providers of services or suppliers, shall maintain an Internet site which—

"(1) provides answers in an easily accessible format to frequently asked questions, and

"(2) includes other published materials of the contractor,

that relate to providers of services and suppliers under the programs under this title (and title XI insofar as it relates to such programs).".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on October 1, 2004.

(f) ADDITIONAL PROVIDER EDUCATION PROVISIONS.—

(1) IN GENERAL.—Section 1889, as added by subsection (a) and as amended by subsections (d) and (e), is further amended by adding at the end the following new subsections:

"(e) ENCOURAGEMENT OF PARTICIPATION IN EDUCATION PROGRAM ACTIVITIES.—A medicare contractor may not use a record of attendance at (or failure to attend) educational activities or other information gathered during an educational program conducted under this section or otherwise by the Secretary to select or track providers of services or suppliers for the purpose of conducting any type of audit or prepayment review.

"(f) CONSTRUCTION.—Nothing in this section or section 1893(g) shall be construed as providing for disclosure by a medicare contractor of information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits.

"(g) DEFINITIONS.—For purposes of this section, the term 'medicare contractor' includes the following:

"(1) A medicare administrative contractor with a contract under section 1874A, including a fiscal intermediary with a contract under section 1816 and a carrier with a contract under section 1842.

"(2) An eligible entity with a contract under section 1893.

Such term does not include, with respect to activities of a specific provider of services or supplier an entity that has no authority under this title or title IX with respect to such activities and such provider of services or supplier.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act.

SEC. 922. SMALL PROVIDER TECHNICAL ASSISTANCE DEMONSTRATION PROGRAM.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary shall establish a demonstration program (in this section referred to as the "demonstration program") under which technical assistance described in paragraph (2) is made available, upon request and on a voluntary basis, to small providers of services or suppliers in order to improve compliance with the applicable requirements of the programs under medicare program under title XVIII of the Social Security Act (including provisions of title XI of such Act insofar as they relate to such title and are not administered by the Office of the Inspector General of the Department of Health and Human Services).

(2) FORMS OF TECHNICAL ASSISTANCE.—The technical assistance described in this paragraph is—

(A) evaluation and recommendations regarding billing and related systems; and

(B) information and assistance regarding policies and procedures under the medicare program, including coding and reimbursement.

(3) SMALL PROVIDERS OF SERVICES OR SUPPLIERS.—In this section, the term "small providers of services or suppliers" means—

(A) a provider of services with fewer than 25 full-time-equivalent employees; or

(B) a supplier with fewer than 10 full-time-equivalent employees.

(b) QUALIFICATION OF CONTRACTORS.—In conducting the demonstration program, the Secretary shall enter into contracts with qualified organizations (such as peer review organizations or entities described in section 1889(g)(2) of the Social Security Act, as inserted by section 5(f)(1)) with appropriate expertise with billing systems of the full range of providers of services and suppliers to provide the technical assistance. In awarding such contracts, the Secretary shall consider any prior investigations of the entity's work by the Inspector General of Department of Health and Human Services or the Comptroller General of the United States.

(c) DESCRIPTION OF TECHNICAL ASSISTANCE.—The technical assistance provided under the demonstration program shall include a direct and in-person examination of billing systems and internal controls of small providers of services or suppliers to determine program compliance and to suggest more efficient or effective means of achieving such compliance.

(d) AVOIDANCE OF RECOVERY ACTIONS FOR PROBLEMS IDENTIFIED AS CORRECTED.—The Secretary shall provide that, absent evidence of fraud and notwithstanding any other provision of law, any errors found in a compliance review for a small provider of services or supplier that participates in the demonstration program shall not be subject to recovery action if the technical assistance personnel under the program determine that—

(1) the problem that is the subject of the compliance review has been corrected to their satisfaction within 30 days of the date of the visit by such personnel to the small provider of services or supplier; and

(2) such problem remains corrected for such period as is appropriate.

The previous sentence applies only to claims filed as part of the demonstration program and lasts only for the duration of such program and only as long as the small provider of services or supplier is a participant in such program.

(e) GAO EVALUATION.—Not later than 2 years after the date of the date the demonstration program is first implemented, the Comptroller General, in consultation with the Inspector General of the Department of Health and Human Services, shall conduct an evaluation of the demonstration program. The evaluation shall include a determination of whether claims error rates are reduced for small providers of services or suppliers who participated in the program and the extent of improper payments made as a result of the demonstration program. The Comptroller General shall submit a report to the Secretary and the Congress on such evaluation and shall include in such report recommendations regarding the continuation or extension of the demonstration program.

(f) FINANCIAL PARTICIPATION BY PROVIDERS.—The provision of technical assistance to a small provider of services or supplier under the demonstration program is conditioned upon the small provider of services or supplier paying an amount estimated (and disclosed in advance of a provider's or supplier's participation in the program) to be equal to 25 percent of the cost of the technical assistance.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to carry out the demonstration program—

(1) for fiscal year 2005, $1,000,000, and

(2) for fiscal year 2006, $6,000,000.

SEC. 923. MEDICARE PROVIDER OMBUDSMAN; MEDICARE BENEFICIARY OMBUDSMAN.

(a) MEDICARE PROVIDER OMBUDSMAN.—Section 1868 (42 U.S.C. 1395ee) is amended—

(1) by adding at the end of the heading the following: "; MEDICARE PROVIDER OMBUDSMAN";

(2) by inserting "PRACTICING PHYSICIANS ADVISORY COUNCIL.—(1)" after "(a)";

(3) in paragraph (1), as so redesignated under paragraph (2), by striking "in this section" and inserting "in this subsection";

(4) by redesignating subsections (b) and (c) as paragraphs (2) and (3), respectively; and

(5) by adding at the end the following new subsection:

"(b) MEDICARE PROVIDER OMBUDSMAN.—The Secretary shall appoint within the Department of Health and Human Services a Medicare Provider Ombudsman. The Ombudsman shall—

"(1) provide assistance, on a confidential basis, to providers of services and suppliers with respect to complaints, grievances, and requests for information concerning the programs under this title (including provisions of title XI insofar as they relate to this title and are not administered by the Office of the Inspector General of the Department of Health and Human Services) and in the resolution of unclear or conflicting guidance given by the Secretary and medicare contractors to such providers of services and suppliers regarding such programs and provisions and requirements under this title and such provisions; and

"(2) submit recommendations to the Secretary for improvement in the administration of this title and such provisions, including—

"(A) recommendations to respond to recurring patterns of confusion in this title and such provisions (including recommendations regarding suspending imposition of sanctions where there is widespread confusion in program administration), and

"(B) recommendations to provide for an appropriate and consistent response (including not providing for audits) in cases of self-identified overpayments by providers of services and suppliers.

The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.".

(b) MEDICARE BENEFICIARY OMBUDSMAN.—Title XVIII, as previously amended, is amended by inserting after section 1809 the following new section:

"MEDICARE BENEFICIARY OMBUDSMAN

"SEC. 1810. (a) IN GENERAL.—The Secretary shall appoint within the Department of Health and Human Services a Medicare Beneficiary Ombudsman who shall have expertise and experience in the fields of health care and education of (and assistance to) individuals entitled to benefits under this title.

"(b) DUTIES.—The Medicare Beneficiary Ombudsman shall—

"(1) receive complaints, grievances, and requests for information submitted by individuals entitled to benefits under part A or enrolled under part B, or both, with respect to any aspect of the medicare program;

"(2) provide assistance with respect to complaints, grievances, and requests referred to in paragraph (1), including—

"(A) assistance in collecting relevant information for such individuals, to seek an appeal of a decision or determination made by a fiscal intermediary, carrier, Medicare+Choice organization, or the Secretary;

"(B) assistance to such individuals with any problems arising from disenrollment from a Medicare+Choice plan under part C; and

"(C) assistance to such individuals in presenting information under section 1860D–2(b)(4)(D)(v); and

"(3) submit annual reports to Congress and the Secretary that describe the activities of the Office and that include such recommendations for improvement in the administration of this title as the Ombudsman determines appropriate.

The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.

"(c) WORKING WITH HEALTH INSURANCE COUNSELING PROGRAMS.—To the extent possible, the Ombudsman shall work with health insurance counseling programs (receiving funding under section 4360 of Omnibus Budget Reconciliation Act of 1990) to facilitate the provision of information to individuals entitled to benefits under part A or enrolled under part B, or both regarding Medicare+Choice plans and changes to those plans. Nothing in this subsection shall preclude further collaboration between the Ombudsman and such programs.".

(c) DEADLINE FOR APPOINTMENT.—The Secretary shall appoint the Medicare Provider Ombudsman and the Medicare Beneficiary Ombudsman, under the amendments made by subsections (a) and (b), respectively, by not later than 1 year after the date of the enactment of this Act.

(d) FUNDING.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to carry out the provisions of subsection (b) of section 1868 of the Social Security Act (relating to the Medicare Provider Ombudsman), as added by subsection (a)(5) and section 1807 of such Act (relating to the Medicare Beneficiary Ombudsman), as added by subsection (b), such sums as are necessary for fiscal year 2004 and each succeeding fiscal year.

(e) USE OF CENTRAL, TOLL-FREE NUMBER (1–800–MEDICARE).—

(1) PHONE TRIAGE SYSTEM; LISTING IN MEDICARE HANDBOOK INSTEAD OF OTHER TOLL-FREE NUMBERS.—Section 1804(b) (42 U.S.C. 1395b–2(b)) is amended by adding at the end the following: "The Secretary shall provide, through the toll-free number 1–800–MEDICARE, for a means by which individuals seeking information about, or assistance with, such programs who phone such toll-free number are transferred (without charge) to appropriate entities for the provision of such information or assistance. Such toll-free number shall be the toll-free number listed for general information and assistance in the annual notice under subsection (a) instead of the listing of numbers of individual contractors.".

(2) MONITORING ACCURACY.—

(A) STUDY.—The Comptroller General of the United States shall conduct a study to monitor the accuracy and consistency of information provided to individuals entitled to benefits under part A or enrolled under part B, or both, through the toll-free number 1–800–MEDICARE, including an assessment of whether the information provided is sufficient to answer questions of such individuals. In conducting the study, the Comptroller General shall examine the education and training of the individuals providing information through such number.

(B) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subparagraph (A).

SEC. 924. BENEFICIARY OUTREACH DEMONSTRATION PROGRAM.

(a) IN GENERAL.—The Secretary shall establish a demonstration program (in this section referred to as the "demonstration program") under which medicare specialists employed by the Department of Health and Human Services provide advice and assistance to individuals entitled to benefits under part A of title XVIII of the Social Security Act, or enrolled under part B of such title, or both, regarding the medicare program at the location of existing local offices of the Social Security Administration.

(b) LOCATIONS.—

(1) IN GENERAL.—The demonstration program shall be conducted in at least 6 offices or areas. Subject to paragraph (2), in selecting such offices and areas, the Secretary shall provide preference for offices with a high volume of visits by individuals referred to in subsection (a).

(2) ASSISTANCE FOR RURAL BENEFICIARIES.—The Secretary shall provide for the selection of at least 2 rural areas to participate in the demonstration program. In conducting the demonstration program in such rural areas, the Secretary shall provide for medicare specialists to travel among local offices in a rural area on a scheduled basis.

(c) DURATION.—The demonstration program shall be conducted over a 3-year period.

(d) EVALUATION AND REPORT.—

(1) EVALUATION.—The Secretary shall provide for an evaluation of the demonstration program. Such evaluation shall include an analysis of—

(A) utilization of, and satisfaction of those individuals referred to in subsection (a) with, the assistance provided under the program; and

(B) the cost-effectiveness of providing beneficiary assistance through outstationing medicare specialists at local offices of the Social Security Administration.

(2) REPORT.—The Secretary shall submit to Congress a report on such evaluation and shall include in such report recommendations regarding the feasibility of permanently out-stationing medicare specialists at local offices of the Social Security Administration.

SEC. 925. INCLUSION OF ADDITIONAL INFORMATION IN NOTICES TO BENEFICIARIES ABOUT SKILLED NURSING FACILITY BENEFITS.

(a) IN GENERAL.—The Secretary shall provide that in medicare beneficiary notices provided (under section 1806(a) of the Social Security Act, 42 U.S.C. 1395b–7(a)) with respect to the provision of post-hospital extended care services under part A of title XVIII of the Social Security Act, there shall be included information on the number of days of coverage of such services remaining under such part for the medicare beneficiary and spell of illness involved.

(b) EFFECTIVE DATE.—Subsection (a) shall apply to notices provided during calendar quarters beginning more than 6 months after the date of the enactment of this Act.

SEC. 926. INFORMATION ON MEDICARE-CERTIFIED SKILLED NURSING FACILITIES IN HOSPITAL DISCHARGE PLANS.

(a) AVAILABILITY OF DATA.—The Secretary shall publicly provide information that enables hospital discharge planners, medicare beneficiaries, and the public to identify skilled nursing facilities that are participating in the medicare program.

(b) INCLUSION OF INFORMATION IN CERTAIN HOSPITAL DISCHARGE PLANS.—

(1) IN GENERAL.—Section 1861(ee)(2)(D) (42 U.S.C. 1395x(ee)(2)(D)) is amended—

(A) by striking "hospice services" and inserting "hospice care and post-hospital extended care services"; and

(B) by inserting before the period at the end the following: "and, in the case of individuals who are likely to need post-hospital extended care services, the availability of such services through facilities that participate in the program under this title and that serve the area in which the patient resides".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to discharge plans made on or after such date as the Secretary shall specify, but not later than 6 months after the date the Secretary provides for availability of information under subsection (a).

Subtitle D—Appeals and Recovery

SEC. 931. TRANSFER OF RESPONSIBILITY FOR MEDICARE APPEALS.

(a) TRANSITION PLAN.—

(1) IN GENERAL.—Not later than October 1, 2004, the Commissioner of Social Security and the Secretary shall develop and transmit to Congress and the Comptroller General of the United States a plan under which the functions of administrative law judges responsible for hearing cases under title XVIII of the Social Security Act (and related provisions in title XI of such Act) are transferred from the responsibility of the Commissioner and the Social Security Administration to the Secretary and the Department of Health and Human Services.

(2) GAO EVALUATION.—The Comptroller General of the United States shall evaluate the plan and, not later than the date that is 6 months after the date on which the plan is received by the Comptroller General, shall submit to Congress a report on such evaluation.

(b) TRANSFER OF ADJUDICATION AUTHORITY.—

(1) IN GENERAL.—Not earlier than July 1, 2005, and not later than October 1, 2005, the Commissioner of Social Security and the Secretary shall implement the transition plan under subsection (a) and transfer the administrative law judge functions described in such subsection from the Social Security Administration to the Secretary.

(2) ASSURING INDEPENDENCE OF JUDGES.—The Secretary shall assure the independence of administrative law judges performing the administrative law judge functions transferred under paragraph (1) from the Centers for Medicare & Medicaid Services and its contractors. In order to assure such independence, the Secretary shall place such judges in an administrative office that is organizationally and functionally separate from such Centers. Such judges shall report to, and be under the general supervision of, the Secretary, but shall not report to, or be subject to supervision by, another other officer of the Department.

(3) GEOGRAPHIC DISTRIBUTION.—The Secretary shall provide for an appropriate geographic distribution of administrative law judges performing the administrative law judge functions transferred under paragraph (1) throughout the United States to ensure timely access to such judges.

(4) HIRING AUTHORITY.—Subject to the amounts provided in advance in appropriations Act, the Secretary shall have authority to hire administrative law judges to hear such cases, giving priority to those judges with prior experience in handling medicare appeals and in a manner consistent with paragraph (3), and to hire support staff for such judges.

(5) FINANCING.—Amounts payable under law to the Commissioner for administrative law judges performing the administrative law judge functions transferred under paragraph (1) from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund shall become payable to the Secretary for the functions so transferred.

(6) SHARED RESOURCES.—The Secretary shall enter into such arrangements with the Commissioner as may be appropriate with respect to transferred functions of administrative law judges to share office space, support staff, and other resources, with appropriate reimbursement from the Trust Funds described in paragraph (5).

(c) INCREASED FINANCIAL SUPPORT.—In addition to any amounts otherwise appropriated, to ensure timely action on appeals before administrative law judges and the Departmental Appeals Board consistent with section 1869 of the Social Security Act (as amended by section 521 of BIPA, 114 Stat. 2763A–534), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to the Secretary such sums as are necessary for fiscal year 2005 and each subsequent fiscal year to—

(1) increase the number of administrative law judges (and their staffs) under subsection (b)(4);

(2) improve education and training opportunities for administrative law judges (and their staffs); and

(3) increase the staff of the Departmental Appeals Board.

(d) CONFORMING AMENDMENT.—Section 1869(f)(2)(A)(i) (42 U.S.C. 1395ff(f)(2)(A)(i)), as added by section 522(a) of BIPA (114 Stat. 2763A–543), is amended by striking "of the Social Security Administration".

SEC. 932. PROCESS FOR EXPEDITED ACCESS TO REVIEW.

(a) EXPEDITED ACCESS TO JUDICIAL REVIEW.—Section 1869(b) (42 U.S.C. 1395ff(b)) as amended by BIPA, is amended—

(1) in paragraph (1)(A), by inserting ", subject to paragraph (2)," before "to judicial review of the Secretary's final decision";

(2) in paragraph (1)(F)—

(A) by striking clause (ii);

(B) by striking "PROCEEDING" and all that follows through "DETERMINATION" and inserting "DETERMINATIONS AND RECONSIDERATIONS"; and

(C) by redesignating subclauses (I) and (II) as clauses (i) and (ii) and by moving the indentation of such subclauses (and the matter that follows) 2 ems to the left; and

(3) by adding at the end the following new paragraph:

"(2) EXPEDITED ACCESS TO JUDICIAL REVIEW.—

"(A) IN GENERAL.—The Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or an individual entitled to benefits under part A or enrolled under part B, or both, who has filed an appeal under paragraph (1) may obtain access to judicial review when a review panel (described in subparagraph (D)), on its own motion or at the request of the appellant, determines that no entity in the administrative appeals process has the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute. The appellant may make such request only once with respect to a question of law or regulation in a case of an appeal.

"(B) PROMPT DETERMINATIONS.—If, after or coincident with appropriately filing a request for an administrative hearing, the appellant requests a determination by the appropriate review panel that no review panel has the authority to decide the question of law or regulations relevant to the matters in controversy and that there is no material issue of fact in dispute and if such request is accompanied by the documents and materials as the appropriate review panel shall require for purposes of making such determination, such review panel shall make a determination on the request in writing within 60 days after the date such review panel receives the request and such accompanying documents and materials. Such a determination by such review panel shall be considered a final decision and not subject to review by the Secretary.

"(C) ACCESS TO JUDICIAL REVIEW.—

"(i) IN GENERAL.—If the appropriate review panel—

"(I) determines that there are no material issues of fact in dispute and that the only issue is one of law or regulation that no review panel has the authority to decide; or

"(II) fails to make such determination within the period provided under subparagraph (B);

then the appellant may bring a civil action as described in this subparagraph.

"(ii) DEADLINE FOR FILING.—Such action shall be filed, in the case described in—

"(I) clause (i)(I), within 60 days of date of the determination described in such subparagraph; or

"(II) clause (i)(II), within 60 days of the end of the period provided under subparagraph (B) for the determination.

"(iii) VENUE.—Such action shall be brought in the district court of the United States for the judicial district in which the appellant is located (or, in the case of an action brought jointly by more than one applicant, the judicial district in which the greatest number of applicants are located) or in the district court for the District of Columbia.

"(iv) INTEREST ON AMOUNTS IN CONTROVERSY.—Where a provider of services or supplier seeks judicial review pursuant to this paragraph, the amount in controversy shall be subject to annual interest beginning on the first day of the first month beginning after the 60-day period as determined pursuant to clause (ii) and equal to the rate of interest on obligations issued for purchase by the Federal Hospital Insurance Trust Fund and by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this paragraph is commenced, to be awarded by the reviewing court in favor of the prevailing party. No interest awarded pursuant to the preceding sentence shall be deemed income or cost for the purposes of determining reimbursement due providers of services or suppliers under this Act.

"(D) REVIEW PANELS.—For purposes of this subsection, a 'review panel' is a panel consisting of 3 members (who shall be administrative law judges, members of the Departmental Appeals Board, or qualified individuals associated with a qualified independent contractor (as defined in subsection (c)(2)) or with another independent entity) designated by the Secretary for purposes of making determinations under this paragraph.".

(b) APPLICATION TO PROVIDER AGREEMENT DETERMINATIONS.—Section 1866(h)(1) (42 U.S.C. 1395cc(h)(1)) is amended—

(1) by inserting "(A)" after "(h)(1)"; and

(2) by adding at the end the following new subparagraph:

"(B) An institution or agency described in subparagraph (A) that has filed for a hearing under subparagraph (A) shall have expedited access to judicial review under this subparagraph in the same manner as providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, may obtain expedited access to judicial review under the process established under section 1869(b)(2). Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1819 during the pendency of an appeal under this subparagraph.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to appeals filed on or after October 1, 2004.

(d) EXPEDITED REVIEW OF CERTAIN PROVIDER AGREEMENT DETERMINATIONS.—

(1) TERMINATION AND CERTAIN OTHER IMMEDIATE REMEDIES.—The Secretary shall develop and implement a process to expedite proceedings under sections 1866(h) of the Social Security Act (42 U.S.C. 1395cc(h)) in which the remedy of termination of participation, or a remedy described in clause (i) or (iii) of section 1819(h)(2)(B) of such Act (42 U.S.C. 1395i–3(h)(2)(B)) which is applied on an immediate basis, has been imposed. Under such process priority shall be provided in cases of termination.

(2) INCREASED FINANCIAL SUPPORT.—In addition to any amounts otherwise appropriated, to reduce by 50 percent the average time for administrative determinations on appeals under section 1866(h) of the Social Security Act (42 U.S.C. 1395cc(h)), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to the Secretary such additional sums for fiscal year 2005 and each subsequent fiscal year as may be necessary. The purposes for which such amounts are available include increasing the number of administrative law judges (and their staffs) and the appellate level staff at the Departmental Appeals Board of the Department of Health and Human Services and educating such judges and staffs on long-term care issues.

SEC. 933. REVISIONS TO MEDICARE APPEALS PROCESS.

(a) REQUIRING FULL AND EARLY PRESENTATION OF EVIDENCE.—

(1) IN GENERAL.—Section 1869(b) (42 U.S.C. 1395ff(b)), as amended by BIPA and as amended by section 932(a), is further amended by adding at the end the following new paragraph:

"(3) REQUIRING FULL AND EARLY PRESENTATION OF EVIDENCE BY PROVIDERS.—A provider of services or supplier may not introduce evidence in any appeal under this section that was not presented at the reconsideration conducted by the qualified independent contractor under subsection (c), unless there is good cause which precluded the introduction of such evidence at or before that reconsideration.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on October 1, 2004.

(b) USE OF PATIENTS' MEDICAL RECORDS.—Section 1869(c)(3)(B)(i) (42 U.S.C. 1395ff(c)(3)(B)(i)), as amended by BIPA, is amended by inserting "(including the medical records of the individual involved)" after "clinical experience".

(c) NOTICE REQUIREMENTS FOR MEDICARE APPEALS.—

(1) INITIAL DETERMINATIONS AND REDETERMINATIONS.—Section 1869(a) (42 U.S.C. 1395ff(a)), as amended by BIPA, is amended by adding at the end the following new paragraphs:

"(4) REQUIREMENTS OF NOTICE OF DETERMINATIONS.—With respect to an initial determination insofar as it results in a denial of a claim for benefits—

"(A) the written notice on the determination shall include—

"(i) the reasons for the determination, including whether a local medical review policy or a local coverage determination was used;

"(ii) the procedures for obtaining additional information concerning the determination, including the information described in subparagraph (B); and

"(iii) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination under this section; and

"(B) the person provided such notice may obtain, upon request, the specific provision of the policy, manual, or regulation used in making the determination.

"(5) REQUIREMENTS OF NOTICE OF REDETERMINATIONS.—With respect to a redetermination insofar as it results in a denial of a claim for benefits—

"(A) the written notice on the redetermination shall include—

"(i) the specific reasons for the redetermination;

"(ii) as appropriate, a summary of the clinical or scientific evidence used in making the redetermination;

"(iii) a description of the procedures for obtaining additional information concerning the redetermination; and

"(iv) notification of the right to appeal the redetermination and instructions on how to initiate such an appeal under this section;

"(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both; and

"(C) the person provided such notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.".

(2) RECONSIDERATIONS.—Section 1869(c)(3)(E) (42 U.S.C. 1395ff(c)(3)(E)), as amended by BIPA, is amended—

(A) by inserting "be written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include (to the extent appropriate)" after "in writing, "; and

(B) by inserting "and a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section" after "such decision,".

(3) APPEALS.—Section 1869(d) (42 U.S.C. 1395ff(d)), as amended by BIPA, is amended—

(A) in the heading, by inserting "; NOTICE" after "SECRETARY"; and

(B) by adding at the end the following new paragraph:

"(4) NOTICE.—Notice of the decision of an administrative law judge shall be in writing in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include—

"(A) the specific reasons for the determination (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination);

"(B) the procedures for obtaining additional information concerning the decision; and

"(C) notification of the right to appeal the decision and instructions on how to initiate such an appeal under this section.".

(4) SUBMISSION OF RECORD FOR APPEAL.—Section 1869(c)(3)(J)(i) (42 U.S.C. 1395ff(c)(3)(J)(i)) by striking "prepare" and inserting "submit" and by striking "with respect to" and all that follows through "and relevant policies".

(d) QUALIFIED INDEPENDENT CONTRACTORS.—

(1) ELIGIBILITY REQUIREMENTS OF QUALIFIED INDEPENDENT CONTRACTORS.—Section 1869(c)(3) (42 U.S.C. 1395ff(c)(3)), as amended by BIPA, is amended—

(A) in subparagraph (A), by striking "sufficient training and expertise in medical science and legal matters" and inserting "sufficient medical, legal, and other expertise (including knowledge of the program under this title) and sufficient staffing"; and

(B) by adding at the end the following new subparagraph:

"(K) INDEPENDENCE REQUIREMENTS.—

"(i) IN GENERAL.—Subject to clause (ii), a qualified independent contractor shall not conduct any activities in a case unless the entity—

"(I) is not a related party (as defined in subsection (g)(5));

"(II) does not have a material familial, financial, or professional relationship with such a party in relation to such case; and

"(III) does not otherwise have a conflict of interest with such a party.

"(ii) EXCEPTION FOR REASONABLE COMPENSATION.—Nothing in clause (i) shall be construed to prohibit receipt by a qualified independent contractor of compensation from the Secretary for the conduct of activities under this section if the compensation is provided consistent with clause (iii).

"(iii) LIMITATIONS ON ENTITY COMPENSATION.—Compensation provided by the Secretary to a qualified independent contractor in connection with reviews under this section shall not be contingent on any decision rendered by the contractor or by any reviewing professional.".

(2) ELIGIBILITY REQUIREMENTS FOR REVIEWERS.—Section 1869 (42 U.S.C. 1395ff), as amended by BIPA, is amended—

(A) by amending subsection (c)(3)(D) to read as follows:

"(D) QUALIFICATIONS FOR REVIEWERS.—The requirements of subsection (g) shall be met (relating to qualifications of reviewing professionals)."; and

(B) by adding at the end the following new subsection:

"(g) QUALIFICATIONS OF REVIEWERS.—

"(1) IN GENERAL.—In reviewing determinations under this section, a qualified independent contractor shall assure that—

"(A) each individual conducting a review shall meet the qualifications of paragraph (2);

"(B) compensation provided by the contractor to each such reviewer is consistent with paragraph (3); and

"(C) in the case of a review by a panel described in subsection (c)(3)(B) composed of physicians or other health care professionals (each in this subsection referred to as a 'reviewing professional'), a reviewing professional meets the qualifications described in paragraph (4) and, where a claim is regarding the furnishing of treatment by a physician (allopathic or osteopathic) or the provision of items or services by a physician (allopathic or osteopathic), a reviewing professional shall be a physician (allopathic or osteopathic).

"(2) INDEPENDENCE.—

"(A) IN GENERAL.—Subject to subparagraph (B), each individual conducting a review in a case shall—

"(i) not be a related party (as defined in paragraph (5));

"(ii) not have a material familial, financial, or professional relationship with such a party in the case under review; and

"(iii) not otherwise have a conflict of interest with such a party.

"(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

"(i) prohibit an individual, solely on the basis of a participation agreement with a fiscal intermediary, carrier, or other contractor, from serving as a reviewing professional if—

"(I) the individual is not involved in the provision of items or services in the case under review;

"(II) the fact of such an agreement is disclosed to the Secretary and the individual entitled to benefits under part A or enrolled under part B, or both, (or authorized representative) and neither party objects; and

"(III) the individual is not an employee of the intermediary, carrier, or contractor and does not provide services exclusively or primarily to or on behalf of such intermediary, carrier, or contractor;

"(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as a reviewer merely on the basis of having such staff privileges if the existence of such privileges is disclosed to the Secretary and such individual (or authorized representative), and neither party objects; or

"(iii) prohibit receipt of compensation by a reviewing professional from a contractor if the compensation is provided consistent with paragraph (3).

For purposes of this paragraph, the term 'participation agreement' means an agreement relating to the provision of health care services by the individual and does not include the provision of services as a reviewer under this subsection.

"(3) LIMITATIONS ON REVIEWER COMPENSATION.—Compensation provided by a qualified independent contractor to a reviewer in connection with a review under this section shall not be contingent on the decision rendered by the reviewer.

"(4) LICENSURE AND EXPERTISE.—Each reviewing professional shall be—

"(A) a physician (allopathic or osteopathic) who is appropriately credentialed or licensed in one or more States to deliver health care services and has medical expertise in the field of practice that is appropriate for the items or services at issue; or

"(B) a health care professional who is legally authorized in one or more States (in accordance with State law or the State regulatory mechanism provided by State law) to furnish the health care items or services at issue and has medical expertise in the field of practice that is appropriate for such items or services.

"(5) RELATED PARTY DEFINED.—For purposes of this section, the term 'related party' means, with respect to a case under this title involving a specific individual entitled to benefits under part A or enrolled under part B, or both, any of the following:

"(A) The Secretary, the medicare administrative contractor involved, or any fiduciary, officer, director, or employee of the Department of Health and Human Services, or of such contractor.

"(B) The individual (or authorized representative).

"(C) The health care professional that provides the items or services involved in the case.

"(D) The institution at which the items or services (or treatment) involved in the case are provided.

"(E) The manufacturer of any drug or other item that is included in the items or services involved in the case.

"(F) Any other party determined under any regulations to have a substantial interest in the case involved.".

(3) REDUCING MINIMUM NUMBER OF QUALIFIED INDEPENDENT CONTRACTORS.—Section 1869(c)(4) (42 U.S.C. 1395ff(c)(4)) is amended by striking "not fewer than 12 qualified independent contractors under this subsection" and inserting "with a sufficient number of qualified independent contractors (but not fewer than 4 such contractors) to conduct reconsiderations consistent with the timeframes applicable under this subsection".

(4) EFFECTIVE DATE.—The amendments made by paragraphs (1) and (2) shall be effective as if included in the enactment of the respective provisions of subtitle C of title V of BIPA, (114 Stat. 2763A–534).

(5) TRANSITION.—In applying section 1869(g) of the Social Security Act (as added by paragraph (2)), any reference to a medicare administrative contractor shall be deemed to include a reference to a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and a carrier under section 1842 of such Act (42 U.S.C. 1395u).

SEC. 934. PREPAYMENT REVIEW.

(a) IN GENERAL.—Section 1874A, as added by section 911(a)(1) and as amended by sections 912(b), 921(b)(1), and 921(c)(1), is further amended by adding at the end the following new subsection:

"(h) CONDUCT OF PREPAYMENT REVIEW.—

"(1) CONDUCT OF RANDOM PREPAYMENT REVIEW.—

"(A) IN GENERAL.—A medicare administrative contractor may conduct random prepayment review only to develop a contractor-wide or program-wide claims payment error rates or under such additional circumstances as may be provided under regulations, developed in consultation with providers of services and suppliers.

"(B) USE OF STANDARD PROTOCOLS WHEN CONDUCTING PREPAYMENT REVIEWS.—When a medicare administrative contractor conducts a random prepayment review, the contractor may conduct such review only in accordance with a standard protocol for random prepayment audits developed by the Secretary.

"(C) CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing the denial of payments for claims actually reviewed under a random prepayment review.

"(D) RANDOM PREPAYMENT REVIEW.—For purposes of this subsection, the term 'random prepayment review' means a demand for the production of records or documentation absent cause with respect to a claim.

"(2) LIMITATIONS ON NON-RANDOM PREPAYMENT REVIEW.—

"(A) LIMITATIONS ON INITIATION OF NON-RANDOM PREPAYMENT REVIEW.—A medicare administrative contractor may not initiate non-random prepayment review of a provider of services or supplier based on the initial identification by that provider of services or supplier of an improper billing practice unless there is a likelihood of sustained or high level of payment error (as defined in subsection (i)(3)(A)).

"(B) TERMINATION OF NON-RANDOM PREPAYMENT REVIEW.—The Secretary shall issue regulations relating to the termination, including termination dates, of non-random prepayment review. Such regulations may vary such a termination date based upon the differences in the circumstances triggering prepayment review.".

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in this subsection, the amendment made by subsection (a) shall take effect 1 year after the date of the enactment of this Act.

(2) DEADLINE FOR PROMULGATION OF CERTAIN REGULATIONS.—The Secretary shall first issue regulations under section 1874A(h) of the Social Security Act, as added by subsection (a), by not later than 1 year after the date of the enactment of this Act.

(3) APPLICATION OF STANDARD PROTOCOLS FOR RANDOM PREPAYMENT REVIEW.—Section 1874A(h)(1)(B) of the Social Security Act, as added by subsection (a), shall apply to random prepayment reviews conducted on or after such date (not later than 1 year after the date of the enactment of this Act) as the Secretary shall specify.

(c) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(h) of the Social Security Act, as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

SEC. 935. RECOVERY OF OVERPAYMENTS.

(a) IN GENERAL.—Section 1893 (42 U.S.C. 1395ddd) is amended by adding at the end the following new subsection:

"(f) RECOVERY OF OVERPAYMENTS.—

"(1) USE OF REPAYMENT PLANS.—

"(A) IN GENERAL.—If the repayment, within 30 days by a provider of services or supplier, of an overpayment under this title would constitute a hardship (as defined in subparagraph (B)), subject to subparagraph (C), upon request of the provider of services or supplier the Secretary shall enter into a plan with the provider of services or supplier for the repayment (through offset or otherwise) of such overpayment over a period of at least 6 months but not longer than 3 years (or not longer than 5 years in the case of extreme hardship, as determined by the Secretary). Interest shall accrue on the balance through the period of repayment. Such plan shall meet terms and conditions determined to be appropriate by the Secretary.

"(B) HARDSHIP.—

"(i) IN GENERAL.—For purposes of subparagraph (A), the repayment of an overpayment (or overpayments) within 30 days is deemed to constitute a hardship if—

"(I) in the case of a provider of services that files cost reports, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services for the cost reporting period covered by the most recently submitted cost report; or

"(II) in the case of another provider of services or supplier, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services or supplier for the previous calendar year.

"(ii) RULE OF APPLICATION.—The Secretary shall establish rules for the application of this subparagraph in the case of a provider of services or supplier that was not paid under this title during the previous year or was paid under this title only during a portion of that year.

"(iii) TREATMENT OF PREVIOUS OVERPAYMENTS.—If a provider of services or supplier has entered into a repayment plan under subparagraph (A) with respect to a specific overpayment amount, such payment amount under the repayment plan shall not be taken into account under clause (i) with respect to subsequent overpayment amounts.

"(C) EXCEPTIONS.—Subparagraph (A) shall not apply if—

"(i) the Secretary has reason to suspect that the provider of services or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in the program under this title; or

"(ii) there is an indication of fraud or abuse committed against the program.

"(D) IMMEDIATE COLLECTION IF VIOLATION OF REPAYMENT PLAN.—If a provider of services or supplier fails to make a payment in accordance with a repayment plan under this paragraph, the Secretary may immediately seek to offset or otherwise recover the total balance outstanding (including applicable interest) under the repayment plan.

"(E) RELATION TO NO FAULT PROVISION.—Nothing in this paragraph shall be construed as affecting the application of section 1870(c) (relating to no adjustment in the cases of certain overpayments).

"(2) LIMITATION ON RECOUPMENT.—

"(A) IN GENERAL.—In the case of a provider of services or supplier that is determined to have received an overpayment under this title and that seeks a reconsideration by a qualified independent contractor on such determination under section 1869(b)(1), the Secretary may not take any action (or authorize any other person, including any medicare contractor, as de-

fined in subparagraph (C)) to recoup the overpayment until the date the decision on the reconsideration has been rendered. If the provisions of section 1869(b)(1) (providing for such a reconsideration by a qualified independent contractor) are not in effect, in applying the previous sentence any reference to such a reconsideration shall be treated as a reference to a redetermination by the fiscal intermediary or carrier involved.

"(B) COLLECTION WITH INTEREST.—Insofar as the determination on such appeal is against the provider of services or supplier, interest on the overpayment shall accrue on and after the date of the original notice of overpayment. Insofar as such determination against the provider of services or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest at the same rate as would apply under the previous sentence for the period in which the amount was recouped.

"(C) MEDICARE CONTRACTOR DEFINED.—For purposes of this subsection, the term 'medicare contractor' has the meaning given such term in section 1889(g).

"(3) LIMITATION ON USE OF EXTRAPOLATION.—A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless—

"(A) there is a sustained or high level of payment error (as defined by the Secretary by regulation); or

"(B) documented educational intervention has failed to correct the payment error (as determined by the Secretary).

"(4) PROVISION OF SUPPORTING DOCUMENTATION.—In the case of a provider of services or supplier with respect to which amounts were previously overpaid, a medicare contractor may request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing.

"(5) CONSENT SETTLEMENT REFORMS.—

"(A) IN GENERAL.—The Secretary may use a consent settlement (as defined in subparagraph (D)) to settle a projected overpayment.

"(B) OPPORTUNITY TO SUBMIT ADDITIONAL INFORMATION BEFORE CONSENT SETTLEMENT OFFER.—Before offering a provider of services or supplier a consent settlement, the Secretary shall—

"(i) communicate to the provider of services or supplier—

"(I) that, based on a review of the medical records requested by the Secretary, a preliminary evaluation of those records indicates that there would be an overpayment;

"(II) the nature of the problems identified in such evaluation; and

"(III) the steps that the provider of services or supplier should take to address the problems; and

"(ii) provide for a 45-day period during which the provider of services or supplier may furnish additional information concerning the medical records for the claims that had been reviewed.

"(C) CONSENT SETTLEMENT OFFER.—The Secretary shall review any additional information furnished by the provider of services or supplier under subparagraph (B)(ii). Taking into consideration such information, the Secretary shall determine if there still appears to be an overpayment. If so, the Secretary—

"(i) shall provide notice of such determination to the provider of services or supplier, including an explanation of the reason for such determination; and

"(ii) in order to resolve the overpayment, may offer the provider of services or supplier—

"(I) the opportunity for a statistically valid random sample; or

"(II) a consent settlement.

The opportunity provided under clause (ii)(I) does not waive any appeal rights with respect to the alleged overpayment involved.

"(D) CONSENT SETTLEMENT DEFINED.—For purposes of this paragraph, the term 'consent settlement' means an agreement between the Secretary and a provider of services or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services or supplier agrees not to appeal the claims involved.

"(6) NOTICE OF OVER-UTILIZATION OF CODES.—The Secretary shall establish, in consultation with organizations representing the classes of providers of services and suppliers, a process under which the Secretary provides for notice to classes of providers of services and suppliers served by the contractor in cases in which

the contractor has identified that particular billing codes may be overutilized by that class of providers of services or suppliers under the programs under this title (or provisions of title XI insofar as they relate to such programs).

"(7) PAYMENT AUDITS.—

"(A) WRITTEN NOTICE FOR POST-PAYMENT AUDITS.—Subject to subparagraph (C), if a medicare contractor decides to conduct a post-payment audit of a provider of services or supplier under this title, the contractor shall provide the provider of services or supplier with written notice (which may be in electronic form) of the intent to conduct such an audit.

"(B) EXPLANATION OF FINDINGS FOR ALL AUDITS.—Subject to subparagraph (C), if a medicare contractor audits a provider of services or supplier under this title, the contractor shall—

"(i) give the provider of services or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider of services or supplier and permits the development of an appropriate corrective action plan;

"(ii) inform the provider of services or supplier of the appeal rights under this title as well as consent settlement options (which are at the discretion of the Secretary);

"(iii) give the provider of services or supplier an opportunity to provide additional information to the contractor; and

"(iv) take into account information provided, on a timely basis, by the provider of services or supplier under clause (iii).

"(C) EXCEPTION.—Subparagraphs (A) and (B) shall not apply if the provision of notice or findings would compromise pending law enforcement activities, whether civil or criminal, or reveal findings of law enforcement-related audits.

"(8) STANDARD METHODOLOGY FOR PROBE SAMPLING.—The Secretary shall establish a standard methodology for medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.".

(b) EFFECTIVE DATES AND DEADLINES.—

(1) USE OF REPAYMENT PLANS.—Section 1893(f)(1) of the Social Security Act, as added by subsection (a), shall apply to requests for repayment plans made after the date of the enactment of this Act.

(2) LIMITATION ON RECOUPMENT.—Section 1893(f)(2) of the Social Security Act, as added by subsection (a), shall apply to actions taken after the date of the enactment of this Act.

(3) USE OF EXTRAPOLATION.—Section 1893(f)(3) of the Social Security Act, as added by subsection (a), shall apply to statistically valid random samples initiated after the date that is 1 year after the date of the enactment of this Act.

(4) PROVISION OF SUPPORTING DOCUMENTATION.—Section 1893(f)(4) of the Social Security Act, as added by subsection (a), shall take effect on the date of the enactment of this Act.

(5) CONSENT SETTLEMENT.—Section 1893(f)(5) of the Social Security Act, as added by subsection (a), shall apply to consent settlements entered into after the date of the enactment of this Act.

(6) NOTICE OF OVERUTILIZATION.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall first establish the process for notice of overutilization of billing codes under section 1893A(f)(6) of the Social Security Act, as added by subsection (a).

(7) PAYMENT AUDITS.—Section 1893A(f)(7) of the Social Security Act, as added by subsection (a), shall apply to audits initiated after the date of the enactment of this Act.

(8) STANDARD FOR ABNORMAL BILLING PATTERNS.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall first establish a standard methodology for selection of sample claims for abnormal billing patterns under section 1893(f)(8) of the Social Security Act, as added by subsection (a).

SEC. 936. PROVIDER ENROLLMENT PROCESS; RIGHT OF APPEAL.

(a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is amended—

(1) by adding at the end of the heading the following: "; ENROLLMENT PROCESSES"; and

(2) by adding at the end the following new subsection:

"(j) ENROLLMENT PROCESS FOR PROVIDERS OF SERVICES AND SUPPLIERS.—

"(1) ENROLLMENT PROCESS.—

"(A) IN GENERAL.—The Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under this title.

"(B) DEADLINES.—The Secretary shall establish by regulation procedures under which there are deadlines for actions on applications for enrollment

(and, if applicable, renewal of enrollment). The Secretary shall monitor the performance of medicare administrative contractors in meeting the deadlines established under this subparagraph.

"(C) CONSULTATION BEFORE CHANGING PROVIDER ENROLLMENT FORMS.—The Secretary shall consult with providers of services and suppliers before making changes in the provider enrollment forms required of such providers and suppliers to be eligible to submit claims for which payment may be made under this title.

"(2) HEARING RIGHTS IN CASES OF DENIAL OR NON-RENEWAL.—A provider of services or supplier whose application to enroll (or, if applicable, to renew enrollment) under this title is denied may have a hearing and judicial review of such denial under the procedures that apply under subsection (h)(1)(A) to a provider of services that is dissatisfied with a determination by the Secretary.".

(b) EFFECTIVE DATES.—

(1) ENROLLMENT PROCESS.—The Secretary shall provide for the establishment of the enrollment process under section 1866(j)(1) of the Social Security Act, as added by subsection (a)(2), within 6 months after the date of the enactment of this Act.

(2) CONSULTATION.—Section 1866(j)(1)(C) of the Social Security Act, as added by subsection (a)(2), shall apply with respect to changes in provider enrollment forms made on or after January 1, 2004.

(3) HEARING RIGHTS.—Section 1866(j)(2) of the Social Security Act, as added by subsection (a)(2), shall apply to denials occurring on or after such date (not later than 1 year after the date of the enactment of this Act) as the Secretary specifies.

SEC. 937. PROCESS FOR CORRECTION OF MINOR ERRORS AND OMISSIONS WITHOUT PURSUING APPEALS PROCESS.

(a) CLAIMS.—The Secretary shall develop, in consultation with appropriate medicare contractors (as defined in section 1889(g) of the Social Security Act, as inserted by section 301(a)(1)) and representatives of providers of services and suppliers, a process whereby, in the case of minor errors or omissions (as defined by the Secretary) that are detected in the submission of claims under the programs under title XVIII of such Act, a provider of services or supplier is given an opportunity to correct such an error or omission without the need to initiate an appeal. Such process shall include the ability to resubmit corrected claims.

(b) PERMITTING USE OF CORRECTED AND SUPPLEMENTARY DATA.—

(1) IN GENERAL.—Section 1886(d)(10)(D)(vi) (42 U.S.C. 1395ww(d)(10)(D)(vi)) is amended by adding after subclause (II) at the end the following:

"Notwithstanding subclause (I), a hospital may submit, and the Secretary may accept upon verification, data that corrects or supplements the data described in such subclause without regard to whether the corrected or supplementary data relate to a cost report that has been settled.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to fiscal years beginning with fiscal year 2004.

(3) SUBMITTAL AND RESUBMITTAL OF APPLICATIONS PERMITTED FOR FISCAL YEAR 2004.—

(A) IN GENERAL.—Notwithstanding any other provision of law, a hospital may submit (or resubmit) an application for a change described in section 1886(d)(10)(C)(i)(II) of the Social Security Act for fiscal year 2004 if the hospital demonstrates on a timely basis to the satisfaction of the Secretary that the use of corrected or supplementary data under the amendment made by paragraph (1) would materially affect the approval of such an application.

(B) APPLICATION OF BUDGET NEUTRALITY.—If one or more hospital's applications are approved as a result of paragraph (1) and subparagraph (A) for fiscal year 2004, the Secretary shall make a proportional adjustment in the standardized amounts determined under section 1886(d)(3) of the Social Security Act (42 U.S.C. 1395ww(d)(3)) for fiscal year 2004 to assure that approval of such applications does not result in aggregate payments under section 1886(d) of such Act that are greater or less than those that would otherwise be made if paragraph (1) and subparagraph (A) did not apply.

SEC. 938. PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES; ADVANCE BENEFICIARY NOTICES.

(a) IN GENERAL.—Section 1869 (42 U.S.C. 1395ff(b)), as amended by sections 521 and 522 of BIPA and section 933(d)(2)(B), is further amended by adding at the end the following new subsection:

"(h) PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES.—

"(1) ESTABLISHMENT OF PROCESS.—

"(A) IN GENERAL.—With respect to a medicare administrative contractor that has a contract under section 1874A that provides for making payments under this title with respect to eligible items and services described in subparagraph (C), the Secretary shall establish a prior determination process that meets the requirements of this subsection and that shall be applied by such contractor in the case of eligible requesters.

"(B) ELIGIBLE REQUESTER.—For purposes of this subsection, each of the following shall be an eligible requester:

"(i) A physician, but only with respect to eligible items and services for which the physician may be paid directly.

"(ii) An individual entitled to benefits under this title, but only with respect to an item or service for which the individual receives, from the physician who may be paid directly for the item or service, an advance beneficiary notice under section 1879(a) that payment may not be made (or may no longer be made) for the item or service under this title.

"(C) ELIGIBLE ITEMS AND SERVICES.—For purposes of this subsection and subject to paragraph (2), eligible items and services are items and services which are physicians' services (as defined in paragraph (4)(A) of section 1848(f) for purposes of calculating the sustainable growth rate under such section).

"(2) SECRETARIAL FLEXIBILITY.—The Secretary shall establish by regulation reasonable limits on the categories of eligible items and services for which a prior determination of coverage may be requested under this subsection. In establishing such limits, the Secretary may consider the dollar amount involved with respect to the item or service, administrative costs and burdens, and other relevant factors.

"(3) REQUEST FOR PRIOR DETERMINATION.—

"(A) IN GENERAL.—Subject to paragraph (2), under the process established under this subsection an eligible requester may submit to the contractor a request for a determination, before the furnishing of an eligible item or service involved as to whether the item or service is covered under this title consistent with the applicable requirements of section 1862(a)(1)(A) (relating to medical necessity).

"(B) ACCOMPANYING DOCUMENTATION.—The Secretary may require that the request be accompanied by a description of the item or service, supporting documentation relating to the medical necessity for the item or service, and any other appropriate documentation. In the case of a request submitted by an eligible requester who is described in paragraph (1)(B)(ii), the Secretary may require that the request also be accompanied by a copy of the advance beneficiary notice involved.

"(4) RESPONSE TO REQUEST.—

"(A) IN GENERAL.—Under such process, the contractor shall provide the eligible requester with written notice of a determination as to whether—

"(i) the item or service is so covered;

"(ii) the item or service is not so covered; or

"(iii) the contractor lacks sufficient information to make a coverage determination.

If the contractor makes the determination described in clause (iii), the contractor shall include in the notice a description of the additional information required to make the coverage determination.

"(B) DEADLINE TO RESPOND.—Such notice shall be provided within the same time period as the time period applicable to the contractor providing notice of initial determinations on a claim for benefits under subsection (a)(2)(A).

"(C) INFORMING BENEFICIARY IN CASE OF PHYSICIAN REQUEST.—In the case of a request in which an eligible requester is not the individual described in paragraph (1)(B)(ii), the process shall provide that the individual to whom the item or service is proposed to be furnished shall be informed of any determination described in clause (ii) (relating to a determination of non-coverage) and the right (referred to in paragraph (6)(B)) to obtain the item or service and have a claim submitted for the item or service.

