

REPORT TO THE CONGRESS

New Approaches in Medicare

MEDpAC Medicare
Payment Advisory
Commission

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Glenn M. Hackbarth, J.D., Chairman
Robert D. Reischauer, Ph.D., Vice Chairman
Mark E. Miller, Ph.D., Executive Director

June 15, 2004

The Honorable Richard B. Cheney
President of the Senate
U.S. Capitol
Washington, DC 20510

Dear Mr. Vice President:

I am pleased to submit the Medicare Payment Advisory Commission's June 2004 *Report to the Congress: New Approaches in Medicare*. This report fulfills MedPAC's legislative mandate to examine issues affecting the Medicare program, including the implications of changes in health care delivery for the Medicare program. In this report, we:

- discuss issues in implementing the new drug benefit and the new chronic care management program mandated under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.
- provide a detailed analysis of beneficiaries who are dually eligible for Medicare and Medicaid.
- consider potential improvements to purchasing and paying for services under the traditional fee-for-service Medicare program. We review innovations in purchasing by the private sector, recommend ways of better targeting the use of long-term care hospitals, and discuss the need for better accountability in the payment and quality measurement systems for hospice.
- explore diffusion of health care information technology—a critical issue in promoting improvements in care coordination and quality for Medicare beneficiaries and others.

The report includes two appendixes. One fulfills our statutory obligation to analyze the Secretary of HHS's estimate of the update for physician services. The other provides a look at changes in beneficiaries' financial liability for health care services over time.

Sincerely,

A handwritten signature in black ink, appearing to read "Glenn M. Hackbarth".

Glenn Hackbarth, J.D.
Chairman

Enclosure



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Glenn M. Hackbarth, J.D., Chairman
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The Honorable J. Dennis Hastert
Speaker of the House of Representatives
U.S. House of Representatives
H232 Capitol Building
Washington, DC 20515

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Executive summary

Executive summary

The major event for Medicare in the last year was the passage of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) in December 2003. In this report, we begin to look at the prescription drug benefit and chronic care provisions of that act. We will continue to follow these issues as implementation proceeds. In this report, we also consider two long standing issues in Medicare: The characteristics and spending patterns of those beneficiaries who have coverage under both Medicare and Medicaid (the dual eligibles) and the health care purchasing strategies the private sector uses that might be useful for Medicare.

We also examine two of the fastest growing sectors of the Medicare program, long-term care hospitals and hospice care. In addition, this report looks at the use of information technology in health care settings and the factors that promote or retard its further diffusion. Because of its potential to improve the quality, safety, and efficiency of health care, this issue is important to the Commission and will be addressed in future work as well.

Finally, the report includes two appendixes. The first fulfills our statutory requirement to respond in our June report to the Secretary of the Department of Health and Human Services' estimate of the payment update for physician services. In the second, we describe Medicare beneficiaries' financial resources and liability for health care costs—important determinants of access to care.

Implementing the Medicare drug benefit

Implementing the Medicare prescription drug benefit in 2006 will raise many policy questions that the Commission and others will consider. In Chapter 1, we begin this work by examining two such questions: How are formulary systems established and maintained, and what issues arise when drug plans enter or exit markets or beneficiaries switch plans?

In establishing formulary systems, plans must balance the need to ensure a cost-effective approach to the drug benefit with the requirement that beneficiaries have access to medically necessary medications. This chapter examines issues related to defining therapeutic categories, the structure and decision-making process of pharmacy and therapeutics committees, the appeals process, and the need for independent drug-to-drug comparison studies. As beneficiaries choose plans, and as plans enter and exit markets, key issues include the prior approval of off-

formulary drugs and informing physicians, pharmacists, and beneficiaries of changes in formularies, cost sharing, and other procedures that differ across plans. We learned from sponsors of private sector plans that adequate time for data transfers and communication is essential for smooth transitions. We note that it is particularly important that physicians and pharmacists have comprehensive information because they usually serve as the point of contact for beneficiaries.

Chronic care improvement

Few incentives and little infrastructure support the coordination of care for beneficiaries in fee-for-service Medicare. In the MMA, the Congress established the Chronic Care Improvement Program to address these issues. We examine this program in Chapter 2. The program targets beneficiaries with diabetes, congestive heart failure, and chronic obstructive pulmonary disease. Much like initiatives used by private plans and state Medicaid agencies, it seeks to improve coordination of care across health care settings and among service providers, educate patients about how to care for themselves, and promote the use of evidence-based treatment guidelines. The program will test different models of care coordination and whether it reduces program spending. The Commission has a strong interest in assuring physician involvement in the initiative and promoting coordination and quality of care for Medicare beneficiaries.

Dual eligible beneficiaries

Beneficiaries who are eligible for both Medicare and Medicaid are known as dual eligibles. Dual eligibles are a vulnerable and costly group, which we describe in Chapter 3. They tend to be poorer, report lower health status, and cost Medicare about 60 percent more than nondual eligibles. Nevertheless, our profile of dual eligibles finds a diverse population, with spending concentrated among a minority of dual eligibles and a significant portion reporting good health and few physical and cognitive limitations. Coverage and payment policies, which affect how beneficiaries receive their care, are complicated because Medicaid differs by state. We find that current policies create incentives to shift costs between payers, hinder efforts to improve quality and coordinate care, and may reduce access to care.

Purchasing strategies

In Chapter 4, we describe the strategies other purchasers are using to increase the value of their health care spending, and begin to consider whether those strategies might apply to the Medicare fee-for-service program. The strategies are intended to reduce spending while maintaining or improving quality. Some examples are measuring and reporting resource use and quality to providers, tiering providers, using hospitalists, and aligning financial incentives across settings. In response to the growth of imaging services, purchasers are using additional strategies, including enforcing safety standards for imaging equipment, limiting the type of providers qualified to deliver a service, and reviewing appropriateness of claims. Evaluating the feasibility and value of particular strategies for Medicare fee-for-service, however, requires consideration of the program's ability to administer these strategies effectively and the potential impact on beneficiaries and the health care delivery system.

Defining long-term care hospitals

Rapid growth in the number of long-term care hospitals (LTCHs) and in Medicare's spending for them highlights the need for more information about these facilities and the care they provide to beneficiaries. In Chapter 5, we find that LTCHs' current role is to provide post-acute care to a small number of medically complex patients. We find that the supply of LTCHs is a strong predictor of their use, that acute hospitals and skilled nursing facilities are the principal alternatives to LTCHs, and that LTCH patients usually cost Medicare more than similar patients using alternative settings. However, we also find that when only patients of the highest severity are considered, the cost differences are smaller. We conclude that a clearer definition of LTCH care is imperative. Thus, the Commission recommends that long-term care hospitals and their care be defined by facility- and patient-level criteria that better differentiate their product and the characteristics of the patients—medically complex with a good chance of improvement—who will benefit the most from LTCH care.

Hospice care in Medicare

In Chapter 6, we review the Medicare hospice benefit, which provides palliative care to beneficiaries with terminal illnesses who are approaching the end of their lives and elect to forgo curative treatment for their

terminal condition. Its use has grown considerably in the last several years with concomitant increases in Medicare spending.

The hospice payment system—based on fixed daily rates—has not been changed since the benefit was established in 1983. As MedPAC has recommended previously, a reexamination of the services hospices provide is needed to assure that payments accurately account for efficient providers' costs while ensuring quality of care. With improved data on the services hospices provide, we could examine refining payments both to reflect factors affecting costs (such as case mix, length of hospice enrollment, care settings, and geographic variation) and to improve quality of care. Better data could also help in examining hospice eligibility requirements and in revising Medicare payments to Medicare Advantage plans to encourage plans to continue care coordination activities for members who elect hospice care.

Information technology in health care

Information technology (IT) has the potential to improve the quality, safety, and efficiency of health care. Yet, diffusion of clinical IT in health care is generally low (and varies with the application and setting) although surveys indicate that providers plan to increase their investments. In Chapter 7, we look at what drives investment in IT and the barriers to its implementation. For many organizations, quality and process improvements motivate investment; for others, gains in efficiency. But investment may be discouraged by the complexity of acquiring and implementing major IT systems, which may include changing work processes and cultures, and by certain characteristics of the health care market—such as the fragmentation of care delivery and payment policies that reward volume rather than quality.

Both the private and public sectors have engaged in numerous efforts to promote clinical IT use within and across health care settings. Additional steps could include financial incentives (e.g., payment policy or loans) and expanded efforts to standardize record formats, nomenclature, and communication protocols to enhance interoperability. However, any policy to stimulate further investment must be carefully considered because of the possibility of unintended consequences. ■

CHAPTER

1

**Implementing the
Medicare drug benefit:
Formulary and plan
transition issues**

Implementing the Medicare drug benefit: Formulary and plan transition issues

In this chapter

- Formulary implementation issues
- Plan transition issues

Implementing the Medicare prescription drug benefit will raise many policy questions that the Commission and others will consider. In this chapter, we examine formulary systems and what issues arise when drug plans enter or exit markets or beneficiaries switch plans.

In establishing formulary systems, plans must balance a cost-effective approach with beneficiaries' access to medically necessary medications. This chapter examines therapeutic category definitions, the structure and decision-making process of pharmacy and therapeutics committees, the appeals process, and the need for independent drug-to-drug comparison studies. As beneficiaries choose plans, and as plans enter and exit markets, key issues include the prior approval process and informing physicians, pharmacists, and beneficiaries of differences in formularies, cost sharing, and other procedures. Employers and plan sponsors in the private sector credit smoother transitions to adequate time for data transfers and communication with those affected by the changes. Physicians and pharmacists need comprehensive information because they usually are beneficiaries' point of contact.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) created Medicare Part D, a voluntary prescription drug benefit scheduled to begin in 2006. Given the size and complexity of the legislation, the cost and value of the benefit will, in large part, be determined by a series of upcoming regulations to be issued by CMS and the responses of states, beneficiaries, and stakeholders to the challenges and opportunities provided by the law. MedPAC is studying a range of topics relating to the drug benefit. Our goal is to inform policymakers about potential implementation issues, including those that might require Congressional action in the future.

In this chapter, we examine two key questions:

- How will formularies and formulary systems be established and maintained?
- What issues arise when beneficiaries move from one drug plan to another or when drug plans enter and leave the program?

For some of these issues, analysis is difficult because minimal data are available and little scholarly research has been done. We have used a variety of methods to gain insight into these questions, including structured interviews with relevant stakeholders, site visits, beneficiary focus groups, and analysis of relevant literature.

We found that formulary design affects the variety and number of drugs available to beneficiaries as well as the ability of drug plan sponsors to manage the benefit and control costs. When therapeutic categories are broad, competition within categories is enhanced, but the number of drugs on the formulary may be more limited. On the other hand, when plans use formularies with narrow categories, they have less ability to steer enrollees to the most cost-effective drugs and negotiate lower prices with manufacturers. The MMA requires an exceptions process to allow enrollees to obtain medically necessary medications not on their plans' formulary. Most plans currently have exceptions processes, but there is considerable variation in the ease with which such exceptions are reviewed and granted. Formularies can change frequently, responding to therapeutic advances, market competition, and deliberations by plans' pharmacy and therapeutics (P&T) committees. Plan

selection of formulary drugs is based on a variety of information sources, but notably lacking are studies which directly compare the effectiveness of one drug to another.

As drug plans enter and exit markets and enrollees switch plans, formulary changes are one of the issues that will have to be addressed. Findings from our study of drug plan changes in the private market can inform policymakers of implementation challenges they will confront. Although some private sector transition experiences are not relevant to Medicare, our findings indicate the importance of ensuring that contractors have sufficient time to implement new drug plans, transfer data, and communicate with patients and others affected by the changes. CMS should ensure that contracts with drug plans include criteria for entering and leaving markets, including timely transfers of data. Of critical importance, beneficiaries (or their caregivers), physicians, and pharmacists must have advance notice of changes in formularies, cost sharing, and other procedures that differ across plans.

Examining formulary systems and drug plan transitions provides insight into some of the key components of the law, including benefit structure, beneficiary education, the grievance and appeals process, and the elements needed to ensure effective competition among plans. Yet this chapter encompasses only a few of the significant issues that must be addressed before the program begins in 2006. In the coming year, MedPAC intends to analyze additional issues including how the drug benefit will be implemented in nursing homes and other long-term care facilities. We also intend to monitor the implementation and effectiveness of the Medicare discount card program to gain further insight into the challenges and opportunities involved in establishing the Medicare drug benefit.

Formulary implementation issues

The MMA allows plans offering Medicare drug coverage to develop and use formularies to manage the costs and use of prescription drugs. Indeed, plans participating in the upcoming Medicare drug benefit are likely to use formularies to designate the coverage or tiered cost-sharing status of prescription drugs. To the extent that formularies help control the costs of drugs, they can be a key to the success of the overall Medicare drug benefit. However, attention to formulary implementation is important to ensure beneficiary access to a range of

needed medications. The MMA allows the Secretary to regulate some features of formulary design and use, but he may not require a particular formulary or price structure for the reimbursement of covered Part D drugs.

The Secretary, the Congress, other policymakers, and stakeholders are likely to encounter a range of formulary-related issues as they implement the new Medicare drug benefit. Some MMA provisions establish detailed requirements on formulary policies and procedures, but others allow greater latitude in formulary development. This section provides a framework for understanding the impact of selected formulary implementation options. To research these issues, MedPAC staff interviewed experts and stakeholders on the topic (including representatives of health plans, pharmacy benefit managers (PBMs), drug manufacturers, physicians, Medicaid plans, the Veterans Health Administration (VHA), the Academy of Managed Care Pharmacy (AMCP), U.S. Pharmacopeia, and consumer advocacy groups), and consulted available research and publications.

This section begins by presenting background information on formularies—how they work and current practices of health plans and PBMs. Then we explore an array of formulary implementation considerations that arise under the new Medicare drug benefit. For example, therapeutic class structures of a formulary can affect ease of access to medications and drug costs. How beneficiaries learn about plan formularies and formulary changes also can affect access. How beneficiaries may obtain coverage for nonformulary drugs is an important issue, considering that nonformulary drugs will not count towards beneficiaries' out-of-pocket spending totals calculated in the drug benefit, unless they are granted a nonformulary exception.

Additionally, this section of the chapter describes the process of selecting drugs for a formulary and examines the research needs and opportunities for improving the information available to make appropriate choices. Provisions in the MMA recognize the need for independent, scientific research that compares the outcomes and clinical effectiveness of prescription drugs. Funding mechanisms may assist in accomplishing this goal.

What are formularies and how do they operate?

On its own, a formulary is a continually updated list of medications that a health plan or other payer will cover. Formularies are a component of a plan's overall formulary

system, which is the set of policies and procedures that plans use to design, implement, and update their formulary. (See text box at the end of this chapter for a glossary of related terms.) A health plan covers all drugs listed on its formulary in some way; however, it may set different levels (tiers) of cost sharing or require that a particular condition is met before certain drugs or groups of drugs will be covered. Hospitals, health plans, PBMs, self-insured employers, and government agencies such as the VHA and Department of Defense (DoD) now widely use formularies. According to one study of employer-sponsored health benefits, 71 percent of workers with prescription drug coverage in 2003 were in plans with closed or partially closed formularies (KFF and HRET 2003).

Health plans have adopted formularies primarily to control continued double-digit growth in drug spending (AAHP 2002). This growth has been driven by three factors: greater use, newer and more expensive drugs replacing older therapies, and increases in manufacturers' prices. Formularies can lower drug costs for plans and enrollees by directing physicians and enrollees to lower-priced, cost-effective drugs. Also, plans gain the ability to negotiate lower prices with a manufacturer when they list the manufacturer's products on their formulary and show a resulting shift in market share (CBO 2002).

The drugs on a formulary may be selected from thousands of available drugs, and many prevalent health conditions now have multiple brand or generic drugs available. According to our analysis of Medline drug information listed on the National Library of Medicine's website, there are at least 6 different statins for use in lowering cholesterol, 5 selective serotonin reuptake inhibitors (SSRIs) to treat depression, and 12 angiotensin-converting enzyme (ACE) inhibitors to treat hypertension. These groups of drugs are among the most highly used, both in terms of volume of prescriptions and sales (Table 1-1 on p. 6 and Table 1-2 on p. 7).

Formulary structures

Most formularies are variations of two basic models: open or closed. In an open formulary, the plan provides coverage for all drugs in most, if not all, therapeutic classes; therefore, even drugs that are not listed on the formulary are covered. Although a payer with an open formulary encourages the prescribing of drugs that are listed, the physician has little incentive to do so. This

**TABLE
1-1**

Leading 20 therapeutic classes by number of prescriptions, 2003

Rank	Class	Total U.S. prescriptions (in millions)	Percent growth	Percent market share
1	Codeine and combinations	148.3	6%	4.4%
2	SSRIs and SNRIs	139.6	11	4.1
3	HMG-CoA reductase inhibitors (statins)	123.4	6	3.6
4	Beta blockers	110.4	7	3.2
5	Ace inhibitors, alone	108.3	3	3.2
6	Proton pump inhibitors	94.9	14	2.8
7	Calcium blockers	89.1	-4	2.6
8	Oral contraceptives	85.6	0	2.5
9	Thyroid hormone, synthetic agents	83.4	5	2.5
10	Seizure disorder agents	77.4	9	2.3
11	Penicillins	72.8	0	2.1
12	Benzodiazepines	72.0	2	2.1
13	Antihistamines, capsules and tablets	59.6	-18	1.8
14	Macrolides and related agents	57.3	4	1.7
15	Antiarthritic agents, plain	57.2	-3	1.7
16	Beta agonists	56.3	-3	1.7
17	Antiarthritic agents, COX-2 inhibitors	53.9	3	1.6
18	Diuretics, other, noninjectable	53.7	0	1.6
19	Hormones, estrogens	51.4	-24	1.5
20	Muscle relaxants, nonsurgical	44.4	5	1.3

Note: SSRI (selective serotonin reuptake inhibitor), SNRI (selective serotonin/norepinephrine reuptake inhibitor), HMG-CoA (3-hydroxy-3-methylglutaryl coenzyme A), COX-2 (cyclo-oxygenase-2). Prescriptions are total dispensed prescriptions, including insulin, dispensed through chain, food store, independent, long-term care, and mail service pharmacies.

Source: IMS Health, National Prescription Audit™ Plus from October 2002 through September 2003.

arrangement usually has minimal impact on prescribing patterns, utilization, and the ability to negotiate manufacturer rebates.¹ On the other hand, in a closed formulary, the payer does not reimburse for drugs unless they are listed on the formulary or are covered through an exceptions process. In this type of formulary, the ability to shift prescriptions and gain rebates from manufacturers increases (AAA 2000).

In practice, most formularies are partially or selectively closed. Most formularies exclude certain types of drug classes completely, such as drugs that the Food and Drug Administration (FDA) has determined lack sufficient efficacy, and weight-loss, cosmetic, and other lifestyle drugs (AMCP 2000a). In addition, individual therapeutic classes may be open or closed. For example, a formulary may close the statin therapeutic class, only covering a few drugs within it, but leave other classes open, covering all available drugs within them.

Incentive-based formularies may be closed, open, or partially closed, and use price differentials or other financial incentives to influence drug choice by physicians and beneficiaries. For example, an incentive-based formulary allows coverage of nonpreferred drugs, but only at higher copay or coinsurance levels. In particular, a majority of commercial plans now offer three-tier incentive formularies. In this structure, the formulary may contain many drugs for each therapeutic class, but they are grouped into three tiers, each with different levels of cost sharing. This structure encourages cost-consciousness on the part of beneficiaries, as they typically pay the lowest copay for generic drugs, a midlevel copay for brand drugs preferred by the plan, and the highest copay for nonpreferred brand drugs. The prevalence of three-tier incentive formularies has steadily increased: In 2003, 63 percent of workers with employer-sponsored health benefits were enrolled in drug plans with this structure, up from 27 percent in 2000 (KFF and HRET 2003).

**TABLE
1-2**

Leading 20 therapeutic classes by sales, 2003

Rank	Class	U.S. sales (dollars in billions)	Percent growth	Percent market share
1	HMG—CoA reductase inhibitors (statins)	\$13.5	10%	6.4%
2	Proton pump inhibitors	12.9	16	6.1
3	SSRIs and SNRIs	10.6	9	5.0
4	Antipsychotics, other	7.8	23	3.7
5	Erythropoietins	7.2	17	3.4
6	Seizure disorder agents	6.6	25	3.1
7	Antiarthritic agents, COX-2 inhibitors	5.2	9	2.5
8	Calcium blockers	4.4	-1	2.1
9	Antihistamines, capsules and tablets	3.8	-21	1.8
10	Codeine and combinations	3.1	14	1.5
11	Quinolones, systemic	3.1	7	1.5
12	Bisphosphonates	3.0	22	1.4
13	Insulin sensitizers	2.9	16	1.4
14	HIV—reverse transcriptase inhibitors	2.8	13	1.3
15	Ace inhibitors	2.8	-21	1.3
16	Oral contraceptives	2.8	4	1.3
17	Immunologic interferons	2.6	24	1.2
18	Newer generation antidepressants	2.6	9	1.2
19	Macrolides and related agents	2.5	10	1.2
20	Gastrointestinal anti-inflammatory agents	2.4	33	1.1

Note: HMG-CoA(3-hydroxy-3-methylglutaryl coenzyme A), SSRI (selective serotonin reuptake inhibitor), SNRI (selective serotonin/norepinephrine reuptake inhibitor), COX-2 (cyclo-oxygenase-2). U.S. sales are prescription pharmaceutical purchases, including insulin, at wholesale prices by retail, food stores and chains, mass merchandisers, independent pharmacies, mail services, nonfederal and federal hospitals, clinics, closed-wall HMOs, long-term care pharmacies, and others.

Source: IMS Health, National Sales Perspectives™ from October 2002 through September 2003.

Aside from excluding certain drugs, formularies may use mechanisms other than pricing differentials to direct utilization. For example, a drug may be listed on a formulary but require prior authorization by the plan or PBM. Also, some drugs may be designated as “first line”: These drugs must be tried first and proven unsuccessful in treating a patient before a nonpreferred drug will be covered.

To accommodate medical need, most formularies have an exceptions process that provides access to and reimbursement for nonformulary drugs that a physician justifies as medically necessary for a patient’s care (AMCP 2000a). Some stakeholders we interviewed stressed the importance of an exceptions process to a well-designed and functioning formulary. Exceptions processes are used more often with closed formularies than with tiered formularies. Most plans’ exceptions processes

require the physician to supply supporting evidence of their medical necessity claims, although one plan we interviewed does not. Most plans aim to resolve all exceptions claims within 48 hours. A plan we interviewed allows the prescribing physician or pharmacist to authorize a three-day emergency supply of a medication while the exceptions claim is being processed.

As a result of different structures and decisions, the number and types of drugs covered on formularies can vary greatly across the marketplace. A survey of HMOs found that the number of drugs on formularies ranges from fewer than 250 drugs to, in most cases, over 750 drugs (Formulary 2003). In the Medicare+Choice (M+C), now Medicare Advantage (MA), marketplace, the scope of the drug benefits offered has decreased markedly. A 2002 study found that 39 percent of M+C enrollees were in plans that limited coverage solely to generic drugs

(Achman and Gold 2003). However, starting in 2006, most types of Medicare Advantage plans are required to offer the Medicare drug benefit as an option.

Therapeutic classes

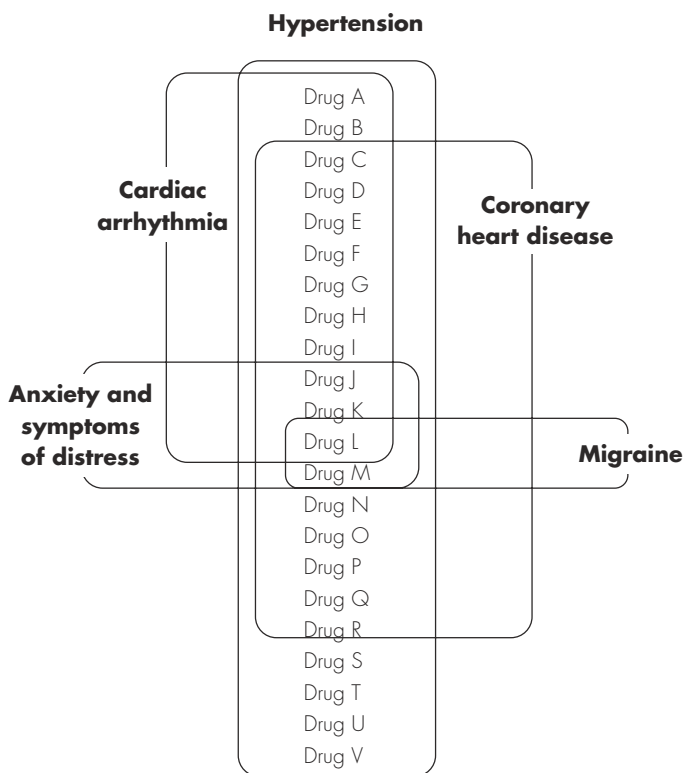
The classification of drugs is complex and variable, with little consensus on the best methodology. Drugs can be classified on the basis of their therapeutic indications, the pharmacological mechanism by which they act, or at the most basic level, their chemical structure. Most classification systems place together drugs that produce similar clinical outcomes (lower cholesterol, alleviate depression) and have similar adverse reaction profiles. Stakeholders we interviewed stated that the classification systems are used as a framework for reviewing, selecting, and inducing price competition among drugs. Some plans offering a drug benefit create their own therapeutic classification system, while others use or modify systems available commercially.

Differences arise in classification systems for many reasons, one being that even drugs that act through the same pharmacological mechanism can have differing therapeutic indications. For example, drugs classified as beta-blockers are primarily used to lower blood pressure by decreasing the heart's output of blood.² However, some beta-blockers may be used to treat or prevent several heart conditions, such as angina or cardiac arrhythmia, because they selectively affect regions of the heart; still others may be used to treat migraines or anxiety. Small chemical differences between the drugs alter their appropriate uses, effectiveness, and safety profiles. Based on these differences, it would be possible to classify beta-blockers in one or several different therapeutic classes (Figure 1-1).

Additionally, drugs may act through different pharmacological mechanisms but achieve somewhat similar therapeutic outcomes. For example, commonly used antidepressants encompass several types of compounds that act by different methods: tricyclic antidepressants, SSRIs, monoamine oxidase inhibitors (MAOIs), and other agents. Some formularies separate antidepressants into these four different therapeutic classes, while others combine some or all of the classes. Some plan representatives we interviewed noted that, because only certain SSRIs work for some patients, they are careful to allow choice within that group of drugs. In another example, cyclo-oxygenase-2 (COX-2) inhibitors

FIGURE 1-1

Beta-blockers may be grouped in one or several therapeutic classes



Source: Adapted from presentation by Robert Guersen at Global Medical Forum Summit, December 5, 2003. <http://www.globalmedicalforum.org/summits/us>.

are a new form of nonsteroidal anti-inflammatory drugs (NSAIDs) for treating symptoms of arthritis (pain, inflammation, swelling, stiffness). Many plans classify COX-2 inhibitors as a class of drugs on their formulary and thus cover at least one (Doshi et al. 2004). However, some plans we interviewed do not classify them separately from other NSAIDs, and thus cover COX-2 drugs only through medical exceptions, citing their high cost and value only for people with gastrointestinal problems or other medical considerations. As these examples show, decisions about formulary inclusion depend on the classification system chosen and other system components.

Classification systems can change; they evolve to reflect the emergence of new drugs and clinical information. One plan noted that, when it chose among commercial classification systems, timely updates were a

consideration. In general, the drugs on a plan's formulary change much more frequently than the formulary's classification system.

Formulary development and drug selection

Formularies are usually developed and maintained by a body of medical experts known as a pharmacy & therapeutics (P&T) committee. All plans and PBMs we interviewed relied on the input of P&T committees for selecting their formulary. P&T committees differ, but they generally have physicians of varying specialties and pharmacists—with physicians usually outnumbering pharmacists. Our interviews revealed that physicians usually hold the majority vote on formulary decisions: In at least one case, pharmacists were present on the committee but could not vote on decisions. Some P&T committees used a voting process for selecting drugs, but others sought a consensus. Also, some plans and PBMs emphasized the independence of committee members. Some recruit experts from academia to serve as members and require or expect disclosure of conflicts of interest.

P&T committees choose whether a drug should be placed on the formulary and, when applicable, assign tier levels and other requirements such as prior authorization. Committees base these decisions on information about the effectiveness and safety of available drugs and net costs. Clinical information may include drug monographs obtained from medical references, therapeutic class reviews prepared by pharmacists, published studies, pharmacoeconomic studies, and internal drug utilization review. Most P&T committees place the greatest weight in their deliberations on published peer-reviewed articles, particularly those which focus on evidence-based clinical outcomes. P&T committees also rely on meta-analyses, including surveys of published literature prepared by a support staff of pharmacists or a contracted entity.

Pharmaceutical manufacturers may provide unpublished information to P&T committees upon request. In 2000, AMCP issued guidelines to standardize the format of the information drug companies provide to P&T committees. The guidelines call for drug companies to present a standardized “dossier” that contains detailed information on each drug's effectiveness, safety, economic value relative to alternative therapies (such as other drugs or treatment protocols), off-label indications, and any other relevant unpublished studies.

All plans we interviewed noted that studies that directly compare two or more drugs or classes of drugs in the treatment of a condition are limited and uncommon, despite their usefulness to plans, physicians, and patients. To address this demand, the National Heart, Lung, and Blood Institute of the National Institutes of Health recently completed a series of comparison studies on drugs that treat hypertension. These studies found that, in the majority of cases, generic diuretic compounds were just as effective in treating hypertension as more expensive ACE inhibitors and calcium-channel blockers (ALLHAT 2002). Both ACE inhibitors and calcium-channel blockers were among the top ten therapeutic classes by sales in 2003 (Table 1-2, p. 7).

Our interviews revealed that net cost seems to become a consideration at different points in the formulary process. Plans may first decide which drugs are therapeutically superior, equivalent, or inferior based only on effectiveness and safety, and then negotiate and consider pricing (including manufacturer rebates and discounts) among those they determine to be therapeutically equivalent. Others may take cost-effectiveness or pharmacoeconomic data into account while reviewing all available drug information.

Most P&T committees meet at least once a year, with many meeting quarterly (Formulary 2003). P&T meetings vary in length, from a minimum of three to four hours, to a full day, to a few days. Some committees stagger their reviews of therapeutic classes across meetings, effectively covering the formulary over the course of a year. Others may review the entire formulary once a year, or set their agenda based on when manufacturer contracts are up for renewal. Most plan representatives stated that their P&T committees reconsider drug selection as needed when generics or significant findings about safety or efficacy become available.

MMA formulary provisions: Issues and analysis

Most plans participating in the Medicare drug benefit will develop and use formularies to manage the costs and utilization of prescription drugs. The MMA stipulates some formulary-related provisions, but also enables the Secretary to regulate future policies on the topic. Plans are likely to have some latitude in designing and implementing formularies. The questions that follow in

this section raise the major issues that policymakers and stakeholders will encounter when drafting and reviewing formulary regulations and policies.

How will therapeutic class structures affect formulary development?

In implementing a formulary, the MMA allows plans to establish their own classification system of therapeutic categories and classes. However, a plan's therapeutic class structure may not be designed to discourage enrollment of beneficiaries with high expected drug costs, such as those with AIDS, mental illness, epilepsy, or other chronic conditions. Due in part to this concern, the MMA designated the United States Pharmacopeia (USP)—a nongovernmental, nonprofit organization—to develop a model classification system. Plans are not required to use USP's classification model, but if they do, they will be granted safe harbor on the issue of discouraging enrollment of high-cost beneficiaries. USP is required to consult with stakeholders when designing its model classification system for the Medicare drug benefit.³

The MMA requires that plans with formularies cover at least two drugs in each therapeutic category.⁴ The structure of a plan's therapeutic categories, therefore, can have a major impact on which and how many drugs a plan covers. In particular, the specificity of a therapeutic class determines the number and mix of generic and brand drugs available. The MMA does not prevent plans from listing a drug on their formularies in more than one category. For example, plans may cover a beta-blocker in two therapeutic classes: hypertension and cardiac arrhythmia (Figure 1-1).

Some of the plan and PBM representatives we interviewed indicated that if, under the Medicare drug benefit, they use a formulary with narrow therapeutic classes, it would minimize their ability to contain costs for two main reasons. First, narrow drug classes are more likely than broad classes to have no generic or moderately priced drugs available. Second, these narrow drug classes are likely to reduce market competition within each drug class. Plans and PBMs maintain that without sufficient competition within a therapeutic category, they will have limited ability to negotiate for discounts and rebates from manufacturers, and thus will need to charge enrollees higher coinsurance or premiums. Plans further contend

that formularies with broad therapeutic classes lower drug costs because they increase the likelihood that generics are included in the drug classes (AAHP 2002, AMCP 2004).

Consumer advocates and representatives of the pharmaceutical industry express concern that a broad classification system with too few therapeutic categories and classes can limit enrollees' access to medically necessary brand name drugs, particularly if the nonformulary exceptions process is too onerous for either the beneficiary or the prescribing physician, or both (NPAF 2003). For example, subpopulations of beneficiaries may be best served by new drugs with less risk of side effects. A formulary with a broad classification system may be less likely to offer these drugs. The industry is also concerned that if formularies use wide classes to steer beneficiaries away from new drugs, companies will be less willing to commit resources toward researching and developing new drugs (Danzon 2000).

AMCP has raised concerns regarding the classification system selected for the new Medicare drug discount card program. Set to run from June 2004 to the end of 2005, this program allows private entities to offer beneficiaries a Medicare-approved drug discount card, which will give discounts on selected drugs. CMS established 209 therapeutic categories for the Medicare drug discount card. These categories were selected primarily because they contain the drugs most commonly used by Medicare beneficiaries. AMCP states that the classification system CMS selected for the drug discount card contains narrowly defined drug classes with significant redundancy (AMCP 2004). As an example, AMCP points to the three chemical subclasses of calcium channel blockers. AMCP contends that this redundant classification system is not as effective in controlling costs as a broader one, with fewer therapeutic categories. Commenting on previously proposed drug discount card regulations, the Pharmaceutical Research and Manufacturers of America (PhRMA) has stated that aggregating therapeutic classes too much could impair beneficiaries' access to discounts on a sufficient range of drugs (PhRMA 2002).

The major implementation issue regarding therapeutic categories and classes will be whether USP's model is accepted by plans, PBMs, and other stakeholders. If plans decide not to use the model, they will need to show that their departure from the model is not designed to encourage or discourage certain beneficiaries from enrolling.

Another issue will be the level of coverage that will be offered within each therapeutic class. Although the MMA states that at least two drugs must be covered in each therapeutic class, the law does not specify a required tier of coverage for these drugs. Future regulations are needed to clarify whether any drugs within a therapeutic class must be covered at the most preferred level.

There are no formal accrediting agencies or accrediting requirements for plan formularies; thus, the quality of a plan's formulary and formulary system is not formally evaluated to ensure that they allow adequate access to necessary drugs. Recognizing this concern, Consumers Union has evaluated the value of drug benefits offered by Medicare managed care plans using its "prescription drug quality index" (Consumer Reports 1998). Further evaluation of the need and feasibility of formulary accreditation may be useful.

How can enrollees obtain coverage for nonformulary drugs?