"(5) EFFECT OF DETERMINATIONS.—

"(A) BINDING NATURE OF POSITIVE DETERMINATION.—If the contractor makes the determination described in paragraph (4)(A)(i), such determination shall be binding on the contractor in the absence of fraud or evidence of misrepresentation of facts presented to the contractor.

"(B) NOTICE AND RIGHT TO REDETERMINATION IN CASE OF A DENIAL.—

"(i) IN GENERAL.—If the contractor makes the determination described in paragraph (4)(A)(ii)—

"(I) the eligible requester has the right to a redetermination by the contractor on the determination that the item or service is not so covered; and

"(II) the contractor shall include in notice under paragraph (4)(A) a brief explanation of the basis for the determination, including on what national or local coverage or noncoverage determination (if any) the determination is based, and the right to such a redetermination.

"(ii) DEADLINE FOR REDETERMINATIONS.—The contractor shall complete and provide notice of such redetermination within the same time period as the time period applicable to the contractor providing notice of redeterminations relating to a claim for benefits under subsection (a)(3)(C)(ii).

"(6) LIMITATION ON FURTHER REVIEW.—

"(A) IN GENERAL.—Contractor determinations described in paragraph (4)(A)(ii) or (4)(A)(iii) (and redeterminations made under paragraph (5)(B)), relating to pre-service claims are not subject to further administrative appeal or judicial review under this section or otherwise.

"(B) DECISION NOT TO SEEK PRIOR DETERMINATION OR NEGATIVE DETERMINATION DOES NOT IMPACT RIGHT TO OBTAIN SERVICES, SEEK REIMBURSEMENT, OR APPEAL RIGHTS.—Nothing in this subsection shall be construed as affecting the right of an individual who—

"(i) decides not to seek a prior determination under this subsection with respect to items or services; or

"(ii) seeks such a determination and has received a determination described in paragraph (4)(A)(ii),

from receiving (and submitting a claim for) such items services and from obtaining administrative or judicial review respecting such claim under the other applicable provisions of this section. Failure to seek a prior determination under this subsection with respect to items and services shall not be taken into account in such administrative or judicial review.

"(C) NO PRIOR DETERMINATION AFTER RECEIPT OF SERVICES.—Once an individual is provided items and services, there shall be no prior determination under this subsection with respect to such items or services.".

(b) EFFECTIVE DATE; TRANSITION.—

(1) EFFECTIVE DATE.—The Secretary shall establish the prior determination process under the amendment made by subsection (a) in such a manner as to provide for the acceptance of requests for determinations under such process filed not later than 18 months after the date of the enactment of this Act.

(2) TRANSITION.—During the period in which the amendment made by subsection (a) has become effective but contracts are not provided under section 1874A of the Social Security Act with medicare administrative contractors, any reference in section 1869(g) of such Act (as added by such amendment) to such a contractor is deemed a reference to a fiscal intermediary or carrier with an agreement under section 1816, or contract under section 1842, respectively, of such Act.

(3) LIMITATION ON APPLICATION TO SGR.—For purposes of applying section 1848(f)(2)(D) of the Social Security Act (42 U.S.C. 1395w–4(f)(2)(D)), the amendment made by subsection (a) shall not be considered to be a change in law or regulation.

(c) PROVISIONS RELATING TO ADVANCE BENEFICIARY NOTICES; REPORT ON PRIOR DETERMINATION PROCESS.—

(1) DATA COLLECTION.—The Secretary shall establish a process for the collection of information on the instances in which an advance beneficiary notice (as defined in paragraph (5)) has been provided and on instances in which a beneficiary indicates on such a notice that the beneficiary does not intend to seek to have the item or service that is the subject of the notice furnished.

(2) OUTREACH AND EDUCATION.—The Secretary shall establish a program of outreach and education for beneficiaries and providers of services and other persons on the appropriate use of advance beneficiary notices and coverage policies under the medicare program.

(3) GAO REPORT REPORT ON USE OF ADVANCE BENEFICIARY NOTICES.—Not later than 18 months after the date on which section 1869(g) of the Social Security Act (as added by subsection (a)) takes effect, the Comptroller General of the United States shall submit to Congress a report on the use of advance beneficiary notices under title XVIII of such Act. Such report shall include information concerning the providers of services and other persons that have provided such notices and the response of beneficiaries to such notices.

(4) GAO REPORT ON USE OF PRIOR DETERMINATION PROCESS.—Not later than 18 months after the date on which section 1869(g) of the Social Security Act (as added by subsection (a)) takes effect, the Comptroller General of the United States shall submit to Congress a report on the use of the prior determination process under such section. Such report shall include—

(A) information concerning the types of procedures for which a prior determination has been sought, determinations made under the process, and changes in receipt of services resulting from the application of such process; and

(B) an evaluation of whether the process was useful for physicians (and other suppliers) and beneficiaries, whether it was timely, and whether the amount of information required was burdensome to physicians and beneficiaries.

(5) ADVANCE BENEFICIARY NOTICE DEFINED.—In this subsection, the term "advance beneficiary notice" means a written notice provided under section 1879(a) of the Social Security Act (42 U.S.C. 1395pp(a)) to an individual entitled to benefits under part A or B of title XVIII of such Act before items or services are furnished under such part in cases where a provider of services or other person that would furnish the item or service believes that payment will not be made for some or all of such items or services under such title.

Subtitle V—Miscellaneous Provisions

SEC. 941. POLICY DEVELOPMENT REGARDING EVALUATION AND MANAGEMENT (E & M) DOCUMENTATION GUIDELINES.

(a) IN GENERAL.—The Secretary may not implement any new documentation guidelines for, or clinical examples of, evaluation and management physician services under the title XVIII of the Social Security Act on or after the date of the enactment of this Act unless the Secretary—

(1) has developed the guidelines in collaboration with practicing physicians (including both generalists and specialists) and provided for an assessment of the proposed guidelines by the physician community;

(2) has established a plan that contains specific goals, including a schedule, for improving the use of such guidelines;

(3) has conducted appropriate and representative pilot projects under subsection (b) to test modifications to the evaluation and management documentation guidelines;

(4) finds that the objectives described in subsection (c) will be met in the implementation of such guidelines; and

(5) has established, and is implementing, a program to educate physicians on the use of such guidelines and that includes appropriate outreach.

The Secretary shall make changes to the manner in which existing evaluation and management documentation guidelines are implemented to reduce paperwork burdens on physicians.

(b) PILOT PROJECTS TO TEST EVALUATION AND MANAGEMENT DOCUMENTATION GUIDELINES.—

(1) IN GENERAL.—The Secretary shall conduct under this subsection appropriate and representative pilot projects to test new evaluation and management documentation guidelines referred to in subsection (a).

(2) LENGTH AND CONSULTATION.—Each pilot project under this subsection shall—

(A) be voluntary;

(B) be of sufficient length as determined by the Secretary to allow for preparatory physician and medicare contractor education, analysis, and use and assessment of potential evaluation and management guidelines; and

(C) be conducted, in development and throughout the planning and operational stages of the project, in consultation with practicing physicians (including both generalists and specialists).

(3) RANGE OF PILOT PROJECTS.—Of the pilot projects conducted under this subsection—

(A) at least one shall focus on a peer review method by physicians (not employed by a medicare contractor) which evaluates medical record information for claims submitted by physicians identified as statistical outliers relative to definitions published in the Current Procedures Terminology (CPT) code book of the American Medical Association;

(B) at least one shall focus on an alternative method to detailed guidelines based on physician documentation of face to face encounter time with a patient;

(C) at least one shall be conducted for services furnished in a rural area and at least one for services furnished outside such an area; and

(D) at least one shall be conducted in a setting where physicians bill under physicians' services in teaching settings and at least one shall be conducted in a setting other than a teaching setting.

(4) BANNING OF TARGETING OF PILOT PROJECT PARTICIPANTS.—Data collected under this subsection shall not be used as the basis for overpayment demands or post-payment audits. Such limitation applies only to claims filed as part of the pilot project and lasts only for the duration of the pilot project and only as long as the provider is a participant in the pilot project.

(5) STUDY OF IMPACT.—Each pilot project shall examine the effect of the new evaluation and management documentation guidelines on—

(A) different types of physician practices, including those with fewer than 10 full-time-equivalent employees (including physicians); and

(B) the costs of physician compliance, including education, implementation, auditing, and monitoring.

(6) PERIODIC REPORTS.—The Secretary shall submit to Congress periodic reports on the pilot projects under this subsection.

(c) OBJECTIVES FOR EVALUATION AND MANAGEMENT GUIDELINES.—The objectives for modified evaluation and management documentation guidelines developed by the Secretary shall be to—

(1) identify clinically relevant documentation needed to code accurately and assess coding levels accurately;

(2) decrease the level of non-clinically pertinent and burdensome documentation time and content in the physician's medical record;

(3) increase accuracy by reviewers; and

(4) educate both physicians and reviewers.

(d) STUDY OF SIMPLER, ALTERNATIVE SYSTEMS OF DOCUMENTATION FOR PHYSICIAN CLAIMS.—

(1) STUDY.—The Secretary shall carry out a study of the matters described in paragraph (2).

(2) MATTERS DESCRIBED.—The matters referred to in paragraph (1) are—

(A) the development of a simpler, alternative system of requirements for documentation accompanying claims for evaluation and management physician services for which payment is made under title XVIII of the Social Security Act; and

(B) consideration of systems other than current coding and documentation requirements for payment for such physician services.

(3) CONSULTATION WITH PRACTICING PHYSICIANS.—In designing and carrying out the study under paragraph (1), the Secretary shall consult with practicing physicians, including physicians who are part of group practices and including both generalists and specialists.

(4) APPLICATION OF HIPAA UNIFORM CODING REQUIREMENTS.—In developing an alternative system under paragraph (2), the Secretary shall consider requirements of administrative simplification under part C of title XI of the Social Security Act.

(5) REPORT TO CONGRESS.—(A) Not later than October 1, 2005, the Secretary shall submit to Congress a report on the results of the study conducted under paragraph (1).

(B) The Medicare Payment Advisory Commission shall conduct an analysis of the results of the study included in the report under subparagraph (A) and shall submit a report on such analysis to Congress.

(e) STUDY ON APPROPRIATE CODING OF CERTAIN EXTENDED OFFICE VISITS.—The Secretary shall conduct a study of the appropriateness of coding in cases of extended office visits in which there is no diagnosis made. Not later than October 1, 2005, the Secretary shall submit a report to Congress on such study and shall include recommendations on how to code appropriately for such visits in a manner that takes into account the amount of time the physician spent with the patient.

(f) DEFINITIONS.—In this section—

(1) the term "rural area" has the meaning given that term in section 1886(d)(2)(D) of the Social Security Act, 42 U.S.C. 1395ww(d)(2)(D); and

(2) the term "teaching settings" are those settings described in section 415.150 of title 42, Code of Federal Regulations.

SEC. 942. IMPROVEMENT IN OVERSIGHT OF TECHNOLOGY AND COVERAGE.

(a) COUNCIL FOR TECHNOLOGY AND INNOVATION.—Section 1868 (42 U.S.C. 1395ee), as amended by section 921(a), is amended by adding at the end the following new subsection:

"(c) COUNCIL FOR TECHNOLOGY AND INNOVATION.—

"(1) ESTABLISHMENT.—The Secretary shall establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services (in this section referred to as 'CMS').

"(2) COMPOSITION.—The Council shall be composed of senior CMS staff and clinicians and shall be chaired by the Executive Coordinator for Technology and Innovation (appointed or designated under paragraph (4)).

"(3) DUTIES.—The Council shall coordinate the activities of coverage, coding, and payment processes under this title with respect to new technologies and procedures, including new drug therapies, and shall coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

"(4) EXECUTIVE COORDINATOR FOR TECHNOLOGY AND INNOVATION.—The Secretary shall appoint (or designate) a noncareer appointee (as defined in section 3132(a)(7) of title 5, United States Code) who shall serve as the Executive Coordinator for Technology and Innovation. Such executive coordinator shall report to the Administrator of CMS, shall chair the Council, shall oversee the execution of its duties, and shall serve as a single point of contact for outside groups and entities regarding the coverage, coding, and payment processes under this title.".

(b) METHODS FOR DETERMINING PAYMENT BASIS FOR NEW LAB TESTS.—Section 1833(h) (42 U.S.C. 1395l(h)) is amended by adding at the end the following:

"(8)(A) The Secretary shall establish by regulation procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005 (in this paragraph referred to as 'new tests').

"(B) Determinations under subparagraph (A) shall be made only after the Secretary—

"(i) makes available to the public (through an Internet site and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount under this subsection is being considered for a year;

"(ii) on the same day such list is made available, causes to have published in the Federal Register notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis under this subsection for establishing payment amounts for the tests on such list;

"(iii) not less than 30 days after publication of such notice convenes a meeting, that includes representatives of officials of the Centers for Medicare & Medicaid Services involved in determining payment amounts, to receive such comments and recommendations (and data on which the recommendations are based);

"(iv) taking into account the comments and recommendations (and accompanying data) received at such meeting, develops and makes available to the public (through an Internet site and other appropriate mechanisms) a list of proposed determinations with respect to the appropriate basis for establishing a payment amount under this subsection for each such code, together with an explanation of the reasons for each such determination, the data on which the determinations are based, and a request for public written comments on the proposed determination; and

"(v) taking into account the comments received during the public comment period, develops and makes available to the public (through an Internet site and other appropriate mechanisms) a list of final determinations of the payment amounts for such tests under this subsection, together with the rationale for each such determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

"(C) Under the procedures established pursuant to subparagraph (A), the Secretary shall—

"(i) set forth the criteria for making determinations under subparagraph (A); and

"(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

"(D) The Secretary may convene such further public meetings to receive public comments on payment amounts for new tests under this subsection as the Secretary deems appropriate.

"(E) For purposes of this paragraph:

"(i) The term 'HCPCS' refers to the Health Care Procedure Coding System.

"(ii) A code shall be considered to be 'substantially revised' if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test).".

(c) GAO STUDY ON IMPROVEMENTS IN EXTERNAL DATA COLLECTION FOR USE IN THE MEDICARE INPATIENT PAYMENT SYSTEM.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study that analyzes which external data can be collected in a shorter time frame by the Centers for Medicare & Medicaid Services for use in computing payments for inpatient hospital services. The study may include an evaluation of the feasibility and appropriateness of using of quarterly samples or special surveys or any other methods. The study shall include an analysis of whether other executive agencies, such as the Bureau of Labor Statistics in the Department of Commerce, are best suited to collect this information.

(2) REPORT.—By not later than October 1, 2004, the Comptroller General shall submit a report to Congress on the study under paragraph (1).

(d) PROCESS FOR ADOPTION OF ICD CODES AS DATA STANDARD.—Section 1172(f) (42 U.S.C. 1320d–1(f)) is amended by inserting after the first sentence the following: "Notwithstanding the preceding sentence, if the National Committee on Vital and Health Statistics has not made a recommendation to the Secretary before the date of the enactment of this sentence, with respect to the adoption of the International Classification of Diseases, 10th Revision, Procedure Coding System ('ICD–10–PCS') and the International Classification of Diseases, 10th Revision, Clinical Modification ('ICD–10–CM') as a standard under this part for the reporting of diagnoses, the Secretary may adopt ICD–10–PCS and ICD–10–CM as such a standard on or after 1 year after such date without receiving such a recommendation.".

SEC. 943. TREATMENT OF HOSPITALS FOR CERTAIN SERVICES UNDER MEDICARE SECONDARY PAYOR (MSP) PROVISIONS.

(a) IN GENERAL.—The Secretary shall not require a hospital (including a critical access hospital) to ask questions (or obtain information) relating to the application of section 1862(b) of the Social Security Act (relating to medicare secondary payor provisions) in the case of reference laboratory services described in subsection (b), if the Secretary does not impose such requirement in the case of such services furnished by an independent laboratory.

(b) REFERENCE LABORATORY SERVICES DESCRIBED.—Reference laboratory services described in this subsection are clinical laboratory diagnostic tests (or the interpretation of such tests, or both) furnished without a face-to-face encounter between the individual entitled to benefits under part A or enrolled under part B, or both, and the hospital involved and in which the hospital submits a claim only for such test or interpretation.

SEC. 944. EMTALA IMPROVEMENTS.

(a) PAYMENT FOR EMTALA-MANDATED SCREENING AND STABILIZATION SERVICES.—

(1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended by inserting after subsection (c) the following new subsection:

"(d) For purposes of subsection (a)(1)(A), in the case of any item or service that is required to be provided pursuant to section 1867 to an individual who is entitled to benefits under this title, determinations as to whether the item or service is reasonable and necessary shall be made on the basis of the information available to the treating physician or practitioner (including the patient's presenting symptoms or complaint) at the time the item or service was ordered or furnished by the physician or practitioner (and not on the patient's principal diagnosis). When making such determinations with respect to such an item or service, the Secretary shall not consider the frequency with which the item or service was provided to the patient before or after the time of the admission or visit.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to items and services furnished on or after January 1, 2004.

(b) NOTIFICATION OF PROVIDERS WHEN EMTALA INVESTIGATION CLOSED.—Section 1867(d) (42 U.S.C. 42 U.S.C. 1395dd(d)) is amended by adding at the end the following new paragraph:

"(4) NOTICE UPON CLOSING AN INVESTIGATION.—The Secretary shall establish a procedure to notify hospitals and physicians when an investigation under this section is closed.".

(c) PRIOR REVIEW BY PEER REVIEW ORGANIZATIONS IN EMTALA CASES INVOLVING TERMINATION OF PARTICIPATION.—

(1) IN GENERAL.—Section 1867(d)(3) (42 U.S.C. 1395dd(d)(3)) is amended—

(A) in the first sentence, by inserting "or in terminating a hospital's participation under this title" after "in imposing sanctions under paragraph (1)"; and

(B) by adding at the end the following new sentences: "Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall also request such a review before making a compliance de-

termination as part of the process of terminating a hospital's participation under this title for violations related to the appropriateness of a medical screening examination, stabilizing treatment, or an appropriate transfer as required by this section, and shall provide a period of 5 days for such review. The Secretary shall provide a copy of the organization's report to the hospital or physician consistent with confidentiality requirements imposed on the organization under such part B.".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to terminations of participation initiated on or after the date of the enactment of this Act.

(d) MODIFICATION OF REQUIRMENT FOR MEDICAL SCREENING EXAMINATIONS FOR PATIENTS NOT REQUESTING EMERGENCY DEPARTMENT SERVICES.—

(1) IN GENERAL.—Section 1867(a) (42 U.S.C. 1395dd(a)) is amended—

(A) by designating all that follows "(a) MEDICAL SCREENING REQUIREMENT.—" as paragraph (1) with the heading "IN GENERAL.—";

(B) by aligning such paragraph with the paragraph added by paragraph (3); and

(C) by adding at the end the following new paragraph:

"(2) EXCEPTION FOR CERTAIN CASES.—The requirement for an appropriate medical screening examination under paragraph (1) shall not apply in the case of an individual who comes to the emergency department and does not request examination or treatment for an emergency medical condition (such as a request solely for prescription refills, blood pressure screening, and non-emergency laboratory and diagnostic tests).".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to terminations of participation initiated on or after the date of the enactment of this Act.

SEC. 945. EMERGENCY MEDICAL TREATMENT AND ACTIVE LABOR ACT (EMTALA) TECHNICAL ADVISORY GROUP.

(a) ESTABLISHMENT.—The Secretary shall establish a Technical Advisory Group (in this section referred to as the "Advisory Group") to review issues related to the Emergency Medical Treatment and Labor Act (EMTALA) and its implementation. In this section, the term "EMTALA" refers to the provisions of section 1867 of the Social Security Act (42 U.S.C. 1395dd).

(b) MEMBERSHIP.—The Advisory Group shall be composed of 19 members, including the Administrator of the Centers for Medicare & Medicaid Services and the Inspector General of the Department of Health and Human Services and of which—

(1) 4 shall be representatives of hospitals, including at least one public hospital, that have experience with the application of EMTALA and at least 2 of which have not been cited for EMTALA violations;

(2) 7 shall be practicing physicians drawn from the fields of emergency medicine, cardiology or cardiothoracic surgery, orthopedic surgery, neurosurgery, pediatrics or a pediatric subspecialty, obstetrics-gynecology, and psychiatry, with not more than one physician from any particular field;

(3) 2 shall represent patients;

(4) 2 shall be staff involved in EMTALA investigations from different regional offices of the Centers for Medicare & Medicaid Services; and

(5) 1 shall be from a State survey office involved in EMTALA investigations and 1 shall be from a peer review organization, both of whom shall be from areas other than the regions represented under paragraph (4).

In selecting members described in paragraphs (1) through (3), the Secretary shall consider qualified individuals nominated by organizations representing providers and patients.

(c) GENERAL RESPONSIBILITIES.—The Advisory Group—

(1) shall review EMTALA regulations;

(2) may provide advice and recommendations to the Secretary with respect to those regulations and their application to hospitals and physicians;

(3) shall solicit comments and recommendations from hospitals, physicians, and the public regarding the implementation of such regulations; and

(4) may disseminate information on the application of such regulations to hospitals, physicians, and the public.

(d) ADMINISTRATIVE MATTERS.—

(1) CHAIRPERSON.—The members of the Advisory Group shall elect a member to serve as chairperson of the Advisory Group for the life of the Advisory Group.

(2) MEETINGS.—The Advisory Group shall first meet at the direction of the Secretary. The Advisory Group shall then meet twice per year and at such other times as the Advisory Group may provide.

(e) TERMINATION.—The Advisory Group shall terminate 30 months after the date of its first meeting.

(f) WAIVER OF ADMINISTRATIVE LIMITATION.—The Secretary shall establish the Advisory Group notwithstanding any limitation that may apply to the number of advisory committees that may be established (within the Department of Health and Human Services or otherwise).

SEC. 946. AUTHORIZING USE OF ARRANGEMENTS TO PROVIDE CORE HOSPICE SERVICES IN CERTAIN CIRCUMSTANCES.

(a) IN GENERAL.—Section 1861(dd)(5) (42 U.S.C. 1395x(dd)(5)) is amended by adding at the end the following:

"(D) In extraordinary, exigent, or other non-routine circumstances, such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program's service area, a hospice program may enter into arrangements with another hospice program for the provision by that other program of services described in paragraph (2)(A)(ii)(I). The provisions of paragraph (2)(A)(ii)(II) shall apply with respect to the services provided under such arrangements.

"(E) A hospice program may provide services described in paragraph (1)(A) other than directly by the program if the services are highly specialized services of a registered professional nurse and are provided non-routinely and so infrequently so that the provision of such services directly would be impracticable and prohibitively expensive.".

(b) CONFORMING PAYMENT PROVISION.—Section 1814(i) (42 U.S.C. 1395f(i)) is amended by adding at the end the following new paragraph:

"(4) In the case of hospice care provided by a hospice program under arrangements under section 1861(dd)(5)(D) made by another hospice program, the hospice program that made the arrangements shall bill and be paid for the hospice care.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to hospice care provided on or after the date of the enactment of this Act.

SEC. 947. APPLICATION OF OSHA BLOODBORNE PATHOGENS STANDARD TO CERTAIN HOSPITALS.

(a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is amended—

(1) in subsection (a)(1)—

(A) in subparagraph (R), by striking "and" at the end;

(B) in subparagraph (S), by striking the period at the end and inserting ", and"; and

(C) by inserting after subparagraph (S) the following new subparagraph:

"(T) in the case of hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970, to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations (or as subsequently redesignated).."; and

(2) by adding at the end of subsection (b) the following new paragraph:

"(4)(A) A hospital that fails to comply with the requirement of subsection (a)(1)(T) (relating to the Bloodborne Pathogens standard) is subject to a civil money penalty in an amount described in subparagraph (B), but is not subject to termination of an agreement under this section.

"(B) The amount referred to in subparagraph (A) is an amount that is similar to the amount of civil penalties that may be imposed under section 17 of the Occupational Safety and Health Act of 1970 for a violation of the Bloodborne Pathogens standard referred to in subsection (a)(1)(T) by a hospital that is subject to the provisions of such Act.

"(C) A civil money penalty under this paragraph shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.".

(b) EFFECTIVE DATE.—The amendments made by this subsection (a) shall apply to hospitals as of July 1, 2004.

SEC. 948. BIPA-RELATED TECHNICAL AMENDMENTS AND CORRECTIONS.

(a) TECHNICAL AMENDMENTS RELATING TO ADVISORY COMMITTEE UNDER BIPA SECTION 522.—(1) Subsection (i) of section 1114 (42 U.S.C. 1314)—

(A) is transferred to section 1862 and added at the end of such section; and

(B) is redesignated as subsection (j).

(2) Section 1862 (42 U.S.C. 1395y) is amended—

(A) in the last sentence of subsection (a), by striking "established under section 1114(f)"; and

(B) in subsection (j), as so transferred and redesignated—

(i) by striking "under subsection (f)"; and

(ii) by striking "section 1862(a)(1)" and inserting "subsection (a)(1)".

(b) TERMINOLOGY CORRECTIONS.—(1) Section 1869(c)(3)(I)(ii) (42 U.S.C. 1395ff(c)(3)(I)(ii)), as amended by section 521 of BIPA, is amended—

(A) in subclause (III), by striking "policy" and inserting "determination"; and

(B) in subclause (IV), by striking "medical review policies" and inserting "coverage determinations".

(2) Section 1852(a)(2)(C) (42 U.S.C. 1395w–22(a)(2)(C)) is amended by striking "policy" and "POLICY" and inserting "determination" each place it appears and "DETERMINATION", respectively.

(c) REFERENCE CORRECTIONS.—Section 1869(f)(4) (42 U.S.C. 1395ff(f)(4)), as added by section 522 of BIPA, is amended—

(1) in subparagraph (A)(iv), by striking "subclause (I), (II), or (III)" and inserting "clause (i), (ii), or (iii)";

(2) in subparagraph (B), by striking "clause (i)(IV)" and "clause (i)(III)" and inserting "subparagraph (A)(iv)" and "subparagraph (A)(iii)", respectively; and

(3) in subparagraph (C), by striking "clause (i)", "subclause (IV)" and "subparagraph (A)" and inserting "subparagraph (A)", "clause (iv)" and "paragraph (1)(A)", respectively each place it appears.

(d) OTHER CORRECTIONS.—Effective as if included in the enactment of section 521(c) of BIPA, section 1154(e) (42 U.S.C. 1320c–3(e)) is amended by striking paragraph (5).

(e) EFFECTIVE DATE.—Except as otherwise provided, the amendments made by this section shall be effective as if included in the enactment of BIPA.

SEC. 949. CONFORMING AUTHORITY TO WAIVE A PROGRAM EXCLUSION.

The first sentence of section 1128(c)(3)(B) (42 U.S.C. 1320a–7(c)(3)(B)) is amended to read as follows: "Subject to subparagraph (G), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be not less than five years, except that, upon the request of the administrator of a Federal health care program (as defined in section 1128B(f)) who determines that the exclusion would impose a hardship on individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, or both, the Secretary may waive the exclusion under subsection (a)(1), (a)(3), or (a)(4) with respect to that program in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community.".

SEC. 950. TREATMENT OF CERTAIN DENTAL CLAIMS.

(a) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended by adding after subsection (g) the following new subsection:

"(h)(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v)) providing supplemental or secondary coverage to individuals also entitled to services under this title shall not require a medicare claims determination under this title for dental benefits specifically excluded under subsection (a)(12) as a condition of making a claims determination for such benefits under the group health plan.

"(2) A group health plan may require a claims determination under this title in cases involving or appearing to involve inpatient dental hospital services or dental services expressly covered under this title pursuant to actions taken by the Secretary.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date that is 60 days after the date of the enactment of this Act.

SEC. 951. FURNISHING HOSPITALS WITH INFORMATION TO COMPUTE DSH FORMULA.

Beginning not later than 1 year after the date of the enactment of this Act, the Secretary shall furnish to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Social Security Act, 42 U.S.C. 1395ww(d)(1)(B)) the data necessary for such hospitals to compute the number of patient days described in subclause (II) of section 1886(d)(5)(F)(vi) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(F)(vi)) used in computing the disproportionate patient percentage under such section for that hospital. Such data shall also be furnished to other hospitals which would qualify for additional payments under part A of title XVIII of the Social Security Act on the basis of such data.

SEC. 952. REVISIONS TO REASSIGNMENT PROVISIONS.

(a) IN GENERAL.—Section 1842(b)(6)(A) (42 U.S.C. 1395u(b)(6)(A)) is amended by striking "or (ii) (where the service was provided in a hospital, critical access hospital, clinic, or other facility) to the facility in which the service was provided if there is a contractual arrangement between such physician or other person and such facility under which such facility submits the bill for such service," and inserting "or (ii) where the service was provided under a contractual arrangement between such physician or other person and an entity (as defined by the Secretary), to the entity if, under the contractual arrangement, the entity submits the bill for the service and the contractual arrangement meets such other program integrity and other safeguards as the Secretary may determine to be appropriate,".

(b) CONFORMING AMENDMENT.—The second sentence of section 1842(b)(6) (42 U.S.C. 1395u(b)(6)) is amended by striking "except to an employer or facility" and inserting "except to an employer, entity, or other person".

(c) EFFECTIVE DATE.—The amendments made by section shall apply to payments made on or after the date that is one year after the date of the enactment of this Act.

SEC. 953. OTHER PROVISIONS.

(a) GAO REPORTS ON THE PHYSICIAN COMPENSATION.—

(1) SUSTAINABLE GROWTH RATE AND UPDATES.—Not later than 6 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the appropriateness of the updates in the conversion factor under subsection (d)(3) of section 1848 of the Social Security Act (42 U.S.C. 1395w–4), including the appropriateness of the sustainable growth rate formula under subsection (f) of such section for 2002 and succeeding years. Such report shall examine the stability and predictability of such updates and rate and alternatives for the use of such rate in the updates.

(2) PHYSICIAN COMPENSATION GENERALLY.—Not later than 12 months after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on all aspects of physician compensation for services furnished under title XVIII of the Social Security Act, and how those aspects interact and the effect on appropriate compensation for physician services. Such report shall review alternatives for the physician fee schedule under section 1848 of such title (42 U.S.C. 1395w–4).

(b) ANNUAL PUBLICATION OF LIST OF NATIONAL COVERAGE DETERMINATIONS.—The Secretary shall provide, in an appropriate annual publication available to the public, a list of national coverage determinations made under title XVIII of the Social Security Act in the previous year and information on how to get more information with respect to such determinations.

(c) GAO REPORT ON FLEXIBILITY IN APPLYING HOME HEALTH CONDITIONS OF PARTICIPATION TO PATIENTS WHO ARE NOT MEDICARE BENEFICIARIES.—Not later than 6 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the implications if there were flexibility in the application of the medicare conditions of participation for home health agencies with respect to groups or types of patients who are not medicare beneficiaries. The report shall include an analysis of the potential impact of such flexible application on clinical operations and the recipients of such services and an analysis of methods for monitoring the quality of care provided to such recipients.

(d) OIG REPORT ON NOTICES RELATING TO USE OF HOSPITAL LIFETIME RESERVE DAYS.—Not later than 1 year after the date of the enactment of this Act, the Inspector General of the Department of Health and Human Services shall submit a report to Congress on—

(1) the extent to which hospitals provide notice to medicare beneficiaries in accordance with applicable requirements before they use the 60 lifetime reserve days described in section 1812(a)(1) of the Social Security Act (42 U.S.C. 1395d(a)(1)); and

(2) the appropriateness and feasibility of hospitals providing a notice to such beneficiaries before they completely exhaust such lifetime reserve days.

SEC. 954. TEMPORARY SUSPENSION OF OASIS REQUIREMENT FOR COLLECTION OF DATA ON NON-MEDICARE AND NON-MEDICAID PATIENTS.

(a) IN GENERAL.—During the period described in subsection (b), the Secretary may not require, under section 4602(e) of the Balanced Budget Act of 1997 or otherwise under OASIS, a home health agency to gather or submit information that relates to an individual who is not eligible for benefits under either title XVIII or title XIX of the Social Security Act (such information in this section referred to as "non-medicare/medicaid OASIS information").

(b) PERIOD OF SUSPENSION.—The period described in this subsection—

(1) begins on the date of the enactment of this Act; and

(2) ends on the last day of the 2nd month beginning after the date as of which the Secretary has published final regulations regarding the collection and use by the Centers for Medicare & Medicaid Services of non-medicare/medicaid OASIS information following the submission of the report required under subsection (c).

(c) REPORT.—

(1) STUDY.—The Secretary shall conduct a study on how non-medicare/medicaid OASIS information is and can be used by large home health agencies. Such study shall examine—

(A) whether there are unique benefits from the analysis of such information that cannot be derived from other information available to, or collected by, such agencies; and

(B) the value of collecting such information by small home health agencies compared to the administrative burden related to such collection.

In conducting the study the Secretary shall obtain recommendations from quality assessment experts in the use of such information and the necessity of small, as well as large, home health agencies collecting such information.

(2) REPORT.—The Secretary shall submit to Congress a report on the study conducted under paragraph (1) by not later than 18 months after the date of the enactment of this Act.

(d) CONSTRUCTION.—Nothing in this section shall be construed as preventing home health agencies from collecting non-medicare/medicaid OASIS information for their own use.

I. INTRODUCTION

A. PURPOSE AND SUMMARY, AND

B. BACKGROUND AND NEED FOR LEGISLATION

Nearly four decades ago, Congress enacted the Medicare program to help provide health care to our nation's seniors. Medicare has improved and lengthened the lives of millions of people. In recent years, Congress has both successfully slowed Medicare's growth rate and added new preventive benefits to keep seniors healthier. Yet Medicare has still not met its true promise because it remains mired in a rigid administrative structure that can only change when Congress enacts a law.

When Medicare was enacted, there were few prescription drugs, and most care was delivered in hospitals and physician offices. Consequently, Medicare did not cover prescription drugs. While about two-thirds of seniors have some prescription drug coverage through various sources, access to such coverage has been declining and oftentimes remains inadequate. Many other seniors lack prescription drug coverage, and therefore, they lack the bargaining power to reduce their drug costs.

Prescription drugs are an integral part of health care today. They prevent and manage diseases and most often are less invasive and costly than alternative health care options (e.g. surgery, hospitalization, nursing home admission, etc.). Most private health plans have voluntarily integrated prescription drugs into their benefits. Nobody today with a blank sheet of paper would design a health care program for seniors that excluded prescription drugs. Yet, the absence of a prescription drug benefit epitomizes how Medicare has not kept pace with modern medicine. While a Medicare prescription drug benefit is long overdue, it is not the only problem afflicting a program so many cherish and want to strengthen.

Irrational and unpredictable payments to physicians are just one example of what is wrong with Medicare's reimbursement policy. While health costs are escalating under the current Sustainable Growth Rate formula, payments to physicians under current law would be substantially reduced. Patients' access to physicians will suffer and the doctors beneficiaries rely on will only become more demoralized. Similarly, rural hospitals continue to struggle and are not paid equitably compared to large urban hospitals. In addition, numerous Medicare+Choice plans are withdrawing from the program and are substantially cutting benefits because government

payments are not related to the actual cost of providing health care.

At the same time, Medicare is overpaying on other counts, such as for durable medical equipment. The Office of Inspector General has documented that taxpayers and Medicare beneficiaries are paying millions more for durable medical equipment than other programs, such as the Federal Employees Health Benefit Program (FEHBP). Similarly, numerous studies by the General Accounting Office, Office of Inspector General and others have documented tremendous overpayments to oncologists and other physicians for currently covered prescription drugs. In some cases, the beneficiary copay exceeds the actual acquisition cost of the drug.

In addition, the health care professionals serving Medicare beneficiaries are being crushed by more than 130,000 pages of overly burdensome regulations—four times more than those governing the Internal Revenue Code. This over-regulation hampers efforts to provide quality care to seniors, and it must be changed.

Finally, and most importantly, Medicare's long-term viability is not on stable ground. When Medicare was enacted, there were more than six workers per beneficiary. Today, there are about four workers per beneficiary. After the baby-boom generation retires (which starts at the end of this decade), there will be about two workers per beneficiary. Absent any change in law, Medicare costs will nearly double over the next 10 years. Medicare needs to become more efficient.

This bill addresses all of these issues and more.

First and foremost, the bill provides a voluntary, affordable prescription drug benefit as an entitlement to all beneficiaries. The proposal is within the $400 billion over 10 years allocated under the budget resolution. Under the bill, Medicare beneficiaries would pay a $250 deductible and then receive 80 percent coverage of their annual drug costs up to $2,000. This 80–20 benefit looks like standard coverage offered by employer plans, and today nearly two-thirds of beneficiaries spend less than $2,000 on drugs annually. In addition, the bill provides catastrophic protection after an individual has incurred $3,500 in out-of-pocket costs. At that threshold, 100 percent of costs will be covered. The Congressional Budget Office (CBO) estimates the average monthly beneficiary premium to be about $35.

Additionally, the bill targets resources to those who need them most. For low-income seniors up to 135 percent of poverty, premiums would be fully subsidized and all cost-sharing, except for nominal copays, would be covered. Those with incomes between 135 and 150 percent would also receive assistance for their premiums. Seniors with incomes above $60,000 or couples with incomes above $120,000 would have a higher catastrophic threshold, but would receive the same front-end benefit. This higher threshold would affect only about five percent of individuals.

The prescription drug benefit would be delivered through competing integrated health plans and private sector entities that already deliver pharmaceutical benefits for millions of people, including every Member of Congress. The bill permits and encourages these plans to utilize private sector tools to aggressively negotiate lower drug prices and provide better service for beneficiaries. By exempting prices negotiated for Medicare beneficiaries from the

Medicaid "best price" provision, the bill encourages steep discounting by pharmaceutical manufacturers that would save taxpayers and beneficiaries billions of dollars. The private sector delivery of benefits is backed up by a government guarantee that all seniors in every area of the country must be covered. Indeed, the Congressional Budget Office and the Centers for Medicare and Medicaid Services (CMS) Office of the Actuary predicts that more than 95 percent of the seniors that lack coverage would voluntarily sign up for this benefit.

The bill would provide seniors with more and better choices for the delivery of their health care. The Medicare+Choice program would be fundamentally reformed by re-linking payments to fee-for-service costs and permitting plans to bid their actual costs, beginning in 2006. Plans would be paid what they bid and savings would be split 75 percent–25 percent between the beneficiary and government for plans that bid below the benchmark. The bill would also implement the President's "enhanced fee-for-service" program, which provides for regional, open-network plans offering better integrated care.

In 2010, the bill would put Medicare on a more stable funding path by moving to a FEHBP-style of competition between plans. Nothing would change Medicare's entitlement to a defined set of benefits, but costs between fee-for-service and private plans would be directly compared. Beneficiaries would be rewarded for enrolling in more efficient plans, regardless of whether the plans are private or traditional fee-for-service. This program would only apply in areas with significant private plan penetration (at least equal to the national average market share), and the fee-for-service plan would have disproportionate influence in establishing the benchmark. This transition would be phased in over five years. This provision provides Medicare the best chance to bend its growth rate in the out-years by enabling beneficiaries to make efficient and rational choices, and by permitting the government to share in the savings when beneficiaries select cost-effective plans.

More than 179 different patient groups, provider groups, and employers have endorsed this legislation because it provides a meaningful benefit, modernizes irrational reimbursements, and reduces burdensome regulatory structures that undermine the quality and accessibility of care. The bill reforms physician payments, addresses payment inequities for rural hospitals and home health providers, and makes responsible decisions on provider reimbursements based on the Medicare Payment Advisory Commission's recommendations. More importantly, the legislation sets Medicare on a path of more rational pricing—determined by the marketplace, rather than government edict—through moving durable medical equipment, currently covered drugs, and Medicare's contractors into a competitive system. In addition to creating a more rational system that saves money over time, these changes get Congress out of the business of micro-managing payments to providers across communities in America based on political decisions in Washington.

The bill provides clear improvements for preventive benefits for beneficiaries. For the first time, in order to diagnose problems early and keep seniors healthy, Medicare would cover initial physicals and provide coverage for cholesterol screening. The bill would also

provide better-coordinated care for the numerous Medicare beneficiaries who suffer from multiple chronic illnesses.

The bill also includes regulatory and contracting reforms—reforms that passed the House twice in the 107th Congress—to reduce unnecessary regulation and modernize how Medicare selects its contractors.

Finally, the bill also establishes a new Medicare Benefits Administration (MBA) to manage and oversee the Medicare Advantage and Enhanced Fee-for-Service Programs as well as the prescription drug benefit. Creating of the MBA eliminates the inherent conflict-of-interest in requiring a government-run fee-for-service plan to regulate competing private plans.

C. LEGISLATIVE HISTORY

Legislative Hearings

During the 107th and 108th Congresses, the Committee on Ways and Means, and its Subcommittee on Health, held 24 hearings exploring how Medicare should be strengthened and modernized. These hearings, which examined all aspects of the Medicare program, included expert testimony from academic, beneficiary and provider representatives. The following lists the hearings in the 107th and 108th Congresses in reverse chronological order:

108TH CONGRESS

May 1, 2003: Medicare Cost-Sharing and Medigap Reform (Subcommittee on Health)

Witnesses

Glenn M. Hackbarth, Chairman, Medicare Payment Advisory Commission.

Stephen W. Still, Esq., Maynard, Cooper & Gale, P.C., Birmingham, Alabama, on behalf of Torchmark Corporation, Birmingham, Alabama, and United American Insurance Company, McKinney, Texas.

Richard White, Vice President, Individual Project Management, Southeast Region, Anthem Blue Cross and Blue Shield, Roanoke, Virginia.

Patricia Neuman, Sc. D., Vice President and Director, Medicare Policy Project, Kaiser Medicare Policy Project, Henry J. Kaiser Family Foundation.

April 9, 2003: Hearing on Expanding Coverage of Prescription Drugs in Medicare (Full Committee)

Witnesses

Douglas Holtz-Eakin, Ph.D., Director, Congressional Budget Office.

The Honorable David M. Walker, Comptroller General, U.S. General Accounting Office.

Bruce Stewart, Ph.D., Director, Peter Lamy Center on Drug Therapy and Aging, University of Maryland, Baltimore, Maryland.

Mark V. Pauly, Ph.D., Chairperson, Health Care Systems Department, The Wharton School, University of Pennsylvania, Philadelphia, Pennsylvania.

Uwe Reinhardt, Ph.D., Professor, Economics and Public Affairs, Department of Economics, and Woodrow Wilson School of Public and International Affairs, Princeton University, Princeton, New Jersey

March 6, 2003: Hearing on the MedPAC Report on Medicare Payment Policies (Subcommittee on Health)

Witnesses

Glenn M. Hackbarth, Chairman, MedPAC.

James Jaruzewicz, President and Chief Executive Officer, Visiting Nurses Association of Erie County, Erie, Pennsylvania, on behalf of the Visiting Nurses Association of America.

Larry C. Buckelew, President and Chief Executive Officer, Gambro Healthcare U.S., and Chairman, Renal Leadership Council.

William G. Plested, III, M.D., Chair-Elect, American Medical Association.

Mary K. Ousley, Chairman, American Health Care Association.

Dennis Barry, President and Chief Executive Officer, Moses Cone Health System, Greensboro, North Carolina, and Chairman, Board of Trustees, American Hospital Association.

Betty Severyn, Member, Board of Directors, AARP.

February 25, 2003: Hearing on Eliminating Barriers to Chronic Care Management in Medicare (Subcommittee on Health)

Witnesses

Stuart Guterman, Director, Office of Research, Development and Information, Centers for Medicare and Medicaid Services.

Jeff Lemieux, Senior Economist, Progressive Policy Institute.

Ed Wagner, M.D., Director, MacColl Institute for Healthcare Innovation, Center for Health Studies, Group Health Cooperative, Seattle, Washington.

George A. Taler, M.D., Director, Long Term Care, Department of Medicine, Washington Hospital Center, on behalf of the American Geriatric Society.

Jan Berger, M.D., Senior Vice President, Clinical Quality and Support, Caremark Rx Incorporated, Northbrook, Illinois.

February 13, 2003: Hearing on Medicare Regulatory and Contracting Reform (Subcommittee on Health)

Witnesses

The Honorable Thomas A. Scully, Administrator, Centers for Medicare and Medicaid Services.

Douglas L. Wood, M.D., Vice Chair, Department of Medicine, Mayo Clinic and Foundation, Rochester, Minnesota.

Michael Luebke, President, Verizon Information Technologies Inc., Tampa, Florida.

Tony Fay, Vice President, Government Affairs, Province Healthcare Company, Brentwood, Tennessee, on behalf of the American Hospital Association.

J. Edward Hill, M.D., Chairman, Board of Trustees, American Medical Association.

Janet B. Wolf, President, Munson Home Health, Traverse City, Michigan, and Past President, Board of Directors, Michigan Home Health Association, Okemos, Michigan, on behalf of the National Association for Home Care and Hospice.

Judith A. Ryan, Ph.D., President and Chief Executive Officer, Evangelical Lutheran Good Samaritan Society, Sioux Falls, South Dakota, on behalf of the American Health Care Association.

Michael Carius, M.D., Immediate Past President, American College of Emergency Physicians, Norwalk, Connecticut, and Founding Member, Alliance of Specialty Medicine.

Vicki Gottlich, Attorney, Healthcare Rights Project, Center for Medicare Advocacy, Inc.

February 6, 2003: Hearing on the President's Fiscal Year 2004 Budget with U.S. Department of Health and Human Services (Full Committee)

Witness

The Honorable Tommy G. Thompson, Secretary, U.S. Department of Health and Human Services.

107TH CONGRESS

October 3, 2003: Medicare Payments for Currently Covered Prescription Drugs (Subcommittee on Health)

July 23, 2002: Medicare's Geographic Cost Adjusters (Subcommittee on Health)

April 17, 2002: Integrating Prescription Drugs into Medicare (Full Committee)

April 16, 2002: Promoting Disease Management in Medicare (Subcommittee on Health)

March 14, 2002: Medicare Supplemental Insurance (Subcommittee on Health)

March 7, 2002: Health Quality and Medical Errors (Subcommittee on Health)

February 28, 2002: Reforming Physician Payments (Subcommittee on Health)

December 4, 2001: Status of the Medicare+Choice Program (Subcommittee on Health)

September 25, 2001: H.R. 2768, Medicare Regulatory and Contracting Reform Act (Subcommittee on Health)

July 19, 2001: Administration's Principles to Strengthen and Modernize Medicare (Full Committee)

June 12, 2001: Rural Health Care in Medicare (Subcommittee on Health)

May 9, 2001: Strengthening Medicare: Modernizing Beneficiary Cost-Sharing (Subcommittee on Health)

May 1, 2001: Medicare+Choice: Lessons for Reform (Subcommittee on Health)

March 27, 2001: Laying the Groundwork for a Prescription Drug Benefit (Subcommittee on Health)

March 20, 2001: Medicare Solvency (Full Committee)

March 15, 2001: Bringing Regulatory Relief to Beneficiaries and Providers (Subcommittee on Health)

March 14, 2001: Administration's Health and Welfare Priorities (Full Committee)

February 28, 2001: Perspectives on Medicare Reform (Subcommittee on Health)

On April 11, 2003, Congress agreed to the conference report for H. Con. Res. 95, "Establishing the congressional budget for the United States Government for fiscal year 2004 and setting forth appropriate budgetary levels for fiscal years 2003 and 2005 through 2013," which provided $400 billion over 10 years for Medicare modernization and prescription drugs.

On June 16, 2003, Committee on Ways and Means Chairman Bill Thomas and Committee on Energy and Commerce Chairman Billy Tauzin introduced H.R. 2473, the "Medicare Prescription Drug and Modernization Act of 2003". (Identical language in the form of a report was released publicly June 13, 2003.) On June 17, 2003, H.R. 2473 was marked up by the full Committee on Ways and Means and ordered favorably reported by a vote of 25–15, after adopted amendments—including the Thomas amendment in the nature of a substitute—were accepted into the bill. The amendments that were accepted to the Thomas amendment in the nature of a substitute were: (1) an amendment offered by Mrs. Johnson to instruct the Secretary of the U.S. Department of Health and Human Services to promptly evaluate existing codes for physician services associated with the administration of covered outpatient drugs; and to use existing processes to establish relative values for such services; (2) an en bloc amendment offered by Mr. Collins to exempt MA private FFS plans from compliance with the drug utilization management program, negotiation of discounts from manufacturers, disclosure of fact that generic drug is available at a lower cost, and TRICARE standards for participation; and (3) an amendment offered by Mr. Nussle and Mr. Pomeroy to adjust the Medicare inpatient hospital prospective payments system wage index to revise the labor-related share of such index, and to provide a five percent bonus payment to physicians operating in physician scarcity areas.

II. EXPLANATION OF PROVISIONS

A. Title I—Medicare Prescription Drug Benefit

Section 101. Establishment of a Medicare Prescription Drug Benefit

CURRENT LAW

Medicare does not cover most outpatient prescription drugs. Beneficiaries in hospitals or skilled nursing facilities may receive drugs as part of their treatment. Medicare payments made to the facilities cover these costs. Medicare also makes payments to physicians for drugs or biologicals that are not usually self-administered. This means that coverage is generally limited to drugs or biologicals administered by injection. However, if the injection is generally self-administered (e.g., insulin), it is not covered.

Despite the general limitation on coverage for outpatient drugs, Medicare statute specifically authorizes coverage for the following: (1) drugs used in immunosuppressive therapy (such as cyclosporin) following discharge from a hospital for a Medicare-covered organ transplant, (2) erythropoietin (EPO) for the treatment of anemia for persons with chronic renal failure who are on dialysis, (3) drugs taken orally during cancer chemotherapy provided they have the

same active ingredients and are used for the same indications as chemotherapy drugs which would be covered if they were not self-administered and were administered as incident to a physician's professional service, and (4) hemophilia clotting factors for hemophilia patients competent to use such factors to control bleeding without medical supervision, and items related to the administration of such factors. The program also pays for supplies (including drugs) that are necessary for the effective use of covered durable medical equipment, including those that must be put directly into equipment (e.g., tumor chemotherapy agents used with an infusion pump). Medicare also covers pneumococcal pneumonia vaccines, hepatitis B vaccines, and influenza virus vaccines.