The MMA requires that plans have a process for enrollees to request coverage for nonformulary drugs, or to reduce a nonpreferred drug's cost sharing to the most preferred level. For such exceptions, a prescribing physician must determine that a nonformulary or nonpreferred drug would be more effective and/or cause fewer or milder adverse side effects than a formulary or preferred drug. If beneficiaries are unable to obtain a nonformulary exception from the plan, they will have to pay high cost sharing, up to the full retail cost of the drug. Further, their costs for purchasing these drugs will not count toward their out-of-pocket spending totals—calculated to determine deductibles and catastrophic spending thresholds. Pharmacists may be the first people beneficiaries approach to learn about the nonformulary exceptions process, since they are often the first ones to explain to beneficiaries that their prescribed drug is not on the formulary.

If a beneficiary's request for a nonformulary drug or for a more preferred cost-sharing status of a drug is denied, the beneficiary may appeal. Plan sponsors must have meaningful grievance and appeals processes that conform to those for the Medicare Advantage program. These include requirements for determinations, reconsiderations, external review, and expedited decisions.

Our interviews and research revealed that plans currently use a continuum of methods for reviewing nonformulary exceptions. Exceptions processes are used more often with closed formularies than with tiered formularies, which involve obtaining preferred level cost sharing for a nonpreferred drug. Most require physicians to submit for approval medical documentation on why formulary alternatives will not be appropriate for a beneficiary, but some use less formal methods, including simple phone approval. Plans with more complex exceptions processes may also require the prescribing physician to document that the beneficiary tried the formulary alternative during a trial period and that either the beneficiary experienced an adverse reaction to the drug or the drug failed as a treatment alternative—often referred to as a step therapy requirement. Step therapy for hypertension was recently suggested in research sponsored by the National Institutes of Health (ALLHAT 2002). Physicians we interviewed cautioned, however, that the elderly and disabled population may not be well suited for some step therapy requirements, given their frailty and increased risk of adverse drug interactions.

Physicians also indicated to us that, although they usually were successful in obtaining nonformulary exceptions, the time spent on the phone was lengthy. Physicians commented that plans are more likely to grant nonformulary exceptions when physicians call than when a staff assistant calls. Additionally, specialists are more likely to obtain nonformulary approval for drugs within their specialty area than general practitioners.

Any burden associated with a medical exceptions process encourages formulary compliance (IOM 2000). Consumer advocates contend that, if the process for obtaining nonformulary exceptions is too burdensome, physicians may be less willing to prescribe nonformulary drugs, even when medically indicated. Alternatively, plan representatives expressed concern that, if nonformulary exceptions were too easy to obtain, the cost-control and drug-management mechanisms built into the formulary would be greatly undermined.

Some plans require physicians to obtain prior authorization from the plan before prescribing some drugs. Plans explained that the prior authorization process is often used to encourage careful prescribing of drugs that carry elevated safety concerns, either when taken on their own or in association with other medications. Plans also noted that extremely expensive drugs are candidates for

prior authorization to assure judicious prescribing. Consumer advocates and some researchers counter that formulary tools that delay patients' access can jeopardize patients' health (NMHA 1998, Huskamp 2003b).

Research suggests that the availability of effective product alternatives is an important consideration when implementing formulary tools that restrict use (Soumerai 2004). A study that examined the effect of prior authorizations of an effective, high-cost drug, when few alternative choices were available, found that it almost eliminated the drug's use and probably reduced appropriate care (Bloom and Jacobs 1985). On the other hand, research has also confirmed that prior authorization of brand name drugs in a class with other generic alternatives greatly reduced drug spending, without increasing costs or use of physician or hospital services (Smalley et al. 1995).

What issues arise if plans change their formularies?

In current practice, formularies are frequently modified to reflect the introduction of new drugs in the market, updated clinical information, and changes in market competition (AAA 2000). The MMA prohibits plans from changing their therapeutic category definitions during the plan year, but allows plans to change the specific drugs listed on their formulary at any time.⁵ Medicare beneficiaries may only switch plans during annual open enrollment periods. Thus, if plans change formularies midyear, enrollees will not be able to retain drug coverage for a particular drug simply by switching to a plan that covers it. Issues that occur when beneficiaries change plans are discussed later in the chapter.

If plans add or remove a drug, or change its tier status, the MMA requires that plans notify affected enrollees, physicians, pharmacies, and pharmacists prior to the change through a website posting. Adequately notifying enrollees about any formulary changes can reduce those instances in which beneficiaries first learn at the pharmacy that their drug is no longer covered or has higher cost sharing. If the plan uses no notification mechanism other than website postings, then affected people must consult a website regularly to learn of formulary changes. Consumer organizations comment that website-based communication with Medicare beneficiaries can be useful, but is not a sufficient mechanism for informing most beneficiaries of formulary changes, considering the limited numbers of

elderly and disabled people who are able to access and use the Internet. A recent study found that only 22 percent of people age 65 and older use the Internet, up from 15 percent in 2000 (Fox 2004). The National Library of Medicine is involved with local library initiatives to increase seniors' internet use, particularly for accessing health-related information (Humphreys 2004).

Regardless of how beneficiaries learn about any formulary changes, balancing this information with their drug needs and their tiered cost-sharing structures can be confusing, particularly for some Medicare beneficiaries. In addition to available family members, pharmacists and physicians are likely to receive many formulary-related questions.

Our interviews revealed that periodic mailings and website postings were the most common methods for plans and PBMs to communicate formulary changes to enrollees and physicians. Physicians reported that it is difficult to keep track of formulary changes for their patients' plans, particularly when plans do not specifically highlight subtractions or additions. One physician reported that because she is unable to keep track of all the formularies and formulary changes in her patients' plans *prior* to writing prescriptions, she typically does not learn that she has prescribed a nonformulary drug until she gets a call from a pharmacist alerting her of the situation. This can be burdensome for the patient, the physician, and the pharmacist.

Another physician we interviewed said that he uses a hand-held computer loaded with drug information in conjunction with hard copies of plan formulary lists, but still unknowingly prescribes nonformulary drugs because of plan formulary changes. Physicians commented that limitations on the frequency of formulary changes could be helpful. For example, if changes, particularly subtractions, could occur only on a quarterly basis, physicians would know when to check for possible changes. The ability to access current formularies online may also be useful. As noted in Chapter 7, physicians' use of internet technologies in clinical practice is growing, but still not routine. Further, physicians pointed out that formulary changes not only affect future prescribing, but also affect all refillable prescriptions written in the past. Rewriting these previous prescriptions to reflect a formulary change can require substantial office time for physicians as well as pharmacists.

In the future, electronic prescribing is likely to become a tremendously useful tool in formulary adherence. However, current use is in its infancy. Although recent experiences suggest major financial and logistical obstacles, the MMA has offered some incentives to promote electronic prescribing.

The MMA does not require plans to alter their nonformulary exceptions process for enrollees taking a drug if it is removed from their formulary. Enrollees are most directly affected by a formulary change if the drug they have been accustomed to using is deleted from their plan's closed or tiered formulary. The change may have health and financial implications for beneficiaries because it requires that they either switch to a new drug that is on the formulary or continue to use the original drug and pay for it themselves, unless they are granted a nonformulary exception. Additionally, as noted earlier, expenditures on nonformulary drugs will not count toward the enrollee's total out-of-pocket spending for purposes of calculating deductibles and catastrophic spending thresholds.

Patient cost sharing can affect drug use. Recent studies show that tiered cost sharing can influence people to switch to preferred drugs (Motheral and Fairman 2001, Joyce et al. 2002). However, other recent research has found that when an employer-sponsored plan more than tripled copays for brand name drugs, some patients stopped taking the drugs rather than switch to less expensive medications (Huskamp et al. 2003a). Physicians we interviewed also commented that patients were less likely to take prescribed drugs with high cost sharing. CMS may wish to monitor the effects of cost sharing on beneficiary use of essential drugs.

A 1999 General Accounting Office study of Medicare managed care plans found that some plans made it difficult for physicians to obtain exceptions for patients to remain on existing medications at no additional cost if the drugs were dropped from the formulary (GAO 1999). Few plans in this study granted automatic nonformulary exceptions to beneficiaries who were in the plan and already taking the dropped drug—a policy referred to as “grandfathering.” Under this policy, as long as the enrollee stays in the plan, the enrollee may purchase the drug under preferred status.

Consumer advocates and researchers have noted the importance of grandfathering coverage for drugs dropped from a formulary, particularly in the case of psychotropic

drugs (NMHA 1998, Huskamp 2003b). Some plan representatives we interviewed noted that, for a limited number of drugs and illnesses, grace periods or grandfathered exceptions for a dropped drug may be granted automatically. However, in cases when a new (less expensive) generic drug becomes available, plans are much less likely to grant exceptions because there are generally no safety issues associated with switching. Plan representatives noted that, because the MMA only requires affected people to be notified of any formulary changes, beneficiaries on a grandfathered drug do not need notification, which can prevent unnecessary anxiety and action.

How can beneficiaries learn about a plan's formulary?

At the time of enrollment and annually thereafter, the MMA requires plans to inform their enrollees how their formulary functions and how to obtain more specific formulary information. For example, upon request, plans must provide information on cost-sharing levels applicable to each drug or class of drugs. Plans must be able to provide such information through a toll-free telephone number and in writing.

The MMA requires plans and the Secretary to provide more general plan information to prospective enrollees. Upon beneficiary request, plans must provide information on their coverage rules, utilization control mechanisms, and grievance procedures, as is required for Medicare Advantage plans. Plans do not, however, have to provide prospective enrollees with a list of covered drugs by name. The MMA requires the Secretary to disseminate plan information to the public, including comparisons of plan benefits, premiums, quality, cost sharing, and consumer satisfaction information, unless the information is unavailable. The Secretary is not required to disseminate formulary comparison information to the public.

The issue of whether plans should be required to provide their formulary to prospective enrollees is complex. Beneficiaries need formulary information if they want to select the plan that can give them the best value and the lowest out-of-pocket costs. Meanwhile, plans with the least restrictive formularies are likely to be attractive to beneficiaries with higher-than-average health care costs. In our interviews, some plans expressed the concern that, if they covered an expensive drug (and other plans did not), a disproportionate share of beneficiaries on those drugs in

their service area would enroll in their plan, particularly if plans were required to disseminate their formularies widely to prospective enrollees. Thus, competitive pressures could lead plans to offer less expansive formularies.

Two additional factors complicate beneficiaries' selection of plans based on their formularies. First, beneficiaries who take multiple drugs will need to determine which plan has the combination of formulary drugs that will yield the lowest out-of-pocket spending. Second, plans may change their formularies after beneficiaries enroll. Thus, beneficiaries who select a plan based on its formulary would likely be frustrated if, after they enroll, the plan drops specific drugs they use from its formulary.

What are the requirements for P&T committees?

The MMA requires that plans have or contract with a P&T committee to develop and review their formularies. The MMA does not specify the number of members that the P&T committee must have, but the law does stipulate that the majority must be practicing physicians and/or pharmacists. In fact, at least two members of the committee—a practicing pharmacist and a practicing physician—must be considered “independent experts.” They cannot have a conflict of interest with the plan, and they must have expertise in the care of elderly or disabled persons.

In our interviews, plan representatives and physicians preferred practicing physicians and pharmacists over nonpracticing ones for P&T committee membership because of their familiarity with formularies.

Plan representatives disagreed on the importance of P&T committee member independence. Some stressed the importance of independence from the plan and from other intermediaries, such as drug manufacturers. Many of the P&T committees did not have a plan representative on the committee, but some did. A recent study cited in a managed care trade publication suggests a decline in the share of P&T committees with plan representatives; it fell from about 40 percent of the P&T committees in 1988 to about 20 percent in 2000 (Cross 2001). Other plan representatives stated that including plan-affiliated physicians and pharmacists on the P&T committees helps assure all physicians and pharmacists in the plan that they are represented in the formulary decision-making process,

thus increasing formulary compliance. Some plans allowed members with conflicts of interest, such as relationships with drug manufacturers, to remain on the P&T committee, but required disclosure and possible abstention from voting on associated drug products. The MMA does not specifically address conflicts of interest between P&T committee members and drug manufacturers.

The MMA does not prescribe a set number of P&T meetings per year, but does require periodic evaluation and analysis of treatment protocols and procedures. The P&T committee may review any information it determines to be appropriate when making decisions regarding drug coverage status. Such information may include peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and information requested from drug manufacturers. The P&T committee must consider the strength of the scientific evidence and standards of practice when making clinical decisions. For example, the P&T committee may weigh randomized clinical trials and drug comparison studies more heavily than other types of studies it considers less definitive. The MMA also requires that P&T committees consider whether including a drug on the formulary or in a preferred tier has therapeutic advantages in terms of safety and efficacy. Consumer advocates state, however, that allowing P&T committees to examine “any information they deem appropriate” weakens the standards for coverage, allowing cost considerations to override effectiveness (NPAF 2003).

The MMA's requirement that at least two P&T committee members have expertise in treating elderly and disabled people may help to assure effective protocols for this population. Without clinical experience, P&T committees have limited information on drug effectiveness and adverse drug interactions in these populations, which are often excluded from studies due to their high rate of coexisting conditions (Hutchins et al. 1999).⁶

Need for drug comparison studies Currently, two drugs are rarely tested against each other for effectiveness in treating the same condition (Goldberg 1997). This lack of direct evidence has led health insurers, providers, consumers, and policymakers to advocate for independent head-to-head drug comparison studies. Such studies could provide improved evidence on which to base formulary and prescribing choices.

In the absence of head-to-head drug comparison studies, P&T committees and prescribing physicians use more indirect means to determine whether drugs are equally effective for the same conditions or if one is better. For example, they may consult or conduct a meta-analysis, which extrapolates findings from relevant single-drug placebo studies. Meta-analysis has many limitations, however, particularly when the research methods among available and selected studies are not parallel (Petitti 2000). In our interviews, plan pharmacy managers stated that single-drug studies do not often provide clear-cut comparisons among drugs that treat the same symptoms because of variance between study methods and protocols. They also raised concerns about the methodology of some studies conducted and submitted by drug manufacturers. In some drug classes, for example, randomized controlled trial studies—considered the gold standard among the research community—are minimal or unavailable.

Physicians and P&T committees are also faced with the question of which type of outcomes to weigh more heavily when choosing a preferred drug. For example, is evidence of a drug's ability to reduce heart attacks more important than a drug's ability to reduce cholesterol levels? How much weight should P&T committees place on side effects of effective drugs? These questions are being debated by researchers and stakeholders alike.

The pharmaceutical industry contends that current research methods are sufficient for physicians and plans to make informed choices. Manufacturers already spend considerable resources demonstrating the safety and effectiveness of their drugs through the FDA approval process, which includes research on drugs even after they are available to the public. In response to growing demand from the medical community for more data, the pharmaceutical research and development process has become increasingly lengthy and complex (PhRMA 2003). In fact, manufacturers have recently funded some head-to-head studies on brand name cholesterol lowering drugs, but these kinds of studies are uncommon.

The plan managers we interviewed identified a need for unbiased information on drug-to-drug comparisons of clinical outcomes. With independent, evidence-based outcomes research, plans could have a better opportunity to select formulary drugs based on clinical effectiveness. Further, studies designed to test drugs for certain

subpopulations can inform formulary protocols for patients with specified characteristics, such as coexisting medical conditions and drug regimens. Without sufficient clinical evidence for selecting one drug over another in a therapeutic class, P&T committees may select drugs based on price factors (AAHP 2002).

Physicians and beneficiaries would also benefit from having an independent resource for drug-to-drug comparisons. Physicians would have greater access to unbiased effectiveness research, which would assist them in selecting drugs to prescribe. Physicians mentioned to us that they currently consult a variety of sources—some considered more trustworthy than others—to select a drug of choice to prescribe. Also, if independent drug-to-drug results were available to the public, beneficiaries would have an objective resource for understanding which drugs work better than others for specified medical conditions. This information could help beneficiaries sort through consumer advertising.

Provisions in the MMA recognize that providers, patients, and health insurers need improved evidence to make informed health care choices. The MMA authorizes the Agency for Healthcare Research and Quality (AHRQ) to conduct and support research studying the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services (including prescription drugs). The law calls for this research to evaluate and synthesize available scientific evidence and identify areas for which existing evidence is insufficient.

Under its Evidence-based Practice Program, AHRQ already supports the systematic review and analysis of scientific literature on a variety of health-related topics and disseminates the findings. However, this program does not currently focus on pharmaceutical care.

The MMA directs the Secretary to collaborate with public and private sector entities to help develop new scientific knowledge regarding health care items and services, including prescription drugs. Such research could include testing drugs' effectiveness against other drugs used to treat the same condition. Results from this research are to be disseminated to plans and beneficiaries. However, CMS may not use data obtained from such outcomes studies to withhold coverage of a prescription drug.

To carry out these research, evaluation, and communication efforts, the MMA authorizes \$50 million in 2004 and additional funds as needed in later years. As yet, these funds have not been appropriated by Congress. Further, no amount was authorized specifically for research on prescription drugs over other types of health care items and services.

In addition to authorizing AHRQ to conduct or sponsor comparative research, the MMA also notes its support of public-private partnerships to do the same. Funding research through a government agency would subject studies to the annual congressional appropriations process, which could leave the research vulnerable to unstable funding. As an alternative to Congressional appropriations, a specified percentage of sales from drug manufacturers, health plans, and PBMs may be an appropriate and available mechanism for funding needed outcomes research.

Uwe Reinhardt, a noted health economist, suggests that independent research institutes, which would function like not-for-profit foundations, conduct cost-benefit analyses on drug therapies. These institutes could attract distinguished researchers and could disseminate findings in scholarly literature and public venues for consumers and physicians (Reinhardt 2001, Reinhardt 2004). Reinhardt notes that drug-to-drug research should be transparent and subject to peer review to garner stakeholder respect.

The independence of the comparative outcomes research is essential to its success. If drug manufacturers were to conduct the research, health insurers and consumer organizations might not trust the findings; if health insurers conducted the research, consumer organizations and drug manufacturers might be distrustful.

Conducting head-to-head studies and other evidence-based outcomes research would be very expensive, and interpretations of the results could vary. At issue, therefore, is who would conduct these tests and who would pay for them. Funding could be provided by the public sector, the private sector, or a collaboration between the two.

In sum, Medicare and the Congress will face numerous formulary implementation issues as details for the drug benefit unfold. Formulary issues could also arise when beneficiaries move from one drug plan to another, when

drug plans enter and leave the program, or when drug plans switch PBMs. Such issues are discussed in the following section.

Plan transition issues

To encourage efficiency, quality, and cost control, the Medicare drug benefit depends upon competition among private plans. The challenge for the Medicare program is to provide opportunities for continued competition among plans while minimizing instability and disruption for beneficiaries. Plans must have the flexibility to make business decisions about their continuing participation in the program, and Medicare must have the ability to reject plan bids that do not meet cost and quality standards. Finally, beneficiaries must be able at periodic open seasons to change enrollment from one prescription drug plan or Medicare Advantage (MA) plan to another that better meets their needs.

As prescription drug plans enroll beneficiaries, as plans enter and exit markets, and as beneficiaries change plans, plan sponsors and the Medicare program will have to ensure that the transition from enrollment in one plan to another is as seamless as possible. Plans must have the infrastructure in place to make sure that enrollees can switch between plans, taking their patient information and benefit history with them. Crucial tasks will include educating beneficiaries, communicating with relevant physicians and pharmacists, distributing new drug benefit cards, transferring data on eligibility and enrollment, and implementing additional processes to minimize problems for beneficiaries arising from disruption of pharmacy networks and formulary systems.

Some health plans and large public and private employers have recently gone through the experience of changing the PBM that manages their drug benefit. PBMs are likely to offer private drug plans under Medicare Part D. MedPAC, with the help of researchers at NORC/Georgetown University, conducted a series of structured interviews with experts and conducted site visits and focus groups with active and retired employees of some of these companies to understand the experiences of stakeholders when these transitions occur. Our goal was to examine the issues that arise when health plan sponsors switch from one pharmacy benefit manager to another to see if there were any policy lessons that could be applied to

implementation of the Medicare drug benefit. We focused on both best practices and the problems that plan sponsors and participants have experienced following a change.

Key findings include:

- Organizations need advance preparation to ensure a smooth change in PBMs. Transition planning requires several months of effort, ideally at least six months in advance of the transition date. Although this time frame may be unrealistic in the Medicare context, CMS should work to ensure that Medicare Part D plans have the longest possible lead time.
- Effective communication of plan changes requires repeated notifications. Beneficiaries need frequent messages through multiple channels to prepare them for coming changes.
- Physicians and pharmacists must be informed about plan changes. In our study, providers reported that they had received little advance notice of changes although they were frequently required to explain the changes to their patients.
- Most transition problems take place in the first few months and then are resolved. However they can be quite disruptive when they occur. Interviewees reported that most problems were handled by staff both in the sponsoring company and the new PBM. CMS and participating drug plans should ensure adequate numbers of trained personnel are available to handle post-transition issues.
- Data transfers are generally well managed. Although interviewees reported that most transfers of enrollment and claims data were handled efficiently, more individualized services such as renewals of open prescriptions and prior authorizations were frequent sources of problems during the transition.

In this section, we will describe our study and present the findings. Next we will explore the implications of this work for implementation of the Medicare drug benefit. In the cases we examined in the study, the decision to change PBMs was made on a company wide basis. Managers from the company made the initial decision and oversaw the transition process for all affected employees. In the case of Medicare, once plans decide to enter or exit markets, individuals will make decisions on whether or not to enroll in a Part D plan and which plan to choose.

The law requires the Secretary to contract with a fallback plan to provide drug benefits in a region if no private plan offers a stand-alone drug plan. If one or more private drug plans enters a region served by a fallback plan, all enrollees in the fallback plan will have to enroll in one of the new plans. Conversely, if all private plans in a region leave and are replaced by a fallback plan, enrollment will have to be transferred to the fallback plan.

In general, it is difficult to predict the number of people who will make plan changes in any one area during any open season. Some of the issues with private plan transitions will not be relevant for Medicare, and some of the solutions will not be practical. Nevertheless, the study suggests a number of lessons that can be applied in the Medicare context.

The role of the pharmacy benefit manager

Medicare drug plans are likely to be managed by pharmacy benefit managers, either alone or in partnership with other entities like health plans, insurers, pharmacies, or pharmaceutical manufacturers. Currently, most drug coverage in the commercial market is managed for health plans or other purchasers by PBMs. They manage drug benefits for about 200 million Americans, processing about 70 percent of the more than 3 billion prescriptions dispensed annually and accounting for nearly 80 percent of all expenditures for prescription drugs (PCMA 2003, HPA 2003). PBMs began as claims processors, organizers of pharmacy networks, and mail-order pharmacies. They now perform a range of functions, including negotiating price discounts and rebates with pharmacies and pharmaceutical companies, conducting drug utilization reviews, and customizing formularies and drug benefit designs for their customers. Thus they play a major role in managing the cost and utilization of prescription drugs nationally.

Recent survey findings indicate that large employers are generally satisfied with the service and performance they receive from their PBMs (Drug Benefit Trends 2003). In results that parallel findings from 2002, 468 large employers (those with more than 2,500 employees) gave their PBMs an average rating of 7.7 out of 10 on their performance.⁷ Satisfaction was highest for administrative functions such as claim processing and maintaining pharmacy networks. It was lowest for services related to

managing cost and utilization of the drug benefit, including disease management programs, formulary management, and rebates.

Survey results also indicate that 66 percent of large employers were very likely to retain their current PBM at the end of the contract period, while 29 percent were unsure, and 5 percent were very unlikely to renew their contracts (Pharmacy Benefit Management Institute 2004). In part, the high likelihood of renewal may reflect the resources required in making a contracting change and the initial disruption that these changes may entail. A third party administrator noted that his company experienced significant increases in labor costs when one PBM they contracted with was acquired by another company (Princeton Consultants 2002). The company had to conduct biweekly meetings with its clients and the PBM to monitor the conversion process. Implementation problems (for example, the failure of maintenance drug prescription refills to transfer from the old plan to the new one) continued to tax the company's resources after the conversion was completed. The fact that PBMs receive their lowest ratings in the first year of a contract indicates that implementing a new drug plan is likely to result in some disruption of services.

Study design

In the absence of detailed information on the dynamics of PBM transitions, MedPAC contracted with researchers at NORC at the University of Chicago and Georgetown University to conduct a series of structured interviews with experts and make site visits with large employers who had recently experienced a change in the PBM that managed their prescription drug benefit (see text box). The visits included focus groups with active and retired employees and interviews with stakeholders. The purpose of the study was to examine their experiences to understand how Medicare may provide opportunities for continued competition among PBMs while minimizing disruption for its beneficiaries. Our findings are based on transitions at about eight different organizations that clearly cannot represent the full range of situations that have arisen across the country. Similarly, focus group participants at the organizations we visited may not reflect all attitudes present at each site. Sample size limits our ability to generalize from our results, but our findings do allow us to pinpoint some of the areas of vulnerability in the transition process as well as some of the most successful ways that companies have handled these issues.

What steps are involved in the transition process?

An organization may decide to change PBMs for several reasons including cost, service problems, restructuring of a health benefit plan, or implementation of a new clinical care management program. In our interviews, cost concerns were the most significant factor. In addition, organizations often made changes because they had service problems, including lack of responsiveness by the current vendor and errors in data management. Some changes were made by large organizations in concert with a reorganization of their health benefit program that included creation of a uniform drug benefit across the organization. By carving out the drug benefit, they sought to simplify management of drug spending and utilization.

Transition processes occur in three phases: planning the change; implementing the change, including communicating it to affected parties; and monitoring post transition problems. Early activities include designing the new benefit, selecting the vendor, working with the vendor on transition issues, and developing the communications strategy. Later activities focus on communicating with employees and retirees and ensuring that the data transfers occur and new benefit cards are issued. Finally, activities after the transition focus on problem solving for people who have service disruptions or do not understand the new benefits.

In this section, we describe how transitions are managed based on findings from both the site visits and the expert interviews. Key questions addressed include:

- What were the steps taken to initiate and implement a transition from one PBM to another?
- Were any criteria used in the selection process for a new PBM to anticipate or limit disruptions?
- What time frame was involved in implementing the change?
- What educational efforts were conducted and how did they vary between active employees and retirees?
- What processes were most likely to be problematic? How were they handled?

Components of the transition study design

Expert interviews

We conducted 10 phone interviews with experts with a wide variety of experiences in drug benefit management and pharmacy issues. Experts included representatives from large pharmacy benefit managers (PBMs), consultants with experience on PBM transitions, representatives from pharmacy trade associations, representatives from health plans and other large organizations that had recently changed PBMs. Individuals were chosen for both their expertise and varying perspectives. We asked them to comment on strategies for planning and managing a PBM transition. Additional questions focused on methods for communicating the transition to members and other key stakeholders. We also asked interviewees to identify best practices and lessons learned.

Site visits

The study targeted two large organizations that had recently undergone PBM transitions. The first site was a large private company. This organization made a transition from one large PBM to another large PBM about two months prior to the site visit. Nearly 25,000 employees and retirees (about three-fourths of its population) were affected. Concurrent with the transition, the organization made significant changes to the plan design, including increased copays, mandatory generic substitution, and mandatory mail-order use for maintenance drugs. The second site was a large public organization. This organization insures approximately 75,000 employees in 5 separate health plans. Approximately one year prior to the site visit, the organization carved out the drug benefits from its five health plans to form one PBM contract. The leadership of this organization also made significant plan design changes simultaneously with the PBM transition.

Focus groups

Each one-day site visit included a series of in-person interviews with key stakeholders in the transition process, a focus group with active employees, and a focus group with retirees. Interviewees were identified in consultation with each organization's benefits office and through background research on each site. The interviews were conducted by three-person teams using structured protocols tailored to each interviewee's perspective as either an employer or group purchaser, a union or employee representative, or a pharmacist or physician.

Each of the focus groups included 8 to 15 participants. A convenience sample of participants was used for both the active and retiree focus groups at each site. Participants responded to advertisements for the focus groups posted in employee areas and newsletters or announcements that were distributed at retiree meetings. Topics discussed at the focus groups included participants' level of satisfaction with both the current and previous drug plan, experiences during the transition, and opinions on the way the organization handled the benefits transition. We recognize the potential bias of using a nonrepresentative sample of focus group respondents, and we understand that our findings may not represent the full range of attitudes present within each site's affected population. Those with negative experiences may have been more motivated to attend the sessions. However, personal experiences discussed during the focus groups provide constructive examples of the potential effects PBM transitions can have on beneficiaries. Furthermore, many participants shared neutral or positive feelings and experiences regarding the transitions. ■

Transition planning

Transition planning and implementation requires several months of effort. Interviewees agreed that the planning should start at least six months before the transition date, though eight to nine months was considered preferable.

One health plan reported that circumstances forced it to implement a new drug plan within 90 days. Although the transition was accomplished, the process was exceedingly difficult for all parties. Following the change, the plan experienced an upsurge in complaints from participants,

with call volume in the first month following the change equaling nearly 60 percent of total calls for the previous year.

Changing vendors to manage a pharmacy benefit is a time consuming process. Internal meetings are required to determine the goals of the change and the relative priority accorded to each goal. These meetings will culminate in the preparation of a request for proposal from potential vendors and a review of the submitted proposals. After a new vendor is chosen, the transition process begins. This process includes developing and testing a system to transfer enrollment and drug data from the old vendor to the new one. Procedures must be developed to communicate changes to affected individuals. Employees will have to receive enrollment cards from the new PBM before the start of the contract to avoid disruption in service. Systems must also be in place at pharmacies to accept the cards and access up-to-date enrollment, formulary, and copay information.

One factor complicating analysis of the transition process is that organizations often change their drug benefit design at the same time as they change PBMs. Interviewees were divided on whether it is preferable to make benefit design changes simultaneously with the switch to a new PBM. Some benefits managers and consultants said making many changes at once avoided having several periods of disruption. Employees and retirees would already be aware of changes, and personnel would be in place to respond to questions and problems. Moreover, because controlling health care costs often motivated the decision to switch, organizations wanted the savings from design changes in addition to those from changing PBMs. Others suggested that making too many changes at once was far too disruptive, and adjustments should be made over the course of several years. One consultant estimated that, in about half of the cases, plans also change benefits.

Data transfers

A core transition activity is the transfer of enrollment and prescription data from one PBM to another. Consultants assisting in transitions, benefits personnel, and PBM staff all said that systems-level data transfers are much more streamlined than they were several years ago, primarily because the large PBMs have standardized their data codes. However, a consultant who works with a pharmacy trade association said that many disruptions with data transfers still occur, along with “lots of surprises that

require pharmacist involvement.” All respondents agreed that data transfers should occur as early as possible to allow time for error checking and testing of the data transfer. Timeliness is particularly important for the transfer of eligibility information and of mail-order prescriptions that still have refills available. The failure to transfer eligibility information correctly will mean that coverage for an individual’s prescription will be rejected, while an error in transferring an open refill makes it illegal for the mail-order pharmacy to dispense the needed drug without a new prescription from the doctor. Once testing of the data transfer has been completed, the final data transfer must occur as close to the actual transition date as possible to minimize errors. The failure of a data transfer to occur for one organization we interviewed caused major difficulties. Enrollees were unable to get prescriptions filled until the eligibility files for the new PBM were updated.

An additional advantage to early transfer is that, given time, the incoming PBM can target mailings to people who will be affected by changes to formularies, copay amounts, or prior authorization requirements; the employer cannot do targeted mailings for privacy reasons.

Pharmacy benefit managers’ relationships

Good relationships with old and new vendors are critical. Generally, interviewees said that the old PBMs had been helpful and the new PBMs had been responsive to both the organization and the employees and retirees. They were also well prepared for the increased volume of inquiries immediately following the transition. Benefits managers from two organizations said one reason for their smooth transition was that the account manager from the incoming PBM was very effective. However, in one organization the incoming PBM was concurrently managing several other transitions, which resulted in greater disruption and less responsiveness. Representatives from two organizations expressed dissatisfaction with their outgoing PBMs because they were not helpful. In one case, the PBM did not transfer any data or provide any assistance.

Post-transition issues

Typically, the post-transition adjustment period lasted two to four months depending on the extent of changes in key procedures, particularly those related to prior authorization. After that time, most transition problems were resolved, although some problems persisted beyond

that period. Those first several months could be very difficult. Several organizations reported extremely high call volumes initially. After three to six months, any remaining issues tended to be associated with benefits design. One consultant said that some organizations “grandfathered” the formularies and prior authorization requirements of the outgoing PBM for the first two to three months of the transition. This practice could minimize the disruption but also reduce the expected savings.

How did organizations communicate changes to plan participants?

Study participants agreed that extensive communication is essential to a smooth transition. People stressed that different modes of communication should be used, including mail, e-mail, internet materials, personal meetings, and, if necessary, one-on-one assistance to answer specific questions. In particular, organizations cannot rely on e-mail and internet access alone for retirees and for employees who do not work in office settings. Moreover, the messages communicated should be clear and concise. Interviewees who were responsible for the communication believed that they did a good job with this. However, some focus group attendees were less positive and did not really understand the changes until they tried to fill a prescription. Study participants consistently stressed the need for frequent and varied communication because of the complexity of the issues and the fact that people do not always read their mail or e-mail. Even with multiple mailings, e-mails, meetings, and notices, many employees and retirees did not actually assimilate the changes until they were filling a prescription. One physician whom we interviewed for our formulary study also noted that it was hard to keep track of all of the communications she received from all of the health plans with whom she participated.

Interviewees stressed that planning the communications strategy should begin early in the transition planning. One organization held meetings about five months prior to the transition to make the business case for the change. In these meetings and in subsequent mailings, senior management and benefits personnel explained that increasing pharmaceutical costs were difficult for the company to absorb and were unsustainable over time. Employees and retirees were told that, in order to continue to provide jobs and benefits in the long term, the organization would have to make some changes. Although

this early communication was unusual, benefits personnel at that company believed that this was an effective strategy for them. A representative of an organization of retired public employees emphasized that communication should begin much earlier for retirees.

There was no consensus on when to start informing employees about specific changes regarding formularies, copays, and the new mail-order systems. Most organizations held meetings and sent out written materials three to four months before the transition date. Some waited until open enrollment, usually two months before the transition, because they believed that it was only then that employees really began focusing on their health benefit options.

The incoming PBM also corresponded with employees and retirees before the transition. The PBM usually mailed materials several months before the transition, often at the time of the normal open season for benefit changes. In addition, incoming PBMs sometimes made their website and 800-number accessible several weeks early. In one instance, some employees did not receive any information until several weeks after the transition, creating many problems for people trying to figure out new formularies and prior authorization requirements.

When possible, targeted mailings were sent to people who would be affected by specific changes, such as those using drugs that would require prior authorization or that would be on a different tier for cost-sharing purposes. However, this kind of individualized communication was sometimes problematic because privacy rules precluded the employer from having this information. The incoming PBM in these cases had to receive the data from the old PBM in time to prepare mailings.

More often, we were told that mailings were sent to everyone, highlighting specific areas of attention such as a listing of all drugs that would require prior authorization. Such a mailing would include general instructions and a number to call for assistance. We were told by one health plan representative that such general mailings can cause confusion and distress to some enrollees who would not actually be affected by the changes. For example, an individual who had already received prior authorization for a particular medication might receive a general mailing indicating that the drug would not be on the formulary.