EXPLANATION OF PROVISION

The provision would establish a new voluntary prescription drug benefit program under a new Medicare Part D of Title XVIII of the Social Security Act. Effective January 1, 2006, a new voluntary benefit would be established. Beneficiaries could purchase either "standard coverage" or actuarially equivalent coverage approved by the Secretary of Health and Human Services. In 2006, "standard coverage" would have a $250 deductible, 80 percent coverage for costs between $251 and $2,000, and all costs after the individual has borne $3,500 in out-of-pocket spending (a.k.a. the catastrophic threshold). The catastrophic threshold would be raised for individuals with income above $60,000 and couples with income above $120,000. Subsidies would be provided for persons with income below 150 percent of poverty. Coverage would be provided through PDPs, Medicare Advantage (MA) plans (formerly known as Medicare+Choice plans), or Enhanced Fee-For-Service plans (EFFS). The program would rely on private plans to provide coverage and to bear some of the financial risk for drug costs. Federal subsidies would be provided to encourage participation. Plans would be expected to negotiate prices for drugs. A new Medicare Benefits Administration (MBA), within the Department of Health and Human Services (HHS), would contract with plans.

New Section 1860D–1. Benefits; Eligibility; Enrollment; and Coverage Period

The new Section 1860A would specify that each individual entitled to Medicare Part A or enrolled in Medicare Part B would be entitled to obtain qualified prescription drug coverage under Medicare. MA plans and EFFS plans (MA–EFFS plans) would be required to offer qualified prescription drug coverage. An individual enrolled in a MA–EFFS plan would obtain their drug coverage through the plan. An individual not enrolled in either a Medicare Advantage or EFFS plan could enroll in a new PDP. The provision would specify that an individual eligible to make an election to enroll in a PDP, or with a MA–EFFS plan, would do so in accordance with regulations issued by the Administrator of the new MBA. Enrollments and changes in enrollment could occur only during a specified election period. The election periods would generally be the same as those established for MA–EFFS programs including annual coordinated election periods and special election periods. An individual discontinuing a MA election during the first year of eligibility would be permitted to enroll in a PDP at the same time as

the election of coverage under the original fee-for-service plan (FFS).

An initial six month election period, beginning on October 1, 2005, would be established for persons entitled to Part A or enrolled under Part B on that date. For persons first entitled to Part A or enrolled in Part B after that date, an initial election period that would be the same as that for initial Part B enrollment, would be established. The MBA Administrator would be required to establish special election periods for persons in specific circumstances, such as having and then involuntarily losing prescription drug coverage; enrollment delays or non-enrollment attributable to government action; becoming eligible for Medicaid drug coverage; or any such exceptional circumstance specified by the MBA Administrator (including circumstances pertaining to MA enrollment).

Guaranteed issue and community-rating protections would be established for beneficiaries. Individuals electing qualified prescription drug coverage under a PDP plan or MA–EFFS plan could not be denied enrollment based on health status or other factor. MA provisions relating to priority enrollment (where capacity limits have been reached) and limitations on terminations of elections would apply to PDP sponsors.

The provision would specify that PDP sponsors and MA–EFFS organizations providing qualified prescription drug coverage could not deny, limit, or condition the coverage or provision of benefits or increase the premium based on any health-related status factor in the case of persons who maintained continuous prescription drug coverage since the date they first qualified to elect drug coverage under Part D. Individuals who did not maintain continuous coverage could be subject to an adjusted premium in a manner reflecting the additional actuarial risk involved. Such risk would be established through an appropriate actuarial opinion.

An individual would be considered to have had continuous prescription drug coverage if the individual could establish that he or she had coverage under one of the following (and coverage in one plan occurred no more than 63 days after termination of coverage in another plan): (1) a qualified PDP or MA–EFFS plan, (2) Medicaid, (3) a group health plan, but only if benefits were at least equivalent to benefits under a qualified PDP, (4) a Medigap plan, but only if the policy was in effect on January 1, 2006, and only if the benefits were at least equivalent to benefits under a qualified PDP, (5) a state pharmaceutical assistance program, but only if benefits were at least equivalent to benefits under a qualified PDP, or (6) a veteran's plan, but only if benefits were at least equivalent to benefits under a qualified PDP. Individuals could apply to the MBA Administrator to waive the requirement that such coverage be at least equivalent to benefits under a qualified PDP if they could establish that they were not adequately informed that the coverage did not provide such level of coverage.

PDP sponsors would make drug coverage available to all eligible individuals residing in the area—without regard to their health, economic status, or place of residence.

Elections would take effect at the same time that they do for MA plans; however, no election could take effect before January 1, 2006. The MBA Administrator would provide for the termination of an election in the case of termination of Part A and Part B cov-

erage or termination of an election for cause (including failure to pay the required premium).

New Section 1860D–2. Requirements for Qualified Prescription Drug Coverage

The new Section 1860D–2 would specify the requirements for qualified prescription drug coverage. Qualified coverage would be defined as either "standard coverage" or actuarially equivalent coverage.

For 2006, "standard coverage" would have a $250 deductible, 80 percent coverage for costs between $251 and $2,000, and full coverage for all costs after the individual has borne $3,500 in out-of-pocket spending (a.k.a. the catastrophic threshold). Beneficiaries would have access to negotiated discounts even where there would be no insurance benefit (between $2,000 in spending and $3,500 in out-of-pocket spending). Beginning in 2007, standard coverage thresholds would be increased by the annual percent increase in average per capita expenditures for covered outpatient drugs for beneficiaries (for the 12-month period ending in July of the previous year).

Plans would be permitted to substitute cost-sharing schedules for costs up to the initial coverage limit ($2,000) that are actuarially consistent with the average expected 20 percent cost-sharing up to the initial coverage limit. They could also apply tiered coinsurance, provided such coinsurance was actuarially consistent with the average 20 percent cost-sharing requirements.

Costs that would count toward meeting the catastrophic limit would only be considered incurred if they were paid for the deductible, cost-sharing, or benefits not paid because of application to the initial coverage limit. Costs would be treated as incurred costs only if they are paid by the individual (or by another family member on behalf of the individual), paid on behalf of a low-income individual under the subsidy provisions, under the Medicaid program, or by a state pharmaceutical assistance program. Substantial new assistance would be provided to those states with pharmaceutical assistance programs through the catastrophic benefit by requiring Medicare to pay 80 percent of the costs above the catastrophic limit. Any costs for which the individual was reimbursed by insurance or otherwise would not count toward incurred costs.

The provision would increase the annual out-of-pocket threshold for each enrollee whose adjusted gross income exceeds a specified income threshold. The portion of income exceeding this income threshold ($60,000 for individuals and $120,000 for couples in 2006), but below an income threshold limit ($200,000 in 2006), would be considered in making this calculation. The increase would be calculated as follows: first, the ratio of the annual out-of-pocket limit to the income limit would be calculated and expressed as a percent; for 2006, this would be $3,500 divided by $60,000, equaling about 5.8 percent. This percentage would be multiplied by income over the income threshold, not exceeding $140,000. Thus, the catastrophic out-of-pocket limit would be $5,820 for an enrollee with an income of $100,000 and $11,620 for persons with incomes at $200,000 or above. Beginning in 2007, the income threshold and income threshold limit would be increased by the percentage in-

crease in the consumer product index (CPI) for all urban consumers, rounding to the nearest $100.

The amount used for making the income determination would be adjusted gross income Individuals filing joint returns would be treated separately with each person considered to have an adjusted gross income equal to one-half of the total. The determination would be the most recent return information disclosed by the Secretary of the Treasury to the Secretary of HHS before the beginning of the year. The Secretary, in coordination with the Secretary of the Treasury, would provide a procedure under which an enrollee could elect to use more recent information, including information for a taxable year ending in the current calendar year. Through the 1–800 toll free Medicare beneficiary line, individuals would have assistance in appealing a determination from the Medicare Ombudsman. The process would require: (1) the enrollee to provide the Secretary with the relevant portion of the more recent return, (2) verification by the Secretary of the Treasury, and (3) payment by the Secretary to the enrollee equal to the benefit payments that would have been payable under the plan if more recent information had been used. If such payments were made, the PDP sponsor would pay the Secretary the requisite amount, less the applicable reinsurance that would have applied.

The Secretary would be required to provide, through the annual Medicare handbook, general information on the calculation of catastrophic out-of-pocket thresholds. The Secretary would periodically transmit to the Secretary of the Treasury the names and Social Security Numbers (SSNs) of enrollees in PDPs or MA–EFFS plans and request that the Secretary of the Treasury disclose income information. The Secretary would disclose to entities offering the plan the amount of the out-of-pocket threshold that would apply to a specified taxpayer. New confidentiality protections and severe criminal and civil penalties would apply to any unauthorized disclosure of information.

The provision would permit a PDP or MA–EFFS sponsor to offer, subject to approval by the MBA Administrator, alternative coverage providing certain requirements were met. The actuarial value of total coverage would have to be at least equal to the actuarial value of standard coverage. The unsubsidized value of the coverage (i.e. the value of the coverage exceeding subsidy payments) would have to be equal to the unsubsidized value of standard coverage. The coverage would be designed (based on actuarially representative patterns of utilization) to provide for payment of incurred costs up to the initial coverage limit of at least the same percentage of costs provided under standard coverage. Further, catastrophic protection would have to be the same as that under standard coverage. It could not vary.

Both standard coverage and actuarially equivalent coverage would offer access to negotiated prices, including applicable discounts. Access would be provided even when no benefits were payable because of the application of cost-sharing or initial coverage limits. Insofar as a State elected to use these negotiated prices for its Medicaid program, the Medicaid drug payment provisions would not apply. Further, the negotiated prices would not be taken into account in making "best price" determinations under Medicaid. Under the current Medicaid best price policy, the largest discount

a pharmaceutical manufacturer negotiates in the private market must be passed along to the Medicaid program as well. Since manufacturers can only influence market share and volume in the private sector, not Medicaid, the "best price" policy has led to less discounting by manufacturers. As a result, arbitrary price floors are created and consumers pay the price as competing manufacturers have had less incentive to steeply discount their prices. This provision saves Medicare billions of dollars by encouraging pharmaceutical manufacturers to offer the same discounts that private plans currently receive. For transparency reasons, the PDP or MA–EFFS sponsor would be required to disclose to the MBA Administrator the extent to which manufacturer discounts or rebates or other remunerations or price concessions are made available to the sponsor or organization and passed through to enrollees through pharmacies. Manufacturers would be required to disclose pricing information to the MBA Administrator under the same conditions currently required for Medicaid. Transparency in pricing and rebate arrangements is a key factor in ensuring beneficiaries and taxpayers are receiving the best value for their resources.

Qualified prescription drug coverage could include coverage exceeding that specified for standard coverage or actuarially equivalent coverage. However, any additional coverage would be limited to covered outpatient drugs. The MBA Administrator could terminate a contract with a PDP or MA–EFFS sponsor if a determination was made that the sponsor or organizations engaged in activities intended to discourage enrollment of classes of eligible Medicare beneficiaries obtaining coverage through the plan on the basis of their higher likelihood of utilizing prescription drug coverage.

Covered outpatient drugs would be defined to include: (1) a drug which may only be dispensed subject to a prescription and which is described in subparagraph (A)(i) or (A)(ii) of Section 1927(k)(2) of the Social Security Act (relating to drugs covered under Medicaid), (2) a biological product described in paragraph B of such subsection, (3) insulin described in subparagraph C of such section, and (4) vaccines licensed under Section 351 of the Public Health Service Act. Drugs excluded from Medicaid coverage would be excluded from the definition except for smoking cessation drugs. The definition includes any use of a covered outpatient drug for a medically accepted indication. Drugs paid for under Medicare Part B would not be covered under Part D. A plan could elect to exclude a drug that would otherwise be covered, if the drug was excluded under the formulary and the exclusion was not successfully appealed under the new Section 1860D–3. In addition, a PDP or MA–EFFS sponsor could exclude from coverage, subject to reconsideration and appeals provisions, any drug that either does not meet Medicare's definition of medical necessity or is not prescribed in accordance with the plan or Part D. Beneficiaries could appeal the placement of a drug in a higher coinsurance tier to an external, independent entity.

New Section 1860D–3. Beneficiary Protections for Qualified Prescription Drug Coverage

The new Section 1860D–3 would specify required beneficiary protections. Plans would have to comply with guaranteed issue and community-rated premium requirements specified in the new Sec-

tion 1860D–1, access to negotiated prices as specified in the new Section 1860D–2, and the non-discrimination provisions specified in the new Section 1860D–6.

The PDP sponsors would be required to disclose to each enrolling beneficiary information about the plan's benefit structure, including information on: (1) access to covered drugs, including access through pharmacy networks, (2) how any formulary used by the sponsor functioned, (3) copayment and deductible requirements (including any applicable tiered copayment requirements), and (4) grievance and appeals procedures. In addition, beneficiaries would have the right to obtain more detailed plan information. The sponsor would be required to make available, through an Internet site and, on request, in writing, information regarding the basis for exclusion of any drug from the formulary. Plans must notify enrollees when a change has been made in the preferred status of a drug or biological, or if there has been a change in a beneficiary's coinsurance. Plans would be required to furnish to enrollees a detailed explanation of benefits, including information on benefits compared to the initial coverage limit and the applicable out-of-pocket threshold.

PDP and MA–EFFs sponsors would be required to permit the participation of any pharmacy that met the plan's terms and conditions. Beneficiaries would be ensured access to any convenient local pharmacy that chose to participate in the plan. PDP and MA–EFFS sponsors could reduce coinsurance for their enrolled beneficiaries below the otherwise applicable level for drugs dispensed through in-network pharmacies; in no case could the reduction result in an increase in subsidy payments made by the MBA Administrator to the plan. Sponsors would be required to secure participation in its network of a sufficient number of pharmacies that dispense drugs directly to patients to assure convenient access. Mail order only pharmacy would be prohibited so that beneficiaries have access to a convenient bricks and mortar pharmacy. The MBA Administrator would establish convenient access rules that were no less favorable to enrollees than rules for convenient access established by the Secretary of Defense on June 1, 2003, for the TRICARE Retail Pharmacy program. The TRICARE standard specifies that, in an urban area, 90 percent of beneficiaries must be within two miles of a participating pharmacy; in a suburban area, 90 percent of beneficiaries must be within five miles of a participating pharmacy; and in rural areas, 70 percent of beneficiaries must be within fifteen miles of a participating pharmacy. According to the Department of Defense, the TRICARE Retail Pharmacy program receives minimal access complaints each year, and problems and disputes related to access are resolved quickly. The rules would include adequate emergency access for enrolled beneficiaries. Sponsors would permit enrollees to receive benefits through a community pharmacy, rather than through mail-order, with any differential in cost paid by enrollees. Pharmacies could not be required to accept insurance risk as a condition of participation. It is important that pharmacies are not put at risk for events they cannot control, such as volume and frequency of prescriptions.

PDP and MA–EFFS sponsors would be required to issue (and reissue as appropriate) a card or other technology that could be used by an enrolled beneficiary to assure access to negotiated prices for

drugs when coverage is not otherwise provided under the plan. The MBA Administrator would provide for the development of uniform standards relating to a standardized format for the card or other technology. These standards would be compatible with the administrative simplification requirements of Title XI of the Social Security Act.

There is no requirement to use a formulary, however, if a PDP or MA–EFFS sponsor uses a formulary, it would have to meet certain requirements. It would be required to establish an independent pharmaceutical and therapeutic committee free of conflict with the plan to develop and review the formulary. The committee would include at least one physician and one pharmacist with expertise in the care of elderly or disabled persons, and the majority of members would be physicians or pharmacists. The committee would be required, when developing and reviewing the formulary, to base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and such other information the committee determined appropriate. Arbitrary determinations to exclude products from the formulary would not be permitted.

The P&T committee would also take into account whether including a particular covered drug had therapeutic advantages in terms of safety and efficacy. In addition, the formulary would have to include at least two drugs within each therapeutic category and class of covered outpatient drugs, although not necessarily all drugs within such categories or classes. When establishing such classes, the committee would take into account the standards published in the United States Pharmacopoeia Drug Information. It would be required to make available to plan enrollees, through the Internet or otherwise, the clinical basis for the coverage of any drug on the formulary. The committee would be required to establish policies and procedures to educate and inform health care providers concerning the formulary. Any removal of a drug from the formulary could not occur until appropriate notice had been provided to beneficiaries and physicians. The plan would provide for periodic evaluation and analysis of treatment protocols and procedures. Further, the PDP or MA–EFFS sponsor would be required to provide for, as part of its overall appeals process, appeals of coverage denials regarding application of the formulary.

Each PDP or MA–EFFS sponsor would ensure that each pharmacy or other dispenser informed enrolled beneficiaries at the time of purchase, of any price differential between their prescribed drug and the price of the lowest cost generic drug covered under the plan that was therapeutically equivalent and bioequivalent.

The PDP or MA–EFFS sponsor would be required to have (directly, or indirectly through arrangements): (1) an effective cost and drug utilization management program, (2) quality assurance measures including a medication therapy management program, (3) for years beginning with 2007, an electronic prescription drug program, and (4) a program to control waste, fraud, and abuse. Utilization management programs would be required to include medically appropriate incentives to use generic drugs and therapeutic interchange where appropriate. Medication therapy management programs would be designed to assure, for beneficiaries at risk for

potential medication problems such as beneficiaries with complex or chronic diseases (such as diabetes, asthma, hypertension, and congestive heart failure) or multiple prescriptions, that drugs under the plan were appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events, including adverse drug interactions. The program would be developed in cooperation with licensed pharmacists and physicians. The PDP sponsor would be required, when establishing fees for pharmacists and other providers, to take into account the resources and time associated with the medication therapy management program. MA private fee-for-service plans would not be required to comply with the drug utilization management program, negotiate discounts from manufacturers, meet the TRICARE standards for participation, or disclose the fact that a lower priced generic drug is available at the time of purchase.

The electronic prescription drug program would have to be consistent with national standards developed by the MBA Administrator. The program would be required to provide for electronic transmittal of prescriptions (except in emergencies and exceptional cases) and for provision of information to the prescribing health professional. To the extent feasible, the program would permit the prescribing health professional to provide, and be provided, information on an interactive real-time basis. The electronic prescribing program would permit health professionals to access information on the different medications a senior may be taking—making it easier to prevent adverse drug interactions and side effects. In addition, electronic prescribing would cut down on both the costs and hassle that pharmacists incur trying to decipher a handwritten script. These systems will increase drug compliance and properly monitor drug utilization.

The MBA Administrator would be required to provide for the development of national standards relating to the electronic prescription drug program. The standards would be compatible with those established for the administrative simplification program established under title XI of the Social Security Act. The MBA Administrator would establish an advisory task force that included representatives of physicians, hospitals, pharmacies, beneficiaries, pharmacy benefit managers, technology experts, and pharmacy benefit experts of the Department of Veterans Affairs, Defense and other appropriate Federal agencies. The task force would provide recommendations to the MBA Administrator on standards including recommendations relating to: (1) range of available computerized prescribing software and hardware and their costs to develop and implement, (2) extent to which such standards and systems reduce medication errors and can be readily implemented by physicians, pharmacies, and hospitals, (3) efforts to develop uniform standards and a common software platform for the secure electronic transmission of medication history, eligibility, benefit and prescription information, (4) efforts to develop and promote universal connectivity and interoperability for the secure exchange of information, (5) cost of implementing such systems in hospital and physician office settings and pharmacies, and (6) implementation issues as they relate to administrative simplification requirements and current Federal and State prescribing laws and regulations and their impact on implementation of computerized prescribing.

The MBA Administrator would be required to establish the task force by April 1, 2004. The task force would be required to submit recommendations to the MBA Administrator by January 1, 2005. The MBA Administrator would be required to promulgate national standards by January 1, 2006. Given current available technology, the committee supports the timely development of standards to facilitate a secure electronic prescription information program between prescribing health care professionals, pharmacists, and pharmacy benefit managers (PBMs) to reduce dangerous drug interactions as well as errors due to poor handwriting and transcribing errors. To this end, the committee believes that it would be to the benefit of the patient for prescribing professionals to have real-time, "up-front" access to the patient's medication history, eligibility for benefits, drug formulary (if applicable), and coverage, when making prescribing decisions.

Each PDP sponsor would be required to have meaningful procedures for the hearing and resolving of any grievances between the organization (including any entity or individual through which the organization provides covered benefits) and enrollees. Enrollees would be afforded access to expedited determinations and reconsiderations, in the same manner afforded under MA. A beneficiary in a plan that provided for tiered cost-sharing could request coverage of a non-preferred drug on the same conditions applicable to preferred drugs if the prescribing physician determines that the preferred drug for the treatment of the same condition was not as effective for the enrollee or could have adverse effects for the enrollee. Such decisions could also be appealed under the MA appeals structure.

In general, PDP sponsors would be required to meet for independent review standards for coverage denials and appeals in the same manner that such standards apply to MA organizations. An individual enrolled in a PDP could appeal to obtain coverage for a drug not on the formulary or in a different cost sharing tier if the prescribing physician determined that the formulary drug for treatment of the same condition was not as effective for the individual or had adverse effects for the individual. The PDP sponsor would be required to meet requirements related to confidentiality and accuracy of enrollee records in the same manner that such requirements apply to MA organizations.

New Section 1860D–4. Requirements for and Contracts With Prescription Drug Plan (PDP) Sponsors

New Section 1860D–4 would specify organizational plan requirements for entities seeking to become PDP sponsors. In general, the section would require a PDP sponsor to be licensed under state law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each state in which it offers a prescription drug plan. Alternatively it could meet solvency standards established by the MBA Administrator for entities not licensed by the state. Plans would be required to assume full financial risk on a prospective basis for covered benefits except: (1) as covered by federal subsidy payments and reinsurance payments for high-cost enrollees, or (2) as covered by federal incentive payments to encourage plans to expand service areas for existing plans or establish

new plans. The entity could obtain insurance or make other arrangements for the cost of coverage provided to enrollees.

PDP sponsors would be required to enter into a contract with the MBA Administrator under which the sponsor agrees to comply both with the applicable requirements and standards and the terms and conditions of payment. The contract could cover more than one plan. The MBA Administrator would have the same authority to negotiate the terms and conditions of the plans as the Director of the Office of Personnel Management has with respect to FEHB plans. The MBA Administrator would be required to take into account subsidy payments for covered benefits in negotiating the terms and conditions regarding premiums. The MBA Administrator would designate at least 10 service areas consistent with the areas established for EFFS plans.

The new section would incorporate, by reference, many of the contract requirements applicable to MA plans, including minimum enrollment, contract periods, allowable audits to protect against fraud and abuse, intermediate sanctions, and contract terminations. Pro rated user fees could be established to help finance enrollment activities; in no case could the amount of the fee exceed 20 percent of the maximum fee permitted for a MA plan.

The new Section would permit the MBA Administrator to waive the state licensure requirement under circumstances similar to those permitted under Part C for provider-sponsored organizations. In such cases, plans would be required to meet financial solvency and capital adequacy standards established by the MBA Administrator. The MBA Administrator would establish such standards by regulation by October 1, 2004.

The standards established under Part D would supersede any state law or regulation (other than state licensing laws or laws relating to plan solvency). In addition, states would be prohibited from imposing premium taxes or similar taxes with respect to premiums paid to PDP sponsors or payments made to such sponsors by the MBA Administrator.

New Section 1860D–5. Process for Beneficiaries To Select Qualified Prescription Drug Coverage

The new Section 1860D–5 would require the MBA Administrator to establish a process for the selection of a PDP or MA–EFFS sponsor that provided qualified prescription drug coverage. The process would include the conduct of annual coordinated election periods under which individuals could change the qualifying plans through which they obtained coverage. The process would also include the active dissemination of information to promote an informed selection among qualifying plans (based on price, quality, and other features) in a manner consistent with and in coordination with the dissemination of information under MA. Further, the process would provide for the coordination of elections through filing with a PDP or MA–EFFS sponsor in a manner consistent with that provided under MA. The plan would have to inform each enrollee at the beginning of the year of the enrollee's annual out-of-pocket threshold.

The section would specify that an EFFS enrollee could only elect to receive drug coverage through the plan.

The MBA Administrator would assure that all eligible individuals residing in the United States would have a choice of enroll-

ment in at least two qualifying plan options, at least one of which is a PDP, in their area of residence. The requirement would not be satisfied if only one PDP or MA–EFFS sponsor offers all the qualifying plans in the area. If necessary to ensure such access, the MBA Administrator would be authorized to provide partial underwriting of risk for a PDP sponsor to expand its service area under an existing prescription drug plan to adjoining or additional areas, or to establish such a plan, including offering such plan on a regional or nationwide basis. The assistance would be available only so long as, and to the extent necessary, to assure the guaranteed access. However, the MBA Administrator could never provide for the full underwriting of financial risk for any PDP sponsor. Additionally, the MBA Administrator would be directed to seek to maximize the assumption of financial risk by PDP sponsors and entities offering MA–EFFS plans. The MBA Administrator would be required to report to Congress annually on the exercise of this authority and recommendations to minimize the exercise of such authority.

New Section 1860D–6. Submission of Bids

The new Section 1860D–6 would require each PDP sponsor to submit to the MBA Administrator specified information in the same manner MA organizations submit information. The submitted information would be the qualified drug coverage to be provided, the actuarial value of the coverage, and details of the bid and coverage premium. The PDP sponsor would include: (1) actuarial certification of the bid and premium, (2) the portion of the bid and premium attributable to benefits in excess of the standard coverage, (3) the reduction in the premium resulting from reinsurance subsidies, (4) the reduction in the bid resulting from direct and reinsurance subsidy payments, and (5) such other information required by the MBA Administrator.

The MBA Administrator would review the submitted information for purposes of conducting negotiations with the plan. The MBA Administrator would approve the premium only if it accurately reflected the actuarial value of the benefits and the 73 percent average subsidy provided for under the new Section 1860D–8. The MBA Administrator would apply actuarial principles to approval of a premium in a manner similar to that used for establishing the monthly Part B premium. These requirements would not apply to MA plans.

The bid and premium for a PDP could not vary among individuals enrolled in the plan in the same service area, provided they were not subject to late enrollment penalties. A PDP sponsor would permit each enrollee to have their premiums withheld from their Social Security checks in the same manner as is currently done for Part B premiums and transferred to the plan in which they are enrolled. Beneficiaries could also make payment of the premium through an electronic funds transfer mechanism. The amount would be credited to the Medicare Prescription Drug Trust Fund. Reductions in Part B premiums attributable to enrollment in MA plans could be used to reduce the premium otherwise applicable.

Under certain conditions, PDP or MA–EFFS sponsors in an area would be required to accept, for an individual eligible for a low-income premium subsidy, the reference premium amount (premium

for standard coverage) as payment in full for the premium for qualified prescription coverage. This requirement would apply if there was no standard coverage available in the area.

New Section 1860D–7. Premium and Cost-Sharing Subsidies for Low-Income Individuals

The new Section 1860D–7 would provide subsidies for low-income individuals. Low-income persons would receive a premium subsidy (based on the value of standard coverage). Individuals with incomes below 135 percent of poverty (and assets below $4,000) would have a subsidy equal to 100 percent of the value of standard drug coverage provided under the plan. For individuals between 135 percent and 150 percent of poverty, there would be a sliding scale premium subsidy ranging from 100 percent of such value at 135 percent of poverty to zero percent of such value at 150 percent of poverty. The asset test for this part is twice the asset test used for determining Supplemental Security Income (SSI) eligibility, indexed to inflation. (Note: the asset test has not previously been indexed.) Not all resources are counted. Excluded resources include: a home (with no limit on its value) if the individual lives in it; household goods and personal effects up to $2,000; one car used to provide necessary transportation regardless of value or if not used to provide transportation, excluded up to $4,500 in value; the value of a burial space; other property essential for self support of the individual; life insurance up to $1,500; the value of a trust, but trusts must meet very specific criteria; and other exclusions. Sponsors and entities could not charge individuals receiving cost-sharing subsidies more than five dollars per prescription. Sponsors and entities could reduce the cost-sharing to zero, which would otherwise be applicable for generic drugs.

State Medicaid programs or the Social Security Administration (SSA) would determine whether an individual would be eligible for a low-income subsidy, as well as the amount of the subsidy. SSA would be appropriated the necessary funds. The Congressional Budget Office (CBO) estimates that 152,000 seniors who would otherwise not enroll in the low-income subsidy program would participate since the enrollment process through SSA avoids the stigma of signing up at a welfare office. Individuals not in the 50 States or the District of Columbia could not be subsidy eligible individuals but could be eligible for financial assistance with drug costs under new Section 1935(e) added by Section 103.

Whether offered by a PDP or MA–EFFS sponsor, the premium subsidy amount would be defined as the benchmark premium amount for the qualified prescription drug coverage chosen by the beneficiary. The benchmark premium amount for a plan means the premium amount for enrollment under the plan (without regard to any subsidies or late enrollment penalties) for standard coverage (or alternative coverage if the actuarial value is equivalent). If a plan provides alternative coverage with a higher actuarial value than that for standard coverage, the benchmark amount would bear the same ratio to the total premium as the actuarial value of standard coverage was to the actuarial value of alternative coverage.

The MBA Administrator would provide a process whereby the PDP or MA–EFFS sponsor would notify an individual that he or

she is eligible for a subsidy as well as the amount of the subsidy. The sponsor would reduce the individual's premium or cost-sharing otherwise imposed by the amount of the subsidy. The MBA Administrator would periodically, and on a timely basis, reimburse the sponsor or entity for the amount of such reductions.

Part D benefits would be primary to any coverage available under Medicaid. The MBA Administrator would be required to develop and implement a plan for the coordination of Part D benefits and Medicaid benefits. Particular attention would be given to coordination of payments and preventing fraud and abuse. The MBA Administrator would be required to involve the Secretary, the States, the data processing industry, pharmacists, pharmaceutical manufacturers, and other experts in the development and administration of the plan.

New Section 1860D–8. Subsidies for All Medicare Beneficiaries for Qualified Prescription Drug Coverage

New Section 1860D–8 would provide for subsidy payments to qualifying entities. The payments would reduce premiums for all enrolled beneficiaries consistent with an overall subsidy level of 73 percent, reduce adverse selection among plans, and promote the participation of PDP sponsors. Such payments would be made as direct subsidies and through reinsurance. The section would constitute budget authority in advance of appropriations and represent the obligation of the MBA Administrator to provide for subsidy payments specified under the section.

Direct subsidies would be made for individuals enrolled in a PDP or MA–EFFS plan, equal to 43 percent of the national weighted average monthly bid amount. Each year, the MBA Administrator would compute a national average monthly bid amount equal to the average of the benchmark bid amounts for each drug plan (not including those offered by private plans) adjusted to add back in the value of reinsurance subsidies. The benchmark bid amount would be defined as the portion of the bid attributable to standard coverage or actuarial equivalent coverage. The bid amount would be a weighted average with the weight for each plan equal to the average number of beneficiaries enrolled in the plan for the previous year. (The MBA Administrator would establish a procedure for determining the weighted average for 2005).

Reinsurance payments would be made for specified costs incurred in providing prescription drug coverage for individuals enrolled in either a PDP or MA–EFFS plan. The MBA Administrator would provide for reinsurance payments to PDP sponsors, and entities offering MA or EFFS plans. Reinsurance payments would be provided for 30 percent of an individual's allowable drug costs over the initial reinsurance threshold ($1,000 in 2006) but not over the initial coverage limit ($2,000 in 2006). Reinsurance of 80 percent would also be provided for allowable costs over the out-of-pocket threshold ($3,500 in 2006). These reinsurance payments would provide additional assistance to those plans that enroll beneficiaries who have multiple or very expensive prescription drug regimens. In the aggregate, reinsurance payments would equal 30 percent of total payments made by qualifying entities for standard coverage.

For purposes of calculating reinsurance payments, allowable costs would be defined as the portion of gross covered prescription

drug costs that were actually paid by the plan, but in no case more than the part of such costs that would have been paid by the plan if the drug coverage under the plan were standard coverage. Gross covered drug costs would be defined as costs (including administrative costs) incurred under the plan for covered prescription drugs dispensed during the year, including costs related to the deductible, whether paid by the enrollee or the plan, regardless of whether coverage under the plan exceeded standard coverage and regardless of when the payment for the drugs was made.

The MBA Administrator would be required to estimate the total reinsurance subsidy payments that would be made during the year (including those made to qualified retiree plans) and total benefit payments to be made by qualifying entities for standard coverage during the year. The MBA Administrator would proportionately adjust payments such that total subsidy payments during the year were equal to 30 percent of total payments made by qualifying plans for standard coverage during the year. The MBA Administrator could adjust direct subsidy payments in order to avoid risk selection. The MBA Administrator would determine the payment method and could use an interim payment system based on estimates. Payments would be made from the Medicare Prescription Drug Trust Fund.

Special subsidy payments would be made to a qualified retiree prescription drug plan. A qualified plan would be defined as employment-based retiree health coverage (including coverage offered pursuant to one or more collective bargaining agreements) meeting certain requirements. The MBA Administrator would approve coverage with at least the same actuarial value as standard coverage. The sponsor (and the plan) would be required to maintain and provide access to records needed to ensure the adequacy of coverage and the accuracy of payments made. Further, the sponsor would be required to provide certifications of coverage. Payment could not be made for an individual unless the individual was covered under the retiree plan and entitled to enroll under a PDP or MA–EFFS plan but elected not to. Subsidy payments would equal 28 percent of allowable costs between $250 and $5,000. (The dollar amounts would be adjusted annually by the percentage increase in Medicare per capita prescription drug costs.)

About one-third of Medicare beneficiaries receive retiree coverage from their former employers. While most of these people are satisfied with their coverage, employers are under increasing pressure to drop or reduce prescription drug coverage. This subsidy provides employers and union plans with maximum flexibility, encouraging them to maintain or expand their retiree plans. Thus, Medicare would reap significant savings from subsidizing employer plans at two-thirds of the cost of other Medicare prescription drug plans.

New Section 1860D–9. Medicare Prescription Drug Trust Fund

New Section 1860D–9 would create a Medicare Prescription Drug Trust Fund. Requirements applicable to the Part B trust fund would apply in the same manner to the Drug Trust Fund as they apply to the Part B Trust Fund. The Managing Trustee would pay from the account, from time to time, low-income subsidy payments, subsidy payments, and payments for administrative expenses. The

Managing Trustee would transfer, from time to time, to the Medicaid account amounts attributable to allowable increases in administrative costs associated with identifying and qualifying beneficiaries eligible for low-income subsidies. Amounts deposited into the Trust Fund would include the federal amount which would otherwise be payable by Medicaid except for the fact that Medicaid becomes the secondary payer of drug benefits for the dual-eligibles. The provision would authorize appropriations to the Trust Fund an amount equal to the amount of payments from the Trust Fund reduced by the amount transferred to the Trust Fund.

The provision would specify that any provision of law relating to the solvency of the Trust Fund would take into account the amounts received by, or payable from, the Trust Fund.

EFFECTIVE DATE

Upon enactment.

New Section 1860D–10. Definitions; Treatment of References to Provisions in Part C

New section 1860D–10 would include definitions of terms and specify how cross-references to Part C would be applied. It would further provide that any reduction or waiver of cost-sharing would not be in violation of kickback and similar prohibitions. The section would further require the Secretary to submit a report to Congress within 6 months of enactment that makes recommendations regarding providing benefits under Part D.

Also within six months of enactment, the Secretary would be required to review the current standards of practice for pharmacy services provided to patients in nursing facilities. Specifically, the Secretary would assess: (1) the current standards of practice, clinical services, and other service requirements generally utilized for such pharmacy services, (2) evaluate the impact of those standards with respect to patient safety, reduction of medication errors, and quality of care, and (3) recommend necessary actions.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Prescription drugs are just as important to modern health care as hospitals and physician services were when Medicare was enacted in nearly 40 years ago. Prescription drugs are more often than not, the health care solution of choice. Most often, they prevent, treat or manage diseases more effectively and less invasively than hospitals and nursing homes. The typical senior now takes more than 20 prescriptions a year to improve their health or manage their diseases. While seniors are taking more drugs than any other demographic group, they are often paying the highest prices because more than one-third of seniors have no prescription drug coverage. Similarly, low-income beneficiaries must often make unacceptable choices between life-savings medicines and other essentials.

The addition of a prescription drug benefit to Medicare, while providing seniors additional choices in how they receive their

health services, is a critical modernization of the program. In designing how these benefits are delivered, the Committee believes competition among plans will lead to the most efficient allocation of resources and will create opportunities to increase the availability of certain drugs, to reduce the cost of drugs, and the cost of the program to taxpayers.

Importantly, guaranteeing issuance of policies, providing uniform plan premiums, ensuring two plans in each area and providing a worst case fall back ensure beneficiaries have the coverage to which they are entitled. Important new beneficiary protections, such as allowing any willing pharmacy to participate, ensuring convenient access to bricks and mortar pharmacies, creating a level playing field for mail order and retail pharmacy, and prohibiting plans from pushing insurance risk onto pharmacists ensure seniors can get the drugs at the pharmacy of their choice. Establishing new appeal rights for coverage denials or tiered cost sharing problems helps beneficiaries access the drugs most appropriate to their medical condition.

In addition, by providing new tools to improve health, such as electronic prescribing, medication therapy management, and utilization review, the provision would greatly improve the quality of services provided to beneficiaries.

In combination, these provisions will provide important new benefits where Medicare is lacking, create new choices for seniors, and create new protections to achieve the goals of reduced costs and improved health.

Section 102. Offering of Qualified Prescription Drug Coverage Under the Medicare Advantage and Enhanced Fee-For-Service Program

CURRENT LAW

Under current law, Medicare+Choice plans may elect to offer prescription drug coverage under Part C. The extent of these benefits varies and is not subject to any explicit standardization requirements. However, as with all Medicare+Choice benefit specifics, the financing and design of such benefits must meet the approval of the Secretary under the adjusted community rate (ACR) approval process. Generally, plans offering drugs must either finance such benefits from the differences between the applicable county payment rate and their costs in providing Medicare's basic benefits, or by assessing beneficiaries who enroll in the plan supplemental premiums.

EXPLANATION OF PROVISION

The provision would specify that, beginning January 1, 2006, a MA organization could not offer a coordinated care MA plan unless either that plan or another plan offered by the organization in the area included qualified drug coverage. It could not offer drug coverage (other than that already required under Medicare) unless the coverage was at least qualified prescription drug coverage. An individual not electing qualified prescription drug coverage under Part D would be treated as ineligible to enroll in a MA plan offering such coverage.

The organization would be required to meet beneficiary protections outlined in the new Section 1860D–3, including requirements relating to information dissemination and grievance and appeals. The organization would also be required to submit the same information required of PDP sponsors when submitting a bid. The MBA Administrator could waive such requirements to the extent the MBA Administrator determined they were duplicative of requirements otherwise applicable to the organization or plan. MA organizations providing qualified drug coverage would receive low-income subsidy payments, and direct and reinsurance subsidies. A single premium would be established for drug and non-drug coverage.

The same requirements would be applicable to an EFFS organization.

EFFECTIVE DATE

Applies to coverage provided on or after January 1, 2006

REASON FOR CHANGE

Ensures MA–EFFS plans offer qualified prescription drug coverage if they offer coverage, consistent with Section 101.

Section 103. Medicaid Amendments

CURRENT LAW

Some low-income aged and disabled Medicare beneficiaries are also eligible for full or partial coverage under Medicaid. Within broad federal guidelines, each state sets its own eligibility criteria, including income eligibility standards. Persons meeting the state standards are entitled to full coverage under Medicaid. Persons entitled to full Medicaid protection generally have all of their health care expenses met by a combination of Medicare and Medicaid. For these "dual-eligibles" Medicare pays first for services both programs cover. Medicaid picks up Medicare cost-sharing charges and provides protection against the costs of services generally not covered by Medicare, including prescription drugs. State Medicaid programs have the option to include prescription drugs in their Medicaid benefit packages. All states include drugs for at least some of their Medicaid beneficiaries and many offer it to all program recipients entitled to full Medicaid benefits.

Federal law specifies several population groups that are entitled to more limited Medicaid protection. These are qualified Medicare beneficiaries (QMBs), specified low-income Medicare beneficiaries (SLMBs), and certain qualifying individuals. QMBs are aged or disabled persons with incomes at or below the federal poverty level and assets below $4,000 for an individual and $6,000 for a couple. QMBs are entitled to have their Medicare cost-sharing charges, including the Part B premium, paid by the federal-state Medicaid program. SLMBs are persons who meet the QMB criteria, except that their income is over the QMB limit; the SLMB limit is 120 percent of the federal poverty level. Medicaid protection for SLMBs is limited to payment of the Medicare Part B premium. QMBs and SLMBs are not entitled to Medicaid's prescription drug benefit unless they are also entitled to full Medicaid coverage under their state's Medicaid program.

Qualifying individuals (QIs) are never entitled to Medicaid drug coverage (because, by definition, they are not eligible for full Medicaid benefits). QI–1s are persons who meet the QMB criteria, except that their income is between 120 percent and 135 percent of poverty. Medicaid protection for QI–1s is limited to payment of the monthly Medicare Part B premium. QI–2s are persons who meet the QMB criteria, except that their income is between 135 percent and 175 percent of poverty. Medicaid protection for QI–2s is limited to payment of that portion of the Part B premium attributable to the gradual transfer of some home health visits from Medicare Part A to Medicare Part B. Expenditures under the QI–1 and QI–2 programs are paid for 100 percent by the Federal government (from the Part B Trust Fund) up to the state's allocation level. A state is only required to cover the number of persons which would bring its spending on these population groups in a year up to its allocation level. Any expenditure beyond that level would be paid by the state. Assistance under the QI–1 and QI–2 programs is available for the period January 1, 1998 to December 31, 2002.

EXPLANATION OF PROVISION

Section 103 would add a new Section 1935 to the Social Security Act entitled "Special Provisions Relating to Medicare Prescription Drug Benefit." The provision requires states, as a condition of receiving Federal Medicaid assistance, to make eligibility determinations for low-income premium and cost-sharing subsidies, inform the MBA Administrator of cases where eligibility has been established, and otherwise provide the MBA Administrator with information that may be needed to carry out Part D. In 2005, the federal matching rate would be increased to 100 percent over 15 years. Beginning in 2020 the, the federal matching rate would be 100 percent. The states would be required to provide the MBA Administrator with the appropriate information needed to properly allocate administrative expenditures that could be made for similar eligibility determinations.

The provision would provide for the Federal phase-in of the costs of premiums and cost-sharing subsidies for dual-eligibles (i.e. persons eligible for Medicare and full Medicaid benefits, including drugs). Over the 2006–2020 period, the Federal matching rate for these costs would be increased to cover 100 percent of what would otherwise be state costs. States would be required to maintain Medicaid benefits as a wrap-around to Medicare benefits for dual-eligibles; states could require that these persons elect Part D drug coverage.

Residents of territories would not be eligible for regular low-income subsidies. However, territories would be able to get additional Medicaid funds, beginning at $25 million in 2006 and increasing in subsequent years by the annual percentage increase in prescription drug costs for Medicare beneficiaries. In order to obtain these funds, territories would be required to formulate a plan on how they would dedicate the funds to assist low-income Medicare beneficiaries in obtaining covered outpatient prescription drugs. The MBA Administrator would be required to report to Congress on the application of the law in the territories.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Seniors should be treated as seniors first and low-income second. The patchwork of state Medicaid programs that can vary from state to state is confusing and demoralizing for many seniors. By federalizing the drug costs of the dual eligibles, we ensure beneficiaries have access to a uniform, Medicare benefit.

Section 104. Medigap Transition

CURRENT LAW

Most beneficiaries have some health insurance coverage in addition to basic Medicare benefits. Some individuals obtain private supplemental coverage through an individually purchased policy, commonly referred to as a "Medigap" policy. Beneficiaries with Medigap insurance typically have coverage for Medicare's deductibles and coinsurance; they may also have coverage for some items and services not covered by Medicare. Individuals generally select from one of ten standardized plans, though not all ten plans are offered in all states. The plans are known as Plans A through plan J. Plan A covers a basic package of benefits. Each of the other nine plans includes the basic benefits plus a different combination of additional benefits. Plan J is the most comprehensive. Plans H, I, and J offer some drug coverage.

The law provided for the development by the National Association of Insurance Commissioners (NAIC) of standardized benefit packages. It also provides for modifications of such packages when Medicare benefit changes are enacted.

All insurers offering Medigap policies are required to offer open enrollment for 6 months from the date a person first enrolls in Medicare Part B (generally when the enrollee turns 65). The law also guarantees issuance of specified Medigap policies for certain persons whose previous supplemental coverage was terminated. Guaranteed issue also applies to certain persons who elect to try out a managed care option under the Medicare+Choice plan program.

EXPLANATION OF PROVISION

The provision would prohibit, effective January 1, 2006, the issuance of new Medigap policies with prescription drug coverage. The prohibition would not apply to policies replacing another policy with drug coverage. Further, it would not apply to policies meeting new standards, or pre-standards, as outlined below. Beneficiaries could keep their existing H, I, and J plans.

The provision would guarantee issuance of a substitute Medigap policy for persons, enrolling in Part D, who at the time of such enrollment were enrolled in and terminated enrollment in a Medigap H, I, or J plan. The guaranteed enrollment would be for any of the Plans A through Plan G. The guarantee would apply for enrollments occurring in the new Medigap plan within 63 days of termination of enrollment in a Medigap H, I, or J plan. The insurer could not impose an exclusion based on a pre-existing condition for

such individuals. Further, the insurer would be prohibited from discriminating in the pricing of such policy on the basis of the individual's health status, claims experience, receipt of health care or medical condition.

The provision would provide for the development by the NAIC of two new standardized Medigap plans and would outline the standards for these policies. The first new policy would have the following benefits (notwithstanding other provisions of law relating to core benefits): (1) coverage of 50 percent of the cost-sharing otherwise applicable (except coverage of 100 percent cost-sharing applicable for preventive benefits), (2) no coverage of the Part B deductible, (3) coverage of all hospital coinsurance for long stays (as in current core package), and (4) a limitation on annual out-of-pocket costs for Part A and Part B beneficiaries of $4,000 in 2005 (increased in future years by an appropriate inflation adjustment as specified by the Secretary). The second new policy would have the same benefit structure as the first new policy, except that: (1) coverage would be provided for 75 percent, rather than 50 percent, of cost-sharing otherwise applicable, and (2) the limitation on out-of-pocket costs would be $2,000, rather than $4,000. Both policies could provide for coverage of Part D cost-sharing; however, neither policy could cover the Part D deductible.

The NAIC would make recommendations to Congress on modernizing the Medigap market.

It is the Committee's intent that the offering of these new Medigap policies would be voluntary on the part of insurers, as is the case for all other Medigap standardized policies beyond plan type A, basic Medigap coverage.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The two new Medigap policies would provide additional cost sharing for beneficiaries without first dollar coverage. This ensures beneficiaries have additional access to cover cost sharing for the new prescription drug benefit if they so choose.

Section 105. Medicare Prescription Drug Discount Card Endorsement Program

CURRENT LAW

On July 12, 2001, the President announced a new national drug discount card program for Medicare beneficiaries. Under this program, CMS would endorse drug card programs that meet certain requirements. This program was intended to be an interim step until a legislative reform package, including both a drug benefit and other Medicare reforms, is enacted. Implementation of the drug discount card program was suspended by court action.

EXPLANATION OF PROVISION

The provision would require the Secretary or Administrator to establish a program to: (1) endorse prescription drug discount card programs that meet certain requirements, and (2) make available

information on such programs to beneficiaries. The Secretary would begin operating the program within 90 days of enactment. The Secretary would provide for an appropriate transition and discontinuation at the time a drug benefit first becomes available under Part D.

Programs endorsed by the Secretary must meet certain requirements. Programs shall pass negotiated discounts on drugs to enrollees. Programs could not be limited to mail order drugs and must provide support services to educate patients and prevent adverse events. Programs must also provide, through the Internet or otherwise, information to enrollees that the Secretary deems necessary for beneficiaries to make informed choices among all endorsed programs. This information would include information on enrollment fees, prices charged to beneficiaries, and services offered under the program. Program sponsors would be required to demonstrate experience and expertise in operating such a program. The sponsor would also be required to have in place adequate procedures for quality assurance. The annual enrollment fee could not exceed $30 (which could be paid in whole or in part by states). Further, the program would be required to meet additional requirements identified by the Secretary to protect and promote the interest of Medicare beneficiaries, including requirements that assure that beneficiaries were not charged more than the lower of the negotiated retail price or the usual and customary price.

The Secretary would provide for the dissemination of information that compared the costs and benefits of available programs. This activity would be coordinated with the dissemination of educational information on MA plans. The Secretary would also oversee the endorsed programs' compliance with the requirements of this section, including verification of discounts, and services provided, the amount of dispensing fees, and audits. The Secretary would be required to provide, through the use of the Medicare toll-free number, for the receipt and response to inquiries and complaints. The Secretary would be required to revoke the endorsement of any program that no longer meets requirements or engages in false or misleading marketing practices. The provision would specify that a beneficiary could only be enrolled in one endorsed program at a time. A beneficiary could change enrollment after he or she has been enrolled in a plan for a minimum period specified by the Secretary.

The provision creates a two-year, temporary, transitional low-income assistance program. Medicare beneficiaries with incomes below 150 percent of poverty would be eligible for assistance in 2004 and 2005. The program provides additional funds in conjunction with the discount card to help low-income seniors purchase prescription drugs prior to the implementation of the drug benefit in 2006. The bill provides for $2 billion in 2004 and $3 billion in 2005.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Immediate help for those without prescription drug coverage will provide a transition into the new Part D drug benefit while ensur-

ing those who cannot afford prescription drugs receive assistance. In addition, drug discount cards can be up and running within 90 days, which will provide savings to seniors at retail between 10 and 20 percent, according to HHS. Discounts must be provided by both manufacturers and pharmacies and must be passed on to beneficiaries.

Section 106. Disclosure of Return Information for Purpose of Carrying Out Medicare Catastrophic Prescription Drug Program

8URRENT LAW

Current law authorizes, under specified circumstances, the Secretary of the Treasury to disclose returns and return information for purposes other than tax administration.

EXPLANATION OF PROVISION

The provision would permit the Secretary of the Treasury, upon written request from the Secretary of the Department of Health and Human Services (HHS), to disclose to officers and employees of HHS specific information with respect to a specified taxpayer for a specific tax year. Information that could be disclosed would be taxpayer identification information and adjusted gross income, or, simply the income threshold limit specified under the new Part D ($200,000 in 2006). A specified taxpayer would be either: (1) an individual who had adjusted gross income for the year in question in excess of the income threshold specified in the new Part D ($60,000 per individual), or (2) an individual who elected to use more recent income information as permitted under Part D. Individuals filing joint returns would be treated separately, each considered to have an adjusted gross income equal to one-half of the total.

Officers and employees of HHS would be authorized to use tax return information only for administering the prescription drug benefit. HHS could disclose a beneficiary's determined annual out-of-pocket threshold to a beneficiary's PDP sponsor. The sponsor could use such information only for the purposes of administering the benefit.

EFFECTIVE DATE

Upon enactment.

Section 107. State Pharmaceutical Assistance Transition Commission

CURRENT LAW

A number of states currently have programs to provide low-income persons, not qualifying for Medicaid, with financial assistance in meeting their drug costs. The state programs differ substantially in both design and coverage.

EXPLANATION OF PROVISION

The provision would establish a State Pharmaceutical Assistance Transition Commission to develop a proposal for dealing with the transitional issues facing state programs and participants due to implementation of the new Part D prescription drug program. The Commission, to be established on the first day of the third month

following enactment, would include: (1) a representative of each governor from each state with a program that the Secretary identifies as having a benefit package comparable to or more generous than the new Part D, (2) representatives from other states that have pharmaceutical assistance programs, as appointed by the Secretary, (3) representatives (not exceeding the total under (1) or (2) above) of organizations that represent interests of participants, appointed by the Secretary, (4) representatives of Medicare Advantage organizations; and (5) the Secretary or the Secretary's designee and other members specified by the Secretary. The Commission would develop the proposal in accordance with specified principles, namely: (1) protection of the interests of program participants in the least disruptive manner, (2) protection of the financial and flexibility interests of states so they are not financially worse off, and (3) principles of Medicare modernization outlined in Title II of the Act. It is the intent of the Committee that Medicare beneficiaries use one prescription drug card for their benefit. The Committee believes presenting beneficiaries with more than one card would be confusing and administratively inefficient.

The Commission would report to the President and Congress by January 1, 2005. The report would contain specific proposals including specific legislative or administrative recommendations, if any. The Commission would terminate 30 days later.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

States, especially those with comprehensive pharmaceutical assistance programs, would benefit significantly. States would receive billions of dollars in assistance under the proposal, with the most help going to those states that have already provided pharmaceutical drug assistance to seniors. Since some states have initiated pharmaceutical assistance for low-income seniors, these states would reap the most savings, as Medicare would become the primary insurer for these beneficiaries. States have several options in relation to the new benefit. First, they could design their pharmacy programs to "wrap around" the Medicare drug benefit. Second, their pharmacy program could subsidize low-income individuals with costs between $2,000 and the $3,500 catastrophic benefit. This spending would count toward the catastrophic cap. Further, state pharmacy assistance programs could use money saved from the Medicare drug benefit to extend their assistance to persons with incomes above 150 percent of poverty. Finally, state pharmacy programs could work to encourage low-income individuals to enroll in a PDP, thereby creating a seamless transition from the perspective of the individual. Their cost-sharing still could not exceed $5 per prescription, and they could get the prescription drugs they need at a convenient pharmacy. From the beneficiary's perspective nothing will have changed.

It is difficult to foresee every issue that may impact states that have already provided substantial assistance to seniors. A State Pharmaceutical Assistance Transition Commission would be established under the bill. This commission would develop a proposal to address the unique transition issues facing these states.

B. TITLE II—MEDICARE ENHANCED FEE-FOR-SERVICE AND MEDICARE ADVANTAGE PROGRAMS; MEDICARE COMPETITION

Section 200. Medicare Modernization and Revitalization

CURRENT LAW

Health Maintenance Organizations (HMOs) and other types of managed care plans have been allowed to participate in the Medicare program, beginning with private health plan contracts in the 1970s and the Medicare risk contract program in the 1980s. BBA 97 replaced the risk contract program with the Medicare+Choice (M+C) program.

EXPLANATION OF PROVISION

This title would establish the Medicare Enhanced Fee-for-Service (EFFS) program, under which Medicare beneficiaries would be provided access to a range of EFFS plans that may include preferred provider networks. It would establish a Medicare Advantage (MA) program to offer improved managed care plans with coordinated care. It would also use competitive bidding, in the same style as FEHBP for certain areas, beginning in 2010, to promote greater efficiency and responsiveness to Medicare beneficiaries.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This title modernizes and revitalizes private plans under Medicare. BBA 97 altered payments for private plans and expanded the types of plans that could be offered under Medicare. Since payment rate changes were implemented, enrollment in private plans has fallen from 6.2 million beneficiaries in 1998 to 4.6 million beneficiaries in May 2003, and the number of plans has decreased from 346 risk plans in 1998 to 153 (149 coordinated care plans and 4 private FFS plans) in May 2003. This disruption has been due, in part, to unpredictable and insufficient payments. BBA 97 fundamentally de-linked payments to plans from FFS payment growth.

To increase beneficiary choice, Title II reforms the payment system in 2004. All plans would be paid at a rate at least as high as the rate for traditional FFS Medicare, as recommended by the Medicare Payment Advisory Commission (MedPAC). After 2004, private plans' capitation rates would grow at the same rate as FFS Medicare. To increase beneficiary choice in more rural areas, Title II would establish the Enhanced Fee-for-Service (EFFS) program, which would encourage private plans to serve Medicare beneficiaries in larger regions, beginning in 2006. Private plans in both Medicare Advantage (MA) and EFFS plans would bid competitively against a benchmark beginning in 2006.

Once private plans became established, and enrollment in private plans increased, plans in certain areas would enter a FEHBP-style competitive bidding program, beginning in 2010. Plan bids from private plans and rates for traditional FFS Medicare would be averaged to create a benchmark for competitive bidding. The competitive program would encourage beneficiaries to enroll in the

most efficient plan, producing savings for both beneficiaries, through reduced premiums, and for taxpayers, through relatively lower Medicare costs.

Subtitle A—Medicare Enhanced Fee-for-Service Program

Section 201. Establishment of Enhanced Fee-for-Service (EFFS) Program under Medicare

CURRENT LAW

Payment. Under current law, Medicare+Choice (M+C) plans are paid an administered monthly payment, called the M+C payment rate, for each enrollee. The per capita rate for a payment area is set at the highest one of three amounts, calculated according to formulas established in statute and updated by law. The three amounts are:

- A minimum payment (or floor) rate,
- A rate calculated as a blend of an area-specific (local) rate and a national rate, or
- A rate reflecting a minimum increase from the previous year's rate.

After preliminary M+C payment rates are determined for each payment area (typically a county), a budget neutrality adjustment is required by law to determine final payment rates. This adjustment is made so that estimated total M+C payments in a given year would be equal to the total payments that would be made if payments were based solely on area-specific rates. The budget neutrality adjustment may only be applied to the blended rates because rates cannot be reduced below the floor or minimum increase amounts. The blend payment is also adjusted to remove the costs of direct and indirect graduate medical education. The blend payment amount is based on a weighted average of local and national rates for all Medicare beneficiaries. Blend payments have been made only once since 1998 (in the year 2000) because of the budget neutrality provision.

Each year, the three payment amounts are updated by formulas set in statute. Both the floor and the blend are updated each year by a measure of growth in program spending per capita, the national growth percentage. The minimum increase provides an additional two percent over the previous year's amount.

Eligibility: Medicare beneficiaries who are entitled to Medicare Part A and are enrolled in Part B may receive benefits through traditional FFS or they may enroll in a M+C plan.

EXPLANATION OF PROVISION

Beginning January 1, 2006 the MBA Administrator would establish an EFFS program to offer EFFS plans to EFFS-eligible individuals in one of not less than 10 regions established by the MBA Administrator. Before establishing regions, the MBA Administrator must conduct a market survey and analysis to determine how regions should be established.

The EFFS plans would be required to provide open network plans—either Fee-for-Service (FFS) or preferred provider coverage. Under FFS coverage, plans would: (1) reimburse hospitals, physicians and other providers at a rate determined by the plan on a

FFS basis, without placing providers at financial risk, (2) not vary rates based on utilization related to the provider, and (3) not restrict the selection of providers from among those who are lawfully authorized to provide covered services and agree to accept the plan's terms and conditions. Preferred Provider Organization (PPO) coverage plans would: (1) require a network of providers who agreed to a contractually specified reimbursement for covered benefits with the organization, and (2) provide for reimbursement for all covered benefits regardless of whether they were provided within the network.

The EFFS-eligible individuals would be those individuals who were entitled to Medicare Part A and enrolled in Part B. EFFS plans could only be offered in a region, if the plan was: (1) available to all EFFS beneficiaries in an entire region, (2) complied with statutory access requirements, (3) uniformly provided all required Parts A and B benefits, and other benefits as may be required, (4) included a single deductible for benefits under Parts A and B, and a catastrophic limit on out-of-pocket expenses, and (5) provided prescription drug coverage for each enrollee electing Part D drug coverage. The MBA Administrator would not approve an EFFS plan if benefits were designed to substantially discourage enrollment by certain eligible individuals.

Each year, beginning in 2006, an EFFS organization would submit a monthly bid amount for each plan in each region, referred to as the "EFFS monthly bid amount". The bid could not vary among EFFS eligible individuals in the EFFS region involved. The EFFS organization would be required to provide the following information: (1) the bid amount for the provision of all required items and services, based on average costs for a typical enrollee residing in the region and the actuarial basis for determining such amount, (2) the proportion of the bid attributed to the provision of statutory non-drug benefits (the "unadjusted EFFS statutory non-drug monthly bid amount"), statutory prescription drug benefits, and non-statutory benefits, (3) the actuarial basis for determining these proportions, and (4) additional information as the MBA Administrator may require. The MBA Administrator would have the negotiation authority that the Director of the Office of Personnel Management has with regard to FEHBP to negotiate the bid amount and could also reject a bid amount or proportion, if it was not supported by the actuarial basis. The MBA Administrator could enter into contract for up to three EFFS plans in any region.

Certain plans, based in part on their monthly bid amount, may be able to provide beneficiary savings. The EFFS plan would provide the enrollee a monthly rebate equal to 75 percent of the average per capita savings, if any. (Calculation of average per capita savings is discussed below.) The rebate could be in the form of a credit towards the EFFS monthly prescription drug premium or the EFFS monthly supplemental beneficiary premium, a direct monthly payment, or other means approved by the MBA Administrator.

The MBA Administrator would determine, at the same time payment rates were announced (beginning in 2006), the average of the risk adjustment factors, by region. For plans offered in the previous year, the MBA Administrator could compute the average based on a previous year's risk adjustment factors. For plans entering a region, in which no plan was offered in the previous year, the MBA

Administrator would estimate the average, and could use factors applied in comparable regions or on a national basis.

For each EFFS plan, the MBA Administrator would adjust the EFFS region-specific non-drug monthly benchmark amount and the unadjusted EFFS statutory non-drug monthly bid amount by the applicable average risk adjustment factor. The average per capita monthly savings would equal the amount by which the risk-adjusted benchmark exceeds the risk-adjusted bid. The EFFS region-specific non-drug monthly benchmark amount would be an amount equal to 1/12 of the average (weighted by the number of EFFS-eligible individuals in each payment area) of the annual capitation rate calculated for that area.

The MBA Administrator would pay plans as follows. For plans with bids below the benchmark (for which there were average per capita monthly savings), the payment would equal the unadjusted EFFS statutory non-drug monthly bid amount, with three adjustments. Payment would be adjusted for demographics factors including age, disability, gender, institutional status, health status, and other factors; intra-regional geographic variations; and the amount of the monthly rebate for the plan and year. For plans with bids at or above the benchmark (for which there were no average per capita monthly savings), the payment amount would equal the EFFS region-specific non-drug monthly benchmark amount, with the demographic, health status and geographic adjustments. Additionally, for an EFFS enrollee who enrolls in Part D and elects qualified prescription drug coverage through the plan, the plan would receive reimbursement for prescription drugs. This reimbursement would include a direct subsidy payment, a reinsurance subsidy payment and reimbursement for premiums and cost-sharing reductions for certain low-income individuals.

Beneficiary EFFS premiums are defined as follows. In the case where a plan provides a rebate, the EFFS monthly basic beneficiary premium would be zero. In the case where a plan does not provide a rebate (the plan's unadjusted EFFS statutory non-drug bid is above the EFFS region specific non-drug benchmark), the EFFS monthly basic beneficiary premium would be the difference between the bid and the benchmark amount. The EFFS monthly prescription drug beneficiary premium would be the portion of the plan's total monthly bid that the statutory drug benefit represents. The EFFS monthly supplemental beneficiary premium would be the portion of the plan's total monthly bid that is attributable to the supplemental non-statutory benefits.

Most of the statutory requirements concerning payment rules (other than the requirements for rates, service areas and MSA payments), organization and financial requirements, the establishment of standards, and contracts, would apply to EFFS plans. However, unlike current law, EFFS plans would not be permitted to segment a region. No Medicare supplemental policy could provide coverage of the single deductible or more than 50 percent of the other cost-sharing imposed under an EFFS plan under Part E.

EFFECTIVE DATE

On or after January 1, 2006.

REASON FOR CHANGE

The EFFS program would encourage the development of regional plans, by requiring EFFS plans to serve all beneficiaries throughout the region. Because enrollees in an EFFS plan must have the same benefits, cost-sharing obligations, and premiums, EFFS would decrease the variation in private plan offerings in the M+C program today. EFFS plans would also encourage plans to enter rural areas, where few M+C plans currently exist.

In carrying out these programs, the Committee believes the existing experience of the Medicare Quality Improvement Organizations (QIOs) would be employed to offer assistance to beneficiaries, providers and plans operating in Parts C, D and E, particularly as it relates to quality improvement. QIOs are currently required to offer assistance with clinical improvement under Parts A and B in hospitals, physicians' offices, nursing homes and home health agencies and to all MA organizations under part C. Expanding the QIOs' work to include the new entities and benefits created in this legislation will help improve the quality of care for Medicare beneficiaries.

Subtitle B—Medicare Advantage Program

CHAPTER 1—IMPLEMENTATION OF PROGRAM

Section 211. Implementation of Medicare Advantage Program

CURRENT LAW

Health Maintenance Organizations (HMOs) and other types of managed care plans have been allowed to participate in the Medicare program, beginning with private health plan contracts in the 1970s and the Medicare risk contract program in the 1980s. BBA 97 replaced the risk contract program with the Medicare+Choice (M+C) program.

EXPLANATION OF PROVISION

This provision would establish the Medicare Advantage (MA) program under Part C of Medicare, replacing the Medicare+Choice provision.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Medicare Advantage would reform Medicare+Choice to increase beneficiary choice.

Section 212. Medicare Advantage Improvements

CURRENT LAW

Payment. Under current law, Medicare+Choice (M+C) plans are paid an administered monthly payment, called the M+C payment rate, for each enrollee. The per capita rate for a payment area is set at the highest one of three amounts, calculated according to formulas established in statute and updated by law. The three amounts are:

- A minimum payment (or floor) rate,
- A rate calculated as a blend of an area-specific (local) rate and a national rate, or
- A rate reflecting a minimum increase from the previous year's rate.

After preliminary M+C payment rates are determined for each payment area (typically a county), a budget neutrality adjustment is required by law to determine final payment rates. This adjustment is made so that estimated total M+C payments in a given year would be equal to the total payments that would be made if payments were based solely on area-specific rates. The budget neutrality adjustment may only be applied to the blended rates because rates cannot be reduced below the floor or minimum increase amounts. The blend payment is also adjusted to remove the costs of direct and indirect graduate medical education. The blend payment amount is based on a weighted average of local and national rates for all Medicare beneficiaries. Blend payments have been made only once since 1998 (in the year 2000) because of the budget neutrality provision.

Each year, the three payment amounts are updated by formulas set in statute. Both the floor and the blend are updated each year by a measure of growth in program spending per capita, the national growth percentage. The minimum increase provides an additional two percent over the previous year's amount.

Eligibility. Medicare beneficiaries who are entitled to Medicare Part A and are enrolled in Part B may receive benefits through the traditional FFS program or they may enroll in a M+C plan.

EXPLANATION OF PROVISION

This provision would change payments for MA plans. A fourth payment option would be added: 100 percent of the adjusted FFS rate for the area (the Adjusted Average Per Capita Cost (AAPCC) for the year, for the MA payment area for services covered under Parts A and B for individuals entitled to benefits under Part A, enrolled under Part B, and who are not enrolled in a MA plan). The AAPCC would be adjusted to include the additional payments that would have been made if Medicare beneficiaries had not received services from facilities of the Department of Veterans Affairs (VA) and the Department of Defense (DoD), and would include payments for indirect medical education costs. The minimum payment (floor) would be increased as under current law. The minimum percentage increase amount would also be changed. For 2004 and beyond, the minimum percent increase would be the greater of: (1) a two percent increase over the previous year, as under current law, or (2) the annual MA capitation rate for the area for the previous year, increased by the national per capita growth percentage increase. There would be no adjustment to the national growth percentage for prior years' errors before 2004, for purposes of calculating the minimum percentage increase in 2004. For 2005, the annual rate would equal the previous year's rate increased by the greater of two percent or the national per capita growth percentage.

No later than 18 months after enactment of this legislation, the Medicare Payment Advisory Commission would report to Congress providing an assessment of the method used for determining the adjusted average per capita cost (AAPCC). The report would exam-

ine: (1) the variation in costs between different areas, including differences in input prices, utilization and practice patterns, (2) the appropriate geographic area for payment, and (3) the accuracy of the risk adjustment methods in reflecting differences in the cost of providing care.

No later than July 1, 2006, the MBA Administrator would submit a report to Congress that describes the impact of additional financing provided under this Act and other Acts, including the Balanced Budget Refinement Act of 1999 (BBRA) and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) on the availability of MA plans in different areas and its impact on lowering premiums and increasing benefits under such plans.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

In some M+C payment areas, the M+C payment rate is lower than the costs of providing FFS care to enrollees in traditional Medicare. Many private plans have seen their Medicare payment rates rise much less rapidly than the costs of FFS Medicare, as they have been held to increases of two percent annually every year since 1998, except for 2001 when a three percent increase was paid due to the BIPA. Health costs in general are running much higher than the two percent payment increases that most plans are receiving in the areas where most of the beneficiaries are enrolled in Medicare+Choice. Plans find it difficult—if not impossible—to contract with providers if FFS Medicare can reimburse providers at higher rates than private plans may offer, given their Medicare payments. If paid less than FFS Medicare, private plans may be forced to increase enrollee premiums or cost-sharing, or decrease supplemental benefits, such as prescription drug coverage. Since 1998, the number of plans participating in M+C has declined from 346 to 153. To level the playing field between traditional Medicare and private plans, under this provision all private plans would be paid at a minimum of the FFS rate. In addition, private plan rates would increase at the same rate as growth in FFS Medicare. The goal is to increase beneficiary choice, by increasing private plan participation in Medicare.

CHAPTER 2—IMPLEMENTATION OF COMPETITION PROGRAM

Section 221. Competition Program Beginning in 2006

CURRENT LAW

See Section 200. Medicare Modernization and Revitalization and Section 201. Establishment of Enhanced Fee-For-Service (EFFS) Program under Medicare.

EXPLANATION OF PROVISION

Each year, beginning in 2006, an MA organization would be required to provide the following information: (1) the bid amount for the provision of all required items and services, based on average

costs for a typical enrollee residing in the area and the actuarial basis for determining such amount, (2) the proportion of the bid attributed to the provision of statutory non-drug benefits (the "unadjusted MA statutory non-drug monthly bid amount"), statutory prescription drug benefits, and non-statutory benefits, (3) the actuarial basis for determining these proportions, and (4) additional information as the MBA Administrator may require. The MBA Administrator would have the negotiation authority that the Director of the Office of Personnel Management has with regard to the FEHBP to negotiate the bid amount and could also reject a bid amount or proportion, if it was not supported by the actuarial basis. Private fee-for-service (PFFS) plans would be exempt from this negotiation and rejection.

Certain plans, based in part on their monthly bid amount, may be able to provide beneficiary savings. The MA plan would provide the enrollee a monthly rebate equal to 75 percent of the average per capita savings, if any, as discussed below. The rebate could be in the form of a credit towards the MA monthly supplemental beneficiary premium or the MA monthly prescription drug premium, a direct monthly payment, or other means approved by the MBA Administrator.

The MBA Administrator would determine, at the same time payment rates were announced (beginning in 2006), the average of the risk adjustment factors, by state, or on a basis other than the state. For plans offered in the previous year, the MBA Administrator could compute the average based on the previous year's risk adjustment factors. For plans entering a state, in which no plan was offered in the previous year, the MBA Administrator would estimate the average, and could use factors applied in comparable states or on a national basis.

For each MA plan, the MBA Administrator would adjust the FFS area-specific non-drug monthly benchmark amount and the unadjusted MA statutory non-drug monthly bid amount by the applicable average risk adjustment factor. The average per capita monthly savings would equal the amount by which the risk-adjusted benchmark exceeds the risk-adjusted bid. The FFS area-specific non-drug monthly benchmark amount would be an amount equal to 1/12 of the annual MA capitation rate calculated for that area.

Beginning in 2006, the MBA Administrator would pay plans as follows. For plans below the benchmark (for which there were average per capita monthly savings), the payment would equal the unadjusted MA statutory non-drug monthly bid amount, with two adjustments. Payment would be adjusted for demographic factors including age, disability, gender, health status, and other factors, and the amount of the monthly rebate for the plan and year. For plans with bids at or above the benchmark (for which there were no average per capita monthly savings), the payment amount would equal the FFS area-specific non-drug monthly benchmark amount, with the demographic and health status adjustments. Additionally, for an MA enrollee who enrolls in Part D and elects qualified prescription drug coverage through the plan, the plan would receive reimbursement for prescription drugs. This reimbursement would include a direct subsidy payment, a reinsurance

subsidy payment and reimbursement for premiums and cost-sharing reductions for certain low-income individuals.

The MBA Administrator would not approve a plan if benefits were designed to discourage enrollment by certain MA-eligible individuals. The MA monthly bid amount, the MA monthly basic and supplemental beneficiary premium and the MA monthly MSA premium, would not vary among individuals enrolled in the plan.

EFFECTIVE DATE

On or after January 1, 2006.

REASON FOR CHANGE

Competitive bidding against a benchmark would encourage plans to become more efficient, in order to lower their bids and gain market share. Beneficiaries, because they would benefit from enrolling in plans with lower bids by receiving 75 percent of the difference between the plan's bid and the benchmark, would be encouraged to enroll in more efficient plans. Plan efficiency and beneficiary enrollment in more efficient plans would reduce the costs of Medicare, easing the threat to insolvency of the Medicare Part A Trust Fund and easing the taxpayers' burden. Indeed, the Congressional Budget Office has estimated that the increased benchmarks are fully paid for through the 25 percent savings to the government. The government would share in the savings as beneficiaries make rational and efficient choices.

CHAPTER 3—ADDITIONAL REFORMS

Section 231. Making Permanent Change in Medicare Advantage Reporting Deadlines and Annual, Coordinated Election Period

CURRENT LAW

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107–188) made temporary changes to reporting dates and deadlines: (1) the plan deadline for submitting adjusted community rates (ACRs) and other information moved from no later than July 1 to no later than the second Monday in September for 2002, 2003, and 2004, (2) the annual coordinated election period moved from the month of November to November 15 through December 31 for 2002, 2003, and 2004, and (3) the M+C payment rate announcement moved from no later than March 1 to no later than the second Monday in May for 2003 and 2004. The Secretary is required to mail information to enrollees at least 15 days before each annual open season, including a list of plan and plan options.

EXPLANATION OF PROVISION

This provision would permanently: (1) move the plan deadline for submitting information to the second Monday in September; (2) change the annual coordinated election period to November 15 through December 31, and (3) move the annual payment rate announcement to no later than the second Monday in May. The requirement for providing information comparing plan options would be amended to require that the information would be provided to

the extent possible at the time of preparation of material for mailing.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The deadlines for reporting and election periods were moved to allow for more accurate information from both CMS and plans. As these dates were shifted to later in the year, consistent changes were made to allow for the annual open season for beneficiary enrollment in private plans. A provision was added to limit CMS' responsibility for mailing to only those materials available at the time of the mailing.

Section 232. Avoiding Duplicative State Regulations

CURRENT LAW

Medicare law currently preempts State law or regulation from applying to M+C plans to the extent that they are inconsistent with Federal requirements imposed on M+C plans, and specifically, relating to benefit requirements, the inclusion or treatment of providers, and coverage determinations (including related appeals and grievance processes).

EXPLANATION OF PROVISION

This provision would stipulate that Federal standards established by this legislation would supersede any state law or regulation (other than state licensing laws or state laws relating to plan solvency), with respect to MA plans offered by MA organizations.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This clarifies that the MA program is a Federal program operated under Federal rules. State laws, do not, and should not apply, with the exception of state licensing laws or state laws related to plan solvency. There has been some confusion in recent court cases. This provision would apply prospectively; thus, it would not affect previous and ongoing litigation.

Section 233. Specialized Medicare Advantage Plans for Special Needs Beneficiaries

CURRENT LAW

One model for providing a specialized M+C plan, EverCare, operates as a demonstration program. EverCare is designed to study the effectiveness of managing acute-care needs of nursing home residents by pairing physicians and geriatric nurse practitioners. EverCare receives a fixed capitated payment, based on a percentage of the adjusted average per capita costs (AAPCC), for all nursing home resident Medicare enrollees.

EXPLANATION OF PROVISION

This provision would establish a new MA option—specialized MA plans for special needs beneficiaries (such as the EverCare demonstration). Special needs beneficiaries are defined as those MA-eligible individuals who are institutionalized, entitled to Medicaid, or meet requirements determined by the Secretary. Enrollment in specialized MA plans could be limited to special needs beneficiaries until January 1, 2007. No later than December 31, 2005 the MBA Administrator would be required to submit a report to Congress that assesses the impact of specialized MA plans for special needs beneficiaries on the cost and quality of services provided. No later than 6 months after enactment of this Act, the Secretary would be required to issue final regulations to establish requirements for special needs beneficiaries.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Specialized MA plans for special needs beneficiaries are designed to serve beneficiaries with certain needs, thus these plans are not meant to handle beneficiaries without special needs. This provision allows these plans to serve beneficiaries for whom their programs were designed.

Section 234. Medicare MSAs

CURRENT LAW

BBA 97 authorized a demonstration to test the feasibility of medical savings accounts (MSA) for the Medicare population. This M+C option is a combination of a health insurance plan with a large deductible and an M+C MSA. Contributions to an M+C MSA may be made annually from the enrollee's capitation rate after the plan's insurance premium has been paid. These contributions, as well as account earnings, are exempt from taxes. Withdrawals used to pay unreimbursed enrollee medical expenses are exempt from taxes if they would be deductible under the Internal Revenue Code. New enrollment is not allowed after 2003, or after the number of enrollees reaches 390,000, if earlier.

EXPLANATION OF PROVISION

This provision would permanently extend Medicare MSAs and remove the enrollment cap. It would eliminate the requirement that Medicare MSA plans report on enrollee encounters since MSAs are not plans but bank accounts. Non-contract providers furnishing services to enrollees of MSAs would be subject to the same balanced billing limitations as non-contract providers furnishing services to enrollees of coordinated care plans.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Medicare MSAs are not being offered in the Medicare program today, despite the legislative authority granted in 1997 and despite the fact that non-Medicare MSAs are being offered. By eliminating the cap on enrollment, the time constraint, and the reporting requirements, the Committee hopes to encourage this additional choice for seniors.

Section 235. Extension of Reasonable Cost Contracts

CURRENT LAW

Medicare reimburses cost-based plans for the actual cost of furnishing covered services, less the estimated value of beneficiary cost-sharing. The Secretary may not extend or renew a reasonable cost reimbursement contract for any period beyond December 31, 2004.

EXPLANATION OF PROVISION

This provision would allow reasonable cost contracts to be extended or renewed indefinitely, with an exception that would begin January 1, 2008. These contracts could not be extended or renewed for a service area, if during the entire previous year, the area had 2 or more coordinated care MA plans or 2 or more EFFS plans which met the following minimum enrollment requirements: (1) at least 5,000 enrollees for the portion of the area within a metropolitan statistical area with a population of more than 250,000 and counties contiguous to such a metropolitan statistical area, and (2) at least 1,500 enrollees for any other portion of such area.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The uncertainty about the continuation of cost contracts would be removed, allowing these plans to operate indefinitely, unless two other plans of the same type (i.e., either 2 MA or 2(c) EFFS plans) enter the cost contract's service area. If other plans are willing to enter the cost contract's service area, then the cost contract would be required to operate under the same provisions as these other private plans.

Section 236. Extension of Municipal Health Service Demonstration Projects

CURRENT LAW

The Municipal Health Services Demonstration Project operates in four cities. These cities use their existing public health programs as the nucleus of a coordinated system to provide community-based health care for the underserved urban poor. The project provides comprehensive health services, including a prescription drug benefit and dental services.

BBA 97 extended the program through 2000. The BBRA extended it through 2002, and the BIPA extended it through December 31, 2004.

EXPLANATION OF PROVISION

This provision would extend the program until December 31, 2009, and permit the programs to enroll up to the number of individuals who were enrolled as of January 1, 1996.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

BBA 97 required demonstration participants to become M+C enrollees. In Baltimore, no M+C plans, and in the other, smaller sites, private sector options for Medicare beneficiaries are also limited. This provision also closed the program to new enrollees. The programs need a certain number of enrollees to remain viable; opening enrollment with a cap at levels from 1996 would permit these programs to reach the enrollment levels they need to operate efficiently.

Subtitle C—Application of FEHBP-Style Competitive Reforms

Section 241. Application of FEHBP-Style Competitive Reform Beginning in 2010

CURRENT LAW

See Section 200. Medicare Modernization and Revitalization and Section 201. Establishment of Enhanced Fee-For-Service (EFFS) Program under Medicare.

EXPLANATION OF ROVISION

Beginning in 2010, FEHBP-style competition would begin nationwide in competitive areas. Competitive areas are defined as areas in which Medicare beneficiaries have access to two private plans—either two MA or two EFFS plans—along with traditional FFS Medicare. Private plan enrollment in the area must be at least as great as private plan enrollment nationwide, or at least 20 percent. For example, if private plan enrollment nationwide is 15 percent, the area must have private plan enrollment of at least 15 percent to become a competitive area. If private plan enrollment nationwide is 40 percent, the area must have private plan enrollment of at least 20 percent to trigger competition. In addition, competitive MA (CMA) areas would be limited to metropolitan statistical areas, or areas with substantial numbers of MA enrollees. The two private plans must be offered during the open season by different organizations, and each must meet minimum enrollment requirements as of March of the previous year.

In competitive areas, private plans would submit bids and the MBA Administrator would calculate FFS amounts, based on the adjusted average per capita cost (AAPCC) in the area or region. The AAPCC would be adjusted to remove costs associated with direct graduate medical education, and to include costs of services provided to Medicare beneficiaries by VA and DoD military facilities. In addition, payments would be adjusted for health and other demographic factors.

The competitive benchmark would be set at the weighted average of the private plan bids and the FFS amount in the competitive area. In order to provide traditional FFS disproportionate influence in competitive areas, the weight of the benchmark for FFS would equal the nationwide proportion of Medicare beneficiaries enrolled in FFS, or the competitive area's proportion, if higher. The weights for all other private plans would equal the national proportion of beneficiaries enrolled in private plans, or the regional proportion if lower.

For the first 5 years of competition, the benchmarks for private plans would be a blend of the competitive benchmark and the older, pre-2010 benchmark. For the first year of competition, the private plan benchmark would be based 80 percent on the older benchmark and 20 percent on the newer benchmark. For the second year, the private plan benchmark would be based 60 percent on the older benchmark and 40 percent on the new benchmark. By the fifth year, the private plan's benchmark would be fully phased in, and equal the new competitive benchmark. This phase-in allows for a transition to a more competitive system based on the new competitive benchmark.

Premium adjustments for beneficiaries remaining in traditional FFS in competitive areas would also be phased-in over the first 5 years as a competitive area. The FFS amount would be compared to the new competitive benchmark. During the first year of competition, 20 percent of the change in beneficiary premiums would occur. During the second year of competition, 40 percent of the change would be implemented, and so forth, until 100 percent of the premium change would be implemented during the fifth year of competition.

Beneficiaries enrolling in plans with bids or FFS amounts below the competitive benchmark would receive 75 percent of the difference between the benchmark and bid/FFS amount, and the government would receive 25 percent of the difference. Beneficiaries enrolling in plans with bids/FFS amounts above the benchmark would pay the excess. Premium adjustments would be moderated over a 5-year period for beneficiaries remaining in traditional FFS in competitive areas. The traditional FFS beneficiary premium would be unaffected in non-competitive areas or regions.

Beginning in 2010, the MBA Administrator would announce the MA area-specific non-drug benchmark yearly. If applicable, the MBA Administrator would also announce, for the year and CMA area: the competitive MA non-drug benchmark; the national FFS market share percentage; the demographic, end-stage renal disease, and health status adjustment factors; the MA area-wide non-drug benchmark amount; the FFS area-specific non-drug amount; and MA enrollment.

To carry out this section, the MBA Administrator would transmit the name, social security number, and adjustment amount to the Commissioner of SSA at the beginning of each year and at periodic times throughout the year.

EFFECTIVE DATE

On or after January 1, 2010.

REASON FOR CHANGE

Market-oriented policymakers have maintained that the best way to reform Medicare is to provide beneficiaries with a choice of plans, similar to the choice available to members of Congress under the Federal Employees Health Benefits Program (FEHBP). The Bipartisan Commission on the Future of Medicare came to the same conclusion.

Medicare must be transformed to bend the growth curve in expenditures to put the program on a sound financial footing. To reduce program growth, true competition, including both traditional fee-for-service and private plans, would begin in 2010 in certain competitive areas.

As areas of the country show increased enrollment in private plans, a more competitive system, based on the structure of the FEHBP, would provide for greater beneficiary savings and reductions in government costs. Allowing for competition for enrollees, between private plans and traditional FFS Medicare, would level the playing field between all options available to Medicare beneficiaries.

If traditional FFS Medicare is able to provide benefits at a lower cost than some or all private plans in a competitive area, then beneficiaries remaining in traditional FFS would see their premiums decline. In this case, beneficiaries enrolling in higher-cost private plans would be required to pay the extra price stemming from that decision. Likewise, if a private plan is able to offer Medicare beneficiaries coverage at a lower cost, then beneficiaries would be encouraged to enroll in the private plan by lowering the beneficiaries' costs of coverage under the private plan. In any case, beneficiaries would be entitled to the same defined benefit package and payments to plans would be fully adjusted for health and other demographic factors. If the traditional FFS plan disproportionately enrolls beneficiaries with poor risk, the beneficiary premium would be adjusted to compensate.

This reform is the only provision in the bill that has the potential to produce the savings needed for long-term solvency. Although the bill provides for bidding against a benchmark prior to 2010, the benchmarks prior to 2010 increase each year, by the rate of growth in Medicare. Without this stage of competition, private plans would not be able to influence the benchmark and would have an incentive to shadow price their benchmarks. A floating benchmark rewards more efficient plans, and it allows these more efficient plans to lower the benchmark and government outlays in future years, as their market share rises.

Several features were added in the Chairman's amendment in the nature of a substitute to allow for a smooth transition to a more competitive system in 2010 in competitive areas/regions, and to prevent shock to the current system. The competitive benchmark, based on private plan bids and traditional FFS rates, would be calculated based on the relative enrollment in FFS versus private plans nationwide (or the area/region if FFS enrollment is a larger proportion in the area/region). This feature ensures that the competitive benchmark is closer to the traditional FFS rate than would otherwise occur. Premium changes for beneficiaries remaining in traditional FFS in competitive areas would be phased-in over

five years to prevent oscillations. In addition, the competitive benchmark would be phased-in over a 5–year period for private plans. This would allow for a more gradual change from the benchmarks under the pre-2010 system to the new competitive benchmark for private plans in competitive areas.

C. TITLE III—COMBATTING WASTE, FRAUD, AND ABUSE

Section 301. Medicare Secondary Payer (MSP) Provisions

CURRENT LAW

In certain instances, Medicare is prohibited from making payment for a health care claim if payment is expected to be made promptly under a worker's compensation law or plan, under automobile or liability insurance (including a self-insured plan), or under no-fault insurance on behalf of a beneficiary. Medicare is permitted to make a conditional payment in certain circumstances including if Medicare could reasonably expect payment to be made under a workers' compensation plan or no-fault insurance claim and Medicare determines that the payment will not be made promptly, as determined in accordance with regulations.

EXPLANATION OF PROVISION

The Secretary would be able to make a Medicare payment if a worker's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan), or a no-fault insurance plan, has not been made or cannot reasonably be expected to be made promptly (as determined in accordance with regulations). This payment would be contingent on reimbursement by the primary plan to the Medicare Trust Funds.

The list of primary plans for which conditional payment could be made would be expanded; an entity engaging in a business, trade, or profession would be deemed as having a self-insured plan if it carries its own risk. Failure to obtain insurance would be required as evidence of carrying risk. A primary plan, as well as an entity that receives payment from a primary plan, would be required to reimburse the Medicare Trust Funds for any payment made by the Secretary if the primary plan was obligated to make payment. The Secretary's authority to recover payment from any and all responsible entities and bring action, including the collection of double damages, to recover payment under the Medicare Secondary Payer provisions also would be clarified.

EFFECTIVE DATE

Subsection (a) would be effective as if included in the enactment of Title III of the Medicare and Medicaid Budget Reconciliation Amendments of 1984 (P.L. 98–369). Subsection (b) would be effective upon enactment.

REASON FOR CHANGE

Recent court decisions such as *Thompson* v. *Goetzmann* resulted in a narrow interpretation of the statutory reference to "promptly." Liability insurers would have been able to draw out their settlements and avoid repaying Medicare for payment of medical expenses. Moreover, firms that self-insure for product liability would

have been able to avoid paying Medicare for past medical payments related to the claim. This provision guards the Medicare trust fund and saves nearly nine-billion dollars over 10 years.

Section 302. Competitive Acquisition of Certain Items and Services

CURRENT LAW

In general, durable medical equipment (DME) is paid for under a set of local (or state) fee schedules subject to certain floors and ceilings as well as limited to the lower of the actual charge for the equipment or the fee schedule amount. Fee schedule amounts received an update of the full consumer price index for urban consumers (CPI–U) in 2003.

BBA 97 authorized the Secretary to conduct up to five demonstration projects to test competitive bidding as a way for Medicare to price and pay for Part B services other than physician services. The Secretary was required to establish up to three competitive acquisition areas for this purpose. Three competitive bidding demonstrations for durable medical equipment, prosthetics, orthotics, and supplies were successfully implemented: two in Polk County, Florida and one in the San Antonio, Texas area.

EXPLANATION OF PROVISION

The Secretary would be required to establish and implement competitive acquisition programs for durable medical equipment, medical supplies, items used in infusion, drugs and supplies used in conjunction with durable medical equipment, parenteral nutrition, and off-the-shelf orthotics (requiring minimal self-adjustment for appropriate use) that would replace the Medicare fee schedule payments. Class III devices—devices that sustain or support life, are implanted, or present potential unreasonable risk (e.g. implantable infusion pumps and heart valve replacements)—are subject to premarket approval by the Food and Drug Administration and would not be covered by the competitive bidding system.

In starting the competitive bidding programs, the Secretary would be required to establish competitive acquisition areas, but would be able to exempt rural areas and areas with low population density within urban areas that are not competitive, unless a significant national market exists through mail order for a particular item or service. The programs would be phased-in over three years with one-third of the areas implemented each year. High-cost and high-volume items and services would be required to be phased-in first. The Secretary would be able to exempt items and services for which competitive acquisition would not likely result in significant savings. The Secretary would be required to establish a process where existing rental agreements for covered DME items entered into contract before implementation of this program would not be affected. The supplier would be required to provide for appropriate servicing and replacement of these rental items.

Certain requirements for the competitive acquisition program would be established. Specifically, the Secretary would be allowed to award contracts in an area only when the following conditions were met: entities met quality and financial standards specified by the Secretary or the Program Advisory and Oversight Committee; total amounts paid under the contracts would be expected to be

less than would be paid otherwise; and beneficiary access to multiple suppliers would be maintained. Beneficiary liability would be reduced to 20 percent of the applicable contract award price.

Contracts would be required to be re-competed at least every three years. The Secretary would be required to award contracts to multiple entities submitting bids in each area for an item or service and would also have the authority to limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for covered items and services. The Secretary would be permitted to waive certain provisions of the Federal Acquisition Regulation that are necessary for the efficient implementation of this program, other than those relating to confidentiality of information. The Secretary would be required to report to Congress annually on savings, reductions in cost-sharing, access to items and services, and beneficiary satisfaction under the competitive acquisition program.

A Program Advisory and Oversight Committee with members appointed by the Secretary would be established. The Committee would be required to provide advice and technical assistance to the Secretary regarding the implementation of the program, data collection requirements, proposals for efficient interaction among manufacturers and distributors of the items and services, providers, and beneficiaries, and other functions specified by the Secretary. The provisions of the Federal Advisory Committee Act would not apply to this Committee.

The Secretary would be required to conduct a demonstration program on using competitive acquisition for clinical laboratory tests that are furnished without a face-to-face encounter between the individual and the hospital personnel or physician performing the tests. The same quality and financial conditions specified for the DME competitive acquisition program would apply for clinical laboratory test competitive acquisition. An initial report to Congress would be required of the Secretary and must be submitted by December 31, 2005 with progress and final reports, as the Secretary would determine appropriate. The General Accounting Office (GAO) would be required to report to Congress on the differences in reimbursement between public and private payors of clinical diagnostic services. The Secretary would be required to study whether suppliers of DME are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability.

The covered items and services included in the competitive acquisition program would be paid as determined under this program. The Secretary would be able to use this payment information to adjust the payment amounts for DME not located in a competitive acquisition area. In this instance, the inherent reasonableness rule would not be applied. Orthotics included in a competitive acquisition program would also be paid the amounts determined by this program. The Secretary would be able to use this payment information to adjust the payment amounts for such items. In this instance, the regular payment rules established by regulation, including the inherent reasonableness rule, would not be applied.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Numerous studies conducted by the HHS Office of the Inspector General (OIG) as well as GAO have found the government-determined fee schedule for durable medical equipment (DME) too high for certain items. For example, the OIG found that Medicare's reasonable payment methodology paid too much for parenteral nutrition. The OIG also found that Medicare payments for hospital beds were substantially higher than rates paid by other payors. Further, the OIG discovered that payments for albuterol were six times the catalog price for the drug.

The DME competitive bidding demonstration has been a success. The taxpayers and beneficiaries saved significantly and quality standards were higher under the demonstration. More, that three-quarters of the DME winners were small businesses and beneficiary satisfaction remained high.

Section 303. Competitive Acquisition of Covered Outpatient Drugs and Biologicals

(a) Adjustment to the Physician Fee Schedule

CURRENT LAW

The relative value associated with a particular physician service is the sum of three components: physician work, practice expense, and malpractice expense. Practice expense includes both direct costs (such as clinical staff time and medical supplies used to provide a specific service to an individual patient) as well as indirect costs such as rent, utilities, and business costs associated with running a practice. When the physician fee schedule was implemented, reimbursement for practice expenses was based on historic charges. The Social Security Act Amendments of 1994 (PL. 103–432) required the Secretary to develop a methodology for a resource-based system for calculating practice expenses for use in CY1998. BBA 97 delayed the implementation of the methodology until CY1999 and established a transition period with full implementation by CY2002. BBRA required the Secretary to establish a data collection process and data standards for determining practice expense relative values. Under this survey process, the Secretary was required to use data collected or developed outside HHS, to the maximum extent practicable, consistent with sound data collection practices.

The Secretary is required to periodically review and adjust the relative values affecting physician payment to account for changes in medical practice, coding changes, new data on relative value components, or the addition of new procedures. Under the budget-neutrality requirement, changes in these factors cannot cause expenditures to differ by more than $20 million from what would have been spent if such adjustments had not been made.

EXPLANATION OF PROVISION

As part of the annual process of establishing the physician fee schedule, the Secretary would be required to increase the practice expense relative values using supplemental survey data provided by entities and organizations. This survey data must meet the Secretary's criteria for acceptance and include expenses for the administration of drugs and biologicals.

The Secretary would be directed to cooperate with representatives of physician specialties affected by reform of the Average Wholesale Price (AWP) method of reimbursement for outpatient prescription drugs. The Secretary would be required to expedite consideration of the Current Procedural Terminology (CPT) codes used to bill for the costs associated with the administration of outpatient drugs affected by AWP reform. In addition, the Secretary would be required to consult with representatives of advisory physician groups, such as the Practice Expense Advisory Committee, when reviewing CPT codes.

Increases in practice expenses resulting from the use of new survey data submitted by the date of enactment, or consideration of CPT codes for drug administration services for drugs affected by AWP reform would not be subject to the budget neutrality. The Secretary would not be prevented from adjusting the practice expense relative values in subsequent years. The Secretary would be required to consult with GAO and groups representing the affected physician specialties before publishing the notice of proposed rulemaking.

The resulting adjustments in practice expense relative value units would not be subject to administrative or judicial review. They would be considered as a change in law and regulation for purposes of determining the sustainable growth rate, used to set the payment update for physician services.

The Secretary would be required to adjust the non-physician work pool methodology so that practice expense relative values for these services are not disproportionately reduced as a result of the above changes.

Any physician specialty would be permitted to submit survey data related to practice expenses through December 31, 2004. Budget neutrality would not be waived.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Physicians would be paid appropriate amounts for the administration of outpatient drugs covered by Medicare. It is the Committee's intent that the Secretary should use the survey data submitted by the American Society of Clinical Oncologists (ASCO) since the data meets all requirements for inclusion. The Committee directs the Secretary to depart from typical procedures and not average new ASCO survey data on practice expenses with older survey data from the American Medical Associations' socioeconomic monitoring system data. The Committee also directs the Secretary not to alter the ASCO survey data by removing any responses, including outliers. The Committee intends that the Secretary use the new ASCO survey data in the Secretary's normal methodology for determining practice expenses.

Furthermore, it is the Committee's intent that the Secretary use current procedures for consideration of CPT codes and modifications to those codes. The provision directs the Secretary to work with specialties affected by AWP reform to ensure that CPT codes, which would permit appropriate payment for drug administration, are in place before AWP reform occurs.

(b) Payment Based on Competition

CURRENT LAW

Although Medicare does not currently provide an outpatient prescription drug benefit, coverage of certain outpatient drugs is specifically authorized by statute. Specifically, under Medicare Part B, outpatient prescription drugs and biologicals are covered if they are usually not self-administered and are provided incident to a physician's services. Drugs and biologicals are also covered if they are necessary for the effective use of covered durable medical equipment, including those that must be put directly into equipment. In addition, Medicare will pay for certain self-administered oral cancer and anti-nausea drugs, erythropoietin (used to treat anemia), immunosuppressive drugs after covered Medicare organ transplants and hemophilia clotting factors. Vaccines for diseases like influenza, pneumonia, and hepatitis B are considered drugs and are covered by Medicare. Payments for covered outpatient drugs are made under Medicare Part B and are based on 95 percent of AWP. The term "AWP" is not defined in statute or regulation, but generally, AWP is intended to represent the average price used by wholesalers to sell drugs to their customers. It has been based on reported prices as published in industry reference publications or drug price compendia. There are no uniform criteria for reporting these numbers. Moreover, these reported prices do not reflect the discounts that manufacturers and wholesalers customarily offer to providers and physicians. To differing degrees, the published prices on which Medicare payment's are based are higher than the amounts actually paid to acquire a given prescription drug.

Since covered outpatient prescription drugs are Part B services, Medicare pays 80 percent of the recognized amount and the beneficiary is liable for the remaining 20 percent coinsurance amount, except in the case of vaccines where no beneficiary cost-sharing is imposed. Also, beneficiaries cannot be charged for any amounts in excess of the recognized payment amount.

EXPLANATION OF PROVISION

New sections 1847A and 1847B in Title XVIII of the Social Security Act would be established to provide physicians in the Medicare program with an annual choice between two payment and delivery systems: (1) a contractor who would deliver drugs to the physician and would be reimbursed on prices established through a competitive bidding process, or (2) the physician would be reimbursed for covered drugs at the Average Sales Price (ASP).

Under Section 1847A, the Secretary would be required to establish a competitive acquisition program to acquire and pay for covered outpatient drugs. Under this program, at least two contractors would be established in each competitive acquisition area (which would be defined as an appropriate geographic region) throughout the United States. Each year, a physician would be required to select contractors who would deliver covered drugs and biologicals to the physician. There would be two categories of drugs under this program: the oncology category (which would include drugs determined by the Secretary as typically primarily billed by oncologists or are otherwise used to treat cancer) that would be implemented beginning in 2005, and the non-oncology category that would be im-

plemented beginning in 2006. In this case, covered drugs means certain drugs currently covered under Section 1842(o) of the Social Security Act which are not covered as part of the competitive acquisition for durable medical equipment. Blood clotting factors, erythropoetin furnished as treatment for end-stage renal disease (ESRD), and radiopharmaceuticals would not be considered covered drugs under the competitive acquisition program. Nothing in the section would affect the carrier invoice pricing method used to pay for radiopharmaceuticals. The Secretary would also be able to exclude other drugs and biologicals or classes of drugs and biologicals that are not appropriate for competitive bidding or would not produce savings.

Certain contractor selection and contracting requirements for the competitive acquisition program would be established. Specifically, the Secretary would be required to establish an annual selection process for contractors in each area for each of the two categories of drugs. The Secretary may not award the two-year contract to any entity that does not have the capacity to supply covered outpatient drugs within the applicable category, or does not meet quality, service, or financial performance and solvency standards established by the Secretary. Specifically the contractor would be required to have: (1) arrangements to ship covered drugs at least 5 days of the week and on an emergency basis, (2) procedures for the prompt response and resolution of physician and beneficiary complaints and inquiries, and (3) grievance resolution procedures, including review by the Medicare Provider Ombudsman established in this legislation. At the Secretary's discretion, the Secretary could refuse to contract with an entity that has had its license for distributing drugs (including controlled substances) suspended or revoked by the Federal or a State government or that has been excluded from Medicare program participation. A contractor would be required to comply with a specified code of conduct, including conflict of interest provisions and all applicable provisions relating to the prevention of fraud and abuse. A contract would include specifications to ensure secure facilities, safe and appropriate storage of covered drugs, maintain record keeping, provide written policies and procedures to ensure drug safety, and retain compliance personnel. Either the Secretary or the entity could terminate contracts with appropriate advance notice. The Secretary would make the list of the available contractors accessible to physicians on an ongoing basis, through a directory posted on the Internet and provided by request.