Interviewees reported that they made some adjustments when communicating with retirees. Several people reported that they used a larger font for retiree mailings. They did not rely too heavily on the Internet because retirees were less likely to be online than current employees, although this was changing as more seniors were becoming familiar with the Internet.

Generally, interviewees said that messages should be simple, focusing on what would change and what people should expect. The information should provide details about what really matters to people, for example, copay changes and new prior authorization requirements.

Communicating with physicians and pharmacists

Interviewees said it was rare for organizations or PBMs to communicate transitions and benefit changes to pharmacists and physicians. On the other hand, both physicians and pharmacists reported that it is not unusual for employees and retirees to first learn of changes to their drug benefits when they were obtaining a prescription or filling it. Lack of notification put the providers in the position of trying to resolve their patients' problems without adequate information. When they had advance knowledge, they acted as a trusted source of information to employees and retirees.

Study participants emphasized the importance of communicating with the pharmacists who play an important role in these transitions. Pharmacists stressed that information should be sent directly to local pharmacies as well as to the corporate headquarters of the major pharmacy chains. One representative from a drugstore trade association noted that pharmacists spend much more time counseling people following a transition or change to benefits because, despite having received information, people do not always understand the changes. These lengthy consultations can be burdensome to pharmacists. Pharmacies are also busier prior to a switch because people often get refills in advance to avoid increased copays and formulary changes. With advance notice—at least 30 days in advance—pharmacies might be able to schedule additional pharmacists or assistants. Interviewees added that information provided to them should include a description of the new benefits structure, formularies, and copay tiers and amounts. Pharmacists should also receive a copy of the new identification card.

Similarly, if doctors are aware of a change, they can schedule longer appointments if they anticipate that patients will need help understanding the changes. Some physicians reported that they first received notice of changes to their patients' formulary or benefit design following a phone call from a pharmacist. In these instances, a patient is likely to be waiting at the pharmacy while the pharmacist attempts to contact the physician and explain that the prescription cannot be filled. This situation creates disruptions for the physician, pharmacist, and the enrollee. Interviewees recommended that information for physicians be sent to office staff.

What problems arise during transitions?

Most transition problems can be classified into two types: those related to the transition and those related to changes in benefits design. Examples of transition disruptions included improper loading of copay information, which led to inaccurate charges at the retail counter; lack of awareness of which drugs were on the formulary on the part of physicians, pharmacists, and employees, which caused confusion or delays when a prescription was rejected; and refill data not transferring, which required the individual to obtain a new prescription from the doctor. The majority of transition problems were resolved within the first several months. However, these disruptions were stressful and time consuming to resolve for both the enrollee, the new PBM, and organization management.

Transfer of prior authorizations was one of the most problematic areas described in our study. Drug plans may require prior authorizations for drugs that are not on the plan formulary but are medically necessary for a particular enrollee, drugs that are particularly expensive, or drugs that are subject to overuse or abuse. The drugs requiring prior authorization may vary from plan to plan. In addition, plans often have different prior authorization requirements, making it administratively difficult for pharmacists to keep track of these procedures. However, even when both plans required prior authorization for the same drug, most plans had a difficult time transferring the information from the old PBM to the new one. A number of interviewees reported that this problem resulted in multiple physician visits simply to rewrite prescriptions.

Interviewees cited problems with mail-order procedures. One common problem occurred when individuals mailed in refill requests to their old PBM just before the transition date and the prescriptions were never transferred to the new PBM.

Many other challenges were related to the new benefits design. People often did not understand the new formularies, prior authorization requirements, or mandatory mail-order, and they disliked the higher copays that often accompanied these changes. These problems likely would have arisen even if an organization did not change PBMs.

What do we know about the factors that ensure a smooth transition from one drug plan to another?

Although disruptions will occur even with the best planned, well-managed transition, interviewees mentioned several activities that could ease the change. All agreed that good communication is essential, that people need to be told in clear and concise language what to expect and what they need to do to minimize disruptions. They also need to be informed multiple times and via different methods, such as mail, meetings, and websites. Organizations should not rely too much on information provided by any one mode of communication.

The presence of a few key people to manage the transition and oversee the technical aspects and communication strategies is essential. These people are also extremely important in the initial months post-transition because they frequently help resolve disruptions. Interviewees emphasized the central roles of the benefits staff as well as a strong implementation team from the incoming PBM. Moreover, knowledgeable staff are more likely to anticipate problems and develop solutions to address them. For example, one organization anticipated that prior authorization requirements could be a difficult adjustment for people. In order to minimize the problems associated with this change, they included the list of drugs that would require prior authorization in several newsletters and mailings. As a result, they had few questions and problems with this aspect of the benefit change.

Several benefits personnel stressed the importance of maintaining good relationships with the outgoing vendors. Good relationships make data transfers go much more smoothly. A representative from one large organization noted that its outgoing PBM refused to transfer any patient

files to the new vendor. As a result, the new PBM could not target any communication to enrollees in advance. He suggested that contracts should include language stating the obligations of the outgoing PBM in the event it loses the contract in the future.

What are the implications of this study for implementation of the Medicare prescription drug benefit?

In this final section, we draw some conclusions from the experiences we examined that should be taken into account as CMS develops regulations for the drug benefit. Our findings are based on situations in which employers or health plans decided to use a new PBM to manage drug benefits. In these situations, the organizations took responsibility for managing the transition to the new PBM. In contrast, private drug plans will compete for individual members under the Medicare drug benefit. Most changes will be made on an individual level without needing large data transfers of the type studied here.⁸ Nevertheless, we believe that certain strategies could encourage smooth transitions for beneficiaries enrolled in Part D who switch between private drug plans, whether these switches result from plans' decisions to withdraw from a particular market, fallback plans entering or exiting markets, or beneficiaries selecting a different plan among a set of competitors.

Regulations that help ensure a smooth transition for beneficiaries between drug plans are important to promote continuing competition between plans. Plans may be unwilling to enter new markets if they find establishing plans and handling post-transition problems to be too costly. Similarly, if beneficiaries find the transition process too burdensome, they may be unwilling to change plans even in the face of higher premiums or lower quality in their current plan. Under these conditions, the benefits of competition might not be realized.

- CMS should ensure that drug plans have sufficient time to implement transition strategies. When transitions ran smoothly for the organizations we studied, a careful planning process over at least six months, extensive communication, and attention to special issues were important factors. The careful oversight by the staff of a corporate benefits office, together with attention to operational details by the incoming PBM, was critical to minimizing problems. Even then, employees and retirees could point to an

array of transition problems. In the Medicare context, less transition time will be available to the new plans. Some drug plans will be required to submit bids to CMS by June 2005, and the agency should try to maximize the available time for plan implementation by responding quickly to plan proposals and providing information to beneficiaries in a timely manner.

- Because of the abbreviated time frame, coordination of data between the old and the new drug plans will be of critical importance. In private sector transitions, new PBMs rarely obtain a complete medication history from the old PBM. This may be even less likely under Part D, unless Medicare requires it. The result may be unnecessary or duplicated efforts to address special situations that had been resolved with the old PBM and diminished ability for the incoming PBM to detect dangerous drug interactions. Plans providing drug benefits to Medicare beneficiaries should report how they will handle enrollment and data transfers for new beneficiaries and how they will transfer data for beneficiaries who leave their plans. These processes should be specified in contracts with CMS.
- Drug plans should ensure that they have sufficient staff available to handle the post-transition problems of beneficiaries. In the private sector, trained staff guide the affected individuals through the transition process. These people take care of the bulk transfer of records and the overall communications, and provide a process for dealing with individual problems. In Medicare transitions, all the shifts will be at the individual level. If their medical records do not transfer to the new drug plan, beneficiaries will have to obtain new mail-order prescriptions or new prior authorizations for maintenance drugs. All Medicare drug plans should have the capacity to provide information on these processes in advance of the transition date. But since it will be difficult, if not impossible to target messages based on individual needs, plans also should be well prepared with effective call-in resources (and dedicated staff) to address individual problems in the days, weeks, and even months immediately following the transition.

- Medicare and participating plans must develop a detailed communication strategy to inform beneficiaries about their options. All of our study participants emphasized the importance of frequent, simple messages repeated through different modes of communication. Messages must be easily understood because the Medicare population is older, frailer, and more likely to have cognitive impairments than the people affected by the transitions we examined.

Transition issues will be far more individualized for Medicare, since each individual, rather than a single employer, will have to choose his or her own plan. In addition, Medicare will provide information to compare plans; choice among plans was not a feature of private sector transitions. Communication will be resource intensive if the withdrawal of a large plan requires many beneficiaries to select new plans or if large numbers of beneficiaries choose new drug plans in a particular open season. CMS should consider providing information to family members or other designated individuals for those beneficiaries who request additional assistance.

- Plans should also develop strategies to ensure that pharmacists and physicians are prepared for benefit changes for their patients following open seasons. Even more so than in private sector transitions, pharmacists and physicians may bear a significant part of the education burden as beneficiaries transition among Medicare plans. They are at the front line when beneficiaries do not understand the differences between plans. And they will have additional demands for medication changes to comply with formulary, prior authorization, and other requirements. Pharmacists will also need to know all of the sources of coverage that a beneficiary may have in order to bill properly. Although the new drug plan will be the first source of information in these situations, many beneficiaries are likely to depend upon help supplied by their physician or pharmacist. ■

Glossary of formulary terms

Drug utilization review (DUR)—a program, implemented by payers, for assessing data on drug use and prescribing patterns against explicit criteria (Cook et al. 2000).

Drug Efficacy Study Implementation (DESI) drugs—a group of drugs of insufficient efficacy based on decisions resulting from a review by the National Academy of Sciences and the Food and Drug Administration (FDA) pursuant to federal law. These drugs are not reimbursable by U.S. government programs (IOM 2000).

Formulary—a continually revised list of preferred drugs that are considered by a health care organization to be the most useful in caring for the patients it serves (IOM 2000).

Open or unrestricted formulary—a comprehensive listing of medications typically including almost every commercially available product in each therapeutic class. Payers provide coverage for these medications since there are no restrictions (IOM 2000).

Closed formulary—an exclusive list of specific drugs limited to only some of the commercially available products in each therapeutic class. Drugs that do not appear on the list of approved products (nonformulary drugs) are not covered by the health plan, pharmacy benefit manager, or employer, and patients are liable for the drugs' full retail prices, unless they obtain prior approvals or nonformulary exceptions (IOM 2000).

Partially/selectively closed formulary—a formulary hybrid that limits drug choices within certain therapeutic classes and offers unlimited choices within other drug classes. Such formularies direct prescribers to preferred agents within therapeutic classes, which may be included in treatment protocols or clinical guidelines. In some cases, entire categories, such as drugs used solely for cosmetic purposes, may be closed to prevent payment for those drugs that are excluded from coverage (IOM 2000).

Formulary system—the policies and procedures by which a health care organization maintains and updates its formulary for coverage. It includes policies and procedures for implementing the formulary, such as a nonformulary exceptions process, if applicable (AMCP 2000a).

Generic drug—a drug containing the same amount of active ingredient in the same dosage form as its brand-name counterpart. A generic drug has similar bioavailability (i.e., the same amount of medication is delivered to the body over the same time period) but may differ in characteristics such as color and shape (AAA 2000).

Generic substitution—substitution of a generically equivalent drug for a multi-source brand drug. In many cases, this can be done without the prescribing physician's approval (AAA 2000).

Incentive-based formulary—a formulary that contains different cost sharing for preferred and nonpreferred brand name drugs, and generic drugs, thereby giving patients an financial incentive to request preferred or generic medications (AAA 2003).

Medicaid preferred drug list—list of medications that Medicaid enrollees may receive without first obtaining prior authorization from the state (Bernasek et al. 2004).

Nonformulary exceptions process—process by which a drug not listed on a formulary may be covered or a nonpreferred drug may be obtained at a lower level of enrollee cost sharing. Nonformulary exceptions can require the physician to establish medical necessity for the drug's use (Cook et al. 2000).

Off-label use—the use of prescription drugs for conditions not approved by the FDA (IOM 2000).

Pharmacy and therapeutics (P&T) committee—an advisory committee, usually with substantial representation by physicians and pharmacists, that is responsible for developing, managing, updating, and administering the drug formulary system (Goldberg 1997).

Continued on page 26

Glossary of formulary terms (*continued*)

Pharmacy benefit managers (PBMs)—companies that, on behalf of health plans, process pharmaceutical claims, negotiate prices with retail pharmacies and drug manufacturers, and manage enrollee drug use (CBO 2002).

Prior authorization or approval—a procedure that requires physicians to obtain permission to prescribe a specified drug before the drug is covered (Cook et al. 2000).

Step therapy protocol—a treatment design that recommends beginning a trial of drug therapy for a medical condition with one particular drug or class of drugs before proceeding to other drugs or drug classes (IOM 2000).

Tiered cost sharing—a pharmacy benefit design that financially rewards beneficiaries for using generic and formulary drugs by requiring progressively higher levels of cost sharing (fixed-dollar copays or coinsurance levels) for brand name and nonformulary drugs (AMCP 2000a).

Therapeutic classification system—a grouping of drug products based on various criteria, which may include similarity of chemical structure, clinical

indications, pharmacology, and therapeutic activity (IOM 2000).

Therapeutic or drug class—a group of drugs that have similar chemical, pharmacological, and/or therapeutic properties (IOM 2000).

Open class—a drug class that contains numerous drug products, all of which are covered whether listed or not (IOM 2000).

Closed class—a drug class that limits coverage to only listed drugs (IOM 2000).

Therapeutic equivalence—property of drugs differing in composition or in their basic drug entity, but of the same pharmacological and/or therapeutic class, that are considered to have very similar pharmacological and therapeutic activities and adverse reaction profiles when administered to patients in clinically equivalent doses (IOM 2000).

Therapeutic interchange—authorized exchange of various therapeutically equivalent drugs by pharmacists through: a) previously established written guidelines or protocols within a formulary system, or b) prescriber permission at the time of exchange (IOM 2000). ■

Endnotes

- 1 If an open formulary has tiered cost sharing, enrollees have financial incentives to use preferred-tier drugs.
- 2 Beta-blockers are formally known as beta-andrenergic blocking agents and work by affecting the response to nerve impulses in certain parts of the body, decreasing the heart's need for blood and oxygen, and therefore its workload.
- 3 USP sets and publishes standards and other information for prescription drugs, dietary supplements, and other health care products. USP assisted the VHA with developing its formulary's classification system.
- 4 Medicare Part D excludes drugs for which payment is available under Parts A and B and those in therapeutic categories that may be excluded under Medicaid, except for smoking-cessation agents.
- 5 Plans can change their formulary classification system midyear if the Secretary makes an exception to account for new therapeutic uses and newly approved covered drugs.
- 6 To address this concern, Medicare has recently begun reimbursing for the medical costs incurred by elderly Medicare patients in clinical trial research.
- 7 This survey does not reflect the experiences of companies that have chosen to manage drug benefits internally and have replaced PBMs with claims processors.
- 8 If a fallback plan is offered in a geographic region and then replaced by a single private drug plan, or if a private drug plan exits a market and is replaced by a fallback plan, the process will be similar to the replacement of one PBM by another in the private market.

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CHAPTER

2

**The Medicare Modernization
Act and chronic
care improvement**

The Medicare Modernization Act and chronic care improvement

There are few incentives and little infrastructure to support the coordination of care for beneficiaries in fee-for-service payment systems. In recent legislation, the Congress established the Chronic Care Improvement Program to address these issues in the traditional Medicare fee-for-service program. The program targets beneficiaries with diabetes, congestive heart failure, and chronic obstructive pulmonary disease. It seeks to improve coordination of care across health care settings and among service providers, educate patients about how to care for themselves, and promote the use of evidence-based treatment guidelines. The program will test different models of care coordination and whether it reduces program spending. The Commission has expressed a strong interest in assuring physician involvement in the initiative and in promoting coordination of care for Medicare beneficiaries to improve quality.

In this chapter

- What types of services are envisioned in a chronic care improvement program?
- What are the existing models for chronic care coordination?
- Who will receive chronic care improvement services?
- What is the role of contractors?
- Evaluating the effectiveness of chronic care improvement programs
- Chronic kidney disease and chronic care improvement programs: A case study

Most beneficiaries have one or more chronic conditions, and too often their care is fragmented and poorly coordinated. Under fee-for-service (FFS) Medicare, they may see multiple physicians, frequently without any single provider responsible for managing their care. Moreover, a small proportion of beneficiaries accounts for a disproportionate share of program spending. These individuals often require repeated costly hospitalizations—some of which might be avoided if care were better coordinated.

Recognizing the need for better care coordination in FFS Medicare, the Congress established the Chronic Care Improvement Program (CCIP) in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The CCIP will begin by December 2004.¹ As distinct from the practice of medicine, the program is geared towards ensuring ongoing coordinated care across health care settings and among service providers, teaching patients how best to care for themselves, and promoting the use of evidence-based treatment guidelines. CMS will initially target two groups of FFS beneficiaries: those with congestive heart failure (CHF) and/or complex diabetes; and those with chronic obstructive pulmonary disease (COPD). Within each group, targeting will be limited to those with moderate to high risk-adjustment scores. Organizations will bid to manage care in specific regions with particular emphasis on areas that have a high prevalence of targeted conditions or poor Medicare quality rankings. Each program will operate under a randomized controlled trial design that requires at least 30,000 beneficiaries with the targeted condition to be split between treatment and control groups. This pilot program may be extended to cover more beneficiaries in a few years if policymakers conclude that care coordination has demonstrated that it can reduce growth in Medicare spending and improve quality.