The Secretary would be able to limit the number of qualified entities in each category and area, but not below two. The Secretary would be required to base selection on bid prices for covered drugs, bid prices for distribution of those drugs, ability to ensure product integrity, customer service, past experience with drug distribution, and other factors. Drugs dispensed under this program would be acquired directly from the manufacturer or from a distributor directly from the manufacturer. Contractors may be required to comply with additional product integrity safeguards for drugs susceptible to counterfeiting or diversion. The bid prices in an area would be effective for that area throughout the two-year contract period, but the contract would allow for appropriate price adjustments to reflect significant increases or decreases in a contractor's reason-

able, net acquisition costs as disclosed to the Secretary. The Secretary would not be able to accept a contract for an area if its aggregate average prices exceed 120 percent of the Average Sales Price established under 1847B. Under the program, the Secretary would be required to compute an area average of the submitted bid prices. For drugs and biologicals for which an average bid price has not been established due to its establishment as a new Medicare covered product, the payment rate would be the payment rate established under 1847B. The Secretary would be able to establish average sales price as the reimbursement amount in other exceptional cases. Beneficiary liability would be limited to 20 percent of the payment basis for the covered drug or biological, and would be collected by the contractor upon drug administration.

The Secretary would be permitted to waive certain provisions of the Federal Acquisition Regulation that are necessary for the efficient implementation of this program, other than those relating to confidentiality of information. The contractor supplying the physician in the area would submit the claim for the drug and would collect the cost-sharing amount from the beneficiary after administration of the drug. Both program payment and beneficiary cost sharing amounts would only be made to the contractor; would only be made upon the administration of the drug; and would be based on the average bid of prices for the drug and biological in the area. The Secretary would be required to establish a process for recovery of payments billed at the time of dispensing for drugs that were not actually administered.

The appropriate contractor, as selected by the physician, would supply covered drugs directly to the physician, except under the circumstances when a beneficiary is able to receive a drug at home. The Secretary would be able to specify other non-physician office settings where a beneficiary would be able to receive a covered drug directly. However, the contractor would not be able to deliver drugs to a physician without first receiving a prescription as well as other necessary information specified by the Secretary. A physician would not be required to submit a prescription for each individual treatment. The Secretary would establish requirements, including adequate safeguards against fraud and abuse and consistent with safe drug practices, in order for a physician to maintain an inventory of drugs in cases where: the drugs or biologicals are immediately required, where the physician could not have reasonably anticipated the immediate requirement, where the contractor could not deliver the product in a timely manner, and in emergency situations related to the patient's health. No applicable State requirements relating to the licensing of pharmacies would be waived.

Current rules related to physician assignment and beneficiary appeal rights in cases of medical necessity denial would remain unchanged. New physician appeal rights would be established similar to those provided to physicians who prescribe durable medical equipment or laboratory tests.

The Secretary would be required to establish an advisory committee to assist in the implementation of this program. The Secretary would be required to report to Congress on savings, reductions in cost-sharing, access to items and services, the availability of contractors as well as beneficiary and provider satisfaction under

the competitive acquisition program. These reports would be due each year from 2005 through 2007.

The new section 1847B would establish an alternative choice for physician reimbursement for covered Part B drugs based on an Average Sales Price methodology (ASP). ASP is calculated for multiple source drugs based on the average of all sales net of volume discounts, prompt pay discounts, cash discounts, free goods to physicians, charge backs and rebates other than Medicaid rebates. For single source products, ASP is calculated using the above methodology or the Wholesale Acquisition Cost, which ever is lower. In an initial period for which sales data is not available, the Secretary may determine the amount payable under the section without regard to the manufacturer's average sales price. In response to a public health emergency, the Secretary may use the wholesale acquisition cost instead of the average sales price until the price and availability of the drug has stabilized. Prices would be reported to the Secretary on a quarterly and confidential basis.

The Secretary would submit an annual report to the Congress on trends in average sales prices, administrative costs associated with compliance with this section, the total value of payments made under this section, and a comparison of the average manufacturer price reported under Medicaid with the average sales price. GAO would be required to assess the impact of this program on the delivery of services, particularly with respect to beneficiary access to drugs and the site of delivery. MedPAC would be required to submit to Congress specific recommendations with respect to payment for blood clotting factors in its 2004 annual report.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The Balanced Budget Act of 1997 (BBA 97, P.L. 105–33) specified that Medicare payment for covered outpatient prescription drugs would equal 95 percent of AWP. Law or regulation does not define AWP. Publishing organizations report AWPs provided by drug manufacturers. Medicare carriers use the published data to payment for Medicare covered drugs, but AWPs are not grounded in any real market transaction, and do not reflect the actual price paid by purchasers. Congress has long recognized AWP is a list price and not a measure of actual prices. Congress is now able to adopt an alternative basis for payment that will more accurately reflect actual acquisition costs for physicians. This will ensure that Medicare no longer bases its payments on prices that do not reflect prices otherwise available through market incentives and transactions.

AWP for a product is often far greater than the acquisition cost paid by suppliers and physicians. Some drug manufacturers use AWP to inflate payments made for drugs. As a result of abuses in the current system, beneficiaries are paying hundreds of millions of dollars in inflated co-payments every year. Medicare also pays upwards of one billion dollars in excess payments every year.

Some physicians assert that the overpayment for drugs covers underpayment for practice expenses. They contend that Medicare does not adequately reimburse them for the practice expenses asso-

ciated with providing care in outpatient settings. This section reduces the overpayment for drugs and biologics, while increasing physician practice expenses.

Over the past 6 years, the OIG has issued a number of reports, all of which have reached the conclusion that Medicare and its beneficiaries pay too much for prescription drugs. The OIG studied the prices for 24 Medicare covered drugs that accounted for $3.1 billion of the $3.9 billion in Medicare drug expenditures in 1999. The OIG compared Medicare reimbursement to prices available to the physician/supplier community, the Department of Veterans Affairs, and Medicaid. They found that Medicare and its beneficiaries would have saved substantial amounts of money on their coinsurance. The savings would have been $761 million a year by paying the actual wholesale prices available to physicians and suppliers. For each drug, Medicare paid more than the wholesale price available to physicians and suppliers.

Subsequently, the findings of the report were updated with more current drug pricing information and estimated that, of the $3.7 billion Medicare spent for 24 drugs in 2000, had Medicare paid the actual wholesale prices available to physicians and suppliers for these 24 drugs, the program and its beneficiaries would save $887 million a year. If Medicare had paid for these drugs based on catalog prices, according to the OIG, beneficiaries would have paid over $175 million less in coinsurance.

GAO's September 2001 report found that physicians can obtain Medicare-covered drugs at prices below current Medicare payments. In fact, wholesalers' and Group Purchasing Organizations' (GPO) prices are less than the AWP currently used to establish Medicare reimbursement for covered drugs. GAO found that the average discount from AWP ranged from 13 percent to 34 percent, and that two drugs had discounts of 65 percent and 86 percent.

In its recommendations to the Congress, the GAO urged CMS to take steps to begin reimbursing providers for part B-covered drugs and related services at levels reflecting providers' acquisition costs using information about actual market transaction prices. CMS should also evaluate expanding competitive bidding approaches to setting payment levels, according to the GAO, and that CMS should monitor beneficiary access to covered drugs in light of any changes to reimbursement.

The GAO also debunked some common myths generally held by many in the health care community. Specifically, the GAO found that despite concerns that the discounts available to large purchasers would not be available to physicians with a small number of drug claims, physicians with low volumes reported that their purchase prices were the same or less than the widely available prices GAO documented. GAO also believes that Medicare should pay for each service appropriately and not rely on overpayments for some services to offset inadequate payments for complementary services. The Committee shares this view, and believes the legislation achieves this goal.

Section 304. Demonstration Project for Use of Recovery Audit Contractors

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The Secretary would be required to conduct a demonstration project for up to three years on the use of recovery audit contractors under the Medicare Integrity Program. The recovery audit contractors would identify underpayments and overpayments in the Medicare program and would recoup overpayments made to providers. Payment would be made to these contractors by providing incentives for good performance. The Secretary would be able to waive Medicare statutory provisions to pay for the services of the recovery audit contractors. The Secretary would be required to examine the efficacy of using these contractors with respect to duplicative payments, accuracy of coding, and other payment policies in which inaccurate payments arise. The demonstration project would be required to cover at least two states among the states with the highest per-capita utilization rates of Medicare services and have at least three contractors.

Recovery of an overpayment through this project would not prohibit the Secretary or the Attorney General from investigating and prosecuting appropriate allegations of fraud and abuse. Fiscal intermediaries, carriers, and Medicare Administrative Contractors would not be eligible to participate as a recovery audit contractor. The Secretary would be required to show preference to contracting with entities that have demonstrated more than three years direct management experience and a proficiency in recovery audits. Within six months of completion, the Secretary would be required to report to Congress on the project's savings to the Medicare program, including recommendations on the cost-effectiveness of extending or expanding the program.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This is a common approach used in the private sector including physicians and hospitals to recover payments from insurers. It provides a useful check on whether the other CMS contractors are paying accurately and identifying potential fraud problems.

D. Title IV—Rural Health Care Improvements

Section 401. Enhanced Disproportionate Share Hospital (DSH) Treatment for Rural Hospitals and Urban Hospitals With Fewer Than 100 Beds

CURRENT LAW

Medicare makes additional payments to certain acute hospitals that serve a large number of low-income Medicare and Medicaid patients as part of its inpatient prospective payment system (PPS). As specified by BIPA, starting with discharges occurring on or after

April 1, 2001, all hospitals are eligible to receive Medicare disproportionate share hospital (DSH) payments when their DSH percentage or threshold amount exceeds fifteen.

Different formulas are used to establish a hospital's DSH payment, depending upon the hospital's location, number of beds and status as a rural referral center (RRC) or sole community hospital (SCH). The DSH adjustment that a small urban or rural hospital can receive is limited to 5.25 percent of total Medicare inpatient payments.

EXPLANATION OF PROVISION

For discharges after October 1, 2003, a small rural or urban hospital that qualifies for a DSH adjustment would potentially receive an increase in DSH payments. The DSH adjustment for these hospitals, except for rural referral centers, would be almost doubled but not to exceed a maximum of 10 percent.

EFFECTIVE DATE

The provision would apply to discharges occurring on or after October 1, 2003.

REASON FOR CHANGE

MedPAC, an independent advisory committee that advises Congress, recommended this policy in its March 2003 report. MedPAC believes this change would mitigate the effects of uncompensated care for many rural hospitals and thereby protect Medicare beneficiaries' access to care in rural communities. Historically, rural and small urban hospitals have been treated unfairly with respect to DSH payments.

Section 402. Immediate Establishment of Uniform Standardized Amount in Rural and Small Urban Areas

CURRENT LAW

Medicare pays for inpatient services in acute hospitals in large urban areas using a standardized amount that is 1.6 percent larger than the standardized amount used to reimburse hospitals in other areas (both rural areas and smaller urban areas). The Consolidated Appropriations Act of 2003 (P.L. 108–7) provided for a temporary payment increase to rural and small urban hospitals; all Medicare discharges from April 1, 2003, to September 30, 2003, would be paid on the basis of the large urban area amount.

EXPLANATION OF PROVISION

Beginning for discharges in FY2004, the standardized amount for hospitals located in areas other than large urban areas would be equal to the amount used to pay hospitals located in large urban areas. Technical conforming amendments would also be adopted.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

MedPAC recommends eliminating this differential in payment. MedPAC found no statistically significant difference in costs between the cost of hospitals in large urban areas (over one million) and other hospitals, after removing the effect of geographic differences in wages, teaching and other Medicare adjustments.

Section 403. Establishment of Essential Rural Hospital Classification

CURRENT LAW

No provision in current law.

EXPLANATION OF PROVISION

An Essential Rural Hospital would be a new designation for the purposes of Medicare reimbursement. To be eligible for the Essential Rural Hospital designation, the hospital must have more than 25 beds and must be located in a rural area. The Secretary must then determine that the closure of the hospital would significantly diminish the ability of beneficiaries to obtain essential health care services based on certain criteria. Specifically, the Secretary must determine that (1) a high proportion of Medicare beneficiaries residing in the hospital's service area receive basic inpatient care from the hospital, and (2) there exists, in the service area, a hospital with more than 200 licensed beds that provides specialized surgical care to a high percentage of beneficiaries. Regardless of the size of the hospital, almost all physicians in the area must have admitting privileges and provide their inpatient services primarily at the hospital. Also, the Secretary must determine that the closure of the hospital would have a significant adverse impact on the availability of health care service in the absence of the hospital.

In making such determination, the Secretary may also consider: (1) whether ambulatory care providers in the hospital's service area are insufficient to handle the outpatient care of the hospital, (2) whether beneficiaries would have difficulty accessing care, and (3) whether the hospital has a commitment to provide graduate medical education in a rural area. The essential rural hospital would have to have a quality of care score above the median state scores.

A hospital classified as an essential rural hospital would not be able to change such classification. An essential rural hospital would not be able to be treated as a sole community hospital, Medicare dependent hospital, or rural referral center. A hospital that is classified as an essential rural hospital for a cost reporting period beginning on or after October 1, 2004 would be reimbursed 102 percent of its reasonable Medicare costs for inpatient and outpatient services. Beneficiary cost-sharing amounts would not be affected and required billing for such services would not be waived.

EFFECTIVE DATE

The provision would apply to cost reporting periods beginning on or after October 1, 2004.

REASON FOR CHANGE

The purpose of this provision is to recognize the impact of certain hospitals whose existence is essential in the health care delivery system of the community. Some rural hospitals have high fixed costs because of the necessity for providing the capacity for essential services in a community. There are also problems with the definition and payment for some communities and rural referral hospitals. This would provide a new crosscutting designation field for hospitals that can meet the criteria.

Section 404. More Frequent Update in Weights Used in Hospital Market Basket

CURRENT LAW

Medicare's standardized amounts, which serve as the basis for its payment per discharge from acute hospitals, are increased annually using an update factor which is determined in part by the projected increase in the hospital market basket. The market basket is a fixed-weight hospital input price index, which measures the average change in the price of goods and services hospitals purchased in order to furnish inpatient care. CMS revises the cost category weights, reevaluates the price proxies for such categories, and rebases (or changes the base period) for the market basket every five years. CMS implemented a revised and rebased market basket using 1997 cost data for use in the FY2003 Medicare hospital payment rates.

EXPLANATION OF PROVISION

The Secretary would be required to revise the market basket cost weights including the labor share to reflect the most currently available data and to establish a schedule for revising the cost weights more often than once every five years. The Secretary would be required to submit a report to Congress by October 1, 2004 on the reasons for and the options considered in establishing such a schedule.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

At the current time the hospital market basket is only updated every ten years using five-year-old data for the weights including the labor share. Statisticians at the Department of Labor and other experts believe the measures of inflation should be updated on a more regular basis to correct consistent inaccuracies over time.

Section 405. Improvements to the Critical Access Hospital (CAH) Program

(a) Increase in Payment Amounts

CURRENT LAW

Generally, a critical access hospital (CAH) receives reasonable, cost-based reimbursement for care rendered to Medicare beneficiaries. CAHs may elect either a cost-based hospital outpatient

service payment or an all-inclusive rate, which is equal to a reasonable cost payment for facility services plus 115 percent of the fee schedule payment for professional services. Ambulance services that are owned and operated by CAHs are reimbursed on a reasonable cost basis if these ambulance services are 35 miles from another ambulance system.

EXPLANATION OF PROVISION

Inpatient, outpatient, and covered skilled nursing facility services provided by a CAH would be reimbursed at 102 percent of reasonable costs of services furnished to Medicare beneficiaries.

EFFECTIVE DATE

This provision would apply to cost reporting periods beginning on or after October 1, 2003.

REASON FOR CHANGE

Small hospitals need the ability to build up reserves and to finance new capital expenditures. This provides a margin for these hospitals under the Medicare program, often their most important payor.

(b) Coverage of Costs for Certain Emergency Room On-Call Providers

CURRENT LAW

BIPA required the Secretary to include the costs of compensation (and related costs) of on-call emergency room physicians who are not present on the premises of a CAH, are not otherwise furnishing services, and are not on-call at any other provider or facility when determining the allowable, reasonable cost of outpatient CAH services.

EXPLANATION OF PROVISION

Reimbursement of on-call emergency room providers would be expanded to include the costs associated with physician assistants, nurse practitioners, and clinical nurse specialists as well as emergency room physicians for covered Medicare services.

EFFECTIVE DATE

This provision would apply to costs for services provided on or after January 1, 2004.

REASON FOR CHANGE

In sparsely populated areas, it is often the physician assistant or nurse practitioner employed by a physician practice or operating independently who is providing the on call services for the emergency room. This recognizes the bonuses that hospitals pay for their services.

(c) Modification of the Isolation Test for Cost-Based CAH Ambulance Services

CURRENT LAW

Ambulance services provided by a CAH or provided by an entity that is owned or operated by a CAH is paid on a reasonable cost basis and not the ambulance fee schedule, if the CAH or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of the CAH.

EXPLANATION OF PROVISION

The 35-mile requirement would not apply to the ambulance services that are furnished by a provider or supplier of ambulance services who is determined by the Secretary to be a first responder to emergencies.

EFFECTIVE DATE

This provision would apply to ambulance services furnished on or after the first cost reporting period that begins after the date of enactment.

REASON FOR CHANGE

CAHs may not be eligible for cost-based reimbursement because other ambulances may come into the area to transport patients between hospitals or to transfer patients to/from nursing homes. This would ensure that CAHs owned-and-operated ambulances would be paid cost when they are the first responders to an emergency.

(d) Reinstatement of Periodic Interim Payment (PIP)

CURRENT LAW

Eligible hospitals, skilled nursing facilities, and hospices, which meet certain requirements, receive Medicare periodic interim payments (PIP) every two weeks; these payments are based on estimated annual costs without regard to the submission of individual claims. At the end of the year, a settlement is made to account for any difference between the estimated PIP payment and the actual amount owed. A CAH is not eligible for PIP payments.

EXPLANATION OF PROVISION

An eligible CAH would be able to receive payments made on a PIP basis for its inpatient services. The Secretary would be required to develop alternative methods based on the expenditures of the hospital for these PIP payments.

EFFECTIVE DATE

This provision would apply to payments made on or after January 1, 2004.

REASON FOR CHANGE

Small rural hospitals often have significant changes in volume due to the season or just on a day-to-day basis. This provision averages payments over time to aid the hospital's financial stability.

(e) Condition for Application of Special Physician Payment Adjustment

CURRENT LAW

As specified by BBRA, CAHs can elect to be paid for outpatient services using cost-based reimbursement for its facility fee and at 115 percent of the fee schedule for professional services otherwise included within its outpatient critical access hospital services for cost reporting periods starting on or after October 1, 2000.

EXPLANATION OF PROVISION

The Secretary would not be able to require that all physicians providing services in a CAH assign their billing rights to the entity in order for the CAH to be able to be paid on the basis of 115 percent of the fee schedule for the professional services provided by the physicians. However, a CAH would not receive payment based on 115 percent of the fee schedule for any individual physician who did not assign billing rights to the CAH.

EFFECTIVE DATE

This provision would be effective as if it had been included as part of BBRA.

REASON FOR CHANGE

This provision ensures that the intent of Congress is for CMS to provide these payments in order to attract physicians to CAHs.

(f) Flexibility in Bed Limitation for Hospitals

CURRENT LAW

A CAH is a limited service facility that must provide 24-hour emergency services and operate a limited number of inpatient beds in which hospital stays can average no more than 96 hours. A CAH cannot operate more than 15 acute-care beds at one time, but can have an additional 10 swing beds that are set up for skilled nursing facility (SNF) level care. SNF beds in a unit of the facility that is licensed as a distinct-part skilled nursing facility at the time of the facility's application for CAH designation are not counted toward these bed limits.

EXPLANATION OF PROVISION

The Secretary would be required to specify standards for determining whether a CAH has seasonal variations in patient admissions that would justify a 5-bed increase in the number of beds it can maintain (and still retain its classification as a CAH). CAHs that operate swing beds would be able to use up to 25 beds for acute care services as long as no more than 10 beds at any time are used for non-acute services. Those CAHs with swing beds that made this election would not be eligible for the 5-bed seasonal adjustment. A CAH with swing beds that elects to operate only 15 of its 25 beds as acute care beds would be eligible for the 5-bed seasonal adjustment.

EFFECTIVE DATE

These provisions would only apply to CAH designations made before, on or after January 1, 2004.

REASON FOR CHANGE

These provisions allow some needed flexibility in the CAH program designation to ensure that if there is a flu epidemic or major accident that the hospital would have the capacity to treat those patients.

(g) Additional 5-Year Period of Funding for Grant Program

CURRENT LAW

The Secretary is able to make grants for specified purposes to States or eligible small rural hospitals that apply for such awards. The authorization to award the grants expired in FY2002.

EXPLANATION OF PROVISION

The authorization to award grants would be established from FY2004 through FY2008 from the Federal Hospital Insurance Trust Fund at amounts of up $25 million each year.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This would continue the planning and monitoring aspects of the states for the CAH program. The Committee expects that the states would work in cooperation with the critical access hospitals in determining the best use of the funds.

Section 406. Redistribution of Unused Resident Positions

CURRENT LAW

Medicare has different resident limits for counting residents, its indirect medical education (IME) adjustment and for reimbursement for a teaching hospital's direct graduate medical education (DGME) costs. Generally, a hospital's IME adjustment depends on a hospital's teaching intensity as measured by the ratio of the number of interns and residents per bed. Prior to BBA 97, the number of residents that could be counted for IME purposes included only those in the hospital inpatient and outpatient departments. Effective October 1, 1997, under certain circumstances a hospital may now count residents in non-hospital sites for the purposes of IME. Medicare's DGME payment to teaching hospital is based on its updated cost per resident (subject to a locality adjustment and certain payment corridors), the weighted number of approved full-time-equivalent (FTE) residents, and Medicare's share of inpatient days in the hospital. Generally, the resident counts of both IME and DGME payments are based on the number of residents in approved allopathic and osteopathic teaching programs that were reported by the hospital for the cost reporting period ending in calendar year 1996. The DGME resident limit is based on the unweighted resident counts. Hospitals that established new training programs be-

fore August 5, 1997 are partially exempt from the cap. Other exceptions apply to certain hospitals including those with new programs established after that date. Hospitals in rural areas (and non-rural hospitals operating training programs in rural areas) can be reimbursed for 130 percent of the number of residents allowed by their cap. Under certain conditions, an affiliated group of hospitals under a specific arrangement may combine their resident limits into an aggregate limit. Subject to these resident limits, a teaching hospital's IME and DGME payments are based on a three-year rolling average of resident counts, that is, the resident count will be based on the average of the resident count in the current year and the two preceding years. The rolling average calculation includes podiatry and dental residents.

EXPLANATION OF PROVISION

A teaching hospital's total number of potentially Medicare-reimbursed resident positions would be reduced for cost reporting periods, starting January 1, 2004, if the resident reference level is less than its applicable resident limit. If so, the reduction would equal to 75 percent of the difference between the hospital's limit and its resident reference level. The resident reference level would be the highest number of allopathic and osteopathic resident positions (before the application of any weighting factors) for the hospital during the reference period. A hospital's reference period would be the 3 most recent consecutive cost reporting periods for which a hospital's cost reports have been settled (or in the absence of such settled cost reports, submitted reports) on or before September 30, 2002. The Secretary would be able to adjust a hospital's resident reference level, upon the timely request for such an adjustment, for the cost reporting period that includes July 1, 2003.

The Secretary would be authorized to increase the applicable resident limits for other hospitals by an aggregate number that does not exceed the overall reduction in such limits. No increase would be permitted for any portion of cost reporting period that occurs before July 1, 2003 or before the date of a hospital's application for such an increase. No increase would be permitted unless the hospital has applied for such an increase by December 1, 2005.

The Secretary would consider the need for an increase in the physician specialty and the location involved. The Secretary would first distribute the increased resident count to programs in hospitals located in rural areas and hospitals that are not in large urban areas on a first-come-first-serve basis. The hospital would have to demonstrate that the resident positions would be filled; not more than 25 positions would be given to any one hospital. These hospitals would be reimbursed for DGME for the increase in resident positions at the locality adjusted national average per resident amount. Changes in a hospital's resident count established under this section would increase a hospital's IME payments. These provisions would not apply to reductions in residency programs that occurred as part of the voluntary reduction program or would affect the ability of certain hospitals to establish a new medical residency training programs. The Secretary would be required to submit a report, including recommendations, on whether to extend the application deadline for increases in resident limits no later than July 1, 2005.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

An unintended effect of the resident cap was to lock in a maldistribution of DGME and IME resident training positions in the country. Due to the strong link between the location of a resident's training and their eventual practice, it is critical to get more residents into training programs in rural areas and small urban cities. This provision redistributes unused residency slots, over a five-year period, to hospitals that have either reached their cap or have been providing DGME residencies without Medicare funding.

Section 407. Two-Year Extension of Hold Harmless Provisions for Small Rural Hospitals and Sole Community Hospitals Under Prospective Payment System for Hospital Outpatient Department Services

CURRENT LAW

The PPS for hospital outpatient departments (HOPDs) was implemented in August 2000 for most acute care hospitals. Under the HOPD PPS, Medicare pays for covered services using a fee schedule based on ambulatory payment classifications (APCs). Rural hospitals with no more than 100 beds are paid no less under this PPS system than they would have received under the prior reimbursement system for covered HOPD services because of hold harmless provisions. The hold harmless provisions apply to services provided before January 1, 2004.

EXPLANATION OF PROVISION

The hold harmless provisions governing HOPD reimbursement for small rural hospitals would be extended to January 1, 2006. The hold harmless provisions would be extended to sole community hospitals located in a rural area starting for services furnished on or after January 1, 2004 until January 1, 2006. The Secretary would be required to conduct a study to determine if the costs by APC groups incurred by rural providers exceed such costs incurred by urban providers. If appropriate, the Secretary would provide a payment adjustment to reflect the higher costs of rural providers by January 1, 2005.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

During the proposed rule for the start of the HOPD PPS, CMS found that rural hospital costs were higher than other hospitals. CMS did not recommend adjusting payments due to the poor quality of the data. This continues the hold harmless from any negative effect from the PPS for small rural hospitals and extends it to sole community hospitals until the Secretary reexamines this issue.

Section 408. Exclusion of Certain Rural Health Clinic and Federally Qualified Health Center Services from the Prospective Payment System for Skilled Nursing Facilities

CURRENT LAW

Under the PPS, skilled nursing facilities (SNFs) are paid a predetermined amount to cover all services provided in a day, including the costs associated with room and board, nursing, therapy, and drugs; the daily payment would vary depending upon a patient's therapy, nursing and special care needs as established by one of 44 resource utilization groups (RUGs). Certain services and items provided a SNF resident, such as physicians' services, specified ambulance services, chemotherapy items and services, and certain outpatient services from a Medicare-participating hospital or critical access hospital, are excluded from the SNF PPS and paid separately under Part B.

EXPLANATION OF PROVISION

Services provided by a rural health clinic (RHCs) and a federally qualified health center (FQHC) after January 1, 2004 would be excluded from SNF PPS, if such services were excluded if furnished by an physician or practitioner who was not affiliated with a RHC or FQHC.

EFFECTIVE DATE

The provision would apply to services furnished on or after January 1, 2004.

REASON FOR CHANGE

In some rural areas, local physicians may be employed in a rural health clinic or federally qualified health clinic. This would allow them to get paid for their professional services to skilled nursing patients like other physicians.

Section 409. Recognition of Attending Nurse Practitioners as Attending Physicians To Serve Hospice Patients

CURRENT LAW

Medicare covers hospice services to care for the terminal illnesses of the beneficiary. In general, beneficiaries who elect the hospice benefit give up other Medicare services that seek to treat the terminal illness or that duplicate services provided by the hospice. Services are provided primarily in the patient's home by a Medicare-approved hospice. Reasonable and necessary medical and support services for the management of the terminal illness are furnished under a written plan-of-care established and periodically reviewed by the patient's attending physician and the hospice. To be eligible for Medicare's hospice care, a beneficiary must be certified as terminally ill by an attending physician and the medical director or other physician at the hospice and elect hospice treatment. An attending physician who may be an employee of the hospice is identified by the patient as having the most significant role in the determination and delivery of his or her medical care when the patient makes an election to receive hospice care.

EXPLANATION OF PROVISION

A beneficiary would be able to identify a nurse practitioner (who is not employed by the hospice) as an attending physician. The nurse practitioner would not be able to certify the beneficiary as terminally ill.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

In rural areas, the independent nurse practitioner provides a significant amount of the care to patients up to and during their terminal illness. This allows them to continue in their clinical role with the patient.

Section 410. Improvement in Payments To Retain Emergency Capacity for Ambulance Services in Rural Areas

CURRENT LAW

Traditionally, Medicare has paid suppliers of ambulance services on a reasonable charge basis and paid provider-based ambulances on a reasonable cost basis. BBA 97 provided for the establishment of a national fee schedule, which was to be implemented in phases. The required fee schedule became effective April 1, 2002 with full implementation by January 2006. In the transition period, a gradually decreasing portion of the payment is to be based on the prior payment methodology (either reasonable costs or reasonable charges which were subject to national limitation amounts).

The fee schedule payment amount equals the base rate for the level of service plus payment for mileage and specified adjustment factors. Additional mileage payments are made in rural areas. BIPA increased payment for rural ambulance mileage for distances greater than 17 miles and up to 50 miles for services provided before January 1, 2004. The amount of the increase was at least one-half of the payment per mile established in the fee schedule for the first 17 miles of transport.

EXPLANATION OF PROVISION

The Secretary would be required to increase the base rate of the fee schedule for ground ambulance services that originate in a qualified rural area to account for the higher average costs incurred by providers furnishing a low volume of services. A qualified rural area is a county that has not been assigned to a metropolitan statistical area (MSA) with a population density of Medicare beneficiaries in the lowest quartile of all rural county populations.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The current adjustment may overpay rural ambulances in more populated areas and underpays them in less populated areas. Recent analyses by the General Accounting Office suggest that it is fixed costs—represented by the base rate—not mileage that are the

significant factor for increased costs in rural areas. In particular, the ambulances in the lowest 25 percent of rural counties may have less than one trip per day.

Section 411. Two-Year Increase for Home Health Services Furnished in a Rural Area

CURRENT LAW

The Medicare home health PPS, implemented on October 1, 2000, provides a standardized payment for a 60–day episode of care furnished to a Medicare beneficiary. Medicare's payment is adjusted to reflect the type and intensity of care furnished and area wages as measured by the hospital wage index. BIPA increased PPS payments by 10 percent for home health services furnished in the home of beneficiaries living in rural areas during the two-year period beginning April 1, 2001, through March 31, 2003, without regard to certain budget-neutrality provisions applying to home health PPS. The temporary additional payment is not included in the base for determination of payment updates.

EXPLANATION OF PROVISION

The provision would extend a five percent additional payment for home health care services furnished in a rural area during FY 2004 and 2005 without regard to certain budget-neutrality requirements.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

MedPAC recommends extending the five percent add-on for one-year while further analysis is done on rural agency home health margins. The two-year extension is to provide Congress with time to evaluate that information and decide what action is needed, if any.

Section 412. Providing Safe Harbor for Certain Collaborative Efforts that Benefit Medically Underserved Populations

CURRENT LAW

People who knowingly and willfully offer or pay a kickback, a bribe, or rebate to directly or indirectly induce referrals or the provision of services under a Federal program may be subject to financial penalties and imprisonment. Certain exceptions or safe harbors that are not considered violations of the anti-kickback statute have been established.

EXPLANATION OF PROVISION

Remuneration in the form of a contract, lease, grant, loan or other agreement between a public or non-profit private health center and an individual or entity providing goods or services to the health center would not be a violation of the anti-kickback statute if such an agreement would contribute to the ability of the health center to maintain or increase the availability or quality of services provided to a medically underserved population. The Secretary would be required to establish standards, on an expedited basis, re-

lated to this safe harbor that would consider whether the arrangement: (1) results in savings of Federal grant funds or increased revenues to the health center, (2) expands or limits a patient's freedom of choice, and (3) protects a health care professional's independence regarding the provision of medically appropriate treatment. The Secretary would also be able to include other standards that are consistent with Congressional intent in enacting this exception. The Secretary would be required to publish an interim final rule in the Federal Register no later than 180 days from enactment that would establish these standards. The rule would be effective immediately, subject to change after a public comment period of not more than 60 days.

EFFECTIVE DATE

Upon enactment

REASON FOR CHANGE

This would finalize policy under development at the Department of Health and Human Services.

Section 413. GAO Study of Geographic Differences

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

GAO would be required to study geographic differences in payment amounts in the physician fee schedule including: (1) an assessment of the validity of each component of the geographic adjustment factors; (2) an evaluation of the measures and the frequency with which they are revised; and (3) an evaluation of the methods used to establish the costs of professional liability insurance including the variation between physician specialties and among different states, the update to the geographic cost of practice index, and the relative weights for the malpractice component. The study, including recommendations concerning use of more current data and use of cost data rather than price proxies, would be due to Congress within 1 year of enactment.

EFFECTIVE DATE

Upon enactment.

Section 414. Treatment of Missing Cost Reporting Periods for Sole Community Hospitals

CURRENT LAW

Sole community hospitals (SCHs) are hospitals that, because of factors such as isolated location, weather conditions, travel conditions, or absence of other hospitals, are the sole source of inpatient services reasonably available in a geographic area, or are located more than 35 road miles from another hospital. The primary advantage of an SCH classification is that these hospitals receive Medicare payments based on the current national PPS national standardize amount or on hospital-specific per discharge costs from either FY 1982, FY1987 or FY1996 updated to the current year,

whatever amount would provide the highest Medicare reimbursement. The FY1996 base year option became effective for discharges on or after FY2001 on a phased in basis and would be fully implemented for SCH discharges on or after FY2004.

EXPLANATION OF PROVISION

A hospital would not be able to be denied treatment as a SCH or receive payment as a SCH because data are unavailable for any cost reporting period due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances, so long as data from at least one applicable base cost reporting period is available.

EFFECTIVE DATE

The provision would apply to cost reporting periods beginning on or after January 1, 2004.

REASON FOR CHANGE

During changes in fiscal intermediaries or in a change of ownership, historical information on a provider can be lost or misplaced. The purpose of the sole community hospital program is to provide for additional payment to protect access, which should not be stymied due to human error. Since sole community hospitals are paid the higher of any of the base years or the Federal rate, this does not result in preferential payments for these hospitals compared to other sole community hospitals.

Section 415. Extension of Telemedicine Demonstration Project

CURRENT LAW

BBA 97 authorized a telemedicine demonstration project for beneficiaries with diabetes mellitus in medically underserved rural or inner-city areas. BBRA required the Secretary to award the demonstration to the best technical proposal as of the bill's enactment date, no later than three months after enactment without additional review. BBRA also clarified that qualified medically underserved rural or urban inner-city areas are federally designated medically underserved areas or Health Provider Shortage Areas (HPSAs) at the time of enrollment in the project. Furthermore, it made changes in the project's data requirements, and limited beneficiary cost-sharing. The demonstration would expire in February 2004.

EXPLANATION OF PROVISION

This provision would extend the demonstration for an additional four years.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Difficulty finding appropriate participants delayed the demonstration's start. This extension would provide additional time to fully evaluate the clinical effectiveness of the program, and to de-

termine the long-term effectiveness of the approach. It would also provide more time to collect clinical data to evaluate the project's cost-effectiveness.

Section 416. Adjustment to the Medicare Inpatient Hospital PPS Wage Index to Revise the Labor-Related Share of Such Index

CURRENT LAW

Hospitals' DRG payments are adjusted by the hospital wage index. The adjusted portion of the payment is determined by the labor share. The labor share has three components: wages (50.7 percent), fringe benefits (11 percent), and rest is the so-called labor related costs.

EXPLANATION OF PROVISION

It reduces the labor share down to 62 percent of wages and fringe benefits for those areas with wage index values under 1.0. All other areas are held harmless from the change in the labor share.

EFFECTIVE DATE

October 1, 2003.

REASON FOR CHANGE

MedPAC and others have questioned whether some or all of the labor related costs in the labor share should be included. This eliminates these costs from the labor share for the areas that benefit from such a change.

Section 417. Medicare Incentive Payment Program Improvements for Physician Scarcity

CURRENT LAW

Under the Medicare Incentive Program, physicians receive a 10 percent bonus payment for services provided in health professional shortage areas. Physicians are responsible for indicating their eligibility for this bonus on their billing forms.

EXPLANATION OF PROVISION

This provision would establish a new five percent bonus payment program for physicians providing care to Medicare beneficiaries in physician scarcity areas. The Secretary would calculate two measures of scarcity. A primary care scarcity area would be determined based on the number of primary care physicians per Medicare beneficiary—the primary care ratio. A specialty care scarcity area would be based on the number of specialty care physicians per Medicare beneficiary—the specialty care ratio. The number of physicians would be based on physicians who actively practice medicine or osteopathy, and would exclude physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services.

The Secretary would rank each county or area based on its primary care ratio. Primary care scarcity counties or areas would be those counties or areas with the lowest primary care ratios, such that 20 percent of Medicare beneficiaries reside in these counties,

when each county or area is weighted by the number of Medicare beneficiaries in the county or area. Specialty care scarcity counties or areas would be identified in the same manner, using the specialty care ratio. There would be no administrative or judicial review of the identification of counties or areas, or of a specialty of any physician.

To the extent feasible, the Secretary would treat a rural census tract of a metropolitan statistical area, as determined under the most recent modification of the Goldsmith Modification, as an equivalent area for purposes of qualifying as a primary care scarcity area or specialty care scarcity area.

The Secretary would be required to publish a list of all areas which would qualify as primary care scarcity counties or specialty care scarcity counties as part of the proposed and final rules to implement the physician fee schedule.

The provision would also include improvement to the Medicare Incentive Payment Program, which provides a 10 percent bonus to physicians in shortage areas. The Secretary would be required to establish procedures under which the Secretary, and not the physician furnishing the service, would be responsible for determining when a bonus payment should be made. As part of the physician proposed and final rule for the physician fee schedule, the Secretary would be required to include a list of all areas which would qualify as a health professional shortage area for the upcoming year.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The new five percent bonus for physicians in either primary care scarcity counties or specialty care scarcity counties would increase financial incentives for physicians to provide care to Medicare beneficiaries in these areas with a shortage of physicians. This bonus payment would make it easier to recruit and retain physicians in these scarcity areas.

Improvements to the Medicare Incentive Program would shift responsibility for identifying eligibility for the 10 percent bonus from physicians to the Secretary.

E. TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

Section 501. Revision of Acute Hospital Payment Updates

CURRENT LAW

Each year, Medicare's operating payments to hospitals are increased or updated by a factor that is determined in part by the projected annual change in the hospital market basket. Congress establishes the update for Medicare's inpatient PPS for operating costs, often several years in advance.

EXPLANATION OF PROVISION

Acute hospitals would receive a market basket update minus 0.4 percent for three years. This results in an average 3.1 percent update for FY2004 through FY2006, equivalent to market basket minus 0.4 percent. The Secretary is also directed to compile and clarify the procedures and policies for billing for blood and blood costs in the hospital outpatient setting as well as the operation of the collection of the blood deductible.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

MedPAC unanimously recommended that Congress increase payments by 3.1 percent instead of the scheduled 3.5 percent. This results in a $3 billion increase in hospital payments for FY 2004. This is 0.4 percent less than current law due to expected increases in productivity. According to MedPAC, the modest expected productivity increase for hospitals is lower than would be considered to be sufficient for many private industries.

There is little precedent for hospitals to receive a full market basket increase. Congress has only given hospitals the full inflationary increase twice since the start of the hospital prospective payment system. Congress has legislated multiple-year changes in every Medicare bill except in the Omnibus Budget Reconciliation Act of 1989. Finally, this is a comparatively generous provision since Congress has typically reduced the inflationary offset by 1.2 percent—three times greater than the 0.4 percent recommended by MedPAC and presented in the bill.

The proposal replaces a historical saw tooth pattern of updates ranging from zero to full market basket to put hospitals' Medicare payments on a predictable stable funding path.

Section 502. Recognition of New Medical Technologies Under Inpatient Hospital PPS

CURRENT LAW

BIPA established that Medicare's inpatient hospital payment system should include a mechanism to recognize the costs of new medical services and technologies for discharges beginning on or after October 1, 2001. The additional hospital payments can be made by means of new technology groups, an add-on payment, a payment adjustment, or other mechanism, but cannot be a separate fee schedule and must be budget-neutral. A medical service or technology will be considered to be new if it meets criteria established by the Secretary after notice and the opportunity for public comment. CMS published the final regulation implementing these provisions on September 7, 2001. This regulation changed the meeting schedule for decisions on the creation and implementation of new billing codes (ICD–9–CM codes). The regulation also established that technology providing a substantial improvement to existing treatments would qualify for additional payments. The add-on payment for eligible new technology would occur when the standard diagnosis-related group (DRG) payment was inadequate; this thresh-

old was established as one standard deviation above the mean standardized DRG. In these cases, the add-on payment for new technology would be the lesser of (a) 50 percent of the costs of the new technology, or (b) 50 percent of the amount by which the costs exceeded the standard DRG payment; however, if the new technology payments are estimated to exceed the budgeted target amount of one percent of the total operating inpatient payments, the add-on payments are reduced prospectively.

Medicare pays hospitals additional amounts for atypical cases that have extraordinarily high costs compared to most discharges classified in the same DRG. The additional payment amount is equal to 80 percent of the difference between the hospital's entire cost for the stay and the threshold amount.

EXPLANATION OF PROVISION

The Secretary would be required to add new diagnosis and procedure codes in April 1 of each year that would not be required to affect Medicare's payment or DRG classification until the fiscal year that begins after that date. The Secretary would not be able to deny a service or technology treatment as a new technology because the service (or technology) has been in use prior to the 2-to-3 year period before it was issued a billing code and a sample of specific discharges where the service has been used can be identified. When establishing whether DRG payments are inadequate, the Secretary would be required to apply a threshold that is 75 percent of one standard deviation for the DRG involved.

The Secretary would be required to provide additional clarification in regulating the criteria used to determine whether a new service represents an advance in technology that substantially improves the existing diagnosis or treatment. The Secretary would be required to deem that a technology provides a substantial improvement on an existing treatment if the technology in question: (1) is a drug or a biological that is designated under section 506 of the Federal Food, Drug, and Cosmetic Act, approved under section 314.510 or 601.41 of Title 21, Code of Federal Regulations, designated for priority review when the marketing application was filed, or (2) is a medical device for which an exemption has been granted under section 520(m) of such Act, or for which priority or expedited review has been provided under section 515(d)(5). For other technologies that may be substantial improvements, the Secretary would be required to: (1) maintain and update a public list of pending applications for specific services and technologies to be evaluated for eligibility for additional payment; (2) accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial improvement; and (3) provide for a meeting at which organizations representing physicians, beneficiaries, manufacturers or other interested parties may present comments, recommendations, and data to the clinical staff of CMS regarding whether a service or technology represents a substantial improvement. These actions would occur prior to the publication of the proposed regulation.

Before establishing an add-on payment as the appropriate reimbursement mechanism, the Secretary would be directed to identify one or more DRGs and assign the technology to that DRG, taking into account similar clinical or anatomical characteristics and the

relative cost of the technology. The Secretary would assign an eligible technology into a DRG where the average cost of care most closely approximates the cost of the new technology. In such a case, no add-on payment would be made; the application of the budget-neutrality requirement with respect to annual DRG reclassifications and recalculation of associated DRG weights would not be affected. The Secretary would be required to increase the percentage associated with add-on payments from 50 percent to the marginal rate or the percentage that Medicare reimburses inpatient outlier cases.

The Secretary would be directed to automatically reconsider an application as a new technology that was denied for FY2003 as a FY2004 application under these new provisions. If such an application were granted, the maximum time period otherwise permitted for such classification as a new technology would be extended by 12 months.

EFFECTIVE DATE

These provisions would be effective for classifications beginning in FY2004.

REASON FOR CHANGE

CMS has only approved one new technology since these provisions were passed. This provision would allow more technologies to be covered and recognizes that the breakthrough technologies are new costs to the system.

Section 503. Increase in Federal Rate for Hospitals in Puerto Rico

CURRENT LAW

Under Medicare's prospective payment system for inpatient services, a separate standardized amount is used to establish payments for discharges from short-term general hospitals in Puerto Rico. BBA 97 provides for an adjustment of the Puerto Rico rate from a blended amount based on 25 percent of the federal national amount and 75 percent of the local amount to a blended amount based on a 50/50 split between national and local amounts.

EXPLANATION OF PROVISION

Hospitals in Puerto Rico would receive Medicare payments based on a 50/50 split between federal and local amounts before October 1, 2003. From FY2004—FY2007, an increasing amount of the payment rate would be based on federal national rates as follows: during FY2004, payment would be 59 percent national and 41 percent local; this would change to 67 percent national and 33 percent local during FY2005 and 75 percent national and 25 percent local during FY2006 and subsequent years.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Puerto Ricans pay the full Hospital Insurance payroll tax but they are not afforded equal Medicare payments to their hospitals.

This partially redresses the inequality between the rates, and is consistent with the MedPAC recommendation.

Section 504. Wage Index Adjustment Reclassification Reform

CURRENT LAW

Acute hospitals may apply to the Medicare Geographic Classification Review Board (MGCRB) for a change in classification from a rural area to an urban area, or reassignment from one urban area to another urban area, based on the level of wages. The MGCRB was created to determine whether a hospital should be redesignated to an area of close proximity for purposes of using that area's standardized amount, wage index, or both. If the MGCRB grants reclassification, the new wage index would be used to calculate Medicare's payment for inpatient and outpatient services. Generally, hospitals must demonstrate a close proximity to the areas where they seek to be reclassified. A hospital can meet this criteria if one of two conditions are met: (1) an urban hospital is no more than 15 miles and a rural hospital is no more than 35 miles from the area where it wants to be reclassified, or (2) at least 50 percent of the hospital's employees are residents of the area. A rural referral center (RRC) or a sole community hospital (SCH) or a hospital that is both a RRC and a SCH does not have to meet the proximity criteria. After establishing appropriate proximity, a hospital may qualify for the payment rate of another area if it proves that its incurred costs are comparable to those of hospitals in that area under established criteria. To use an area's wage index, a rural hospital must demonstrate that its average hourly wage is equal to at least 82 percent of the average hourly wage of hospitals in the area to which it seeks redesignation; an urban hospital must demonstrate that its average hourly wage is at least 84 percent of such an area. In addition, an urban hospital cannot be reclassified unless its average hourly wage is at least 108 percent of the average hourly wage of the area in which it is located. This standard is 106 percent for rural hospitals seeking reclassification to another area.

For redesignations starting in FY2003, the average hourly wage comparisons used to determine whether a hospital can use another area's wage index are based on 3 years worth of lagged data submitted by hospitals as part of their cost report. For instance, FY2003 wage index reclassifications were based on weighted three-year averages of average hourly wages using data from FY1997, FY1998, and FY1999 cost reports. Wage index reclassifications are effective for 3 years unless the hospital notifies the MCGRB and withdraws or terminates its reclassification.

EXPLANATION OF PROVISION

The Secretary would be required to establish an application process and payment adjustment to recognize the commuting patterns of hospital employees. A hospital that qualified for such a payment adjustment would have average hourly wages that exceed the average wages of the area in which it is located and have at least ten percent of its employees living in one or more areas that have higher wage index values. This qualifying hospital would have its wage index value increased by the average difference in wage index values between the higher areas and its own, weighted by the percent-

age of its employees who live in these areas. The process would be based on the MGCRB reclassification process and schedule with respect to data submitted. Such an adjustment would be effective for three years unless a hospital withdraws or terminates its payment. A hospital that receives a commuting wage adjustment would not be eligible for reclassification into another area by the MCGRB for the purposes of using its wage index or standardized amount. These commuting wage adjustments would not affect the computation of the wage index of the area in which the hospital is located or any other area. It would also be exempt from certain budget neutrality requirements.

ENACTMENT DATE

Upon enactment.

REASON FOR CHANGE

Labor market areas may differ from the distance requirements in the regulations on reclassification. Thus, using commuting patterns of employees more clearly reflects the underlying labor market that hospitals confront. This policy will have the effect of blurring the current hard line of payment adjustments between two adjacent MSAs.

Section 505. MedPAC Report on Specialty Hospitals

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

MedPAC would be required to conduct a study of specialty hospitals compared with other similar general acute hospitals including the number and extent of patients referred by physicians with an investment interest in the facility, the quality of care furnished, the impact of the specialty hospital on the acute general hospital, and the differences in the scope of services, Medicaid utilization and the amount of uncompensated care that is furnished. The report, including recommendations, would be due to Congress no later than 1 year from enactment.

ENACTMENT DATE

Upon enactment.

Subtitle B—Other Services

Section 511. Payment for Covered Skilled Nursing Facility Services

CURRENT LAW

Medicare uses a system of daily rates to pay for care in a skilled nursing facility (SNF). There are 44 daily rate categories, known as resource utilization groups (RUGs), and each group reflects a different case mix and intensity of services, such as skilled nursing care and/or various therapies and other services.

EXPLANATION OF PROVISION

The per diem RUG payment for a SNF resident with acquired immune deficiency syndrome (AIDS) would be increased by 128 percent. This payment increase would not apply after the date when the Secretary certifies that the SNF case mix adjustment adequately compensates for the facility's increased costs associated with caring for a resident with AIDS.

ENACTMENT DATE

The provision would be effective for services on or after October 1, 2003.

REASON FOR CHANGE

According to prior work by the Urban Institute, AIDS patients have much higher costs than other patients in the same resource utilization groups in skilled nursing facilities. The adjustment is based on that data analysis.

Section 512. Coverage of Hospice Consultation Services

CURRENT LAW

Current law authorized coverage of hospice services, in lieu of certain other Medicare benefits, for terminally ill beneficiaries who elect such coverage.

EXPLANATION OF PROVISION

Coverage of certain physicians' services for certain terminally ill individuals would be authorized. Persons entitled to these services would be individuals who have not elected the hospice benefit and have not previously received these physicians' services. Covered services would be those furnished by a physician who is the medical director or employee of a hospice program. Services would include evaluating the individual's need for pain and symptom management, counseling the individual with respect to end-of-life issues and care options, and advising the individual regarding advanced care planning. Payment for such services would equal the amount established for similar services under the physician fee schedule, excluding the practice expense component.

EFFECTIVE DATE

The provision would apply to consultation services provided by a hospice program on or after January 1, 2004.

REASON FOR CHANGE

Many patients, especially those with congestive heart failure, are not educated about the option of receiving hospice services to alleviate their pain and suffering. Moreover, hospice lengths of stay keep dropping, suggesting that patients are referred too late in their illness. This provision would encourage physicians to talk more with patients about hospice.

F. TITLE VI—PROVISIONS RELATING TO PART B

Subtitle A—Physicians' Services

Section 601. Revision of Updates for Physicians' Services

CURRENT LAW

Medicare pays for services of physicians and certain non-physician practitioners on the basis of a fee schedule. The fee schedule, in place since 1992, is intended to relate payments for a given service to the actual resources used in providing that service. The fee schedule assigns relative values to services. These relative values reflect physician work (i.e., the time, skill, and intensity it takes to provide the service), practice expenses, and malpractice costs. The relative values are adjusted for geographic variations in costs. The adjusted relative values are then converted into a dollar payment amount by a conversion factor.

The law provides a specific formula for calculating the annual update to the conversion factor. The intent of the formula is to place a restraint on overall increases in spending for physicians' services. Several factors enter into the calculation of the formula. These include: (1) the sustainable growth rate (SGR), which is essentially a target for Medicare spending growth for physicians' services, (2) the Medicare economic index (MEI), which measures inflation in the inputs needed to produce physicians' services, and (3) an adjustment that modifies the update, which would otherwise be allowed by the MEI, to bring spending in line with the SGR target. The SGR target is not a limit on expenditures. Rather, the fee schedule update reflects the success or failure in meeting the target. If expenditures exceed the target, the update for a future year is reduced.

The annual percentage update to the conversion factor equals the MEI, subject to an adjustment (known as the update adjustment factor) to match target spending for physicians' services under the SGR system. (During a transition period, 2001–2005, an additional adjustment is made to achieve budget neutrality.) The update adjustment sets the conversion factor at a level so that projected spending for the year would meet allowed spending by the end of the year. Allowed spending for the year is calculated using the SGR. However, in no case can the update adjustment factor be less than minus seven percent or more than plus three percent.

The update adjustment factor is the sum of: (1) the prior year adjustment component, and (2) the cumulative adjustment component. The prior year adjustment component is determined by: (1) computing the difference between allowed expenditures for physicians' services for the prior year and the amount of actual expenditures for that year, (2) dividing this amount by the actual expenditures for that year, and (3) multiplying that amount by 0.75. The cumulative adjustment component is determined by: (1) computing the difference between allowed expenditures for physicians' services from April 1, 1996 through the end of the prior year and the amount of actual expenditures during such period, (2) dividing that difference by actual expenditures for the prior year as increased by the SGR for the year for which the update adjustment factor is to be determined, and (3) multiplying that amount by 0.33.

The law also specifies a formula for calculating the SGR that is based on changes in four factors: (1) the estimated change in fees, (2) the estimated change in average number of Part B enrollees (excluding Medicare+Choice beneficiaries), (3) the estimated projected growth in real gross domestic product (GDP) per capita, and (4) the estimated change in expenditure due to changes in law or regulations. This formula is designed to adjust for how well actual expenditures meet SGR target expenditures.

Provisions in the Consolidated Appropriations Resolution of 2003 (P.L. 108–7) permitted redeterminations of SGR for prior years to correct for faulty data for the number of FFS beneficiaries in 1998 and 1999. As a result, the conversion factor for 2003 was increased 1.6 percent over the 2002 level. Other aspects of the formula for the annual payment rate were not addressed.

CMS estimates an update of −4.2 percent for 2004, followed by a smaller negative update in 2005.

EXPLANATION OF PROVISION

The update to the conversion factor for 2004 and 2005 would be not less than 1.5 percent.

The formula for calculating the sustainable growth rate would be modified. Starting in 2003, the GDP factor would be based on the annual average change over the preceding 10 years (a 10-year rolling average.) The current GDP factor measures the 1-year change from the preceding year.

EFFECTIVE DATE

Upon enactment. The 10-year rolling average calculation of the GDP would apply to computations of the SGR starting in 2003.

REASON FOR CHANGE

CMS actuaries project a −4.2 percent update for 2004 and a smaller negative update for 2005. This provision would prevent those negative updates from occurring, and provide for modest increases in physician payment rates. These modest increases would ensure continuing access to physician services for Medicare beneficiaries.

The provision also includes a 10–year rolling average calculation of GDP as a modest change to the update formula. This change would promote stability in the physician updates over time by limiting the volatility of the SGR payments, which now oscillate dramatically based on year-to-year changes in economic performance.

Section 602. Studies on Access to Physicians Services

CURRENT LAW

Periodic analyses by the Physician Payment Review Commission, MedPAC, and CMS showed that access to physicians' services remained generally adequate for most beneficiaries through 1999. Detailed data is not available for a subsequent period; however, several recent surveys show a decline in the percentage of physicians accepting new Medicare patients.

EXPLANATION OF PROVISION

GAO would be required to conduct a study on access of Medicare beneficiaries to physicians' services under Medicare. The study would include an assessment of beneficiaries' use of services through an analysis of claims data. It would also examine changes in use of physicians' services over time. Further, it would examine the extent to which physicians are not accepting new Medicare beneficiaries as patients. GAO would be required to submit a report to Congress on this study within 18 months of enactment. The report would include a determination whether data from claims submitted by physicians indicate potential access problems for beneficiaries in certain geographic areas. The report would also include a determination whether access by beneficiaries to physicians' services has improved, remained constant, or deteriorated over time.

The Secretary would be required to request the Institute of Medicine to conduct a study on the adequacy of the supply of physicians (including specialists) in the country and the factors that affect supply. The Secretary would be required to submit the results of the study in a report to Congress no later than 2 years of the date of enactment.

EFFECTIVE DATE

Upon enactment.

Section 603. MedPAC Report on Payment for Physicians' Services

CURRENT LAW

Medicare pays for physicians' services on the basis of a fee schedule. The fee schedule assigns relative values to services. These relative values reflect physician work, practice expenses and malpractice expenses. Resource-based practice expense relative values were phased-in beginning in 1999. Beginning in 2002, the values were totally resource-based.

Certain services have a professional component and a technical component. The technical component does not include a relative value for physician work. A global value includes both the professional and technical components. The physician must bill for the global value if the physician furnishes both the professional component and the technical component.

EXPLANATION OF PROVISION

MedPAC would be required to report to Congress on the effects of refinements to the practice expense component in the case of services for which there are no physician work relative value units. The report is to examine the following by specialty: (1) the effects of refinements on payments for physicians services, (2) interaction of the practice expense component with other components of and adjustments to payment for physicians' services, (3) appropriateness of the amount of compensation by reason of such refinements, (4) effect of such refinements on access to care by Medicare beneficiaries to physicians' services, and (5) effect of such refinements on physician participation under the Medicare program. The report would be due within one year of enactment.

EFFECTIVE DATE

Upon enactment.

Subtitle B—Preventive Services

Section 611. Coverage of an Initial Preventive Physical Examination

CURRENT LAW

Medicare covers a number of preventive services. However, it does not cover routine physical examinations.

EXPLANATION OF PROVISION

Medicare would cover an initial free preventive physical examination. The physical examination would be defined as physicians' services consisting of a physical examination with the goal of health promotion and disease detection. It would include items and services (excluding clinical laboratory tests) consistent with the recommendations of the United States Preventive Services Task Force as determined by the Secretary. A covered initial preventive physical examination would be one performed no later than six months after the individual's initial coverage date under Part B. Initial preventive physical exams would be included in the definition of physicians' services for purposes of the physician fee schedule. The Part B deductible and coinsurance would be waived for initial preventive physical exams.

EFFECTIVE DATE

The provision would apply to services furnished on or after January 1, 2004 for those individuals whose coverage begins on or after such date.

REASON FOR CHANGE

The US Preventive Services Task Force has recommended coverage of a preventive physical exam. An initial physical exam for new Medicare beneficiaries would permit identification of any health problems and allow for initiation of appropriate treatment, thereby reducing more acute and expensive interactions with the health care system in the future.

Section 612. Coverage of Cholesterol and Blood Lipid Screening

CURRENT LAW

Medicare covers a number of preventive services. However, it does not cover cholesterol and blood lipid screening.

EXPLANATION OF PROVISION

Medicare coverage of cholesterol and blood lipid screening would be authorized. The screening would be defined as diagnostic testing of cholesterol and other lipid levels of the blood for the purpose of early detection of abnormal cholesterol and other lipid levels. The Secretary would be required to establish standards regarding the frequency and type of these screening tests, but not more often than once every two years.

EFFECTIVE DATE

The provision would apply to services furnished on or after January 1, 2005.

REASON FOR CHANGE

The US Preventive Services Task Force has recommended coverage of cholesterol and blood lipid screening for the elderly. This preventive care benefit would allow for early detection and treatment of health problems.

Section 613. Waiver of Deductible for Colorectal Cancer Screening Tests

CURRENT LAW

Covered colorectal screening tests for prevention purposes include: (1) an annual fecal-occult blood test for individuals age 50 and older, (2) flexible sigmoidoscopy every four years for individuals age 50 and older, (3) colonoscopy for high-risk individuals every two years and for other individuals every 10 years, and (4) screening barium enemas every four years for individuals age 50 and older who are not at high risk of developing colorectal cancer or every two years for high risk individuals. Payment is made according to the applicable payment system for the provider performing the test.

Colorectal cancer screening tests are subject to beneficiary cost sharing amounts, including an annual deductible and coinsurance amount.

EXPLANATION OF PROVISION

The Part B deductibles would be waived for colorectal cancer screening tests.

EFFECTIVE DATE

The provision would apply to items and services furnished on or after January 1, 2004.

REASON FOR CHANGE

Beneficiaries have not availed themselves of preventive colorectal cancer screening tests to the extent anticipated after Medicare coverage of these tests became available under BBA 97. This provision would waive the deductible to increase beneficiary use of these important screening tests.

Section 614. Improved Payment for Certain Mammography Services

CURRENT LAW

Screening mammography coverage includes the radiological procedure as well as the physician's interpretation of the results of the procedure. The usual Part B deductible is waived for tests. Payment is made under the physician fee schedule.

Certain services paid under fee schedules or other payment systems including ambulance services, services for patients with end-stage renal disease paid under the ESRD composite rate, professional services of physicians and non-physician practitioners paid

under the physician fee schedule, and laboratory services paid under the clinical diagnostic laboratory fee schedule are excluded from Medicare's HOPD PPS.

EXPLANATION OF PROVISION

Unilateral and bilateral diagnostic mammography as well as screening mammography services would be excluded from the HOPD PPS. The Secretary would be required to provide an appropriate adjustment to the physician fee schedule for the technical component of the diagnostic mammography based on the most recent cost data available. This adjustment would be applied to services provided on or after January 1, 2004.

EFFECTIVE DATE

The provision would apply to mammography performed on or after January 1, 2004.

REASON FOR CHANGE

Mammography services are paid at a much lower rate under the HOPD PPS than in the physician office. This establishes a level playing field across sites of service, thereby increasing beneficiary access to important preventive services.

Subtitle C—Other Services

Section 621. Hospital Outpatient Department (HOPD) Payment Reform

(a) Payment for Drugs

CURRENT LAW

Under the HOPD PPS, the unit of payment is the individual service or procedure as assigned to one of about 570 ambulatory payment classifications (APCs) groups. Services are classified into APCs based on their Health Csare Common Procedure Coding System (HCPCS), a standardized coding system used to identify products, supplies, and services for claims processing and payment purposes. To the extent possible, integral services and items including drugs are bundled or packaged within each APC. For instance, an APC for a surgical procedure would include operating and recovery room services, anesthesia and surgical supplies. Medicare's payment for HOPD services is calculated by multiplying the relative weight associated with an APC by a geographically adjusted conversion factor. The conversion factor is updated on a calendar year schedule and the annual updates are based on the hospital market basket (MB). Currently, the CY 2004 HOPD update would equal the projected change in the MB.

Medicare pays for covered outpatient drugs in one of three ways: (1) as a transitional pass-through, (2) as a separate APC, or (3) packaged into an APC with other services.

Transitional pass-through payments are supplemental payments to cover the incremental cost associated with certain medical devices, drugs and biologicals that are inputs to an existing service. The additional payment for a given item is established for two or three years and then the costs are incorporated into the APC rel-

ative weights. BBRA specified that pass-through payments would be made for current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current cancer therapy drugs, biologicals, and brachytherapy; current radiophamaceutical drugs and biological products; and new drugs and biological agents.

Generally, CMS has established that a pass-through payment for an eligible drug is based on the difference between 95 percent of its average wholesale price and the portion of the otherwise applicable APC payment rate attributable to the existing drug, subject to a budget neutrality provision. The pass-through amount for new drugs with a substitute drug recognized in a separate drug APC payment is the difference between 95 percent of new drug AWP and the payment rate for the comparable dose of the associated drug APC.

Hospital costs for these drugs are used to establish the beneficiary copayment amounts as well as to project the amount of pass-through spending to calculate the uniform reduction to payments under the budget neutrality constraint. These hospital costs are imputed by multiplying the drug's AWP by the applicable cost to charge ratio, which varies by the class of drug. Although transitional pass-through payments are subject to a budget neutrality requirement, the applicable budget neutrality requirement (2.5 percent through CY2003) was not effective until April 2002.

Current drugs and biologicals that have been in transitional pass-through status on or prior to January 1, 2000, were removed from that payment status effective January 1, 2003. CMS established separate APC payments for certain drugs, including orphan drugs, blood and blood products, and selected higher cost drugs in CY2003. CMS established a threshold of $150 for a drug to qualify for a separate APC payment as a higher-cost drug. Other drugs that had qualified for a transitional pass-through payment were packaged in to procedural APCs. For example, in some instances, brachytherapy seeds (radioactive isotopes used in cancer treatments) were packaged into payments for brachytherapy procedures. Essentially, the payment rates for these drug-related APCs are based on a relative weight calculated in the same way as procedural APCs are calculated.

Temporary HCPCS codes are used exclusively to bill pass-through payments for new technology items paid under the HOPD PPS. These codes cannot be used to bill other Medicare payment systems. These codes are added, changed or deleted on a quarterly basis to expedite the processing of requests for pass-through status.

EXPLANATION OF PROVISION

Starting for services furnished on or after January 1, 2004, certain covered HOPD drugs would be paid no more than 95 percent of AWP or less than the transition percentage of the AWP from CY2004 through CY2006. In subsequent years, payment would be equal to average price for the drug in the area and year established by the competitive acquisition program under 1847A. The covered HOPD drugs affected by this provision are radiopharmaceuticals and outpatient drugs that were paid on a pass-through basis on or before December 31, 2002. These would not include drugs for which pass-through payments are first made on or after January 1, 2003,

or those drugs for which a temporary HCPCS code has not been assigned. Drugs for which a temporary HCPCS code has not been assigned would be reimbursed at 95 percent of AWP.

The transition percentage to AWP for sole-source drugs manufactured by one entity is 83 percent in CY2004, 77 percent in CY2005, and 71 percent in CY2006. The transition percentage to AWP for innovator multiple source drugs is 81.5 percent in CY2004, 75 percent in CY2005, and 68 percent in CY2006. The transition percentage to AWP for multiple source drugs with generic drug competitors is no more than 46 percent in CY2004 through CY2006. Generally, a multiple source drug is a covered drug for which there are two or more therapeutically equivalent drug products. An innovator multiple source drug is a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration (FDA). A sole source drug is not a multiple source drug. The additional expenditures resulting from these provisions would not be subject to the budget neutrality requirement.

Starting in CY2004, the Secretary would be required to lower the threshold for establishing a separate APC group for higher cost drugs from $150 to $50. These separate drug APC groups would not be eligible for outlier payments because their payment already increases when the dose increases.

Starting in CY2004, Medicare's transitional pass-through payments for drugs and biologicals covered under a competitive acquisition contract would reflect the amount paid under that contract, not 95 percent of AWP.

REASON FOR CHANGE

A GAO study found significant problems with the reimbursement for drugs and biologicals under the hospital outpatient system. Some drugs were reimbursed a small amount of AWP while others were paid far in excess of AWP. Hospital charges were not designed to specifically capture the resource costs for specific items. Some hospitals charge a flat markup on all drugs; some hospitals charge a lower markup on low cost drugs compared to high cost drugs while others do the opposite. As a result, the APC drug prices ranged from paying 0.2 percent of AWP to 29,000 percent of 95 percent AWP, and paid the median generic drugs more than sole source drugs. This provision establishes a glide path to the hospital acquisition cost numbers from the Kathpol survey undertaken by CMS. Thereafter, a level playing field with drug prices across sites of service would be established. CMS is asked to collect data from hospitals on their acquisition to be used to adjust the rates if necessary.

(b) Special Payment for Brachytherapy

CURRENT LAW

Current drugs and biologicals that have been in transitional pass-through status on or prior to January 1, 2000 were removed from that payment status effective January 1, 2003. CMS established separate APC payments for certain drugs, including orphan drugs, blood and blood products, and selected higher cost drugs in CY2003. CMS established a threshold of $150 per claim for a drug

to qualify for a separate APC payment as a higher-cost drug. Other drugs that had qualified for a transitional pass-through payment were packaged into procedural APCs. For example, in some instances, brachytherapy seeds (radioactive isotopes used in cancer treatments) were packaged into payments for brachytherapy procedures. Essentially, the payment rates for these drug-related APCs are based on a relative weight calculated in the same way as procedural APCs are calculated.

EXPLANATION OF PROVISION

From January 1, 2004 through December 31, 2006, Medicare's payments for brachytherapy devices would equal the hospital's charges adjusted to costs. The Secretary would be required to create separate APCs to pay for these devices that reflect to the number, isotope, and radioactive intensity of such devices. This would include separate groups for palladium-103 and iodine-125 devices. GAO would be required to study the appropriateness of payments for brachytherapy devices and submit a report including recommendations to Congress no later than January 1, 2005.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The amount of seeds necessary to treat the patient can vary significantly. This changes the payment methodology to reflect differences in clinical resources.

(c) Functional Equivalence

CURRENT LAW

In the November 1, 2002, Federal Register final rule, CMS decided that a new anemia treatment for cancer patients was no longer eligible for pass-though payments because it was functionally equivalent (although not structurally identical or therapeutically equivalent) to an existing treatment. The transitional pass-through rate for the drug was reduced to zero starting for services in 2003.

EXPLANATION OF PROVISION

The Secretary would be prohibited from applying a functional equivalence standard or any similar standard that deems a particular drug or biological to be similar or identical to another drug (and therefore ineligible for pass-through payment status) without first developing these standards by regulation. Such regulation would be required to: (1) be published after a public comment period, (2) contain criteria that provides for coordination with the Food and Drug Administration, and (3) be based on scientific studies that demonstrate the clinical relationship between the drugs in question. This provision would apply to the application of a functional equivalent determination on or after the date of enactment. The provision prohibits the application of this standard to a drug or biological prior to June 13, 2003.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The concept of functional equivalence is new to the Medicare program and should be open to comment by Congress and the public through proposed rulemaking. The FDA should be involved since these are scientific issues for which CMS lacks expertise.

(d) Hospital Acquisition Cost Study

CURRENT LAW

CMS estimates hospital costs to establish beneficiary copayment amounts as well as to project the amount of pass-through spending to calculate the uniform reduction to payments under the budget neutrality constraint. These hospital costs are imputed by multiplying AWP for the drug by the applicable cost to charge ratio, which varies by the class of drug.

EXPLANATION OF PROVISION

The Secretary would be required to study the hospital acquisition costs related to covered outpatient drugs that cost $50 and more that are reimbursed under the HOPD PPS. The study would encompass a representative sample of urban and rural hospitals. The report should include recommendations on the usefulness of the cost data and frequency of subsequent data collection and would be due to Congress no later than January 1, 2006. The report should also discuss whether the data is appropriate for making adjustments to payments made under the competitive acquisition contract established by section 1847A and whether separate estimates should be made for overhead costs (i.e. handling and administering drugs).

EFFECTIVE DATE

Upon enactment.

Section 622. Payment for Ambulance Services

CURRENT LAW

Traditionally, Medicare has paid suppliers of ambulance services on a reasonable charge basis and paid provider-based ambulances on a reasonable cost basis. BBA 97 provided for the establishment of a national fee schedule, which was to implemented in phases, in an efficient and fair manner. The required fee schedule became effective April 1, 2002, with full implementation by January 2006. In the transition period, a gradually decreasing portion of the payment is to be based on the prior payment methodology (either reasonable costs or reasonable charges).

The fee schedule payment amount equals the base rate for the level of service plus payment for mileage and specified adjustment factors. Additional mileage payments are made in rural areas. BIPA increased payment for rural ambulance mileage for distances greater than 17 miles and up to 50 miles for services provided before January 1, 2004. The amount of the increase was at least one-

half of the payment per mile established in the fee schedule for the first 17 miles of transport.

EXPLANATION OF PROVISION

The phase-in methodology and schedule for full implementation of the ambulance fee schedule would be modified. The calculation of ambulance fees in the phase-in period would incorporate a decreasing portion of the payment based on regional fee schedules calculated for each of nine census regions for those regions that lose financially under the fee schedule. Generally, the regional fee schedules would be based on the same methodology and data used to construct the national fee schedule. For services provided in 2004, the blended rate would be based on 20 percent of the national fee schedule and 80 percent of the regional fee schedule; in 2005 blended rate would be based on a 40 percent national and 60 percent regional split; in 2006, the blended rate would be based on a 60 percent national and 40 percent regional split; from 2007–2009, the blended rate would be based on an 80 percent national and 20 percent regional split; and in 2010 and subsequently, the ambulance fee schedule would be based on the national fee schedule.

Medicare's payments for ground ambulance services would be increased by one quarter of the amount otherwise established for trips longer than 50 miles occurring on or after January 1, 2004 and before January 1 2009. The payment increase would apply regardless of where the transportation originated. GAO would be required to submit an initial report to Congress on the access and supply of ambulance services in regions and states where ambulance payments are reduced by December 31, 2005. GAO would be required to submit a final report to Congress by January 1, 2004.

EFFECTIVE DATE

The provision would apply to ambulance services furnished on or after January 1, 2004.

REASON FOR CHANGE

New PPS systems cannot capture all the reasons for past regional differences in cost. This proposal is modeled on the transition of the hospital inpatient PPS and acts to slow down the losses in regions that lose significantly under the new fee schedule.

Section 623. Renal Dialysis Services

(a) Demonstration of Alternative Delivery Models

CURRENT LAW

The Secretary announced a demonstration project establishing a disease-management program that would allow organizations experienced with treating end-stage renal disease (ESRD) patients to develop financing and delivery approaches to better meet the needs of beneficiaries with ESRD. CMS is soliciting a variety of types of organizations to coordinate care to patients with ESRD, encourage the provision of disease-management services for these patients, collect clinical performance data and provide incentives for more effective care.

EXPLANATION OF PROVISION

The provision would require the Secretary to establish an advisory board for the ESRD disease management demonstration. The advisory board would be comprised of representatives patient organizations, clinicians, MedPAC, the National Kidney Foundation, the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health, ESRD networks, Medicare contractors to monitor quality of care, providers of services and renal dialysis facilities furnishing end-stage renal disease services, economists, and researchers.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This provision would allow more patient oversight of the demonstration of changes to the payments system for such a frail population.

(b) Restoring Composite Rate Exceptions for Pediatric Facilities

CURRENT LAW

Prior to BIPA, an increase in the composite rate would trigger an opportunity for facilities to request an exception to the composite rate in order to receive higher payments. BIPA prohibited the Secretary from granting new exceptions to the composite rate from applications received after July 1, 2001.

EXPLANATION OF PROVISION

The prohibition on exceptions would not apply to pediatric ESRD facilities as of October 1, 2002. Pediatric facilities would be defined as a renal facility with 50 percent of its patients under 18 years old.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Pediatric patients require more nursing oversight and more time to receive dialysis treatment. This would recognize the higher costs of facilities that treat these patients.

(c) Increase in Renal Dialysis Composite Rate for Services Furnished in 2004

CURRENT LAW

Dialysis facilities providing care to beneficiaries with end-stage renal disease (ESRD) receive a fixed prospectively determined payment amount (the composite rate) for each dialysis treatment. BBRA increased the composite rates by 1.2 percent for dialysis services furnished in both 2000 and 2001. BIPA subsequently increased the mandated 2001 update to 2.4 percent, an increase that was to be implemented on the following schedule in order to avoid

a disruption in claims processing: for services furnished from January through March, 2001, the 1.2 percent increase specified by BBRA applied; for the remainder of 2001, a transition increase of 2.79 percent applied. Effective January 1, 2002, the composite rates reflected the 2.4 percent increase. There is no rate increase scheduled for ESRD composite payment rate in 2004.

EXPLANATION OF PROVISION

The provision would increase the ESRD composite payment rate by 1.6 percent for 2004.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The Medicare Payment Advisory Commission recommended this increase in the composite rate for 2004.

Section 624. One-Year Moratorium on Therapy Caps; Provisions Relating to Reports

CURRENT LAW

BBA 97 established annual payment limits per beneficiary for all outpatient therapy services provided by non-hospital providers. The limits applied to services provided by independent therapists as well as to those provided by comprehensive outpatient rehabilitation facilities (CORFs) and other rehabilitation agencies. There are two beneficiary limits. The first is a $1,500 per beneficiary annual cap for all outpatient physical therapy services and speech language pathology services. The second is a $1,500 per beneficiary annual cap for all outpatient occupational therapy services. Beginning in 2002, the amount increases by the Medicare Economic Index (MEI), rounded to the nearest multiple of $10. The limits do not apply to outpatient services provided by hospitals. BBRA 99 percent suspended application of the therapy limits in 2000 and 2001. BIPA extended the suspension through 2002. Although the therapy caps were scheduled for implementation in January 2003, they are not yet being enforced. CMS has scheduled implementation for July 2003.

Therapy patients must be under the care of a physician. The physician or therapist must develop a treatment plan, and the physician must review the plan periodically.

BBA 97 required the Secretary to report to Congress by January 1, 2001, on recommendations for a revised coverage policy of outpatient physical therapy and occupational therapy services based on a classification of individuals by diagnostic category and prior use of services, in both inpatient and outpatient settings, in place of uniform dollar limitations. BIPA required the Secretary to conduct a study on the implications of eliminating Medicare's in-room supervision requirement for physical therapy assistants supervised by physical therapists its implication on the physical therapy cap. A report on the study was due within 18 months of enactment.

EXPLANATION OF PROVISION

Application of the therapy caps would be suspended during CY 2004. The Secretary would be required to submit the reports required by BBA 97 and BIPA by December 31, 2003. The Secretary would be required to request the Institute of Medicine to identify conditions or diseases that should justify conducting an assessment of the need to waive the therapy caps. The Secretary would be required to submit to Congress a preliminary report on the conditions and diseases identified by July 1, 2004. A final report, including recommendations, would be due by October 1, 2004.

GAO would be required to conduct a study on access to physical therapist services in states authorizing access to such services without a physician referral compared to states that require such a physician referral. The study would: (1) examine the use of and referral patterns for physical therapist services for patients age 50 and older in states that authorize such services without a physician referral and in states that require such a referral, (2) examine the use of and referral patterns for physical therapist services for patients who are Medicare beneficiaries, (3) examine the physical therapist services within the facilities of the Department of Defense, and (4) analyze the potential impact on beneficiaries and on Medicare expenditures of eliminating the need for a physician referral for physical therapist services under the Medicare program. GAO would be required to submit a report to Congress on the study within one year of enactment.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The Secretary has not provided a recommendation to Congress of criteria, with respect to conditions and diseases, under which a waiver of therapy caps would apply for individual Medicare beneficiaries. The implementation of therapy caps would be waived for 2004 because the Secretary has failed to provide a recommendation. The Secretary would have until October 1, 2004 to provide a recommendation to Congress.

Section 625. Adjustment to Payments for Services Furnished in Ambulatory Surgical Centers

CURRENT LAW

Medicare uses a fee schedule to pay for the facility services related to a surgery provided in an ACS. The associated physician services (surgery and anesthesia) are reimbursed under the physician fee schedule. CMS maintains the list of approved ASC procedures that is required to be updated every 2 years. The Secretary is required to update ASC rates based on a survey of the actual audited costs incurred by a representative sample of ASCs every 5 years beginning no later than January 1, 1995. Between revisions, the rates are to be updated annually on a calendar year schedule using the CPI–U. From FY1998 through FY2002, the update was established as the CPI–U minus 2.0 percentage points, but not less than zero.

EXPLANATION OF PROVISION

The update would be reduced two percentage points for five years. ASCs would get an increase calculated as the CPI–U minus 2.0 percentage points (but not less than zero) in each of the fiscal years from 2004 through 2008.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

MedPAC made three recommendations regarding ASCs, including a freeze on payments for 2004. This update would allow ASCs a small increase in payments while a more permanent solution is developed. The Committee urges CMS and ASCs to complete the collection of recent ASC charge and cost data, so that the ASC payment system can be analyzed and revised. Furthermore, the Committee recognizes the inconsistency in payments to ASCs and HOPD PPS rates for the same procedures. ASCs are urged to cooperate with CMS in providing recent charge and cost data to prevent changes to ASC payments that might not be supported if full data were available.

Section 626. Payment for Certain Shoes and Inserts under the Fee Schedule for Orthotics and Prosthetics

CURRENT LAW

Subject to specified limits and under certain circumstances, Medicare would pay for extra-depth shoes with inserts or custom molded shoes with inserts for an individual with severe diabetic foot disease. Coverage is limited to one of the following within a calendar year: (1) one pair of custom-molded shoes (including inserts provided with such shoes) and two additional pairs of inserts, or (2) one pair of extra-depth shoes (not including inserts provided with such shoes) and three pairs of inserts. An individual may substitute modifications of custom-molded or extra-depth shoes instead of obtaining one pair of inserts, other than the initial pair of inserts. Footwear must be fitted and furnished by a podiatrist or other qualified individual such as a pedorthist, orthotist, or prosthetist. The certifying physician may not furnish the therapeutic shoe unless the physician is the only qualified individual in the area.

Payment is made on a reasonable charge basis, subject to upper limits established by the Secretary. These limits are based on 1988 amounts that were set forth in Section 1833(o) of the Act and then adjusted by the same percentage increases allowed for DME fees except that if the updated limit is not a multiple of $1, it is rounded to the nearest multiple of $1. The Secretary or a carrier may establish lower payment limits than established by statute if shoes and inserts of an appropriate quality are readily available at lower amounts.

Although updates in payment for diabetic shoes is related to that used to increase the DME fee schedule, the shoes are not subject to DME coverage rules or the DME fee schedule. In addition, dia-

betic shoes are neither considered DME nor orthotics, but a separate category of coverage under Medicare Part B.

EXPLANATION OF PROVISION

Payment for diabetic shoes would be limited by the amount that would be paid if they were considered to be a prosthetic or orthotic device. The Secretary or a carrier would be able to establish lower payment limits than these amounts if shoes and inserts of an appropriate quality are readily available at lower amounts. The Secretary would be required to establish a payment amount for an individual substituting modifications to the covered shoe that would assure that there is no net increase in Medicare expenditures.

EFFECTIVE DATE

The provision would apply to items furnished on or after January 1, 2004.

REASON FOR CHANGE

The payment for shoes was determined based on an arbitrary amount set in the statute. The amount exceeded the retail price for some comparable items. This treats diabetic shoes the same as all other durable medical equipment.

Section 627. Waiver of Part B Late Enrollment Penalty for Certain Military Retirees; Special Enrollment Period

CURRENT LAW

A late enrollment penalty is imposed on beneficiaries who do not enroll in Medicare Part B upon becoming eligible for Medicare.

EXPLANATION OF PROVISION

Congress enacted TRICARE for Life, which re-established TRICARE health care coverage as a wraparound to Medicare for military retirees, age 65 and older. To take advantage of the TRICARE for Life program, military retirees must be enrolled in Medicare Part B. There is a late enrollment penalty for military retirees who do not enroll in Medicare Part B upon becoming eligible for Medicare. This provision would waive the late enrollment penalty for military retirees, 65 and older, who enroll(ed) in the TRICARE for Life program from 2001–2004.

The Secretary would also be required to provide a special enrollment period for these military retirees beginning as soon as possible after enactment and ending December 31, 2004. For the individual who enrolls during the special enrollment period, coverage would begin on the first day of the month, following the month in which the individual enrolled.

EFFECTIVE DATE

The provision would apply to premiums for months beginning with January 2004. A method would be established to provide rebates of premium penalties paid for by military retirees for months on or after January 2004.

REASON FOR CHANGE

The Floyd A. Spence National Defense Authorization Act for FY 2001 opened TRICARE to Medicare-eligible military retirees for the first time, allowing them to keep their military health benefits past the age of 65. This benefit became available for the first time on January 1, 2001.

This provision would eliminate two barriers prevent many retirees from accessing these benefits. First, many retirees who received military care in military health facilities on a space-available basis did not purchase Part B coverage when initially eligible. Upon late enrollment, they must pay a 10 percent penalty for each year that enrollment was delayed. Second, because Medicare enrollment is only available during an annual open enrollment season, from January 1 to March 31 each year, many retirees would have to wait until 2004 to secure coverage.

The waiver of the late-enrollment penalty and provision for a special enrollment period would remove these barriers.

Section 628. Part B Deductible

CURRENT LAW

Under Part B, Medicare generally pays 80 percent of the approved amount for covered services after the beneficiary pays an annual deductible of $100. The Part B deductible has set at $100 since 1991.

EXPLANATION OF PROVISION

The Medicare Part B deductible would rise from $100 in 2003 to $104 in 2004, and grow with Medicare inflation thereafter. As a result, the Part B deductible would grow at the same rate as expenditures per capita for Part B services. The amount would be rounded to the nearest dollar.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

In 1966, Medicare's $50 Part B deductible equaled about 45 percent of Part B charges. Today's $100 deductible equals about three percent of such charges. Indexing the Part B deductible to grow at the same rate as total Part B spending per beneficiary would maintain the deductible at 3 percent of such charges over time.

An unchanged Part B deductible is a benefit increase over time, as costs of medical care rise. Beneficiaries pay about 25 percent of this benefit increase, through increased Part B premiums; taxpayers finance the remaining 75 percent. The Part B deductible has increased only three times since the beginning of Medicare, when it was $50. The deductible has since been increased to $60 in 1973, $75 in 1982, and $100 in 1991. About one-half of beneficiaries are insulated from Part B deductibles through Medigap, Medicaid, or employer-sponsored supplemental insurance that covers the Part B deductible.

Section 629. Extension of Coverage of Intravenous Immune Globulin (IVIG) for the Treatment of Primary Immune Deficiency Diseases in the Home

CURRENT LAW

Currently, Medicare provides reimbursement under Part B for the infusion of IVIG in a hospital outpatient or physician office setting.

EXPLANATION OF CHANGE

The proposal would permit patients with primary immune deficiency to receive IVIG at home instead of in the currently covered settings. Unlike the other settings, however, home coverage would include only the cost of the drug; patients would be responsible for the cost of a nurse or other health care professional to administer the infusion.

EFFECTIVE DATE

Applies to items furnished on or after January 1, 2004.

REASON FOR CHANGE

Primary immune deficiency diseases are inherited disorders in which parts of the body's immune system are missing or do not function properly. These disorders affect more than 50,000 Americans. In order to maintain their health, most primary immune deficiency patients require monthly infusions of a plasma derivative known as intravenous immune globulin (IVIG). Without this life saving therapy, primary immune deficient patients would be subject to serious infection, illness and premature death.

Given their compromised immune systems, these patients are particularly vulnerable to the many infections to which individuals in a hospital or other health care facility are exposed. Home coverage of these infusions for appropriate patients would reduce this health risk and be significantly more convenient.

The Balanced Budget Refinement Act directed the Department of Health and Human Services to study the feasibility of allowing the existing covered drug to be reimbursed when delivered in the home. The study, conducted by the Lewin Group, examined issues such as cost, safety, access to care, and the practices of private insurers. The study concluded home coverage of IVIG is appropriate.

G. Title VII—Provisions Relating to Parts A and B

Subtitle A—Home Health Services

Section 701. Update in Home Health Services

CURRENT LAW

Home health service payments are increased on a federal fiscal year basis that begins in October. The FY 2004 statutory update would be the full increase in the market basket index.

EXPLANATION OF PROVISION

This provision would increase home health agency payments by the home health market basket percentage increase minus 0.4 per-

centage points for 2004 through 2006. The update for subsequent years would be the full market basket percentage increase. The provision would also change the time frame for the update from the federal fiscal year to a calendar year basis. The home health prospective payment rates would not increase for the October 1 through December 31, 2003, period.

EFFECTIVE DATE

Upon enactment.s

REASON FOR CHANGE

The Medicare Payment Advisory Commission recommended that Congress should eliminate the update to payment rates for home health services for fiscal year 2004. The Medicare margins for all agencies are 23.3 percent, even given the October 1, 2003 reduction. The mb-0.4 provides substantial payment increases for home heath agencies. However, they would be lower than current law and would provide stability.

Section 702. Establishment of Reduced Copayment for a Home Health Service Episode of Care for Certain Beneficiaries

CURRENT LAW

The home health benefit does not have any cost sharing requirement.

EXPLANATION OF PROVISION

This provision would establish a beneficiary copayment for each 60–day episode of care beginning January 1, 2004. The amount of the copayment would be 1.5 percent of the national average payment per episode in a calendar year, as projected by the Secretary before the beginning of the year. The copayment amount would be rounded to the nearest multiple of five dollars. For 2004, the copayment would be $40 unless the Secretary provides the results of the statutory formula in a timely manner. Medicare payment for each episode would be reduced to reflect the copayment amount. Qualified Medicare beneficiaries (low-income beneficiaries for whom Medicaid pays Medicare premiums, deductibles, and coinsurance), beneficiaries dually eligible for Medicare and Medicaid, and beneficiaries receiving five or fewer home health visits per episode of care would not face any cost-sharing requirements. Administrative and judicial review of the calculated copayment amounts would be prohibited.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Unlike almost all Part B services, the Medicare home health benefit does not have a copayment. The typical beneficiary receives about $3,000 worth of free home health care (CBO estimate). At the same time, home health spending is increasing rapidly rising almost 13 percent a year between 2004 and 2012 (CBO). In fact, the Congressional Budget Office estimates home health spending

will have almost tripled in size in that same period. When spending increases, so do beneficiary premiums because they are tied to program's costs.

Part of the reason for the spending increases it because it is difficult to determine if the beneficiary really needs home health (GAO and CMS). Requiring even nominal copays encourages beneficiaries to use care more prudently.

For the 90 percent of beneficiaries that have supplemental policies or other coverage, the Medicare program collects the copayments by automatically crossing over the claim to their insurance companies. Thus, the copayments generate little administrative cost for an agency.

Section 703. MedPAC Study of Medicare Margins of Home Health Agencies

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The provision would require MedPAC to study payment margins of home health agencies paid under the Medicare prospective payment system. The study would examine whether systematic differences in payment margins were related to differences in case mix, as measured by home health resource groups (HHRGs). MedPAC would be required to submit a report to Congress on the study within two years of enactment.

EFFECTIVE DATE

Upon enactment.

Subtitle B—Direct Graduate Medical Education

Section 711. Extension of Update Limitation on High Cost Programs

CURRENT LAW

Medicare pays hospitals for its share of direct graduate medical education (DGME) costs in approved programs using a count of the hospitals number of full-time equivalent residents and a hospital-specific historic cost per resident, updated for inflation. BBRA changed Medicare's methodology for calculating DGME payments to teaching hospitals to incorporate a new benchmark set at the national average amount based on FY1997 hospital specific per resident amounts. Starting in FY2001, hospitals received no less than 70 percent of a geographically adjusted national average amount. BIPA increased this floor to 85 percent of the locality adjusted, updated, and weighted national per resident amounts starting for cost report periods beginning during FY2002. Hospitals with per resident amounts above 140 percent of the geographically adjusted national average amount had payments frozen at current levels for FY2001 and FY2002, and in FY2003–FY2005 would receive an update equal to the Consumer Price Index (CPI) increase minus two percentage points. Currently, hospitals with per resident amounts between 85 percent and 140 percent of the geographically adjusted

national average would continue to receive payments based on their hospital-specific per resident amounts updated for inflation.

EXPLANATION OF PROVISION

The hospitals with per resident amounts above 140 percent of the geographically adjusted national average amount would not get an update from FY2004 through FY2013.

EFFECTIVE DATE

Upon enactment

REASON FOR CHANGE

The DGME amounts in these high cost hospitals are far higher that can be explained by the cost of living and legitimate difference in overhead. High quality medical training is delivered in most facilities for a fraction of the cost of high-cost institutions. The Medicare payments to these institutions have nothing to do with actual costs of training these physicians.

Subtitle C—Chronic Care Improvement

Section 721. Voluntary Chronic Care Improvement Under Traditional Fee-for-Service

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The Secretary would be required to establish a process for providing chronic care improvement programs for Medicare beneficiaries in FFS Medicare (Parts A and B) who have certain chronic conditions such as congestive heart failure, diabetes, chronic obstructive pulmonary disease, stroke or other diseases as identified by the Secretary. The Secretary would establish administrative regions, Chronic Care Improvement Administrative regions (CCIAs) within the United States for chronic care improvement programs. Within each CCIA, the Secretary would select at least two contractors under a competitive bidding process on the basis of the ability of each bidder to achieve improved health outcomes of the participating beneficiaries and improved financial outcomes of the Medicare program. A contractor would be a disease improvement organization, health insurer, provider organization, group of physicians, or any other legal entity that the Secretary determines appropriate. Contractors would be required to meet certain clinical, quality improvement, financial, and other requirements specified by the Secretary either directly or indirectly through the use of subcontractors. The Secretary would be able to phase-in implementation of the program beginning one-year after enactment.

Each program would be required to have a method for identifying targeted Medicare beneficiaries who would be offered participation in the program. The Secretary would be required to assist the program in identifying beneficiaries. Each beneficiary would be assigned to only one contractor that would be responsible for guiding beneficiaries in managing their health including all co-morbidities. Initial contact with a Medicare beneficiary would be from the Sec-

retary who would provide information about the program, including a description of advantages in participating. The Secretary would inform the beneficiary that the contractor would contact the beneficiary directly concerning participation, the voluntary nature of program participation, and a means of declining to participate or decline being contacted by the program. Each program would be required to develop an individualized, goal-oriented chronic care improvement plan with the beneficiary. The chronic care improvement plan would be required to contain: a single point of contact to coordinate care; self-improvement education for the individual and support education for health care providers, primary caregivers, and family members; coordination between prescription drug benefits, home health, and other health care services; collaboration with physicians and other providers to enhance communication of relevant clinical information; the use of monitoring technologies, where appropriate; and information about hospice care, pain and palliative care, and end-of-life care, as appropriate. In developing the chronic care improvement plan, programs would be required to use decision support tools such as evidence-based practice guidelines and a clinical information database to track and monitor each beneficiary across care settings and evaluate outcomes. The program would be required to meet any additional requirements that the Secretary finds appropriate. Programs would be accredited by qualified organizations to be deemed to have met such requirements as specified by the Secretary.

Contractor payments for each chronic care improvement program would be required to result in Medicare program outlays that would otherwise have been incurred in the absence of the program for the three-year contract period. The Secretary would be required to assure that there would be no net aggregate increase in Medicare payments, in entering into a contract for the program over the three-year period. Contracts for chronic care improvement programs would be treated as a risk-sharing arrangement. In addition, payment to contractors would be subject to the contractor meeting clinical and financial performance standards established by the Secretary.

Program contractors would be required to report to the Secretary on the quality of care and efficacy of the program in terms of process measures (such as reductions in errors and re-hospitalization rates), beneficiary and provider satisfaction, health outcomes, and financial outcomes. The Secretary would be required to submit to Congress annual reports on the program including information on progress made toward national coverage, common delivery models, and information on improvements in health outcomes, as well as financial efficiencies resulting from the program. The Secretary would also be required to conduct a randomized clinical trial to assess the potential for cost reductions under Medicare by comparing costs of beneficiaries enrolled in chronic care improvement programs and beneficiaries who are eligible to participate but are not enrolled.

Appropriations of such sums as necessary to provide for contracts with chronic care improvement programs would be authorized from the Medicare Trust Funds.

EFFECTIVE DATE

The provision would be effective upon enactment and the Secretary would be required to begin implementing the chronic care improvement programs no later than one-year after enactment.

REASON FOR CHANGE

Under current law, FFS Medicare does not offer coordinated care programs for the chronically ill. Chronic care management is an important issue, because 84 percent of seniors have one or more chronic conditions. In addition, individuals with chronic conditions account for 80 percent of all health care spending, with two-thirds of Medicare spending being spent on seniors with five or more chronic conditions. CMS has run demonstration programs in the Medicare program, particularly for high cost or especially frail adults. CMS is currently managing more than a dozen demonstration programs on disease and case management. A permanent program should be established within FFS Medicare that offers chronic care management to high-cost chronically ill seniors.

Section 722. Chronic Care Improvement Under Medicare Advantage and Enhanced Fee-for-Service Programs

CURRENT LAW

Under the Medicare+Choice program, organizations are required to have quality assurance programs that include measuring outcomes, monitoring and evaluating high volume and high risk services and the care of acute and chronic conditions, and evaluating the effectiveness of the efforts.

EXPLANATION OF PROVISION

Each Medicare Advantage plan offered would be required to have a chronic care improvement program for enrollees with multiple or sufficiently severe chronic conditions such as congestive heart failure, diabetes, chronic obstructive pulmonary disease, stroke or other disease as identified by the Secretary. The program would be required to have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions and to develop with an enrollee's consent an individualized, goal-oriented chronic care improvement plan.

The chronic care improvement plan would be required to include: a single point of contact to coordinate care; self-improvement education for the individual and support education for health care providers, primary caregivers, and family members; coordination between prescription drug benefits, home health, and other health care services; collaboration with physicians and other providers to enhance communication of relevant clinical information; the use of monitoring technologies, where appropriate; and information about hospice care, pain and palliative care, and end-of-life care, as appropriate. In developing the chronic care improvement plan, programs would be required to use decision support tools such as evidence-based practice guidelines and a clinical information database to track and monitor each beneficiary across care settings and evaluate health outcomes. The program would be required to meet any additional requirements that the Secretary finds appropriate.

Programs that have been accredited by qualified organizations would be deemed to have met such requirements as specified by the Secretary.

Each Medicare Advantage organization would be required to report to the Secretary on the quality of care and efficacy of the chronic care improvement program.

EFFECTIVE DATE

The provision would apply for contract years beginning on or after one year after enactment.

REASON FOR CHANGE

Many Medicare Health Maintenance Organizations (HMOs) already provide chronic care management programs. These programs target high-cost beneficiaries suffering from one or more chronic conditions and coordinate their care within plan. This requirement for private plans would continue the chronic care/disease management programs most Medicare HMOs already have in place.

Section 723. Institute of Medicine Report

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The Secretary would be required to contract with the Institute of Medicine of the National Academy of Sciences to study the barriers to effective integrated chronic care improvement for Medicare beneficiaries with multiple or severe chronic conditions across settings and over time. The study would examine the statutory and regulatory barriers to coordinating care across settings for Medicare beneficiaries in transition from one setting to another. The Institute of Medicine would be required to submit the report of the study to the Secretary and Congress no later than 18 months after enactment.

EFFECTIVE DATE

Upon enactment.

Section 724. MedPAC Report

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

MedPAC would be required to evaluate the chronic care improvement program. The evaluation would include a description of the status concerning implementation of the program, the quality of health care services provided to individuals participating in the program, and the cost savings attributed to implementation. The report of the evaluation would be submitted to Congress not later than two years after implementation of the program.

EFFECTIVE DATE

Upon enactment.

Subtitle D—Other Provisions

Section 731. Modifications to MedPAC

CURRENT LAW

The Medicare Payment Advisory Commission is a 17-member body that reports and makes recommendations to Congress regarding Medicare payment policies. The Comptroller General is required to establish a public disclosure system for Commissioners to disclose financial and other potential conflicts of interest.

EXPLANATION OF PROVISION

MedPAC would be required to examine the budgetary consequences of a recommendation before making the recommendation and to review the factors affecting the efficient provision of expenditures for services in different health care sectors under FFS Medicare. MedPAC would be required to submit two additional reports no later than June 1, 2003. The first report would study the need for current data, and the sources of current data available, to determine the solvency and financial circumstances of hospitals and other Medicare providers. MedPAC would be required to examine data on uncompensated care, as well as the share of uncompensated care accounted for by the expenses for treating illegal aliens. The second report would address investments and capital financing of hospitals participating under Medicare and access to capital financing for private and not-for-profit hospitals. The provision would also require that members of the Commission be treated as employees of Congress for purposes of financial disclosure requirements.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Congress needs to ensure that the Commission remains the objective impartial agency that it is today. Moreover, the Commission cannot be removed from the same constraints that Congress itself must face through considerations of the budget.

Section 732. Demonstration Project for Medical Adult Day Care Services

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

Subject to earlier provisions, the Secretary would be required to establish a demonstration project under which a home health agency, directly or under arrangement with a medical adult day care facility, provide medical adult day care services as a substitute for a portion of home health services otherwise provided in a bene-

ficiary's home. Such services would have to be provided as part of a plan for an episode of care for home health services established for a beneficiary. Payment for the episode would equal 95 percent of the amount that would otherwise apply. In no case would the agency or facility be able to charge the beneficiary separately for the medical adult day care services. The Secretary would reduce payments made under the home health prospective payment system to offset any amounts spent on the demonstration project. The three-year demonstration project would be conducted at not more than five sites, selected by the Secretary, in states that license or certify providers of medical adult day care services. Participation of up to 15,000 Medicare beneficiaries would be on a voluntary basis.