The Commission strongly supports the goal of this program. Improving coordination of care for Medicare beneficiaries is central to MedPAC's quality agenda and has the potential to reduce program spending, especially since contractors will be at risk for meeting performance goals. However, implementation of the legislation will be challenging. The law requires contractors to assume risk for achieving savings and quality targets, coordinate care for a large identified population, manage all enrollees' chronic conditions, and, if needed, provide more intensive case management services to the highest-risk individuals.

The program will be evaluated on the basis of savings targets, quality indicators, and satisfaction measures. CMS requires contractors to guarantee at least 5 percent savings over three years. The agency does not indicate how quality and satisfaction factors will affect fees—bidders will propose adjustments to fees if they do not achieve performance targets, which are subject to negotiation with CMS. Improvements in quality will be an important factor in evaluating the success of the program.

In order for the CCIP to be successful, physician groups and disease management organizations will need to collaborate. It will be difficult for any single type of organization to meet all program goals. Beneficiaries, particularly those with multiple chronic conditions, rely on their physicians to guide and manage their care. However, it is unlikely that many physician groups will be able to participate in the program on their own. Physician groups generally do not accept performance risk and are unlikely to have the resources to coordinate care for populations of the size targeted by CMS. Disease management organizations have more experience educating large populations of patients about their conditions, often have more limited interactions with physicians, and generally depend upon external case managers for more complex patients. They also work primarily with people under age 65. Under the CCIP, contractors will have to coordinate care for a more medically complex group than is typically found among non-Medicare populations. For all of these reasons, we believe that CMS should encourage a partnership approach for the CCIP.

The Congress determined the overall design of the CCIP (see text box opposite), but left many of the details of individual programs to negotiations between CMS and participating organizations. Programs offered under the CCIP can be provided by disease management organizations, insurers, physician group practices, integrated delivery systems, or consortia of entities that meet CMS requirements. Contractors will bid to provide services to beneficiaries with the targeted conditions in a specific geographic area. Their fees, or a portion of them, will be withheld or returned if their programs do not meet contracted goals, but the organizations will not be responsible for the medical costs of beneficiaries. The Congress intended for the CCIP to be budget neutral over the long run, but provided for some initial start-up costs. For fiscal years 2004 through 2006, the MMA specifies that aggregate expenditures for payments to chronic care

improvement organizations net of program savings cannot exceed \$100 million. Payments to organizations who win CCIP contracts could total more than this amount, but the Congress anticipated that either the program would reduce other types of Medicare spending or that CMS would recoup contractor fees. Some analysts argue that the

conditions targeted in the CCIP lend themselves to even greater savings than CMS requires. However, given the complexity of the Medicare population, it remains to be seen the extent to which savings can be gained and quality improved within the program's three-year period.

The Medicare Modernization Act and chronic care improvement

Section 721 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) calls for voluntary chronic care improvement programs for fee-for-service (FFS) beneficiaries that focus on people with one or more chronic conditions as specified by CMS. The programs will be implemented in two phases. In the first phase, initial contracts will be awarded in areas where, in the aggregate, 10 percent of Medicare beneficiaries live. If independent evaluations find the first stage successful, additional contracts would cover other geographic regions or operate nationally. At least one contract must be awarded by December 2004; contracts may last up to three years.

According to the MMA, each program must:

- have a process to screen beneficiaries for comorbidities aside from the targeted condition;
- provide each program participant with a care management plan;
- carry out the care management plan and other chronic care improvement activities;
- guide participants in managing their health, including all comorbidities, relevant health care services, and pharmaceutical needs;
- use decision support tools such as evidence-based practice guidelines;
- develop a clinical information database to enable tracking and monitoring of each participant across practice settings and to evaluate each participant's outcomes; and
- report health care quality, cost, and outcomes for the program.

The care management plan, individualized for each enrollee, should include a point of contact for participants and providers and, if suitable, develop a program that includes nutritional information; teaches enrollees and their families how to manage their condition, using monitoring technologies as appropriate; provides information about treatment options including end-of-life care; and communicates relevant clinical information to the physicians who are treating program enrollees.

Overall, Medicare program spending for participants, including fees paid to contractors, cannot exceed what would have been spent in the absence of the program. For the short term, however, the Congress provided for initial start-up costs by authorizing \$100 million in aggregate expenditures to contractors net of any program savings over the first three years. The initial stage of the CCIP will use a randomized controlled trial design, and independent contractors will evaluate programs on improvement to clinical quality of care, beneficiary and provider satisfaction, and achievement of target savings. However, the MMA does not specify the relative importance of each of these factors. Contracts will put administrative fees at risk if programs do not achieve their performance targets.

CMS will identify potential participants within a geographic region proposed by a contractor and will randomly assign beneficiaries to treatment or control groups. It will also notify targeted beneficiaries about the program and encourage them to participate. CMS's request for proposals states that 30,000 or more people will be split between treatment and control groups.

If contracts awarded during the initial phase meet standards for quality improvement, beneficiary satisfaction, and savings targets, the Secretary may expand programs to other geographic areas without

(continued on next page)

The Medicare Modernization Act and chronic care improvement (*continued*)

further Congressional authorization. The broader expansion of the program could take place two to three years following the start of the initial phase.

The MMA includes additional provisions that touch on chronic care. These include a quality improvement program for beneficiaries enrolled in Medicare Advantage plans and a requirement for sponsors of Medicare Part D prescription drug plans to establish drug therapy management programs for beneficiaries with multiple chronic conditions requiring several

medications. Another section of the MMA initiates a pay-for-performance demonstration program with physicians to improve care management for FFS beneficiaries with chronic conditions. Finally, the law requires the Secretary to develop a plan to improve quality of care and reduce costs for chronically ill beneficiaries. The Secretary must plan to integrate existing data sets, identify data needs, develop a capacity to store and process Medicare data quickly, and develop a research agenda using the data. ■

In this chapter, we summarize the provisions of the CCIP and discuss the issues that CMS and its contractors will need to address when implementing the program. Few could deny the need for greater care coordination and improvements in quality, but questions remain about how to attain these goals. The way in which the CCIP is implemented—particularly in its initial years—will determine its effectiveness and broader applicability. We begin by discussing the concept of care coordination and the approaches taken by organizations that provide such services today. We also identify outstanding issues that must be addressed as the CCIP is implemented, such as:

- Who will receive services?
- What is the role of contractors?
- What services will contractors provide?
- How will contractors be paid?
- How will contractors and CMS coordinate responsibilities?
- Can contractors meet the special needs of Medicare beneficiaries?
- How will CMS evaluate program effectiveness?

In addressing these issues, we highlight what we have learned from interviews with CMS officials, disease management organizations, insurers, physician groups, medical device manufacturers, academics, and other stakeholders. Finally, we include a case study of chronic

kidney disease (CKD) to examine the potential for better care coordination to improve quality of care or to result in savings. We selected CKD because of the Commission's longstanding interest in improving the quality of renal care.

What types of services are envisioned in a chronic care improvement program?

Programs to improve care for individuals with chronic conditions can take a number of different forms. The goals of all programs are to improve health, coordinate care among providers, improve patients' compliance with their treatment regimens, and encourage provider adherence to evidence-based treatment guidelines. These programs attempt to contain or reduce health care spending for patients who incur higher costs, on average, than other patients.

The two most typical approaches to coordinating care for people with chronic conditions are disease management and intensive case management. These approaches tend to provide different services, summarized in Table 2-1. Typically, health plans combine the disease management approach with intensive case management as required for high-risk individuals who have multiple chronic conditions and more complex situations.

- Disease management services are generally provided on a broader scale than case management services. They teach patients to help manage their own

**TABLE
2-1**

Differences between disease management and case management

Program element	Disease management	Case management
Target population	People diagnosed with a specific disease	People at high risk for costly, adverse medical events and poor health outcomes
Reliance on evidence-based treatment guidelines	High	Low to medium
Reliance on protocols and standardized approaches	High	Low
Use of nonmedical social support services	Low	High

Source: Adapted from Chen et al. 2000 and Crippen 2002.

conditions and help to coordinate medical care (see text box). Programs typically use certain conditions to target individuals or populations for interventions. Currently, most disease management programs target individuals with specific conditions but then take responsibility for managing all the additional chronic conditions of the targeted individuals. Program interventions aim to ensure patient compliance with evidence-based treatment guidelines.

- Generally, case management services involve fewer people than disease management. These services are intensive and individualized, including coordination of medical care and social support services for a group of high-risk individuals. Support services provided to patients may include transportation, meals, homemaker or chore services, and recreational therapy. Case management focuses less upon patient adherence to medical guidelines.

What are disease management services?

Typically, the goal of services provided by disease management organizations is to educate patients in management of their own chronic diseases by making them more self-reliant and knowledgeable about their condition. Although companies use different models, they frequently use services such as those below.

- Nurses at call centers periodically contact enrollees and assess their health status, collect data about their care that may not be obtainable from claims data like laboratory test results, explain the meaning of these results, remind them to seek preventive services, and answer their questions. The nurses provide patients with information about their conditions and how best to manage them. Enrollees may also call in if they have questions.
- Call centers also encourage patients to share concerns that may be unrelated to their health conditions. For example, one interviewee reported that an enrollee's concern with the health of her spouse may prevent her from managing her own medical condition. By acting as an interested and informed listener, the nurse may help alleviate the patient's concern and allow her to comply with physician instructions about her own care. Many programs provide written information and reminder notices to patients about the need for physician visits or preventive services.
- Enrollees may use monitoring devices so that, for example, they can track their weight and blood pressure between doctor appointments.
- Programs supply information to help patients make decisions about their treatment options. The program might explain options open to patients and provide them with lists of questions to ask their physicians. In some cases, this includes providing information on end-of-life care. ■

Since it will focus on large populations, the CCIP emphasizes those services typically offered by disease management organizations. But because of the higher prevalence of multiple chronic conditions and other complications, more Medicare beneficiaries are likely to require case management services than beneficiaries in non-Medicare populations. As a result, any organization that operates as a contractor for the CCIP will need to provide access to both types of services.

What are the existing models for chronic care coordination?

The MMA provides the Secretary with broad authority to contract with different types of organizations—disease management companies, health insurers, integrated delivery systems, physician group practices, or consortia of these groups—for different approaches to chronic care management. All of these entities have already established programs designed to enhance care coordination and patient compliance with physician regimens using a variety of models.

In this section we look at the varied role of physicians in current care coordination models. We focus on two approaches at the opposite end of the spectrum: one in which programs are run by or for physicians, and another in which most or all communication between disease management organizations and physicians is mediated through the patient. In our interviews with providers and purchasers of these services, we found little agreement on the way these approaches affect program outcomes.

No matter what entity provides chronic care improvement services, the Commission believes that the role of the physician is critical. Most Medicare beneficiaries already have established and valued relationships with a regular provider. According to the 2002 Consumer Assessment of Health Plans Survey, nearly 90 percent of FFS beneficiaries have a regular doctor or nurse and almost 80 percent have seen their regular practitioner for two or more years. Sixty percent reported seeing their primary provider (usually a doctor) for over five years (MedPAC 2004).

Having a physician play a central role in coordinating a patient's entire plan of care is of particular importance to the Medicare population. Medicare beneficiaries are likely

to have more complex medical conditions than the general population. A physician who knows the history of a patient and has an established relationship with him or her, will have the greatest capacity to tailor a care management plan to fit the needs of the individual. Because of this, some interviewees noted that beneficiaries were unlikely to participate in care coordination programs without encouragement from their physicians.

But some analysts contend that there is room for other models of care coordination (Foote 2003). They argue that the status quo—where Medicare beneficiaries see multiple providers who may or may not know about each other's actions—is inadequate. It can be difficult to identify a single provider who would be responsible for coordinating treatment regimens across providers and care settings. Disease management organizations say that while they do not practice medicine, they can help to keep providers informed about their patients' care. And by educating beneficiaries about how to help manage their conditions, care coordinators may encourage patients to comply with treatment plans more closely.

Physician-centered approaches

Physician-centered approaches to chronic care management often include fixed monthly payments for physicians charged with coordinating care for specific patients. In Medicaid, the approach may involve designation of a physician as the primary care case manager (PCCM) for a recipient. In North Carolina, for example, the Medicaid program links more than 75 percent of eligible participants with a primary care provider (Simms 2003). Although the program pays for medical services on an FFS basis, it also pays the PCCM \$2.50 per recipient per month to coordinate care. Since 1998, the program has linked participating physicians in 13 local community networks with hospitals, health departments, and departments of social services. The state also gives these networks \$2.50 per recipient per month and helps them determine how best to use the money to coordinate care, improve quality, or reduce unnecessary expenditures. Some networks use funds to hire case managers for patients requiring intensive services. Among other projects, the networks have implemented disease management programs for asthma and diabetes. Networks have also worked to reduce excessive emergency department use and inappropriate prescribing.

A number of large physician group practices have developed their own models for chronic care improvement. For example, the Geisinger Health System and the Marshfield Clinic, health care delivery systems based upon large multispecialty group practices, have created disease management programs for patients with chronic conditions. The programs give physicians more time to practice medicine by employing nurses to handle patient education and care coordination. Geisinger also has implemented an innovative electronic health record system. Geisinger staff believe that the future development of information technology could reduce the need for other types of disease management programs. Information recorded in the medical record could lead to prompts for office visits, prescription refills, and reminder phone calls. However, while information technology could incorporate some disease management functions, it would not fully address the need for case management of high-risk individuals.

Certain requirements of the MMA may discourage physician group practices—particularly smaller entities—from bidding to become contractors in the initial phase of the CCIP. For example, under the experimental design of the CCIP’s first phase, bidders must assume that 20,000 beneficiaries will be in the intervention group and another 10,000 will serve as controls—both with the targeted condition. Smaller organizations have raised concerns that they will not be able to serve a big geographic area. Physician practices that wish to provide care coordination services only for their current patients would find it even harder to participate.

CMS is currently testing several other models of care coordination, albeit on a small scale, that focus more directly on physician groups. The MMA calls on CMS to establish a pay-for-performance demonstration program with physicians to serve FFS beneficiaries who have one or more chronic conditions identified by the Secretary. The demonstration aims to help stabilize medical conditions, limit acute exacerbations that can result in expensive hospitalizations, and reduce adverse outcomes such as drug interactions. The three-year demonstration program will operate in four sites throughout the country. Physicians who meet or exceed performance standards set by CMS will receive a fixed payment per member per month. The MMA specifies that the demonstration must be budget neutral.

Another vehicle for testing the physician-centered model for coordinating care is the physician group practice demonstration mandated in the Medicare, Medicaid, and SCHIP Benefits Improvement & Protection Act of 2000 (Table 2-2, p. 40). The demonstration is designed to encourage coordination of care and reward physicians for improving health outcomes. It tests a payment methodology for physician group practices that combines FFS payment and a bonus pool derived from savings achieved from improvements in managing care and services. CMS is working with 11 group practices that have been recommended for award. In contrast to the CCIP, this program is a demonstration project of limited size and duration.

Approaches used by disease management organizations

Programs run by disease management organizations differ from physician-centered approaches and have widely varying relationships with physicians. These programs do not practice medicine but seek to help enrollees better understand their conditions and comply with medical regimens. All programs rely on physicians to develop protocols for the management of patients with chronic conditions. Nearly all disease management organizations try to contact physicians when they enter a region to let them know that their patients may be targeted for a program, to answer questions, and to provide a contact point for any issues that may arise. They may also provide data on practice patterns to physicians and contact them if an emergency situation exists for a particular patient. Some programs seek physician aid in identifying patients who would benefit from program enrollment and in encouraging them to participate.

Typically, disease management programs establish physician advisory boards to foster communication between the program and the local medical community. Sometimes these advisory groups will contact physicians if they perceive problems in the medical care the physicians are providing. A number of programs have developed tools labeled “smart registries” to provide doctors with information on their patients and allow them to benchmark their care patterns with other physicians in their health plan. Some programs focus on providing patients with questions to ask their physicians about treatment options.

**TABLE
2-2**

Demonstrations of care coordination and disease management in Medicare prior to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Title and dates	Goals	Target population	Payment
Medicare coordinated care demo (BBA, 1997) 2/2001–6/2006	Test models of coordinated care to improve quality of services and manage Medicare expenditures.	Controlled trial design for 14,500 FFS beneficiaries with CHF, cardiac and other conditions at 15 sites.	All-inclusive monthly rate for coordinated care services.
Medicare disease management demo (BIPA, 2000) 11/2003–11/2006	Test disease management for beneficiaries with advanced-stage CHF, diabetes, or CAD.	Controlled trial design. Will enroll up to 30,000 beneficiaries in four states.	All-inclusive monthly rate for disease management services and prescription drug costs. DMOs must accept performance risk.
Capitated disease management demo Awards expected by summer 2004	Test capitated payments for case management of specific conditions. Contractors to provide all Medicare-covered services plus disease management services.	Enrollees must have a chronic disease such as stroke, CHF, or diabetes, or qualify as a dual eligible or frail elderly.	Full capitation with risk-sharing option. Payment greater of MA rate or 99 percent of risk-adjusted county FFS rate.
Physician group practice demo (BIPA, 2000) Not awarded yet, to run 3 years	Encourage coordination of care and investment in administrative structures among physician group practices.	CMS will assign 250,000 beneficiaries to physician group practices based on where they receive evaluation and management services.	Combines FFS payment with a bonus pool of savings from improved management of care.
Intensive case management 11/2001–11/2004	Test whether case management improves clinical outcomes, quality of life, and satisfaction.	Controlled trial design: 500 beneficiaries at one site. High-risk patients with CHF and diabetes.	All-inclusive monthly rate for coordinated care services.
ESRD managed care demo (OBRA, 1993) 2/1998–9/2001	Enroll ESRD patients in managed care settings. Health outcomes generally the same or better than in FFS Medicare. Provision of additional benefits such as prescription medicine found to be cost effective.	Demo enrolled 2,500 beneficiaries with ESRD at two sites.	Two M+C plans were paid 100 percent of risk-adjusted FFS spending.
ESRD disease management demo (OBRA, 1993) Not yet awarded, will run 4 years	Three models: FFS (expanded bundle), health plan, and PACE-like plan (interdisciplinary team).	Beneficiaries with ESRD.	FFS includes add-on for expanded bundle. Five percent of payment being withheld for quality incentive.
Social health maintenance organization demo (DEFRA, 1984) 1985–12/2004	Test S/HMO model. MedPAC reviewed performance of S/HMOs and recommended they be converted to M+C plans.	Enrolled 122,000 frail beneficiaries in four plans.	Risk-adjusted MA county payment rate.

Note: Demo (demonstration), BBA (Balanced Budget Act of 1997), CHF (congestive heart failure), FFS (fee-for-service), BIPA (Medicare, Medicaid, and SCHIP Benefits Improvement & Protection Act of 2000), CAD (coronary artery disease), DMO (disease management organization), MA (Medicare Advantage), ESRD (end-stage renal disease), OBRA (Omnibus Budget Reconciliation Act), M+C (Medicare+Choice), PACE (Program of All-Inclusive Care for the Elderly), DEFRA (Deficit Reduction Act), S/HMO (social health maintenance organization). Demonstrations not mandated by law are conducted by CMS under its general demonstration authority.

Source: Compiled by MedPAC from information on CMS's website, Federal Registers published from 1999 to 2003, and interviews with CMS staff.

In our interviews, officials from disease management organizations reported a range of physician reactions to their programs, from enthusiasm to active hostility. Some commercial programs have little direct involvement with physicians; they focus on educating patients to manage their own care. They emphasize the difficulty of identifying the primary physician for many patients outside health maintenance organizations. However, other programs do seek more active physician involvement. One interviewee remarked that primary care physicians tended to participate in the program largely because contact with disease management programs often led patients to use more primary care services and fewer specialist services.

Another representative of an insurer that uses disease management services reported that his organization focused on aligning physician incentives with improved care. One approach involves rewarding physicians for teaching patients techniques for managing their care and paying for improved performance on quality measures. In a second approach, the plan defines quality measures for specific chronic conditions and lets the physician determine how best to achieve the goals.

Who will receive chronic care improvement services?

If care coordination services were directed toward all Medicare enrollees with a chronic condition, the potential number of participants in the program would be very large. As estimated from Medicare claims data, about 78 percent of the Medicare population had at least one chronic condition in 1999, and 63 percent had two or more (Anderson 2002). Self-reported statistics put that number even higher, with over 70 percent reporting two or more conditions (CMS 2003).

In selecting who to identify for the CCIP, CMS must strike a balance between the cost of delivering services to a large population and the lost opportunities for savings and quality improvements that may occur with narrow targeting. Providing the same intervention to all beneficiaries with certain conditions would be costly. Interventions that cast too wide a net may be unable to provide the level of services necessary to improve outcomes or achieve savings. On the other hand, focusing solely on a sick, high-use population may mean that

healthier beneficiaries who might benefit from better chronic care management to prevent future hospitalizations will not be helped.

CMS is using a population-based approach to target enrollees. Through claims data, it is prospectively identifying people who might benefit from care coordination based on the presence of one or more targeted conditions and past use of services. In its solicitation for proposals, CMS identified two groups of conditions that the CCIP will target: 1) CHF and/or complex diabetes; and 2) COPD. Eligible beneficiaries will also have high or moderate hierarchical condition category (HCC) risk-adjustment scores, which suggests that for the CCIP's first phase, CMS will enroll beneficiaries who are sicker than average and at higher risk for future Medicare spending.² Contractors who enroll beneficiaries in their programs must manage all of the participants' comorbidities, not just the targeted conditions. Beneficiaries with end-stage renal disease (ESRD), enrolled in hospice or a Medicare Advantage plan, or living in a region with an FFS chronic care demonstration project will not be eligible. Any program participant who develops ESRD or enrolls in hospice can no longer participate in the program.

Once CMS identifies potential participants, it will randomly assign them into treatment and control groups. Participation in care coordination programs is voluntary. CMS will send a letter to identified beneficiaries in the treatment group, explain the program, and encourage them to participate. Beneficiaries must opt out if they do not wish to be in the program. CMS will choose one contractor in each region and give it the names, Medicare claims data, and other information for all beneficiaries in the intervention group who did not decline to be contacted.

Each contractor will have six months to contact participants, confirm participation, and initiate services. After that period, CMS will only pay fees on behalf of beneficiaries that confirm participation in the program. Contractors will contact participants to screen them for additional chronic conditions, evaluate the level of complexity of their conditions, and determine the type of care management services to provide for each person. Among the group of participants, contractors may use their own predictive models to further target services toward individuals who they believe are most at risk for acute exacerbations of their conditions.

CMS will hire an independent organization to evaluate each contractor’s program by comparing outcomes of the control group to the entire intervention group, including those beneficiaries who chose not to be contacted, those who dropped out of the program, and those whom the program could not contact.

Not all beneficiaries in the selected regions are eligible to participate in chronic care improvement programs. Specifically, people who do not have Medicare claims data indicating that they were diagnosed with a targeted condition would be excluded, as will those who have a condition but have lower risk-adjustment scores. In addition, a large group of people who reach the stage of being identified by CMS as potential participants will be randomly assigned to a control group that will not receive care coordination services. And among participants, contractors may choose to provide fewer services to those whom they believe are already managing their conditions well or those who cannot be managed.

The Commission supports the basic approach to the CCIP’s first phase, which uses a randomized controlled trial design. By operating individual programs on a fairly large scale, CMS may have sufficient numbers of enrollees to test whether treatment and control groups have statistically significant differences in savings or clinical outcomes. That approach allows CMS to evaluate the effectiveness of the CCIP’s approach before expanding it. Such an evaluation is an important step because past evaluations of disease management programs in non-Medicare populations suffered from methodological shortcomings that made it difficult to draw conclusions about quality improvements and savings, or to generalize from their results.

Nevertheless, one tradeoff in using a randomized controlled trial design is that it may initially limit the types of regions in which programs are offered—in particular, rural ones. While the approach does not preclude care coordination programs in rural areas, it means that programs would need to cover larger geographic regions than they would in more densely populated metropolitan centers to have a large enough sample. One provision of the MMA requires CMS to offer programs in areas where, in aggregate, at least 10 percent of all Medicare beneficiaries live. Given the short time frame for starting the CCIP, initial programs are apt to be centered in more densely populated regions.

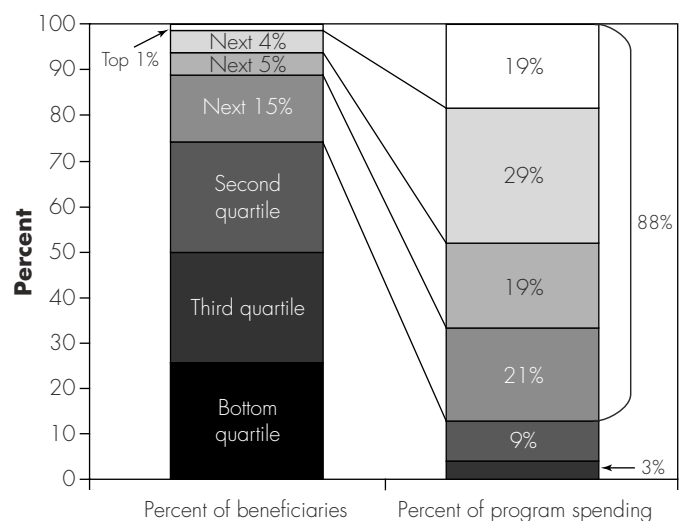
How will eligible participants be identified?

CMS can use risk scores to identify beneficiaries because Medicare program spending is highly concentrated. In 2002, for example, the top 5 percent of beneficiaries ranked by spending accounted for nearly half of total FFS program spending, and the top quartile (25 percent) accounted for nearly 90 percent of spending (Figure 2-1). Concentration in spending relates directly to the cost of providing inpatient care, and people who experience an inpatient stay usually consume more of all types of care during the year. If CMS could identify in advance people who will have very high costs, it could design a program that focuses on better managing their care, potentially improving the quality of their care and slowing growth in Medicare program spending.

But focusing solely on the highest-cost beneficiaries may not be an effective strategy for targeting care coordination services if people do not continue to have high costs over time. Data from Medicare claims show a substantial turnover among those beneficiaries who have the very highest program costs in any given year. Yet, beneficiaries who make up the top quartile of people ranked by program spending tend to remain high spenders over time.

FIGURE 2-1

FFS program spending is highly concentrated in a small group of beneficiaries, 2002



Note: FFS (fee-for-service).

Source: Direct Research, LLC, based on a 0.1 percent sample of Medicare fee-for-service enrollees and their claims.

Most of the year-to-year change in the cohort of people who are among the costliest 1 percent of Medicare FFS beneficiaries can be attributed to their high rate of mortality. Figure 2-2 shows that in the base years 1996, 1997, and 1998, an average of 28 percent of the costliest 1 percent of beneficiaries remained in that highest ranking in the subsequent year, and 18 percent remained in that ranking the year after that. More than 60 percent of those beneficiaries died during the base year, and nearly 30 percent of those who survived died in the subsequent year.

Figure 2-2 also demonstrates some “regression toward the mean”—people who had high costs in one year had levels of spending that were lower (i.e., closer to the mean) in the following year. For example, only 38 percent of beneficiaries ranked among the top 5 percent by FFS program spending in the base year were also among the top 5 percent the next year. Even though some

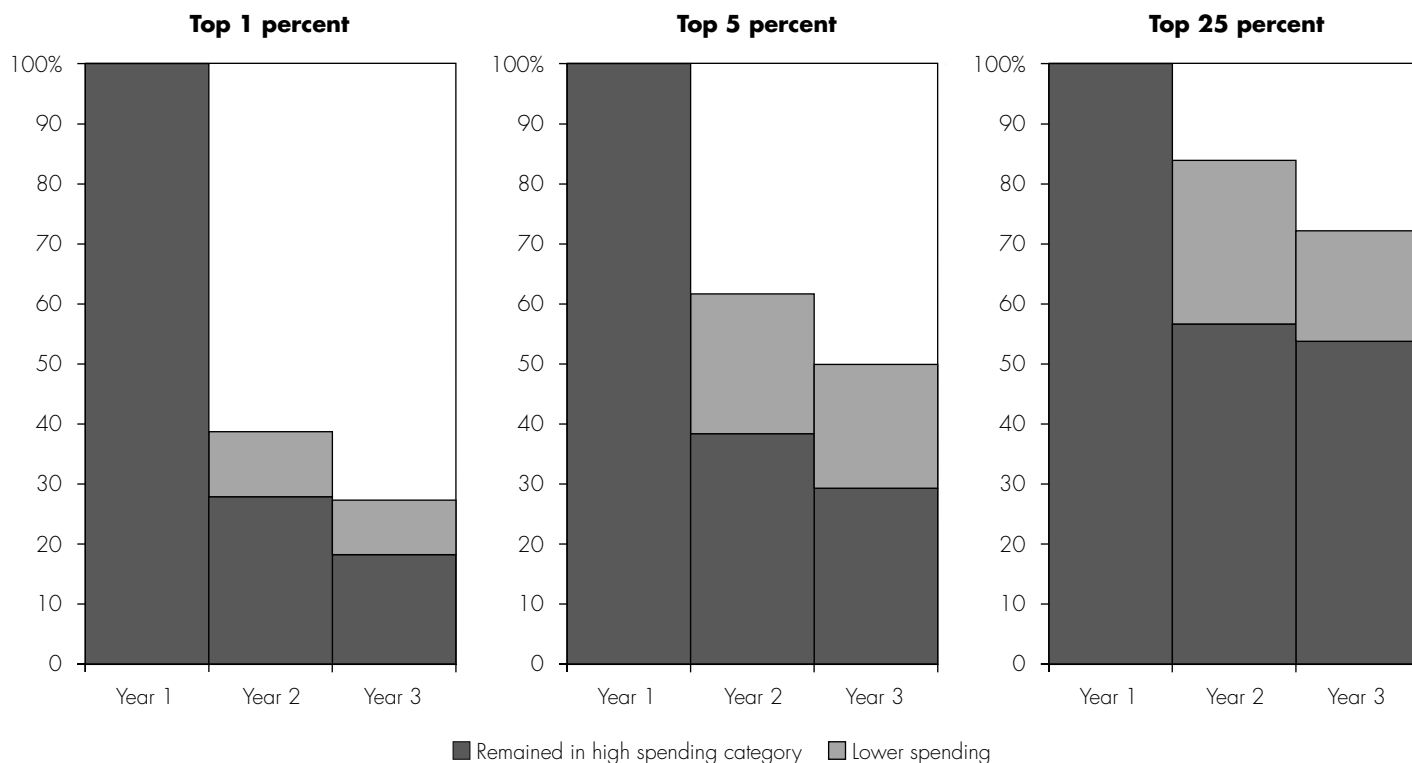
beneficiaries in the group died, a sizable portion of people in the top 5 percent during the base year subsequently had lower spending.

These data suggest that many beneficiaries move into and out of low- or high-risk status over time. Thus, focusing interventions on beneficiaries who have already had high program spending may not always be the most effective strategy for generating savings through preventing hospital admissions.

However, many beneficiaries remain in the top quartile of FFS program spending; enough to suggest some promise to targeting high-cost beneficiaries. For example, Figure 2-2 shows that among people in the top quartile during the base year, 57 percent remained among the top 25 percent in the subsequent year, and more than 50 percent fell into that category in the following year.

FIGURE 2-2

Persistence of high spending and mortality in the FFS program, by year



Note: FFS (fee-for-service). The total height of the bars shows the percentage of beneficiaries who survived into the subsequent year. The difference in height of bars between years primarily reflects the percent of beneficiaries who died. A small percent were lost from the sample between years either because they joined a Medicare+Choice plan or their claims data could not be matched. Base years are pooled from 1996–1998.

Source: Direct Research, LLC, based on a 0.1 percent sample of Medicare fee-for-service enrollees and their claims linked over the 1996–2002 period.

In addition to Medicare claims, other types of data may help CMS and its contractors better target care coordination services. Today, disease management organizations often use predictive modeling to identify potential enrollees prospectively, using spending and information about diagnoses from claims data. Although claims data contain valuable information, they can suffer from inaccuracies in coding or inconsistencies in certain diagnoses from year to year, depending on whether or not the beneficiary sought care (see text box). For these reasons, diseases management organizations routinely use data—such as health assessments and prescriptions filled—in addition to medical claims.

Once Medicare's Part D benefit begins in 2006, CMS may have the benefit of prescription drug claims to use in its targeting for the CCIP. Knowing a patient's drug therapies

may help CMS identify their conditions.³ That information could also help the contractors to evaluate whether the patient's therapy follows evidence-based care guidelines. Part D is, however, a voluntary program, and it is not yet clear what share of the Medicare population will enroll.

It is also important for contractors to obtain physiological information from laboratory testing—such as the results from hemoglobin A1c for diabetes and lipid tests for cholesterol levels. Currently, however, Medicare does not obtain this information from the laboratories performing these tests. Medicare only collects physiological information for dialysis adequacy and hematocrit on the claims submitted by outpatient dialysis facilities. Several interviewees told us that laboratory results are important for planning and evaluating private disease management interventions, but that they have not been able to obtain

Methodology for MedPAC's analysis of fee-for-service spending

The database consists of a 0.1 percent sample of Medicare beneficiaries for the years 1996 through 2002, or about 38,000 persons per year. Statistics on total program spending for this sample are similar to other data published by CMS. To be included in a given year of data, the beneficiary had to have at least one month of Part A or Part B entitlement and no months of Medicare Advantage (MA) enrollment. This differs slightly from CMS's Chronic Care Improvement Program, in which beneficiaries must be enrolled in Part A and Part B but not enrolled in an MA plan. Payments were summed from Medicare fee-for-service claims for physicians, facilities, and durable medical equipment. Payments on facility claims include both pass-through amounts and capital amounts when those were reported separately.

For each person in the file, and for each year, program spending and enrollment data were combined to calculate a per member per month (PMPM) cost for that person. Each person's PMPM cost is that person's total program spending divided by months of A or B entitlement.

We identified individuals who had congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), and diabetes, using definitions from the hierarchical condition category risk-adjustment model

that CMS developed to pay MA plans. All diagnoses from all claims files were summarized by file and month. We required that a relevant diagnosis be reported twice—either in two different files, or in the same file in two different months. That requirement screens out a significant fraction of the population. By comparison, CMS will classify beneficiaries as having a targeted condition if they find two or more professional visits on separate dates or a hospitalization for CHF or COPD.

Several caveats apply whenever researchers use claims data to identify the prevalence of conditions. First, the list of diagnoses we used may vary from other definitions. Second, the actual prevalence of a disease is probably higher than that shown by a single year of diagnoses from claims data because diagnoses are not always reported persistently in claims data from year to year, even for conditions presumed permanent. Third, the population captured via diagnoses on claims will have higher costs than the true population that has the disease. In general, diagnoses are mostly reported when a beneficiary is actively being treated for that disease. This means that persons who have a condition (such as CHF) but whose condition is stable and does not require active intervention in a given year may not have diagnosis information appear in that year. ■

them. Similarly, it is not yet clear how CMS and contractors will collect such information for evaluating quality outcomes in the CCIP.

How prevalent and costly are the targeted conditions?

How prevalent are the conditions that CMS chose for the CCIP? Based on MedPAC’s analysis of Medicare claims data, about 10 percent of FFS enrollees had CHF in 2002, 10 percent had COPD, and 17 percent had diabetes (see Table 2-3). But these figures are estimates: In general, claims data tend to understate prevalence (text box, opposite), and at least one condition, diabetes, sometimes goes undetected.