When selecting participants, the Secretary would give preference to home health agencies that are currently licensed to furnish medical adult day care services and have furnished such services to Medicare beneficiaries on a continuous basis for a prior two-year period. A medical adult day care facility would: (1) have been licensed or certified by a State to furnish medical adult day care services for a continuous two-year period, (2) have been engaged in providing skilled nursing services or other therapeutic services directly or under arrangement with a home health agency, and (3) would meet quality standards and other requirements as established by the Secretary. The Secretary would be able to waive necessary Medicare requirements except that beneficiaries must be homebound in order to be eligible for home health services.

The Secretary would be required to evaluate the project's clinical and cost effectiveness and submit a report to Congress no later than 30 months after its commencement. The report would include: (1) an analysis of patient outcomes and comparative costs relative to beneficiaries who receive only home health services for the same health conditions, and (2) recommendations concerning the extension, expansion, or termination of the project.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This demonstration would test the delivery of home health services in a group setting. While many of these patients are very frail, social interaction may prove to have a clinical benefit. At the same time, the current quality standards remain for delivering home health care.

Section 733. Improvements in National and Local Coverage Determination Process To Respond to Changes in Technology

(a) National and Local Coverage Determination Process

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

Subsection (a) would require the Secretary to make available to the public the general guidelines used in making national coverage determinations under Medicare. These determinations would be re-

quired to include the way in which the Secretary considers evidence to assess whether a procedure or device is reasonable or necessary. The provision would establish a time frame for decisions regarding national coverage determinations of six months after a request when a technology assessment is not required and 12 months when a technology assessment is required and in which a clinical trial is not requested. Following the six- or 12-month period, the Secretary would be required to make a draft of the proposed decision available in the HHS website or by other means; to provide a 30-day public comment period; to make a final decision on the request with 60 days following the conclusion of the public comment period; and make the clinical evidence and data used in making the decision available to the public. In instances where the Medicare Coverage Advisory Committee does not review a request for a national coverage determination, the Secretary would be required to consult with appropriate outside clinical experts.

The Secretary would also be required to develop a plan to evaluate new local coverage determinations to decide which local decisions should be adopted nationally and to decide to what extent greater consistency can be achieved among local coverage decisions, to require the Medicare contractors within an area to consult on new local coverage policies, and to disseminate information on local coverage determination among Medicare contractors to reduce duplication of effort.

EFFECTIVE DATE

The provision would be effective for determinations as of January 1, 2004.

REASON FOR CHANGE

The General Accounting Office reported in April 2003 problems with both the national coverage and local coverage process. Even though CMS assigned a 90-day process for coverage decisions, the average time was seven months with several taking over a year. GAO recommended establishing new time frames and a public process. GAO also found the local coverage process resulted in inequities for beneficiaries and wasteful duplication of administrative costs.

(b) Medicare Coverage of Routine Costs Associated With Certain Clinical Trials

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

Subsection (b) would provide for the coverage of the routine costs of care for Medicare beneficiaries participating in clinical trials that are conducted in accordance with an investigational device exemption approved under section 530(g) of the Federal Food, Drug, and Cosmetic Act.

EFFECTIVE DATE

The provision would be effective for clinical trials begun before, on, or after the date of enactment and to items and services furnished on or after enactment.

REASON FOR CHANGE

There is a discontinuity between the coverage of clinical trials using breakthrough devices and the coverage afforded other routine clinical trials. This provision would resolve this problem.

(c) Issuance of Temporary National Codes

CURRENT LAW

The Secretary issues temporary national Health Care Common Procedure Coding System (HCPCS) codes under Medicare Part B that are used until permanent codes are established.

EXPLANATION OF PROVISION

Subsection (c) would require that the Secretary implement revised procedures for the issuance of temporary national HCPCS codes.

EFFECTIVE DATE

The provision would be effective not later than one year after enactment.

REASON FOR CHANGE

Coding for HCPCs under Part B is a patchwork with temporary codes allowed for some services and not for others. This would create national uniformity.

Section 734. Extension of Treatment for Certain Physician Pathology Services Under Medicare

CURRENT LAW

In general, independent laboratories cannot directly bill for the technical component of pathology services provided to Medicare beneficiaries who are inpatients or outpatients of acute care hospitals. BIPA permitted independent laboratories with existing arrangements with acute hospitals to bill Medicare separately for the technical component of pathology services provided to the hospitals' inpatients and outpatients. The arrangement between the hospital and the independent laboratory had to be in effect as of July 22, 1999. The direct payments for these services apply to services furnished during a two-year period starting on January 1, 2001 and ending December 31, 2002.

EXPLANATION OF PROVISION

Medicare would make direct payments for the technical component for these pathology services. A change in hospital ownership would not affect these direct billing arrangements.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Many hospitals do not have on-site pathology services and this provision would continue the prior arrangements.

H. TITLE VIII—MEDICARE BENEFITS ADMINISTRATION

Section 801. Establishment of Medicare Benefits Administration

CURRENT LAW

The authority for administering the Medicare program resides with the Secretary of Health and Human Services. The Secretary originally created the agency that administers the Medicare and Medicaid programs in 1977 under his administrative authority. Regulations regarding Medicare are required to be promulgated by the Secretary. The Medicare statute requires the President to appoint the Administrator of CMS (formerly known as the Health Care Financing Administration) with the advice and consent of the Senate. Title V of the U.S. Codes sets the MBA Administrator's salary at level IV of the Executive Schedule. The Medicare statute requires the CMS Administrator to appoint a Chief Actuary who reports directly to such Administrator and receives pay at the highest rate of basic pay for the Senior Executive Service.

EXPLANATION OF PROVISION

The section would amend Title XVIII to add a new Section 1809 that, under subsection (a), would establish a new Medicare Benefits Administration (MBA) within the Department of Health and Human Services.

Subsection (b) would provide for an Administrator and Deputy Administrator of the MBA. The President with the advice and consent of the Senate would appoint both for 4-year terms. If a successor did not take office at the end of the term, the Administrator would continue in office until the successor enters the office. In that event, the confirmed successor's term would be the balance of the 4-year period. The Administrator would be paid at level III of the Executive Schedule and the Deputy Administrator at level IV of the Executive Schedule. The Administrator would be responsible for the exercise of all powers and the discharge of duties of the MBA and has authority and control over all personnel. The provision would permit the Administrator to prescribe such rules and regulations as the Administrator determined necessary or appropriate to carry out the functions of MBA, subject to the Administrative Procedure Act. The Administrator would be able to establish different organizational units within the MBA except for any unit, component, or provision specifically provided for by section 1809. The Administrator may assign duties, delegate, or authorize re-delegations of authority to MBA officers and employees as needed. The Secretary shall ensure appropriate coordination between the Administrators of MBA and CMS to administer the Medicare program. The provision also would establish a position of Chief Actuary within the MBA who would be appointed by the Administrator and paid at the highest rate of basic pay for the Senior Executive Service. The Chief Actuary would exercise such duties as are appropriate for the office of Chief Actuary and in accordance with professional standards of actuarial independence.

Subsection (c) would prescribe the duties of the Administrator and administrative provisions relating to the MBA. In administering parts C, D, and E of Medicare, the Administrator would be required to negotiate, enter into, and enforce contracts with PDP and MA–EFFS sponsors. The Administrator would be required to carry out any duty provided for under Part C, D, or E, including implementation of the prescription drug discount card program and demonstration programs (carried out in whole or in part under Part C, D, or E). The provision specifically prohibits the Administrator from requiring a particular formulary or instituting a price structure for the reimbursement of covered drugs; from interfering in any way with negotiations between PDP and MA–EFFS sponsors, drug manufacturers, wholesalers, or other suppliers of covered drugs; and from otherwise interfering with the competitive nature of providing prescription drug coverage. The Administrator would be required to submit a report to Congress and the President on the administration of parts C, D, and E during the previous year by not later than March 31 of each year.

The Administrator, with the approval of the Secretary, would be permitted to hire staff to administer the activities of MBA without regard to chapter 31 of title 5 of the U.S. Code B other than sections 3110, the prohibition against officials hiring relatives, and 3112, the hiring preferences given to veterans. The Administrator would be required to employ staff with appropriate and necessary experience in negotiating contracts in the private sector. The staff of MBA would be paid without regard to chapter 51 (other than section 5101 requiring classification of positions according to certain principles) and chapter 53 (other than section 5301 relating to the principles of pay systems) of title 5 of the U.S. Code. The rate of compensation for staff of MBA would not be able to exceed level IV of the Executive Schedule. The Administrator would be limited in the number of full-time-equivalent (FTEs) employees for the MBA to the number of FTEs within CMS performing the functions being transferred at the time of enactment. The Secretary, the Administrator of MBA, and the Administrator of CMS would be required to establish an appropriate transition of responsibility to redelegate the administration of Medicare part C from CMS to MBA. The provision requires the Secretary to ensure that the Administrator of CMS transfers such information and data as the Administrator of MBA requires to carry out the duties of MBA.

Subsection (d) would require the Secretary to establish an Office of Beneficiary Assistance within MBA to coordinate Medicare beneficiary outreach and education activities, and provide Medicare benefit and appeals information to Medicare beneficiaries under parts C, D, and E.

Subsection (e) would establish the Medicare Policy Advisory Board (the Board) within the MBA to advise, consult with, and make recommendations to the Administrator regarding the administration and payment policies of parts C, D, and E. The Board would be required to report to Congress and to the Administrator of MBA such reports as the Board determines appropriate and may contain recommendations that the Board considers appropriate regarding legislative or administrative changes to improve the administration of parts C, D, and E including: increasing competition under part C, D, or E for services furnished to beneficiaries; im-

proving efforts to provide beneficiaries information and education about Medicare, parts C, D, and E, and Medicare enrollment; evaluating implementation of risk adjustment under parts C and E; and improving competition and access to plans under parts C, D, and E. The reports would be required to be published in the Federal Register. The reports would be submitted directly to Congress and no officer or agency of the government would be allowed to require the Board to submit a report for approval, comments, or review prior to submission to Congress. Not later than 90 days after a report is submitted to the Administrator, the Administrator would be required to submit to Congress and the President an analysis of the recommendations made by the Board. The analysis would be required to be published in the Federal Register.

The Board would be made up of 7 members serving three-year terms, with three members appointed by the President, two appointed by the Speaker of the House of Representatives, and two appointed by the President pro tempore of the Senate. Board members may be reappointed but may not serve for more than 8 years. The Board shall elect the Chair to serve for three years. The Board is required to meet at least three times a year and at the call of the Chair.

The Board is required to have a director who, with the approval of the Board, may appoint staff without regard to certain sections of chapter 31 of title 5 of the United States Code (which addresses authority for employment). In addition, the director and staff may be paid without regard to certain provisions of chapter 51 and 53 of title 5 which are related to classification and pay rates and pay systems B although the rate of compensation is capped at level IV of the Executive Schedule. The Board may contract with and compensate government and private agencies or persons to carry out its duties without regard to section 3709 of the Revised Statutes (41 U.S.C. (5).

Subsection (f) authorizes an appropriation of such sums as are necessary from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund (including the Prescription Drug Account) to carry out section 1808.

EFFECTIVE DATE

The provision would be effective upon enactment; however, the enrollment and eligibility functions and implementation of parts C and E would be effective January 1, 2006.

REASON FOR CHANGE

A new agency, the Medicare Benefits Administration, would provide a more flexible and contemporary structure that is citizen-centered, results-oriented, and market-based. The administration of Parts C, D, and E would be separated from the administration of other parts of Medicare to ensure appropriate conduct of those parts of Medicare involving contracts with private organizations.

Implementing the M+C program in the past, CMS's decisions have made it difficult for private plans to participate in the program. Indeed, CMS has an inherent conflict of interest in administering traditional FFS while regulating the private plans. Placing the administration of Parts C, D, and E under a new MBA would create an agency whose main responsibility is the implementation

and operation of successful private plan programs that enhance beneficiary choice.

The MBA would reshape the federal bureaucracy to better coordinate health plans and the prescription drug benefit, and replace a current system that is inefficient and outdated.

Civil service law reforms would permit the MBA to hire the best possible staff, with private sector experience in negotiating with plans. The MBA would have the ability to create a modern workforce by paying for performance, disciplining bad workers without lengthy appeals, and hiring employees more quickly. These changes would promote general government efficiency.

(c) Miscellaneous Administrative Provisions

CURRENT LAW

The Board of Trustees of the Medicare Trust Funds is composed of the Commissioner of Social Security, the Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services and two members of the public. The Administrator of the Centers for Medicare & Medicaid Services serves as the Secretary of the Board of Trustees.

Title 5 of the U.S. Code sets the Administrator's salary at level IV of the Executive Schedule.

EXPLANATION OF PROVISION

Paragraph (1) would add the Administrator of MBA as an ex officio member of the Board of Trustees of the Medicare Trust Funds.

Paragraph (2) would increase the pay level for the Administrator of CMS from level IV of the Executive Schedule to level III.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The Administrator of the MBA should be a member of the Board of Trustees to represent that part of Medicare involving contracts with private entities. The Administrator of CMS should be paid at the same level as the Administrator of the MBA.

I. TITLE IX—REGULATORY RELIEF

Subtitle A—Regulatory Reform

Section 901. Construction; Definition of Supplier

CURRENT LAW

Section 1861 of the Social Security Act contains definitions of services, institutions, and so forth under Medicare. Supplier is not explicitly defined.

EXPLANATION OF PROVISION

Nothing in this title would be construed as compromising or affecting existing legal remedies for addressing fraud or abuse, whether it be criminal prosecution, civil enforcement or administrative remedies (including the False Claims Act) or to prevent or im-

pede HHS from its efforts to eliminate waste, fraud, or abuse in Medicare. The provision also would clarify that consolidation of the Medicare administrative contractors does not consolidate the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund. The provision would also clarify thats term. A supplier means a physician or other practitioner, a facility or other entity (other than a provider of services) furnishing items or services under Medicare.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The Committees are committed to extending needed regulatory relief to providers and suppliers while at the same time protecting taxpayers from waste, fraud and abuse.

Section 902. Issuance of Regulations

CURRENT LAW

The Secretary must publish a list of all manual instructions, interpretative rules, statements of policy, and guidelines that are promulgated to carry out Medicare law in the Federal Register no less frequently than every three months.

There is no explicit statutory instruction on logical outgrowth. The courts have repeatedly held that new matter in final regulations must be a logical outgrowth of the proposed rule and is an inherent aspect of notice and comment rulemaking.

EXPLANATION OF PROVISION

The provision would require the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed rule or an interim final regulation. The timeframe established would not be permitted to be longer than three years, except under extraordinary circumstances. If the Secretary were to vary the timeline he established, the provision would require him to publish a notice in the Federal Register the new timeline and an explanation of the variation. In the case of interim final regulations, the provision would require that if the Secretary did not meet his established timeframe, then the interim final regulation would not be able to continue in effect unless the Secretary published a notice of continuation of the regulation that included an explanation of why the regular timeline had not been complied with.

The provision also would require that a provision of a final regulation that is not a logical outgrowth of the proposed regulation or interim final regulation would be treated as a proposed regulation. The provision would not be able to take effect until public comment occurred and the provision published as a final regulation.

EFFECTIVE DATE

The provision regarding the establishment of regulatory timeframes would be effective upon enactment and would require the

Secretary to provide for an appropriate transition to take into account the backlog of previously published interim final regulation. The provision regarding logical outgrowth would be effective for final regulations published on or after enactment.

REASON FOR CHANGE

The volume of Medicare regulations issued by CMS can be difficult for health care providers and suppliers, particularly small providers and suppliers, to monitor. By requiring regulations to be released on a certain date, providers and suppliers would be better able to keep informed of program changes. The Secretary may stagger the notice and comment periods of regulations issued on the same day, so that the comment deadlines for these regulations do not occur simultaneously, in order to ensure that interested parties have the opportunity to comment on multiple regulations.

The collective impact provision ensures that the Department would consider the overall impact of any changes it is making on categories of providers and suppliers. If the Department determines that many changes affecting a particular category of providers or suppliers are underway, the Department should consult with representatives of that category to determine whether providers and suppliers would be better able to make the systems changes needed to accommodate those changes if all the new regulations were released simultaneously or staggered. Because of the burden implementing multiple regulations simultaneously can cause, the Secretary needs to coordinate new regulations based on an analysis of the collective impact the regulatory changes will have on any given category of provider or supplier.

Section 903. Compliance With Changes in Regulations and Policies

CURRENT LAW

No explicit statutory instruction. As a result of case law, there is a strong presumption against retroactive rulemaking. In *Bowen* v. *Georgetown University Hospital,* the Supreme Court ruled that there must be explicit statutory authority to engage in retroactive rulemaking.

EXPLANATION OF PROVISION

The provision would bar retroactive application of any substantive changes in regulation, manual instructions, interpretative rules, statements of policy, or guidelines unless the Secretary determines retroactive application is needed to comply with the statute or is in the public interest. No substantive change would go into effect until 30 days after the change is issued or published unless it would be needed to comply with statutory changes or was in the public interest. Compliance actions would be able to be taken for items and services furnished only on or after the effective date of the change. If a provider or supplier follows written guidance provided by the Secretary or a Medicare contractor when furnishing items or services or submitting a claim and the guidance is inaccurate, the provider or supplier would not be subject to sanction or repayment of overpayment (unless the inaccurate information was due to a clerical or technical operational error).

EFFECTIVE DATE

The prohibition of retroactive application of substantive changes would apply to changes issued on or after the date of enactment. The provisions affecting compliance with substantive changes would apply to compliance actions undertaken on or after the date of enactment. The reliance on guidance would take effect upon enactment but would not apply to any sanction for which notice was provided on or before the date of enactment.

REASON FOR CHANGE

This provision would ensure that Medicare's rules are not generally applied retroactively. It would also ensure providers and suppliers have sufficient time to make any changes to systems needed to comply with changes in regulations. This provision would ensure that providers and suppliers, who, in good faith, based on the information received from contractors, would not be vulnerable to recovery if it turns out that the contractor was in error. Providers should be able to rely on the directions or guidance provided by their Medicare contractors.

Section 904. Reports and Studies Relating to Regulatory Reform

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The GAO would be required to study the feasibility and appropriateness of the Secretary providing legally binding advisory opinions on appropriate interpretation and application of Medicare regulations. The report would be due to Congress one year after enactment.

The Secretary would be required to report to Congress every two years on the administration of Medicare and areas of inconsistency or conflict among various provisions under law and regulation. The report would include recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts. The first report would be due to Congress two years after enactment.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The Committees are interested in receiving additional information regarding both advisory opinions and inconsistencies in Medicare regulations.

Subtitle B—Contracting Reform

Section 911. Increased Flexibility in Medicare Administration

CURRENT LAW

The Secretary is authorized to enter into agreements with fiscal intermediaries nominated by different provider associations to

make Medicare payments for health care services furnished by institutional providers. For Medicare part B claims, the Secretary is authorized to enter into contracts only with health insurers (or carriers) to make Medicare payments to physicians, practitioners and other health care suppliers. Section 1834(a)(12) of the Act authorizes separate regional carriers for the payment of durable medical equipment (DME) claims. The Secretary is also authorized to contract for certain program safeguard activities under the Medicare Integrity Program (MIP).

Certain terms and conditions of the contracting agreements for fiscal intermediaries (FIs) and carriers are specified in the Medicare statute. Medicare regulations coupled with long-standing agency practices have further limited the way that contracts for claims administration services can be established.

Certain functions and responsibilities of the fiscal intermediaries and carriers are specified in the statute as well. The Secretary may not require that carriers or intermediaries match data obtained in its other activities with Medicare data in order to identify beneficiaries who have other insurance coverage as part of the Medicare Secondary Payer (MSP) program. With the exception of prior authorization of DME claims, an entity may not perform activities (or receive related payments) under a claims processing contract to the extent that the activities are carried out pursuant to a MIP contract. Performance standards with respect to the timeliness of reviews, fair hearings, reconsiderations and exemption decisions are established as well.

A Medicare contract with an intermediary or carrier may require any of its employees certifying or making payments provide a surety bond to the United States in an amount established by the Secretary. Neither the contractor nor the contractor's employee who certifies the amount of Medicare payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States. Neither the contractor nor the contractor's employee who disburses payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States, if such payments are based upon a voucher signed by the certifying employee.

EXPLANATION OF PROVISION

This provision would add Section 1874A to the Social Security Act and would permit the Secretary to competitively contract with any eligible entity to serve as a Medicare contractor. The provision would eliminate the distinction between Part A contractors (fiscal intermediaries) and Part B contractors (carriers) and take the separate authorities for fiscal intermediaries and carriers and merge them into a single authority for the new contractor. These new contractors would be called Medicare Administrative Contractors (MACs) and would assume all the functions of the current fiscal intermediaries and carriers: determining the amount of Medicare payments required to be made to providers and suppliers, making the payments, providing education and outreach to beneficiaries, providers and suppliers, communicating with providers and suppliers, and additional functions as are necessary.

The Secretary would be permitted to renew the MAC contracts annually for up to 5 years. All contracts would be required to be

re-competed at least every 5 years using competitive processes. Federal Acquisition Regulations (FAR) would apply to these contracts except to the extent any provisions are inconsistent with a specific Medicare requirement, including incentive contracts. The contracts would be required to contain performance requirements that would be developed by the Secretary who could consult with beneficiary, provider, and supplier organizations, would be consistent with written statements of work and would be used for evaluating contractor performance. MAC would be required to furnish the Secretary such timely information as he may require and to maintain and provide access to records the Secretary finds necessary. The Secretary could require a surety bond from the MAC or certain officers or employees as the Secretary finds appropriate. The Secretary would be prohibited from requiring that the MAC match data from other activities for Medicare secondary payer purposes.

The provision would limit liability of certifying and disbursing officers and the Medicare Administrative Contractors except in cases of reckless disregard or the intent to defraud the United States. This limitation on liability would not limit liability under the False Claims Act. The provision also establishes circumstances where contractors and their employees would be indemnified, both in the contract and as the Secretary determines appropriate.

The provision would make numerous conforming amendments as the authorities for the fiscal intermediaries and carriers are stricken.

The Secretary would be required to submit a report to Congress and the GAO by no later than October 1, 2004, that describes the plan for implementing these provisions. The GAO is required to evaluate the Secretary's plan and, within six months of receiving the plan, report on the evaluation to Congress and make any recommendations the Comptroller General believes appropriate. The Secretary is also required to report to Congress by October 1, 2008 on the status of implementing the contracting reform provisions including the number of contracts that have been competitively bid, the distribution of functions among contracts and contractors, a timeline for complete transition to full competition, and a detailed description of how the Secretary has modified oversight and management of Medicare contractors to adapt to full competition.

Competitive bidding for the MACs would be required to begin for annual contract periods that begin on or after October 1, 2011.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Medicare's current contracting represents an antiquated, inefficient, and closed system based on cozy relationships between the government, contractors and providers.

Medicare contracting is antiquated because contractors may not provide service for the entire Medicare program, or particular functions within the program; rather Fiscal Intermediaries administer claims for facilities and carriers administer claims for all other providers. It has failed to keep pace with integrated claims administration practices in the private sector.

Medicare contracting is inefficient because Medicare does not award contracts through competitive procedures, but rather on provider nomination.

Medicare contracting is closed. All but one of the contractors today have been with Medicare since the program's inception 36 years ago, and only insurers can provide contracting services.

This provision permits greater flexibility in contracting for administrative services between the Secretary and the Medicare contractors (entities that process claims under part A and part B of the Medicare program), including the flexibility to separately contract for all or parts of the contractor functions. The Secretary also may contract with a wider range of entities, so that the most efficient and effective contractor can be selected.

These amendments require the Secretary to contract competitively at least once every five years for the administration of benefits under parts A and B. In conjunction with the elimination of cost contracts, it is intended to create incentives for improved service to beneficiaries and to providers of services and suppliers.

These amendments provide a basis for a unified contracting system for the administration of parts A and B, identical to the recent Congressionally mandated structure of the Medicare Integrity Program contractors. Consolidation of contracting duties as set forth in this legislation does not constitute consolidation of the Hospital Insurance and Medical Supplementary Insurance Trust Funds, or reflect any position on that issue. In addition, the elimination of provider nomination, which hospitals have rarely been allowed to exercise in recent years, is essential for bringing full and open competition into the contracting functions of the Medicare program.

The provision establishes a basis for a unified contracting system, identical to the structure implemented for the Medicare Integrity Program contractors. It is important to note, however, that consolidation of contracting duties as set forth in this legislation does not constitute consolidation of the Hospital Insurance and Medical Supplementary Insurance Trust Funds, or reflect any position on that issue. In addition, the Secretary would have the flexibility to choose the best contractor(s) to provide telephone information on suppliers, which is intended to reduce administrative costs and improve quality. Since the carrier fair hearing requirement was eliminated in previous legislation, the requirements for the hearing are eliminated in order to conform to existing law.

Section 912. Requirements for Information Security for Medicare Administrative Contractors

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

Medicare administrative contractors (as well as fiscal intermediaries and carriers until the MACs are established) would be required to implement a contractor-wide information security program to provide information security for the operation and assets of the contractor for Medicare functions. The information security program would be required to meet certain requirements for information security programs imposed on Federal agencies under title

44 of the United States Code. Medicare administrative contractors would be required to undergo an annual independent evaluation of their information security programs. Existing contractors would be required to undergo the first independent evaluation within one year after the date the contractor begins implementing the information security program and new contractors would be required to have such a program in place before beginning the claim determination and payment activities. The results of the independent evaluations would be submitted to the Secretary and the HHS Inspector General. The Inspector General of HHS would be required to report to Congress annually on the results of the evaluations. The Secretary would be required to address the results of the evaluations in required management reports.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The increased reliance by the Federal government on the Internet and related telecommunications technologies has resulted in enhanced inter-connectivity and interdependencies associated with Federal computer systems and between federal and private computer systems. Over the past several years, this inter-connectivity or networking has resulted in increased security vulnerabilities that have put at greater risk computer systems and data that are critical to ensuring national and economic security and public health and welfare, including sensitive, non-public information that is collected and maintained by CMS and its business partners.

On May 23, 2001, the Committee on Energy and Commerce held a hearing to investigate the extent to which sensitive, non-public information related to collecting and processing Medicare claims was adequately secure on the computer networks operated by CMS and its business partners, including Medicare contractors. That investigation revealed significant weaknesses, which the agency has been working to address. Some of the computer security concerns identified include weak password management, inadequate access controls, excessive user privileges, improper network configurations, and inadequate testing of critical systems. In addition, the OIG conducted assessments of financial controls—including electronic data processing controls—at CMS and its major Medicare contractors; in every year since 1997, the OIG has identified computer security controls as a material weakness at CMS and its contractors.

Section 812 is intended to assist CMS in identifying and working with contractors to address potential security deficiencies in order to ensure that sensitive, non-public information related to the processing of Medicare claims is adequately secure from unauthorized access, misuse, or destruction.

Subtitle C—Education and Outreach

Section 921. Provider Education and Technical Assistance

(a) Coordination of Education Funding

CURRENT LAW

Medicare provider education activities are funded through the program management appropriation and through Education and Training component of the Medicare Integrity Program (MIP). Both claims processing contractors (fiscal intermediaries and carriers) and MIP contractors may undertake provider education activities.

EXPLANATION OF PROVISIONS

The provision would add Section 1889 to the Social Security Act, which would require the Secretary to coordinate the educational activities through the Medicare contractors to maximize the effectiveness of education efforts for providers and suppliers and to report to Congress with a description and evaluation of the steps taken to coordinate provider education funding.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This provision is intended to ensure that federal spending on provider education is coordinated and used as efficiently as possible to maximize the value obtained from the investment. It is not intended to change the proportion of Medicare Integrity Program funds spent on provider education.

(b) Incentives To Improve Contractor Performance

CURRENT LAW

No specific statutory provision. Since FY1996, as part of the audit required by the Chief Financial Officers Act, an annual estimate of improper payments under FFS has been established. As a recent initiative, CMS is implementing a comprehensive error rate-testing program to produce national, contractor specific, benefit category specific and provider specific paid claim error rates.

EXPLANATION OF PROVISIONS

The Secretary would be required to use specific claims payment error rates (or similar methodology) to provide incentives for contractors to implement effective education and outreach programs for providers and suppliers and would require the Comptroller General to study the adequacy of the methodology and make recommendations to the Secretary and the Secretary to report to Congress regarding how he intends to used the methodology in assessing Medicare contractor performance.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This provision would ensure that the Department monitors contractor performance for claims payment error rates, and it would identify best practices for provider education—all with the goal of reducing payment errors and helping providers and suppliers better comply with program requirements. It is the Committees' intent that, in consultation with representatives of providers and suppliers, the Secretary shall identify and encourage best practices developed by contractors for educating providers and suppliers.

(c) Provision of Access to and Prompt Responses From Medicare Administrative Contractors

CURRENT LAW

No specific statutory provision. Statutory provisions generally instruct carriers to assist providers and others who furnish services in developing procedures relating to utilization practices and to serve as a channel of communication relating information on program administration. Fiscal intermediaries are generally instructed to: (1) provide consultative services to institutions and other agencies to enable them to establish and maintain fiscal records necessary for program participation and payment, and (2) serve as a center for any information as well as a channel for communication with providers.

EXPLANATION OF PROVISIONS

The Secretary would be required to develop a strategy for communicating with beneficiaries, providers and suppliers. Medicare contractors would be required to provide responses to written inquiries that are clear, concise and accurate within 45 business days of the receipt of the inquiry. The Secretary would be required to ensure that Medicare contractors have a toll-free telephone number where beneficiaries, providers and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate Medicare information. Medicare contractors would be required to maintain a system for identifying the person supplying information to beneficiaries, providers and supplier and to monitor the accuracy, consistency, and timeliness of the information provided. The Secretary would be required to establish and make public standards to monitor the accuracy, consistency, and timeliness of written and telephone responses of Medicare contractors as well as to evaluate the contractors against these standards.

EFFECTIVE DATE

The provision would be effective October 1, 2004.

REASON FOR CHANGE

This provision is intended to improve contractor accountability to make contractors more responsive to providers and suppliers, and to increase the accuracy and reliability of the information provided in response to the questions received.

(d) Improved Provider Education and Training

CURRENT LAW

In FY2003, approximately $122 million was budget by CMS for provider education and training.

EXPLANATION OF PROVISION

The provision would authorize $25 million to be appropriated from the Medicare Trust Funds for fiscal years 2005 and 2006, and such sums as necessary for succeeding fiscal years for Medicare contractors to increase education and training activities for providers and suppliers. Medicare contractors would be required to tailor education and training activities to meet the special needs of small providers or suppliers. The provision defines a small provider as an institution with fewer than 25 full-time equivalents (FTEs) and a small supplier as one with fewer than 10 FTEs.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This provision acknowledges that contractors are being instructed to significantly improve their provider education and training efforts, and accordingly authorizes new funds to be available for those purposes.

(e) Requirement To Maintain Internet Sites

CURRENT LAW

No statutory provision. CMS and Medicare contractors currently maintain Internet sites.

EXPLANATION OF PROVISION

The provision would require that the Secretary and the Medicare contractors maintain Internet sites to answer frequently asked questions and provide published materials of the contractors beginning October 1, 2004.

EFFECTIVE DATE

The provision would be effective October 1, 2004.

REASON FOR CHANGE

This provision would facilitate greater ease of provider and supplier access to information provided by Medicare's contractors.

(f) Additional Provider Education Provisions

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The provision would bar Medicare contractors from using a record of attendance (or non-attendance) at educational activities to

select or track providers or suppliers in conducting any type of audit or prepayment review.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This provision addresses a concern raised by providers and suppliers that their participation in educational forums has been used to trigger audits. Participation in educational forums should be encouraged not discouraged.

Nothing in this section or section 1893(g) shall be construed as preventing the disclosure by a Medicare contractor of information on attendance at education activities for law enforcement purposes. Nothing in this section or section 1893(g) shall be construed as providing for the disclosure by a Medicare contractor of the claims processing screens or computer edits used for identifying claims that would be subject to review.

Section 922. Small Provider Technical Assistance Demonstration Program

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The Secretary would be required to establish a demonstration program to provide technical assistance to small providers and suppliers, when they have requested the assistance, to improve compliance with Medicare requirements. If errors are found, the Secretary would be barred from recovering any overpayments barring evidence of fraud and if the problem that is the subject of the compliance review has been satisfactorily corrected within 30 days and the problem remains corrected. A GAO study is required not later than two years after the demonstration program begins. Appropriations would be authorized for $1 million for FY 2005 and $6 million for FY 2006 to carry out the demonstration.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Many large providers and suppliers have contracts with private consulting firms to help them navigate their interactions with the Medicare program. This type of assistance can be prohibitively expensive for small providers and suppliers—but they too are required to comply with complex program rules and regulations. This provision creates a new demonstration program to facilitate small provider and supplier access to expert technical assistance. The demonstration would also test whether encouraging technical assistance on the front-end (to help providers and suppliers play by the rules) could save the program money in the long-term by promoting greater program compliance.

Section 923. Medicare Provider Ombudsman; Medicare Beneficiary Ombudsman

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

A Medicare Provider Ombudsman would be required to be appointed by the Secretary and located within the Department of Health and Human Services. The Provider Ombudsman would be required to provide confidential assistance to providers and suppliers regarding complaints, grievances, requests for information, and resolution of unclear or conflicting guidance about Medicare. The Ombudsman would submit recommendations to the Secretary regarding improving the administration of Medicare, addressing recurring patterns of confusion under Medicare, and ways to provide for an appropriate and consistent response in cases of self-identified overpayments by providers and suppliers. Such sums as necessary would be authorized to be appropriated for FY2004 and subsequent years.

A Medicare Beneficiary Ombudsman would be required to be appointed by the Secretary and located within HHS. The Beneficiary Ombudsman would be required to have expertise and experience in health care, education of, and assistance to Medicare beneficiaries. The Beneficiary Ombudsman would be required to receive complaints, grievances, and requests for information submitted by Medicare beneficiaries. The Beneficiary Ombudsman would also be required to assist beneficiaries in collecting relevant information to seek an appeal of a decision or determination made by the Secretary, a Medicare contractor, or a Medicare+Choice organization and assisting a beneficiary with any problems arising from un-enrolling in a Medicare+Choice plan. The Beneficiary Ombudsman would be required to work with state health insurance counseling programs.

Appropriations would be authorized to be appropriated in such sums, as are necessary for fiscal year 2004 and each succeeding fiscal year to carry out the ombudsmen provisions.

This provision would also require the use of 1–800–Medicare for all individuals seeking information about, or assistance with Medicare. Rather than listing individual telephone numbers for Medicare contractors in the Medicare handbook, only 1–800–Medicare would be shown. The Comptroller General would be required to study the accuracy and consistency of information provided by the 1–800–Medicare line and to assess whether the information sufficiently answers the questions of beneficiaries. The report on the study would be required to be submitted to Congress no later than one year after enactment.

EFFECTIVE DATE

The Secretary would be required to appoint both ombudsmen no later than one year from the date of enactment.

REASON FOR CHANGE

Providers are currently confronted with a morass of bureaucracy and regulation, with no clear individual to assist them. The new ombudsman would help providers navigate Medicare's complicated rules and regulations.

Medicare Provider Ombudsman shall make recommendations to the Secretary concerning how to respond to recurring patterns of confusion in the Medicare program. Such a recommendation may include calling for the suspension of the imposition of provider sanctions (except those sanctions relating to the quality of care) or where there is widespread confusion in program administration. Nothing in this section shall be construed as allowing for the suspension of provider sanctions relating to the quality of care, regardless of whether widespread confusion in the Medicare program exists.

Beneficiaries confront a morass of bureaucracy and regulation, with no clear individual to assist them. This new ombudsman would help beneficiaries navigate Medicare's complicated rules and regulations.

The Committees acknowledge that implementing these new functions would have a cost and have accordingly authorized necessary appropriations.

The beneficiary handbook currently provides a multitude of phone numbers, which is very confusing for beneficiaries, rather than a single number that can triage and transfer beneficiaries to the appropriate person or entity. This provision would promote better access to information for beneficiaries.

Section 924. Beneficiary Outreach Demonstration Program

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

Subsection (a) would require the Secretary to conduct a three-year demonstration program where Medicare specialists would provide assistance to beneficiaries in at least six local Social Security offices (two would be located in rural areas) that have a high volume of visits by Medicare beneficiaries. The Secretary would be required to evaluate the results of the demonstration regarding the feasibility and cost-effectiveness of permanently out-stationing Medicare specialists at local Social Security offices and report to Congress.

Subsection (b) would require that the Secretary establish a demonstration project to test the administrative feasibility of providing a process for Medicare beneficiaries, providers, suppliers and other individuals or entities furnishing items or services under Medicare to request and receive a determination as to whether the item or service is covered under Medicare by reasons of medical necessity, before the item or service involved is furnished to the beneficiary. The Secretary would be required to evaluate the demonstration and report to Congress by January 1, 2006.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This provision makes Medicare experts available in six Social Security Administration offices to assist beneficiaries and answer their questions. The demonstration would test whether such outsourced Medicare specialists improve beneficiary utilization, understanding of the program, and beneficiary satisfaction.

Section 925. Inclusion of Additional Information in Notices to Beneficiaries About Skilled Nursing Facility Benefits

CURRENT LAW

Although the statute requires that beneficiaries receive a statement listing the items and services for which payment has been made, there is no explicit statutory instruction that requires the notice to include information about the number of days of coverage remaining in either the hospital or skilled nursing facility (SNF) benefit or the spell of illness.

EXPLANATION OF PROVISION

The Secretary would be required to provide information about the number of days of coverage remaining under the SNF benefit and the spell of illness involved in the explanation of Medicare benefits.

EFFECTIVE DATE

The provision would apply to notices provided on and after the calendar quarter beginning more than six months after enactment.

Section 926. Information on Medicare-Certified Skilled Nursing Facilities in Hospital Discharge Plans

CURRENT LAW

The hospital discharge planning process requires evaluation of a patient's likely need for post-hospital services including hospice and home care.

EXPLANATION OF PROVISION

The Secretary would be required to make information publicly available regarding whether SNFs are participating in the Medicare program. Hospital discharge planning would be required to evaluate a patient's need for SNF care.

EFFECTIVE DATE

The provision would apply to discharge plans made on or after the date specified by the Secretary, but no later than six months after the Secretary provides information regarding SNFs that participate in the Medicare program.

Subtitle D—Appeals and Recovery

Section 931. Transfer of Responsibility for Medicare Appeals

CURRENT LAW

Denials of claims for Medicare payment may be appealed by beneficiaries (or providers who are representing the beneficiary) or in certain circumstances, providers or suppliers directly. The third level of appeal is to an Administrative Law Judge (ALJ). The Social Security Administration employs ALJs that hear Medicare cases, a legacy from the inception of the Medicare program, when Medicare was part of Social Security.

EXPLANATION OF PROVISION

The Commissioner of SSA and the Secretary would be required to develop a plan to transfer the functions of the ALJs who are responsible for hearing Medicare cases from SSA to HHS. This plan would be due to Congress no later than October 1, 2004. A GAO evaluation of the plan would be due within six months of the plan's submission. ALJ functions would be transferred no earlier than July 1, 2005 and no later than October 1, 2005.

The Secretary would be required to place the ALJs in an administrative office that is organizationally and functionally separate from the Centers for Medicare & Medicaid Services and the ALJs would be required to report to, and be under the general supervision of the Secretary. No other official within the Department would be permitted to supervise the ALJs. The Secretary would be required to provide for appropriate geographic distribution of ALJs, would have the authority to hire ALJs and support staff, and would be required to enter into arrangements with the Commissioner, as appropriate, to share office space, support staff and other resources with appropriate reimbursement.

Such sums are authorized to be appropriated as are necessary for FY2005 and each subsequent fiscal year to increase the number of ALJs, improve education and training of ALJs and to increase the staff of the Departmental Appeals Board (the final level of appeal).

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The Office of Inspector General has identified moving the functions of the Medicare Administrative Law Judges to the Department of Health and Human Services as an important priority in improving the appeals system. This provision makes that transition and increases the emphasis on providing training Administrative Law Judges and their staffs to increase their expertise in Medicare's rules and regulations. The Commissioner of SSA and the Secretary are instructed to work together on the transition plans in order to assure that the transition does not adversely affect the SSA ALJ appeals system.

The transition plan shall include information on the following:

- Workload—The number of such administrative law judges and support staff required now and in the future to hear and decide such cases in a timely manner, taking into account the

current and anticipated claims volume, appeals, number of beneficiaries, and statutory changes;

- Cost Projections—Funding levels required under this subsection to hear such cases in a timely manner;
- Transition Timetable—A timetable for the transition;
- Regulations—The establishment of specific regulations to govern the appeals process;
- Case Tracking—The development of a unified case tracking system that will facilitate the maintenance and transfer of case-specific data across both the fee-for-service and managed care components of the Medicare program;
- Feasibility of Precedential Authority—The feasibility of developing a process to give binding, precedential authority to decisions of the Departmental Appeals Board in the Department of Health and Human Services that address broad legal issues; and
- Access to Administrative Law Judges—The feasibility of filing appeals with administrative law judges electronically, and the feasibility of conducting hearings using tele- or videoconference technologies.

Section 932. Process for Expedited Access to Review

CURRENT LAW

In general, administrative appeals must be exhausted prior to judicial review.

EXPLANATION OF PROVISION

The Secretary would be required to establish a process where a provider, supplier, or a beneficiary may obtain access to judicial review when a 3-member review panel (composed of ALJs, members of the Departmental Appeals Board, or qualified individuals from qualified independent contractors designated by the Secretary) determines, within 60 days of a complete written request, that it does not have the authority to decide the question of law or regulation and where material facts are not in dispute. The decision would not be subject to review by the Secretary. Interest would be assessed on any amount in controversy and would be awarded by the reviewing court in favor of the prevailing party. This expedited access to judicial review would also be permitted for cases where the Secretary does not enter into or renew provider agreements.

Expedited review would also be established for certain remedies imposed against SNFs including denied payments and imposition of temporary management. The Secretary would be required to develop a process for reinstating approval of nurse aide training programs that have been terminated (before the end of the mandatory two-year disapproval period). The appropriation of such sums as needed for FY2005 and subsequent years would be authorized to reduce by 50 percent the average time for administrative determinations, to increase the number of ALJs and appellate staff at the DAB, and to educate these judges and their staffs on long-term care issues.

EFFECTIVE DATE

This provision would be effective for appeals filed on or after October 1, 2004.

REASON FOR CHANGE.

The provisions in 402 (a–c) on expedited access to judicial review ensure that if a review board certifies that there are no material facts in dispute and that the appeals process does not have authority to resolve the question at issue, the provider, supplier, or beneficiary may take their case to court in an expedited manner. This would facilitate more prompt resolution of challenges to the underlying validity of CMS regulations and determinations. To the extent that any part of an appeal poses a factual dispute that is being adjudicated before an administrative tribunal, this provision would not authorize the severance of the legal issues from the underlying factual dispute.

Section 933. Revisions to Medicare Appeals Process

(a) Requiring Full and Early Presentation of Evidence

CURRENT LAW

No provision. New evidence can be presented at any stage of the appeals process.

EXPLANATION OF PROVISION

The provision would require providers and suppliers to present all evidence at the reconsideration that is conducted by a QIC unless good cause precludes the introduction of the evidence.

EFFECTIVE DATE

October 1, 2004.

REASON FOR CHANGE

The Office of Inspector General identified this change as a priority to promote more expeditious resolution of appeals of denied claims. This provision requires prompt introduction of evidence relevant to a provider appeal. When deciding whether there is good cause to introduce new evidence, the adjudicator should ensure, after consideration of the totality of the circumstances that disallowing the introduction of such new evidence would unfairly prejudice the case. The totality of the circumstances may include, but is not limited to, the following: evidence is not yet available; the appellant was not represented at a lower level of appeal; the appellant was not aware of her rights; or the appellant did not understand the proceeding.

(b) Use of Patients' Medical Records

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The provision would provide for the use of beneficiaries' medical records in qualified independent contractors reconsiderations.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

In the determination of whether an item or service is reasonable and necessary for an individual, a beneficiary's medical records should be considered with other relevant information.

(c) Notice Requirements for Medicare Appeals

CURRENT LAW

No statutory provision. Determinations and denials of appeals currently include the policy, regulatory, or statutory reason for the denial and information on how to appeal the denial. The Benefits Improvement and Protection Act (BIPA) of 2000 changed the appeals process and created a new independent review (the qualified independent contractors or QICs), which has not yet been implemented.

EXPLANATION OF PROVISION

The provision would require that notice of and decisions from determinations, redeterminations, reconsiderations, ALJ appeals, and DAB appeals be written in a manner understandable to a beneficiary and that includes, as appropriate, reasons for the determination or decision and notice of the right to appeal decisions and the process for further appeal. The initial determination of a claim would also be specifically required to include: the reasons for the determination, including whether a local review policy or coverage determination was used and the procedures for obtaining additional information (including, upon request, the specific provision of the policy manual, or regulation used in making the determination). Redeterminations, the first level of appeal, would also specifically be required to include: the specific reasons for the decision; as appropriate a summary of the clinical or scientific evidence used in making the redetermination; and a description of the procedures for obtaining additional information concerning the redetermination (including, upon request, the specific provision of the policy manual, or regulation used in making the determination).

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Currently, Medicare only provides beneficiaries with a brief statement about the initial determination of her claim on the Medicare Summary Notice. This provision provides additional information to beneficiaries (or providers who appeal on their behalf) about Medicare's denial of their claim for benefits; the reasons for the denial, and the rights to further appeal so that beneficiaries can have

a clear and concise understanding of decisions affecting their medical care.

(d) Qualified Independent Contractors

CURRENT LAW

BIPA established a new and independent second level of appeal called the qualified independent contractors. BIPA called for at least 12 QICs. The QICs have not yet been implemented.

EXPLANATION OF PROVISION

The provision would clarify eligibility requirements for qualified independent contractors and their reviewer employees including medical and legal expertise, independence requirements, and the prohibition on compensation being linked to decisions rendered. The required number of qualified independent contractors would be reduced from not fewer than twelve to not fewer than four.

EFFECTIVE DATE

The provisions regarding the eligibility requirements of QICs and QIC reviews would be effective as if included in the enactment of BIPA.

REASON FOR CHANGE

The BIPA 2000 law laid out broad provisions for revision of the Medicare appeals process. These provisions strengthen the appeals process by enhancing the criteria related to the independence and expertise of the reviewers and review entities.

Section 934. Prepayment Review

CURRENT LAW

No explicit statutory instruction. Under administrative authorities, CMS has instructed the contractors to use random prepayment reviews to develop contractor-wide and program-wide error rates. Non-random payment reviews are permitted in certain circumstances laid out in instructions to the contractors.

EXPLANATION OF PROVISION

Medicare contractors would be permitted to conduct random prepayment reviews only to develop a contractor-wide or program-wide error rate or such additional circumstances as the Secretary provides for in regulations that were developed in consultation with providers and suppliers. Random prepayment review would only be permitted in accordance with standard protocol developed by the Secretary. Nonrandom payment reviews would be permitted only when there was a likelihood of sustained or high level of payment error. The Secretary would be required to issue regulations regarding the termination and termination dates of non-random prepayment review. Variation in termination dates would be permitted depending upon the differences in the circumstances triggering prepayment review.

EFFECTIVE DATE

The Secretary would be required to issue the required regulations not later than one year after enactment. The provision regarding the use of standard protocols when conducting prepayment reviews would apply to random prepayment reviews conducted on or after the date specified by the Secretary (but not later than one year after enactment). The remaining provisions would be effective one year after enactment.

REASON FOR CHANGE

These provisions build greater consistency and predictability into Medicare's rules for prepayment review, while protecting program integrity.

Section 935. Recovery of Overpayments

CURRENT LAW

No explicit statutory instruction. Under administrative authorities, CMS negotiates extended repayment plans with providers that need additional time to repay Medicare overpayments.

EXPLANATION OF PROVISION

In situations where repaying an Medicare overpayment within 30 days would be a hardship for a provider or supplier, the Secretary would be required to enter into an extended repayment plan of at least six months duration. The repayment plan would not be permitted to go beyond three years (or five years in the case of extreme hardship, as determined by the Secretary). Interest would be required to accrue on the balance through the repayment period. Hardship would be defined if, for providers that file cost reports, the aggregate amount of the overpayment exceeded 10 percent of the amount paid by Medicare to the provider for the time period covered by the most recently submitted cost report. In the case of a provider or supplier that is not required to file a cost report, hardship would be defined if the aggregate amount of the overpayment exceeded 10 percent of the amount paid under Medicare for the previous calendar year. The Secretary would be required to develop rules for the case of a provider or supplier that was not paid under Medicare during the previous year or for only a portion of the year. Any other repayment plans that a provider or supplier has with the Secretary, would not be taken into account by the Secretary in calculating hardship. If the Secretary has reason to suspect that the provider or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in Medicare or there is an indication of fraud or abuse, the Secretary would not be obligated to enter into an extended repayment plan with the provider or supplier. If a provider or supplier fails to make a payment according to the repayment plan, the Secretary would be permitted to immediately seek to offset or recover the total outstanding balance of the repayment plan, including interest.

The Secretary would be prohibited from recouping any overpayments until a reconsideration-level appeal (or a redetermination by the fiscal intermediary or carrier if the QICs are not yet in place) was decided, if a reconsideration was requested. Interest would be

required to be paid to the provider if the appeal was successful (beginning from the time the overpayment is recouped) or that interest would be required to be paid to the Secretary if the appeal was unsuccessful (and if the overpayment was not paid to the Secretary).

Extrapolation would be limited to those circumstances where there is a sustained or high level of payment error, as defined by the Secretary in regulation, or document educational intervention has failed to correct the payment error.

Medicare contractors would be permitted to request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing in the case of a provider or supplier with prior overpayments.

The Secretary would be able to use consent settlements to settle projected overpayments under certain conditions. Specifically the Secretary would be required to communicate with the provider or supplier that medical record review has indicated an overpayment exists, the nature of the problems identified, the steps needed to address the problems, and afford the provider or supplier 45 days to furnish additional information regarding the medical records for the claims reviewed. If, after reviewing the additional information an overpayment continues to exist, the Secretary would be required to provide notice and an explanation of the determination and then may offer the provider two mechanisms to resolve the overpayment: either an opportunity for a statistically valid random sample or a consent settlement (without waiving any appeal rights).

The Secretary would be required to establish a process to provide notice to certain providers and suppliers in cases where billing codes were over-utilized by members of that class in certain areas, in consultation with organizations that represent the affected provider or supplier class.

If post-payment audits were conducted, the Medicare contractor would be required to provide the provider or supplier with written notice of the intent to conduct the audit. The contractor would further be required to give the provider or supplier a full and understandable explanation of the findings of the audit and permit the development of an appropriate corrective action plan, inform the provider or supplier of appeal rights and consent settlement options, and give the provider or supplier the opportunity to provide additional information to the contractor, unless notice or findings would compromise any law enforcement activities.

The Secretary would be required to establish a standard methodology for Medicare contractors to use in selecting a sample of claims for review in cases of abnormal billing patterns.

EFFECTIVE DATE

In general, the provisions would be effective upon enactment. The limitation on extrapolation would apply to samples initiated after the date that is one year after the date of enactment. The Secretary would be required to establish the process for notice of over-utilization of billing codes not later than one year after enactment. The Secretary would be required to establish a standard methodology for selecting sample claims for abnormal billing patterns not later than one year after enactment.

REASON FOR CHANGE

These provisions build greater consistency and predictability into Medicare's rules for recovery of overpayments, while protecting program integrity.

Section 936. Provider Enrollment Process; Right of Appeal

CURRENT LAW

No explicit statutory instruction. Under administrative authorities, CMS has established provider enrollment processes in instructions to the contractors.

EXPLANATION OF PROVISION

The Secretary would be required to establish in regulation a provider enrollment process with hearing rights in the case of a denial or non-renewal. The process would be required to include deadlines for actions on applications for enrollment and enrollment renewals. The Secretary would be required to monitor the performance of the Medicare contractors in meeting the deadlines he establishes. Before changing provider enrollment forms, the Secretary would be required to consult with providers and suppliers. The provision would also establish hearing rights in cases where the applications have been denied.

EFFECTIVE DATE

The enrollment process would be required to be established within six months of enactment. The consultation process on provider enrollment forms would be required for changes in the form beginning January 1, 2004. The provision of hearing rights would apply to denials that occur one year after enactment or an earlier date specified by the Secretary.

REASON FOR CHANGE

This provision gives providers and suppliers an opportunity to appeal denials of their applications to participate in the Medicare program.

ection 937. Process for Correction of Minor Errors and Omissions on Claims without Pursuing Appeals Process

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

This provision would require the Secretary to establish a process so providers and suppliers could correct minor errors in claims that were submitted for payment.

EFFECTIVE DATE

The proposal would require that the process be developed not later than one year after enactment.

REASON FOR CHANGE

Many of the providers and suppliers who testified before the Subcommittee or contacted members directly emphasized the need to create a process in which they could correct claims that were denied because they were incomplete or contained minor errors without having to pursue a formal appeal. This provision instructs the Secretary to create such a process, which will alleviate pressure on the appeals system. The Committees would be concerned, however, if this process were to become an incentive for providers to knowingly or negligently submit incomplete information.

The Committees intend that the process for correction of minor errors and omissions on claims cover both the submission of prepayment and post-payment review claims. For example, if in the case of a home health claim, the physician has signed the plan of care and/or physician's order but has not dated it, the claim shall be returned to the home health agency and may be resubmitted by the home health agency with any incomplete or missing information without having to appeal the claim.

Section 938. Prior Determination Process for Certain Items and Services; Advance Beneficiary Notices

CURRENT LAW

Medicare law prohibits payment for items and services that are not medically reasonable and necessary for the diagnosis or treatment of an illness or an injury. Under certain circumstances, however, Medicare will pay for non-covered services that have been provided if both the beneficiary and the provider of the services did not know and could not have reasonably been expected to know that Medicare payment would not be made for these services.

A provider may be held liable for providing uncovered services, if, for example, specific requirements are published by the Medicare contractor or the provider has received a denial or reduction of payment on the same or similar service. In cases where the provider believes that the service may not be covered as reasonable and necessary, an acceptable advance notice of Medicare's possible denial of payment must be given to the patient if the provider does not want to accept financial responsibility for the service. The notice must be given in writing, in advance of providing the service; include the patient's name, date and description of service as well as reasons why the service would not be covered; and must be signed and dated by the patient to indicate that the beneficiary will assume financial liability for the service if Medicare payment is denied or reduced.

EXPLANATION OF PROVISION

The Secretary would be required to establish a process through regulation where physicians and beneficiaries can establish whether Medicare covers certain categories of items and services before such services are provided. An eligible requestor would be a physician, but only in case of items and services for which the physician is paid directly and a Medicare beneficiary who receives an advance beneficiary notice from a physician would receive direct payment for that service. The provisions would establish that: (1) such

prior determinations would be binding on the Medicare contractor, absent fraud or misrepresentation of facts, (2) the right to redetermination in the case of a denial, (3) the applicability of existing deadlines with respect to those redeterminations, (4) that contractors' advance determinations (and redeterminations) are not subject to further administrative or judicial review, and (5) an individual retains all rights to usual administrative or judicial review after receiving the service or receiving a determination that a service would not be covered. These provisions would not affect a Medicare beneficiary's right not to seek an advance determination. The prior determination process would be established in time to address such requests that are filed by 18 months of enactment. The Secretary would be required to collect data on the advance determinations and to establish a beneficiary outreach and education program. GAO is required to report on the use of the advance beneficiary notice and prior determination process within 18 months of its implementation.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The Committees believe that when there is a question of whether Medicare will cover certain care for a beneficiary, the beneficiary should have the right to find out what would be covered before getting the service and risking financial liability. Doctors also should be able to make such a request on behalf of a particular patient. This provision is particularly important for seniors and disabled individuals who tend to be risk adverse and live on fixed incomes.

Subtitle V—Miscellaneous

Section 941. Policy Development Regarding Evaluation and Management (E&M) Documentation Guidelines

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The Secretary would not be permitted to implement any new documentation guidelines for, or clinical examples of, evaluation and management (E&M) physician services unless the Secretary: (1) developed the guidelines in collaboration with practicing physicians (both generalists and specialists) and provided for an assessment of the proposed guidelines by the physician community, (2) established a plan containing specific goals, including a schedule, for improving the use of the guidelines, (3) conducted pilot projects to test modifications to the guidelines, (4) finds the guidelines have met established objectives, and (5) established and implemented an education program on the use of the guidelines with appropriate outreach. The Secretary would make changes to existing E&M guidelines to reduce paperwork burdens on physicians. The provision establishes objectives for modifications of the E&M guidelines: (1) identify clinically relevant documentation needed to code accurately and assess coding levels accurately, (2) decrease the non-

clinically pertinent documentation in the medical record, (3) increase reviewers accuracy, and (4) educate physicians and reviewers.

The pilot projects would be required to be conducted on a voluntary basis in consultation with practicing physicians (both generalists and specialists) and be of sufficient length to educate physicians and contractors on E&M guidelines. A range of different projects would be established and include at least one project: using a physician peer review method, using an alternative method based on face-to-face encounter time with the patient, in a rural area, outside a rural area, and where physicians bill under physician services in a teaching setting and non-teaching setting. The projects would examine the effect of modified E&M guidelines on different types of physician practices in terms of the cost of compliance. Data collected under these projects would not be the basis for overpayment demands or post-payment audits. This protection would apply to claims filed as part of the project, would last the duration of the project, and would last for as long as the provider participated in the project. Each pilot conducted would examine the effect of the new E&M documentation guidelines on different types of physician practices (including those with fewer than 10 full-time equivalent employees) and the costs of physician compliance including education implementation, auditing, and monitoring. The Secretary would be required to submit periodic reports to Congress on these pilot projects.

The provision would require a study of an alternative system for documenting physician claims. Specifically the Secretary would be required to study developing a simpler system for documenting claims for evaluation and management services and to consider systems other than current coding and documentation requirements. The Secretary would be required to consult with practicing physicians in designing and carrying out the study. This study would be due to Congress no later than October 1, 2005. MedPAC would be required to analyze the results of the study and report to Congress. The Secretary would also be required to study the appropriateness of coding in cases of extended office visits in which no diagnosis is made and report to Congress no later than October 1, 2005. The Secretary would be required to include in the report recommendations on how to code appropriately for these visits in a manner that takes into account the amount of time the physician spent with the patient.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

This provision is designed to promote greater consultation with practicing physicians with regard to the complicated evaluation and management and coding requirements governing Medicare payment for physician services.

Section 942. Improvement in Oversight of Technology and Coverage

(a) Council for Technology and Innovation

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The Secretary would be required to establish a Council for Technology and Innovation within CMS. The council would be composed of senior CMS staff and clinicians with a chairperson designated by the Secretary who reports to the CMS Administrator. The Chairperson would serve as the Executive Coordinator for Technology and Innovation would be the single point of contact for outside groups and entities regarding Medicare coverage, coding, and payment processes. The Council would coordinate Medicare's coverage, coding, and payment processes as well as information exchange with other entities with respect to new technologies and procedures, including drug therapies.

If the National Committee on Vital and Health Statistics has not made a recommendation to the Secretary by enactment regarding implementation of the ICD–10 coding system for diagnosis and procedures, the Secretary may adopt such standards one year after the date of enactment.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

After the FDA pre-market approval, the Medicare program does a second evaluation of breakthrough technologies to determine effectiveness and cost of those technologies compared to existing technologies. The review is necessary and appropriate, but it can take months between FDA approval and the availability of new technology for Medicare beneficiaries. By coordinating FDA and CMS approval of breakthrough medical devices, where feasible, this provision is intended to facilitate a more efficient process for the coverage of certain new technology by the Medicare program.

The ICD–9 coding system was adopted in 1979, and remains in effect for diagnosis and procedure coding in hospital inpatient and outpatient settings. ICD–9 has "run out" of codes for certain new procedures. For example, no code was available for the anthrax attack in 2001. NCVHS began investigating adoption of an updated coding system—ICD–10—in 1990. ICD–10 is more clinically accurate, and has available codes for new technologies and procedures. In 1996, as part of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Congress required NCVHS to make a recommendation on adoption prior to Secretarial approval. To date, NCVHS still has not issued a recommendation.

ICD–9 has run out of codes for new technologies and procedures. ICD–10 has room for those procedures, which would improve accuracy in claims processing. Every developed country in the world except the US and Israel has adopted ICD–10 as the standard coding system because it is superior to ICD–9. Some hospitals are eager to adopt ICD–10 because ultimately they believe it would improve

efficiency. The Committee agrees, although nothing in this provision requires the Secretary to adopt the ICD–10 in any health care setting.

(b) Methods for Determining Payment Basis for New Lab Tests

CURRENT LAW

Outpatient clinical diagnostic laboratory tests are paid on the basis of area wide fee schedules. The law establishes cap on the payment amounts, which is currently set at 74 percent of the median for all fee schedules for that test. The cap is set at 100 percent of the median for tests performed after January 1, 2001 that the Secretary determines are new tests for which no limitation amount has previously been established.

EXPLANATION OF PROVISION

The Secretary would be required to establish procedures (by regulation) for determining the basis for and amount of payments for new clinical diagnostic laboratory tests. New laboratory tests would be defined as those assigned a new, or substantially revised Health Care Procedure Coding System (HCPCS) code on or after January 1, 2005. The Secretary, as part of this procedure, would be required to: (1) provide a list (on an Internet site or other appropriate venue) of tests for which payments are being established in that year, (2) publish a notice of a meeting in the Federal Register on the day the list becomes available, (3) hold the public meeting no earlier than 30 days after the notice to receive public comments and recommendations, (4) take into account the comments, recommendations and accompanying data in both proposed and final payment determinations. The Secretary would set forth the criteria for making these determinations; make public the available data considered in making such determinations; and could convene other public meetings as necessary.

EFFECTIVE DATE

Effective for codes assigned on or after January 1, 2005.

(c) GAO Study on Improvements in External Data Collection for Use in the Medicare Inpatient Payment System

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

GAO would be required to study which external data could be collected by CMS in a shorter time frame for use in calculating payments for inpatient hospital services. GAO could evaluate feasibility and appropriateness of using quarterly samples or special surveys and would include an analysis of whether other executive agencies would be better suited to collect this information. The report would be due to Congress no later than October 1, 2004.

EFFECTIVE DATE

Upon enactment.

Section 943. Treatment of Hospitals for Certain Services Under Medicare Secondary Payer (MSP) Provisions

CURRENT LAW

In certain instances when a beneficiary has other insurance coverage, Medicare becomes the secondary insurance. Medicare Secondary Payer is the Medicare program's coordination of benefits with other insurers. Section 1862(b)(6) of the Social Security Act requires an entity furnishing a Part B service to obtain information from the beneficiary on whether other insurance coverage is available.

EXPLANATION OF PROVISION

The Secretary would not require a hospital or a critical access hospital to ask questions or obtain information relating to the Medicare secondary payer provisions in the case of reference laboratory services if the same requirements are not imposed upon those provided by an independent laboratory. Reference laboratory services would be those clinical laboratory diagnostic tests and interpretations of it that are furnished without a face-to-face encounter between the beneficiary and the hospital where the hospital submits a claim for the services.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Hospitals would not have to directly contact each beneficiary on their retirement date, black lung status and other insurance information for reference laboratory services. While current law provisions for a claim containing valid insurance information are maintained, this provision is intended to reduce the amount of paperwork and regulatory burden related to the provision of these reference laboratory services by hospital-based entities.

Section 944. EMTALA Improvements

CURRENT LAW

Medicare requires participating hospitals that operate an emergency room to provide necessary screening and stabilization services to a patient in order to determine whether an emergency medical situation exists prior to asking about insurance status of the patient.

Hospitals that are found to be in violation of Emergency Medical Treatment and Active Labor Act (EMTALA) requirements may face civil monetary penalties and termination of their provider agreement. Prior to imposing a civil monetary penalty, the Secretary is required to request a peer review organization (PRO), currently called quality improvement organizations (QIOs), to assess whether the involved beneficiary had an emergency condition, which had not been stabilized and provide a report on its findings. Except in the case where a delay would jeopardize the health or safety, the Secretary provides a 60-day period for the requested PRO review.

EMTALA is enforced by general guidelines issued by CMS. Patients who present to the emergency room and request services (or another person does so on their behalf) are required to be screened and stabilized.

EXPLANATION OF PROVISIONS

Emergency room services provided to screen and stabilize a Medicare beneficiary furnished after January 1, 2004, would be evaluated as reasonable and necessary on the basis of the information available to the treating physician or practitioner at the time the services were ordered; this would include the patient's presenting symptoms or complaint and not the patient's principal diagnosis. The Secretary would not be able to consider the frequency with which the item or service was provided to the patient before or after the time of admission or visit.

The Secretary would be required to establish a procedure to notify hospitals and physicians when an EMTALA investigation is closed.

Except in the case where a delay would jeopardize the health and safety of individuals, the Secretary would be required to request a PRO review before making a compliance determination that would terminate a hospital's Medicare participation because of EMTALA violations and provide a period of 5 business days for such review. The PRO shall provide a copy of the report on its findings to the hospital or physician that is consistent with existing confidentiality requirements. This provision would apply to terminations initiated on or after enactment.

The provision also clarifies the responsibility of the hospital when the individual does not request examination or treatment for an emergency condition.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Providers have reported that some Medicare contractors are looking at final diagnoses (not presenting symptoms) in applying local medical review policies (LMRPs) that match particular tests to particular diagnoses—if a test does not match a listed diagnosis, payment is denied. Other claims are reportedly being denied based on LMRPs that set frequency limits for certain tests—if the test's use in the emergency room exceeds a frequency limit, payment is denied. In its January 2001 report entitled The Emergency Medical Treatment and Labor Act: The Enforcement Process, at the OIG recommended that CMS ensure that peer review occurs before a provider is terminated from the Medicare program for an EMTALA violation. This section implements that recommendation, making the current discretionary PRO review process mandatory in cases that involve a question of medical judgment. Finally, it clarifies CMS guidelines for persons or individuals who arrive at the emergency room for non-emergency services.

Section 945. Emergency Medical Treatment and Active Labor (EMTALA) Task Force

CURRENT LAW

No provision.

EXPLANATION OF PROVISION

The Secretary would be required to establish a 17-member technical advisory group under specified requirements to review issues related to EMTALA. The advisory group would be comprised of: the CMS Administrator; the OIG; four hospital representatives who have EMTALA experience, (including 1 person from a public hospital and two of whom have not experienced EMTALA violations); five practicing physicians with EMTALA experience; two patient representatives; two regional CMS staff involved in EMTALA investigations; one representative from a state survey organization and one from a PRO. The Secretary would select qualified individuals who are nominated by organizations representing providers and patients.

The advisory group would be required to: (1) elect a member to as chairperson, (2) schedule its first meeting at the direction of the Secretary and meet at least twice a year subsequently, (3) terminate 30 months after the date of its first meeting, and (4) be exempt from the Federal Advisory Committee Act. The advisory group would review EMTALA regulations; provide advice and recommendations to the Secretary; solicit public comments from interested parties; and disseminate information on the application of the EMTALA regulations.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

In its January 2001 report entitled The Emergency Medical Treatment and Labor Act: The Enforcement Process, the OIG recommended that CMS establish an EMTALA technical advisory group that includes all EMTALA stakeholders to help the agency resolve any emerging issues related to implementation of the law. Some of these current issues include specialists who refuse to service on call panels and inconsistencies between Stat and Federal law governing emergency medical services. In its June 2001 report entitled Emergency Care: EMTALA Implementations and Enforcement Issues, the GAO also concluded that the establishment of a technical advisory group could help CMS work with hospitals and physicians to achieve the goals of EMTALA and avoid creating unnecessary burdens for providers. This section implements the OIG recommendation, establishing a 19-member technical advisory group within HHS.

Section 946. Authorizing Use of Arrangements To Provide Core Hospice Services in Certain Circumstances

CURRENT LAW

A hospice is a public agency or private organization, which is primarily engaged in providing and making available certain care to a terminally ill Medicare beneficiary under a written plan.

EXPLANATION OF PROVISIONS

A hospice would be permitted to: (1) enter into arrangements with another hospice program to provide care in extraordinary, exigent or other non-routine circumstances, such as unanticipated high patient loads, staffing shortages due to illness, or temporary travel by a patient outside the hospice's service area, and (2) bill and be paid for the hospice care provided under these arrangements.

EFFECTIVE DATE

For hospice care provided on or after enactment.

REASON FOR CHANGE

Hospice programs would be allowed to use personnel from other hospice programs to provide services to hospice patients. The program is given the flexibility so that a hospice program could continue to serve a patient if he or she was temporarily out of the area due to travel. Otherwise, the provision of the care to the patient might be delayed by the paperwork and requirements in starting up a new service at another agency. It is the intent of Congress that the originating hospice maintains control over the billing and quality of care.

Section 947. Application of OSHA Bloodborne Pathogens Standards to Certain Hospitals

CURRENT LAW

Section 1866 establishes certain conditions of participation that providers must meet in order to participate in Medicare.

EXPLANATION OF PROVISION

Public hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 would be required to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations. A hospital that fails to comply with the requirement would be subject to a civil monetary penalty, but would not be terminated from participating in Medicare.

EFFECTIVE DATE

The provision would apply to hospitals as of July 1, 2004.

REASON FOR CHANGE

Last year, Congress enacted legislation that requires hospitals to utilize safe needles. However, that legislation only applies to non-government hospitals. Twenty-four states have similar require-

ments on public hospitals. This provision would protect the health and safety of health care workers in those facilities by requiring public hospitals in the other 26 states and the District of Columbia to comply with this important standard.

Section 948. BIPA-Related Technical Amendments and Corrections

CURRENT LAW

BIPA established an advisory process for national coverage determinations where panels of experts formed by advisory committees could forward their recommendations directly to the Secretary without prior approval of the advisory committee or the Executive Committee.

EXPLANATION OF PROVISION

The statutory reference in BIPA would be changed from the Social Security Act to the Public Health Service Act. Other BIPA references would be changed from a policy to a determinations.

EFFECTIVE DATE

The provision would be effective as if included in BIPA.

Section 949. Conforming Authority To Waive A Program Exclusion

CURRENT LAW

The Secretary is required to exclude individuals and entities from participation in Federal Health Programs that are (1) convicted of a criminal offense related to health care delivery under Medicare or under State health programs, (2) convicted of a criminal offense related to patient abuse or neglect under Federal or State law, (3) convicted of a felony relating to fraud, theft, or financial misconduct relating to a health care finance program or operated by the Federal, State or local government, or (4) convicted of a felony related to a controlled substance.

EXPLANATION OF PROVISIONS

The Administrator of a Federal health program would be permitted to waive certain 5-year exclusions if the exclusion of a sole community physician or source of specialized services in a community would impose a hardship. The mandatory exclusions that could be waived would be those related to convictions associated with program-related crimes, health care fraud and controlled substances.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

The Office of Inspector General requested this technical correction.

Section 950. Treatment of Certain Dental Claims

CURRENT LAW

The Medicare benefit does not include most dental services. Some insurers may require a claim denial from Medicare before accepting the dental claim for payment review, even if Medicare does not cover the service.

EXPLANATION OF PROVISION

A group health plan providing supplemental or secondary coverage to Medicare beneficiaries would not be able to require dentists to obtain a claim denial from Medicare for non-covered dental services before paying the claim.

EFFECTIVE DATE

The provision would be effective 60 days after enactment.

REASON FOR CHANGE

The Committees are concerned about private insurers requiring dentists to submit claims to Medicare for non-covered services before making a determination for coverage under the group health plan. Because of this requirement, dentists have been forced to enroll in the Medicare program to submit claims for services that are categorically excluded from Medicare coverage. Dentists view Medicare's enrollment application process as overly burdensome, particularly in light of the fact that Medicare does not cover most dental services. This provision would alleviate the enrollment burden placed on dentists providing services clearly excluded from Medicare coverage, consistent with the overarching goal of this legislation to reduce regulatory burdens.

Section 951. Furnishing Hospitals With Information To Compute DSH Formula

CURRENT LAW

Disproportionate share hospital (DSH) payments under Medicare are calculated using a formula that includes the number of patient days for patients eligible for Medicaid.

EXPLANATION OF PROVISION

The provision would require the Secretary to arrange for the information such as number of paid or unpaid Medicaid days, and the number of dual eligibles that hospitals need to calculate the Medicare DSH payment formula.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Hospitals find it difficult to compute certain critical numbers for the purposes of Medicare DSH such as unpaid days used by Medicaid eligibles or Medicare dual eligibles. This helps ensure accuracy for hospitals and for the Trust Fund.

Section 952. Revisions to Reassignment Provisions

CURRENT LAW

Under certain circumstances, a person or entity other than the individual providing the service may receive Medicare payments.

EXPLANATION OF PROVISION

Entities, as defined by the Secretary, could receive Medicare payments for services provided by a physician or other person if the service was provided under a contractual arrangement and if the arrangement included joint and several liability (liability for several parties) for overpayment and the entities meet program integrity specifications determined by the Secretary.

EFFECTIVE DATE

The provision would be effective for payments made on or after one year after the date of enactment.

Section 953. Other Provisions

CURRENT LAW

No provisions.

EXPLANATION OF PROVISION

GAO Report on Physician Compensation. No later than six months from enactment, GAO would be required to report to Congress on the appropriateness of the updates in the conversion factor including the appropriateness of the sustainable growth rate (SGR) formula for 2002 and subsequently. The report would examine the stability and the predictability of the updates and rate as well as the alternatives for use of the SGR in the updates. No later than 12 months from enactment, GAO would be required to report to Congress on all aspects of physician compensation for Medicare services. The report would review the alternatives for the physician fee schedule.

Annual Publication of List of National Coverage Determinations. The Secretary would be required to publish an annual list of national coverage determinations made under Medicare in the previous year. Included would be information on how to get more information about the determinations. The list would be published in an appropriate annual publication that is publicly available.

GAO Report on Flexibility in Applying Home Health Conditions of Participation to Patients Who Are Not Medicare Beneficiaries. The GAO would be required to report to Congress on the implications if the Medicare conditions of participation for home health agencies were applied flexibly with respect to groups or types of patients who are not Medicare beneficiaries. The report would include an analysis of the potential impact of this flexibility on clinical operations and the recipients of such services and an analysis of methods for monitoring the quality of care provided to these recipients. The report would be due no later than six month after enactment.

OIG Report on Notices Relating to Use of Hospital Lifetime Reserve Days. The Inspector General of HHS would be required to re-

port to Congress on the extent to which hospitals provide notice to Medicare beneficiaries, in accordance with applicable requirements, before they use the 60 lifetime reserve days under the hospital benefit. The report would also include the appropriateness and feasibility of hospitals providing a notice to beneficiaries before they exhaust the lifetime reserve days. The report would be due no later than one year after enactment.

EFFECTIVE DATE

Upon enactment.

Section 954. Temporary Suspension of OASIS Requirement for Collection of Data on Non-Medicare and Non-Medicaid Claims

CURRENT LAW

Under the Conditions of Participation, home health agencies are required to complete the OASIS form on all patients.

EXPLANATION OF PROVISION

The OASIS data collected on non-Medicare or non-Medicaid patients is not collected or used by the Federal government. This provision suspends collection until the Secretary has published final regulations regarding the collection and use of this data. Moreover it requires a study of how the data is used by the agencies as well as recommendations from quality assessment experts. Agencies may continue collecting the data during the suspension.

EFFECTIVE DATE

Upon enactment.

REASON FOR CHANGE

Data mandates on the collection of data on non-Medicare and non-Medicaid patients by the Federal government should be carefully reviewed for privacy issues by the agency.

III. VOTES OF THE COMMITTEE

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the following statements are made concerning the votes of the Committee on Ways and Means in its consideration of the bill, H.R. 2473.

MOTION TO REPORT THE BILL

The bill, H.R. 2473, as amended, was ordered favorably reported by a rollcall vote of 25 yeas to 15 nays (with a quorum being present). The vote was as follows:

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Thomas	X			Mr. Rangel		X	
Mr. Crane	X			Mr. Stark		X	
Mr. Shaw	X			Mr. Matsui		X	
Mrs. Johnson	X			Mr. Levin		X	
Mr. Houghton	X			Mr. Cardin		X	
Mr. Herger	X			Mr. McDermott		X	
Mr. McCrery	X			Mr. Kleczka		X	
Mr. Camp	X			Mr. Lewis (GA)		X	

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Ramstad	X			Mr. Neal		X	
Mr. Nussle	X			Mr. McNulty		X	
Mr. Johnson	X			Mr. Jefferson		X	
Ms. Dunn	X			Mr. Tanner		X	
Mr. Collins	X			Mr. Becerra		X	
Mr. Portman	X			Mr. Doggett		X	
Mr. English	X			Mr. Pomeroy	X		
Mr. Hayworth	X			Mr. Sandlin			
Mr. Weller	X			Ms. Tubbs Jones		X	
Mr. Hulshof	X						
Mr. McInnis	X						
Mr. Lewis (KY)	X						
Mr. Foley	X						
Mr. Brady	X						
Mr. Ryan	X						
Mr. Cantor	X						

VOTES ON AMENDMENTS

An amendment in the nature of a substitute by Chairman Thomas was agreed to by a rollcall vote of 25 yeas to 15 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Thomas	X			Mr. Rangel		X	
Mr. Crane	X			Mr. Stark		X	
Mr. Shaw	X			Mr. Matsui		X	
Mrs. Johnson	X			Mr. Levin		X	
Mr. Houghton	X			Mr. Cardin		X	
Mr. Herger	X			Mr. McDermott		X	
Mr. McCrery	X			Mr. Kleczka		X	
Mr. Camp	X			Mr. Lewis (GA)		X	
Mr. Ramstad	X			Mr. Neal		X	
Mr. Nussle	X			Mr. McNulty		X	
Mr. Johnson	X			Mr. Jefferson		X	
Ms. Dunn	X			Mr. Tanner		X	
Mr. Collins	X			Mr. Becerra		X	
Mr. Portman	X			Mr. Doggett		X	
Mr. English	X			Mr. Pomeroy	X		
Mr. Hayworth	X			Mr. Sandlin			
Mr. Weller	X			Ms. Tubbs Jones		X	
Mr. Hulshof	X						
Mr. McInnis	X						
Mr. Lewis (KY)	X						
Mr. Foley	X						
Mr. Brady	X						
Mr. Ryan	X						
Mr. Cantor	X						

A rollcall vote was conducted on the following amendments to the Chairman's amendment in the nature of a substitute.

An amendment by Mr. Cardin, which would amend section 1860D–5(d) of the Social Security Act as proposed to be inserted by section 101, to require the U.S. Department of Health and Human Services to takes such steps as may be necessary to qualify and serve as a prescription drug plan sponsor and to offer a prescription drug plan that offers standard coverage throughout the United States, was defeated by a rollcall vote of 15 yeas to 23 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Thomas		X		Mr. Rangel	X		

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Crane		X		Mr. Stark	X		
Mr. Shaw				Mr. Matsui	X		
Mrs. Johnson		X		Mr. Levin	X		
Mr. Houghton		X		Mr. Cardin	X		
Mr. Herger		X		Mr. McDermott	X		
Mr. McCrery		X		Mr. Kleczka	X		
Mr. Camp		X		Mr. Lewis (GA)	X		
Mr. Ramstad		X		Mr. Neal	X		
Mr. Nussle		X		Mr. McNulty	X		
Mr. Johnson		X		Mr. Jefferson			
Ms. Dunn		X		Mr. Tanner	X		
Mr. Collins		X		Mr. Becerra	X		
Mr. Portman		X		Mr. Doggett	X		
Mr. English		X		Mr. Pomeroy	X		
Mr. Hayworth		X		Mr. Sandlin			
Mr. Weller		X		Ms. Tubbs Jones	X		
Mr. Hulshof		X					
Mr. McInnis		X					
Mr. Lewis (KY)		X					
Mr. Foley		X					
Mr. Brady		X					
Mr. Ryan		X					
Mr. Cantor		X					

An amendment by Mr. McDermott, to strike Subtitle C of Title II, eliminating the privatization of plans, was defeated by a rollcall vote of 14 yeas to 23 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Thomas		X		Mr. Rangel	X		
Mr. Crane		X		Mr. Stark	X		
Mr. Shaw				Mr. Matsui	X		
Mrs. Johnson		X		Mr. Levin	X		
Mr. Houghton		X		Mr. Cardin	X		
Mr. Herger		X		Mr. McDermott	X		
Mr. McCrery		X		Mr. Kleczka	X		
Mr. Camp		X		Mr. Lewis (GA)	X		
Mr. Ramstad		X		Mr. Neal	X		
Mr. Nussle		X		Mr. McNulty	X		
Mr. Johnson		X		Mr. Jefferson			
Ms. Dunn		X		Mr. Tanner	X		
Mr. Collins		X		Mr. Becerra	X		
Mr. Portman		X		Mr. Doggett	X		
Mr. English		X		Mr. Pomeroy	X		
Mr. Hayworth		X		Mr. Sandlin			
Mr. Weller		X		Ms. Tubbs Jones			
Mr. Hulshof		X					
Mr. McInnis		X					
Mr. Lewis (KY)		X					
Mr. Foley		X					
Mr. Brady		X					
Mr. Ryan		X					
Mr. Cantor		X					

An amendment by Mrs. Johnson, which would amend section 1848(c)(2)(H) of the Social Security Act, as proposed to be added by section 303(a)(1)(B), to direct the Secretary of Health and Human Services to expedite the process for adjusting existing CPT codes for costs associated with the administration of covered drugs, was agreed to by a rollcall vote of 32 yeas to 5 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Thomas	X			Mr. Rangel		X	
Mr. Crane	X			Mr. Stark		X	
Mr. Shaw				Mr. Matsui	X		
Mrs. Johnson	X			Mr. Levin	X		
Mr. Houghton	X			Mr. Cardin	X		
Mr. Herger	X			Mr. McDermott	X		
Mr. McCrery	X			Mr. Kleczka	X		
Mr. Camp	X			Mr. Lewis (GA)		X	
Mr. Ramstad	X			Mr. Neal		X	
Mr. Nussle	X			Mr. McNulty		X	
Mr. Johnson	X			Mr. Jefferson			
Ms. Dunn	X			Mr. Tanner	X		
Mr. Collins	X			Mr. Becerra	X		
Mr. Portman	X			Mr. Doggett	X		
Mr. English	X			Mr. Pomeroy	X		
Mr. Hayworth	X			Mr. Sandlin			
Mr. Weller	X			Ms. Tubbs Jones			
Mr. Hulshof	X						
Mr. McInnis	X						
Mr. Lewis (KY)	X						
Mr. Foley	X						
Mr. Brady	X						
Mr. Ryan	X						
Mr. Cantor	X						

An amendment by Mr. Doggett, which would amend section 1860D–3(c) of the Social Security Act as proposed to be inserted by section 101, to require each participating manufacturer of a covered outpatient drug to enter into arrangements with prescription drug plan sponsors or entities offering an MA–EFF prescription plan, was defeated by a rollcall vote of 12 yeas to 23 nays The vote was as follows:

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Thomas		X		Mr. Rangel	X		
Mr. Crane		X		Mr. Stark	X		
Mr. Shaw				Mr. Matsui	X		
Mrs. Johnson		X		Mr. Levin	X		
Mr. Houghton		X		Mr. Cardin	X		
Mr. Herger		X		Mr. McDermott	X		
Mr. McCrery		X		Mr. Kleczka	X		
Mr. Camp		X		Mr. Lewis (GA)	X		
Mr. Ramstad		X		Mr. Neal	X		
Mr. Nussle		X		Mr. McNulty	X		
Mr. Johnson		X		Mr. Jefferson			
Ms. Dunn		X		Mr. Tanner			
Mr. Collins		X		Mr. Becerra	X		
Mr. Portman		X		Mr. Doggett	X		
Mr. English		X		Mr. Pomeroy		X	
Mr. Hayworth		X		Mr. Sandlin			
Mr. Weller				Ms. Tubbs Jones			
Mr. Hulshof		X					
Mr. McInnis		X					
Mr. Lewis (KY)		X					
Mr. Foley		X					
Mr. Brady		X					
Mr. Ryan		X					
Mr. Cantor		X					

An en bloc amendment by Mr. Collins, which would add at the end of section 1851(j) of the Social Security Act, as added by section 102(a), to apply fee-for-service Medicare+Choice rules to prescription drug benefits; and as added by section 221(d), to provide the same treatment for premiums for MA private fee-for-service plans,

was agreed to by a rollcall vote of 24 yeas to 12 nays, with 2 voting present. The vote was as follows:

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Thomas	X			Mr. Rangel		X	
Mr. Crane	X			Mr. Stark		X	
Mr. Shaw	X			Mr. Matsui		X	
Mrs. Johnson	X			Mr. Levin		X	
Mr. Houghton	X			Mr. Cardin		X	
Mr. Herger	X			Mr. McDermott		X	
Mr. McCrery	X			Mr. Kleczka			X
Mr. Camp	X			Mr. Lewis (GA)		X	
Mr. Ramstad	X			Mr. Neal		X	
Mr. Nussle	X			Mr. McNulty		X	
Mr. Johnson	X			Mr. Jefferson			
Ms. Dunn	X			Mr. Tanner			
Mr. Collins	X			Mr. Becerra			X
Mr. Portman	X			Mr. Doggett		X	
Mr. English	X			Mr. Pomeroy		X	
Mr. Hayworth	X			Mr. Sandlin			
Mr. Weller	X			Ms. Tubbs Jones		X	
Mr. Hulshof	X						
Mr. McInnis	X						
Mr. Lewis (KY)	X						
Mr. Foley	X						
Mr. Brady	X						
Mr. Ryan	X						
Mr. Cantor	X						

An amendment by Messrs. Nussle and Pomeroy, which would add the following new sections at the end of Title IV: Sec. 416—Adjustment to the Medicare Inpatient Hospital PPS Wage Index to Revise the Labor-Related Share of Such Index; and Sec. 417—Medicare Incentive Payment Program Improvements for Physician Scarcity, was agreed to by a rollcall vote of 39 yeas to 0 nays, with 1 voting present. The vote was as follows:

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Thomas	X			Mr. Rangel	X		
Mr. Crane	X			Mr. Stark			X
Mr. Shaw	X			Mr. Matsui	X		
Mrs. Johnson	X			Mr. Levin	X		
Mr. Houghton	X			Mr. Cardin	X		
Mr. Herger	X			Mr. McDermott	X		
Mr. McCrery	X			Mr. Kleczka	X		
Mr. Camp	X			Mr. Lewis (GA)	X		
Mr. Ramstad	X			Mr. Neal	X		
Mr. Nussle	X			Mr. McNulty	X		
Mr. Johnson	X			Mr. Jefferson	X		
Ms. Dunn	X			Mr. Tanner	X		
Mr. Collins	X			Mr. Becerra	X		
Mr. Portman	X			Mr. Doggett	X		
Mr. English	X			Mr. Pomeroy	X		
Mr. Hayworth	X			Mr. Sandlin			
Mr. Weller	X			Ms. Tubbs Jones	X		
Mr. Hulshof	X						
Mr. McInnis	X						
Mr. Lewis (KY)	X						
Mr. Foley	X						
Mr. Brady	X						
Mr. Ryan	X						
Mr. Cantor	X						

A substitute amendment by Mr. Stark was defeated by a rollcall vote of 14 yeas to 26 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representatives	Yea	Nay	Present
Mr. Thomas		X		Mr. Rangel	X		
Mr. Crane		X		Mr. Stark	X		
Mr. Shaw		X		Mr. Matsui	X		
Mrs. Johnson		X		Mr. Levin	X		
Mr. Houghton		X		Mr. Cardin	X		
Mr. Herger		X		Mr. McDermott	X		
Mr. McCrery		X		Mr. Kleczka	X		
Mr. Camp		X		Mr. Lewis (GA)	X		
Mr. Ramstad		X		Mr. Neal	X		
Mr. Nussle		X		Mr. McNulty	X		
Mr. Johnson		X		Mr. Jefferson	X		
Ms. Dunn		X		Mr. Tanner		X	
Mr. Collins		X		Mr. Becerra	X		
Mr. Portman		X		Mr. Doggett	X		
Mr. English		X		Mr. Pomeroy		X	
Mr. Hayworth		X		Mr. Sandlin			
Mr. Weller		X		Ms. Tubbs Jones	X		
Mr. Hulshof		X					
Mr. McInnis		X					
Mr. Lewis (KY)		X					
Mr. Foley		X					
Mr. Brady		X					
Mr. Ryan		X					
Mr. Cantor		X					

IV. BUDGET EFFECTS OF THE BILL

The Congressional Budget Office has not submitted a final score of the legislation at the time of the filing of this report (July 15, 2003).

V. OTHER MATTERS REQUIRED TO BE DISCUSSED UNDER HOUSE RULES

A. Committee Oversight Findings and Recommendations

In compliance with clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee reports that the need for this legislation was confirmed by the oversight hearings of the Subcommittee on Health. The hearings were as follows:

The Subcommittee on Health held a series of hearings on Medicare Reform during the 108th Congress to examine the implications of different proposals aimed at helping seniors gain more affordable access to prescription drugs. A list of these hearings may be found in this report in Section I. Introduction, Part C. Legislative History (Page xx).

B. Summary of General Performance Goals and Objectives

In compliance with clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee states that the primary purpose of H.R. 2473 is to create a prescription drug benefit into the Medicare program while modernizing other aspects of the program.

C. Constitutional Authority Statement

In compliance with clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, relating to constitutional Authority, the Committee states that the Committee's action in reporting the bill is derived from Article I of the Constitution, Section 8 ("The Con-

gress shall have power to lay and collect taxes, duties, imposts, and excises, to pay the debts and to provide for * * * the General Welfare of the United States * * *").

VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

Legislative Counsel has not prepared a Ramseyer at the time of the filing of this report (July 15, 2003).

VII. DISSENTING VIEWS

We oppose the Republican Medicare bill reported by the Committee on Ways and Means. This is not a bill designed to ensure that seniors and people with disabilities get a long overdue Medicare prescription drug benefit that is available and affordable to all. Instead, it is an effort by the Republican Majority to complete their ideological mission to have Medicare "wither on the vine".

Despite the legislation's paltry benefit and fundamentally flawed structure, our committee could have reported a bill supported by a strong bipartisan majority with only two simple changes that we offered as amendments. But Republicans rejected our efforts to find a compromise. This absolute refusal to negotiate reinforces our firm belief that privatizing Medicare is their real goal in this so-called reform effort.

Prescription drug coverage

This legislation has a grossly inadequate drug benefit that was designed to fit into the Republican budget, not the budget of America's elderly and disabled citizens. If the majority hadn't squandered trillions on tax breaks for the wealthy, we would have had more resources to improve this benefit.

Unlike Medicare Part B, where every beneficiary pays the same premium, the premium for prescription drug coverage would not be set in the statute. Although Republicans claim that the premium for this coverage will be $35 per person per month, that is merely a guesstimate. Premiums could be much higher and will vary in different areas of the country and even among plans in the same area. Private insurance premiums in the commercial market are rising at double-digit percentages each year, with most insurers citing prescription drugs as the primary driver. Unstable premiums translate into an unreliable benefit for senior citizens and other Medicare beneficiaries who are living on fixed incomes.

In addition, after the initial coverage limit of $2,000, beneficiaries are forced to pay 100 percent of the cost until total drug spending reaches $4,900, after which the plan will pick up the costs. This patchwork quilt of coverage doesn't exist today in any other public or private plan. Almost half of all beneficiaries—48 percent—will fall into this gap and only 10 percent will have drug needs high enough to get the catastrophic coverage on the other side of the gap. This means that a senior citizen with average drug spending in 2006 would find themselves with coverage for their medications until August, after which they would receive no coverage for the rest of the year while still paying a sizeable premium.

This legislation also would tie the level of benefits to income. The point at which catastrophic coverage would begin would be based on a beneficiary's income. People in the highest category would have no coverage from $2,000 to $13,200 in drug spending. If they

needed more than $13,200 worth of drugs, coverage would begin again. Given that wealthier beneficiaries have already paid more through the payroll taxes during their working years, this double taxation of Medicare benefits should be rejected. Even worse, however, is that this misguided policy would require the IRS and the Department of Health and Human Services (HHS) to share sensitive income data on beneficiaries for the first time. HHS would then have to give information to the plan to indicate the level of the benefit for each beneficiary, a de facto disclosure of income. It appears that beneficiaries who refuse to authorize the sharing of this information might be excluded from the drug coverage. It's an offensive invasion of privacy that undermines the social insurance nature of Medicare and it ought to be rejected.

While Republicans purport to protect those on the lower-ends of the income scale, even those provisions fall far short. Help for even the poorest seniors—those with incomes below $8,980—is contingent on meeting an assets test. This means that they will not get the extra help if they have even modest savings ($4,000 or more). Data suggest that more than one-third of otherwise eligible low-income beneficiaries would be excluded as a result of this hidden hatchet.

Republican Members of the Ways and Means Committee and the President of the United States are fond of saying that Medicare beneficiaries should get the same choices as Members of Congress do with respect to prescription drug coverage. They like to say that as a rhetorical point, but their rhetoric doesn't match the reality of this bill. As Members of Congress, we get our health insurance through the Federal Employees Health Benefits Plan like all federal employees. There isn't a single plan option in FEHBP as bad as the one they're promoting for seniors in Medicare.

We're also very concerned that the Republican Medicare bill will cause employers to drop retiree prescription drug coverage. The Congressional Budget Office informed us at the mark-up that those concerns are real. They estimate that 32% of employers who are currently providing retiree prescription drug benefits will drop that coverage if this bill becomes law as written. That needs to be fixed in this bill as well. We should be using this opportunity to reinforce the better coverage that is out there, not erode it.

While there are many other problems in this legislation, we are also particularly troubled by the fact that it does nothing to guarantee lower prices. In fact, it includes language that actually prohibits the Secretary of Health and Human Services from "interfering" in negotiations between private plans and drug companies. This is an extraordinary prohibition that affects Medicare beneficiaries and taxpayers alike. It is fiscally irresponsible.

Fundamental flaws

All of these are very serious concerns, but we would still be willing to accept this bill as a good faith effort to add a prescription drug benefit to Medicare if Republicans would accept two changes. First, the bill must be amended to include a uniform, defined prescription drug benefit that is universally available through Medicare. Second, the bill must reject proposals to privatize the program. These two changes are critical.

No real Medicare drug benefit

The lack of a uniform nationally available, defined prescription drug benefit in Medicare in the Republican bill is a fundamental flaw. The bill relies solely on private plans to provide the new prescription drug benefit. Unlike every other benefit in Medicare—doctor's visits, hospitalizations, and physical therapy as examples—a beneficiary would not have coverage through Medicare for prescription drugs. Instead, a Medicare enrollee would be "entitled" to purchase a private prescription drug plan at varying prices around the country, provided one was even available—and affordable—in their community. That is not an entitlement at all.

On top of that, we're concerned the bill won't work. Beneficiaries who want to remain in traditional Medicare would theoretically purchase new private drug-only plans; all others would get their prescription drugs through HMOs, PPOs and other managed care plans. The bill would divide the country into regions and would require that beneficiaries have the choice of two private drug plans (only one of which need be a drug-only plan) in each of those regions. But, there is no provision in the bill to account for the possibility that two plans simply won't appear in each region! It may be that no plans appear. As President Bush's Medicare Administrator, Tom Scully, has said, these drug-only plans "don't exist in nature and won't work in practice." We have yet to see any proof from the Republican authors of this program or insurance companies that these plans will materialize. In fact, Wall Street analysts, insurance companies and pharmaceutical benefit managers have cast considerable doubt on this scheme. The legislation would allow the government to try to bribe the plans to participate, but if they turned down that offer, there is no backup plan and beneficiaries would have no place to buy coverage.

Even worse, if two plans do appear, but the HMO offers a more affordable benefit than the drug-only plan, beneficiaries in traditional Medicare may be left with no option but to give up Medicare and enroll in an HMO to get prescription drug coverage. That's wrong. We repeatedly inquired about what would happen in such a situation, but failed to get any suitable answer from the Republicans.

Democratic amendments

Add a guaranteed Medicare benefit. The first key change necessary for us to support the Republican Medicare bill is to provide a guaranteed drug benefit managed by Medicare in the same way that we manage Medicare Part A (hospital services) and Medicare Part B (physician services). We can accept that private plans be allowed to compete to provide Medicare benefits, but only if beneficiaries in traditional Medicare are not disadvantaged as a result. All our amendment would do is add a stable, defined drug benefit in Medicare that is available everywhere in the country. The Republican private plans could still operate as envisioned under this program, but a Medicare option with a national, defined benefit would also be in place in every community, regardless of how many private plans were offering coverage in the area. That's the promise of Medicare today with respect to health services and it should hold true for medications as well.

Republicans shouldn't be threatened by this amendment. If the private sector truly is more efficient and able to offer better options than government-run Medicare, people will leave the traditional Medicare plan and join the private sector options developed in this Republican bill.

This is a sensible amendment that does nothing more than maintain the promise of Medicare since its inception in 1965 and carry that promise into the future. However, Republicans opposed this amendment on a strictly party line basis.

Eliminate privatization of Medicare. The second fundamental concern we have with the Republican bill is its goal to privatize Medicare. Make no mistake about it. The ultimate goal of this bill is to end Medicare's entitlement to defined benefits. Providing a drug benefit to seniors is simply the window dressing. It includes a whole scheme starting in 2010 that will end Medicare as a defined benefit universally available at a uniform price for all of America's seniors and people with disabilities. Instead, seniors' ability to get the health care they need would depend upon their ability to afford a plan that meets their needs. Beneficiaries who need or want to stay in traditional Medicare will have to pay more to do so.

Remember, Medicare was created because the private health care system would not provide affordable health insurance coverage for seniors. We shouldn't be turning back the clock to those times. But that's exactly what the Republican bill—as written—will do.

The Bipartisan Commission on the Future of Medicare already rejected this proposal. At that time, the Medicare Actuary estimated that converting Medicare to a competitive model of this nature would result in premium increases in traditional Medicare of 47%.

Increasing Medicare premiums at that rate would absolutely force seniors to leave the program—they wouldn't be able to afford to stay. They would have to go into the "competitive" side of the program and join HMOs, PPOs or other similar private plans. These private options restrict choice of physicians, hospitals and other providers and enforce limitations that don't exist in traditional Medicare. America's seniors don't want to be forced into private health plans that don't meet their needs and, more importantly, limit their choice of physician and doctor. We won't support any bill that takes away the security of Medicare. This section needs to go. Again, we offered an amendment to eliminate it. We were defeated on a party line vote.

Eliminate sweetheart deal for drug companies. This bill creates a new bureaucracy to work with the private plans. Embedded in the section establishing this new agency is a provision that actually prohibits the Secretary of Health and Human Services from "interfering" in negotiations between private plans and drug companies. This is an unprecedented restriction of authority for a government program of this magnitude. With hundreds of billions of federal dollars at stake, Republicans put their friends in the pharmaceutical industry ahead of taxpayers.

During the anthrax crisis, Secretary Thompson negotiated with the manufacturer of the antibiotic Cipro and cut prices by more than half. The VA negotiates directly for prescription drugs it pur-

chases on behalf of veterans. Even the office that is responsible for the Federal Employees Health Benefits plan does not have its hands tied in this fashion. This is an extraordinary prohibition that affects Medicare beneficiaries and taxpayers alike. We offered an amendment to delete it. But this, too, was defeated on a largely party-line vote.

The Republican bill fails senior citizens

Democrats have supported Medicare from day one—and have consistently worked to improve it. We want a prescription drug benefit added to the program. But, we won't go along with allowing the promise of a drug benefit become the Trojan Horse that ends Medicare as we know it. We are willing to work with House Republicans on a more limited benefit than we know is needed, but they have to be willing to protect the promise of Medicare. The bill reported out of our Committee fails that test, and is a bad deal for America's senior citizens and the individuals with disabilities who depend on Medicare.

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