Medicare spends disproportionately on behalf of people who have these conditions. For example, beneficiaries with CHF accounted for 35 percent of total spending, with mean monthly spending of nearly \$1,900 in 2002, or nearly four times that for the average FFS enrollee. Because of CHF’s high prevalence within the Medicare

population and its high average level of spending, patients with CHF made up 57 percent of those beneficiaries who ranked among the top 1 percent by program spending, and 38 percent of the top 10 percent.

CMS will identify beneficiaries in a very specific manner, using its own combinations of diagnosis codes to define the presence of a targeted condition.⁴ In addition, beneficiaries must have moderate to high risk-adjustment scores to be eligible to participate. Using MedPAC’s claims database and our own estimates of HCC scores, we estimate that nationwide nearly 6 percent of FFS enrollees would qualify under CMS’s criteria for CHF or complex diabetes, and about 2 percent would qualify within CMS’s criteria for COPD. By requiring that beneficiaries have moderate to high risk-adjustment scores, CMS significantly reduces the number of people who are eligible for the treatment and control groups. But eligible beneficiaries still account for a disproportionate share of Medicare program spending—18 percent and 8 percent, respectively.

TABLE 2-3

Prevalence of certain conditions and average monthly Medicare program spending among FFS enrollees, 2002

Category	Category as a percent of:					
	FFS Medicare enrollees	Total program spending	Most costly 1% of beneficiaries	Most costly 10% of beneficiaries	Mean monthly spending	Ratio of spending to overall mean
All persons	100%	100%	100%	100%	\$502	1.0
MedPAC’s definitions of conditions						
CHF	10	35	57	38	1,877	3.7
Diabetes	17	31	42	33	942	1.9
CHF or diabetes	21	51	72	53	1,102	2.5
COPD	10	28	42	31	1,483	3.0
CMS’s definitions of conditions and moderate to high risk-adjustment scores						
CHF or diabetes	6	18	18	23	1,414	2.8
COPD	2	8	8	10	1,543	3.1

Note: FFS (fee-for-service), CHF (congestive heart failure), COPD (chronic obstructive pulmonary disease). Beneficiaries may have had more than one of the conditions shown above. Spending values are averages within each category and are adjusted for the number of months of FFS enrollment. Percent of total program spending and mean monthly spending include all Medicare FFS program spending, including that associated with comorbidities. CMS’s definitions of threshold conditions are based on certain diagnoses codes for two or more professional visits on separate dates or (for CHF or COPD) a hospitalization for the condition in one year of claims data.

Source: Direct Research, LLC, based on a 0.1 percent sample of Medicare fee-for-service enrollees and their claims.

Using MedPAC’s definitions of conditions, 26 percent of FFS enrollees have CHF, diabetes, or COPD, 20 percent have one targeted condition, 5 percent have two, and the remainder have all three (Figure 2-3). Even though limiting the CCIP to CHF, diabetes, and COPD excludes most Medicare beneficiaries, people with one or more of those three conditions account for about 60 percent of FFS program spending.

Some providers of disease management services contend that certain chronic conditions require a shorter time period to show improvements in outcomes and spending than other conditions. Interviewees told us that their interventions focusing on CHF provide a greater return on investment in the short term than diabetes. This is likely to be the case if CHF patients have, on average, a greater number of hospitalizations during the year that are avoidable through better care coordination than patients with other conditions.

Using MedPAC’s definitions of the presence of targeted conditions, claims data show that more CHF patients have hospitalizations than beneficiaries with other targeted

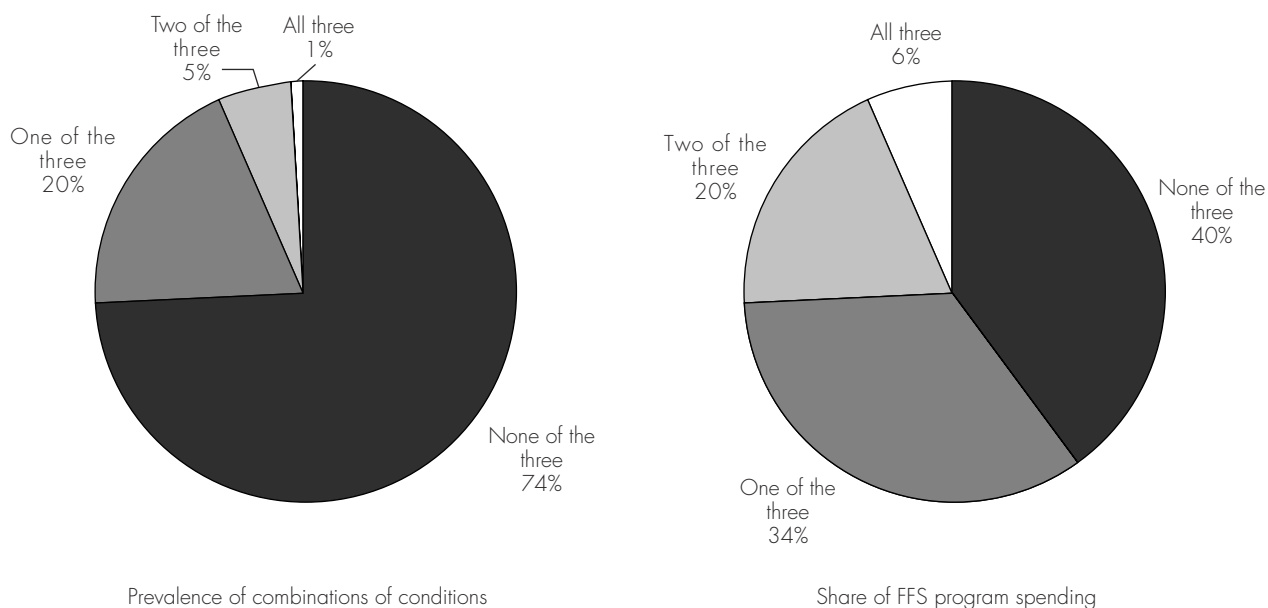
conditions. On average, 62 percent of CHF patients had one or more hospitalizations during the year over the 1996–2002 period (Figure 2-4). By comparison, 35 percent of diabetes patients, 53 percent of beneficiaries with COPD, and 20 percent of all FFS beneficiaries had one or more hospitalizations. In addition, a larger share of CHF patients had repeated hospitalizations.

However, among CHF patients who had a hospitalization, CHF was not necessarily the main reason for their stay. About 17 percent had CHF as their principal diagnosis, 46 percent had it as a secondary diagnosis, and 37 percent were hospitalized but CHF was not reported as one of the diagnoses (Table 2-4).

The MMA specifically identifies CHF, COPD, and diabetes as targeted conditions, but allows CMS to include others as well. The question of whether to target additional conditions is not a simple one. On the one hand, most FFS enrollees could benefit in some manner from services that help to coordinate their care or educate them to help manage their own conditions. But such a strategy would not necessarily improve the quality of care for everyone:

FIGURE 2-3

About one quarter of FFS beneficiaries with CHF, COPD, or diabetes account for three-fifths of program spending, 1996–2002

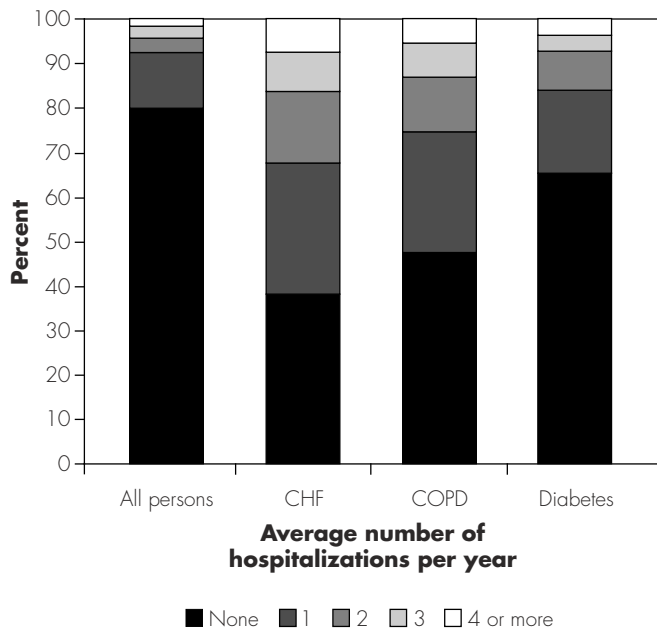


Note: FFS (fee-for-service), CHF (congestive heart failure), COPD (chronic obstructive pulmonary disease). Medicare FFS program spending includes that associated with comorbidities. Values are based on MedPAC’s definitions of conditions.

Source: Direct Research, LLC, based on a 0.1 percent sample of Medicare fee-for-service enrollees and their claims.

FIGURE 2-4

Beneficiaries with CHF, COPD, or diabetes are more likely to be hospitalized, 1996–2002



Note: CHF (congestive heart failure), COPD (chronic obstructive pulmonary disease). Values are based on definitions of conditions from the hierarchical condition category risk-adjustment model.

Source: Direct Research, LLC, based on a 0.1 percent sample of Medicare fee-for-service enrollees and their claims.

Some people’s conditions are already well-managed, and the complexity of others’ circumstances may make it extremely difficult to keep their health stable. On the other hand, CMS has limited resources, and it is not clear that organizations can provide these services to a broader share of the Medicare population in a cost-effective manner.

Although one could suggest several candidates for other conditions to target, MedPAC chose CKD as a case study for analyzing the potential for care coordination. (The case study is the last section of this chapter.) Treating beneficiaries whose kidneys deteriorate to the point of ESRD is extremely expensive—in 2002, program spending for ESRD beneficiaries was nearly \$3,900 per month. Although only 1 percent of FFS enrollees have ESRD, these patients account for 6 percent of total program spending. Delaying the progression of kidney disease could both improve quality of care and help to use Medicare’s resources more efficiently.

What is the role of contractors?

This section describes the role of contractors within the care coordination program: What services they will provide, how they will be paid, and how they will coordinate activities with other programs.

What services will contractors provide?

The MMA establishes general service requirements but allows contractors maximum flexibility in designing and targeting specific interventions. Among the services outlined in its solicitation, CMS will evaluate applicants’ plans for outreach to and assessment of participants; the proposed frequency and type of interventions, including how they will provide support for participants with more intensive needs; descriptions of proposed services and educational materials; mechanisms for encouraging physician participation; plans for coordinating with state and local agencies; and plans for data collection and analysis.

Most current disease management contractors base their intervention on evidence-based guidelines that are developed by unbiased organizations and accepted by the majority of providers. However, most guidelines are developed for a single chronic disease and may be of

TABLE 2-4

Acute inpatient discharges for beneficiaries with certain chronic conditions, 1996–2002

Presence of code for condition	CHF	COPD	Diabetes
Principal diagnosis	17%	11%	5%
Secondary diagnosis	46	56	71
Condition not listed on discharge	37	33	24
Total	100	100	100

Note: CHF (congestive heart failure), COPD (chronic obstructive pulmonary disease). The percentages above exclude all transfers, which are defined as a discharge and readmission of the beneficiary on the same day.

Source: Direct Research, LLC, based on a 0.1 percent sample of Medicare fee-for-service enrollees and their claims.

limited help for a patient with many comorbidities because key clinical protocols and performance measures can differ when managing patients with multiple chronic conditions.⁵ For example, a physician might use a lower target level of low-density lipoprotein for a patient with diabetes and coronary artery disease than if that person did not have diabetes. Contractors will need to ensure that the guidelines they use are current and appropriate for patients with multiple chronic conditions. Chronic care programs managed by physicians who already have detailed knowledge of a patient's medical history may have clear advantages in this regard.

The MMA requires contractors to provide any services in their care management plan that are generally not covered by Medicare, such as at-home monitoring technologies. Contractors can also furnish other services not explicitly mentioned in the MMA and not covered under FFS Medicare that will help them meet quality and financial goals.

Among all types of noncovered services, case management is likely to be particularly important to certain Medicare beneficiaries with complex medical conditions or who are near the end of life. Currently, most commercial disease management programs refer patients to case management services provided by the sponsoring health plan and do not have internal capacity to provide these services. Other organizations specialize in these types of activities but may not be well equipped for handling population-based approaches to care coordination. Organizations that provide distinct sets of services may need to partner or contract with one another in order to address the CCIP's population-based approach and the case management needs of the Medicare population.

How will the contractors be paid?

The MMA requires that contractors be paid on a per member per month basis, but the law is not specific as to how the payment will be set. CMS plans to pay varied fees to contractors because it aims to test a variety of models that include different services and thus have different cost structures. Applicants will propose a fee in their bid, subject to negotiation with CMS. In addition, fees will be adjusted based on whether contractors achieve targets for program savings, clinical outcomes, and satisfaction. Fees

paid to contractors are distinct from the medical claims for program participants, which CMS will continue to pay in the usual manner as part of the FFS program.

In principle, the CCIP's approach of requiring contractors to take performance risk for their fees is consistent with the Commission's goal of holding providers accountable and linking payment to quality. As we learn from the CCIP's initial phase, CMS may want to consider approaches that make even greater use of contractor incentives to achieve savings and quality improvements.

CMS's proposed relationship between payment and quality is not yet clear. The request for proposals states that bidders must be willing to guarantee that total Medicare claims for the treatment group and chronic care improvement fees will be no more than 95 percent of total Medicare claims payments for the control group over a three-year period. In other words, if a contractor does not reach a 5 percent savings target, CMS will reduce its fees by the amount needed to ensure those savings with up to 100 percent of fees at risk. After 2006, Medicare drug expenditures will be included in the calculations of Medicare program spending for treatment and control groups.

The solicitation is less clear about the relationship between payment and outcome measures and satisfaction targets. Although it provides measures of clinical outcomes, CMS did not specify performance targets for those measures. The agency plans to negotiate targets based on bidders' proposals.

Applicants will use data made available by CMS to set their bids; they will propose the geographic area where the program will operate, performance targets and how their fees will be adjusted if they do not meet the goals. CMS's solicitation requests applicants to assume that they will serve 20,000 beneficiaries in the treatment group, even though the ultimate number may differ. This will allow CMS to evaluate bids that are more comparable to one another. If the prevalence of disease or use of services by beneficiaries differs in the proposed region from that in nationally representative data, bidders may propose adjustment factors to reflect those differences.

CMS's solicitation permits applicants to propose up to two alternative payment structures if bidders want to serve a larger population or if they believe they can achieve more than 5 percent net savings. For example, an organization

with experience coordinating care for CHF patients might argue that it could lower program spending by, say, 15 percent. In return, it might propose higher fees such that net program savings would reach 10 percent rather than 5 percent.

Contractors will be paid the same amount per enrolled beneficiary, but they can choose where to place their resources in order to see the greatest returns in quality, satisfaction, and savings. That approach corresponds to current practices by many disease management organizations. Interviewees told us that they believe it is most effective to target broadly, but to stratify people who have the same condition by their level of complexity and provide a different level of service to each risk segment. For those with controlled diabetes, for example, some organizations contact patients once or twice a year to make sure they have received the appropriate preventive services. By contrast, organizations may contact patients with uncontrolled diabetes more frequently, maintain closer contact with the patients' physicians, and use case management services.

Contractors may require a higher monthly fee for participating in the CCIP than they customarily receive from private clients. In general, the Medicare population is more medically complex than other populations, and CMS plans to target sicker than average beneficiaries. In addition, programs will have to offer a broader array of services, likely including case management, than is provided by many current programs. However, the risk provisions of the program should limit the amount of the bids. Contractors must achieve program savings in order to avoid returning some or all of their fees to Medicare because they could not meet financial performance goals.

How will contractors and CMS coordinate responsibilities?

Implementing the CCIP will require contractors and CMS to interact with each other, with FFS providers, with state Medicaid programs, and with other programs implemented by Medicare.

Furnishing data in a timely fashion to contractors

Contractors will need claims data from CMS for:

- developing predictive models to determine appropriate levels of intervention for the targeted population,

- reevaluating the risk levels of participants, and
- assessing the effectiveness of intervention strategies.⁶

Interviewees indicated that they usually supplement claims data with health assessment information obtained from patients. In the future, drug claims data should also be useful for these purposes.

It is not clear how frequently CMS will provide contractors with this information, but some interviewees suggest they would need data at least quarterly, and ideally, monthly. These data could come directly from CMS or the agency's contractors. A strong commitment from CMS will be absolutely critical for these data to be available in a timely manner.

Contractors must coordinate with fee-for-service providers

The MMA requires contractors to collaborate with physicians and other providers to improve communication of relevant clinical information. In current disease management programs, the ability to provide effective feedback to physicians relies heavily on the underlying relationship between the physician and the health plan or disease management organization. This relationship is important as a source of referrals to the disease management program. Physicians also may be enlisted to help design care coordination strategies.

Contractors will need to create new relationships in geographic areas where they do not currently furnish disease management and care coordination services, and build upon their existing networks in areas where they furnish services. In addition to physicians, contractors will also need to communicate with other providers, particularly providers of end-of-life care. The law explicitly requires that care management plans include information about hospice care, pain and palliative care, and end-of-life care where appropriate.

Coordinating efforts with state Medicaid programs

The MMA is silent on whether and how Medicare's CCIP should coordinate with state Medicaid programs for beneficiaries who are eligible for both programs. Almost half of all states have implemented or are in the process of implementing disease management programs (Center on an Aging Society 2004). The number of state programs

will probably increase at the same time that Medicare's CCIP is launched. CMS recently announced that Medicare will match the Medicaid costs states incur in furnishing disease management programs aimed at improving health outcomes while lowering the medical costs associated with chronic illnesses (CMS 2004).

Beneficiaries who are dually eligible for Medicare and Medicaid are likely to account for a disproportionate share of participants in the CCIP because the prevalence of targeted conditions is much higher in this population than among all other FFS enrollees. CHF and COPD are about twice as prevalent, and 26 percent of Medicaid dual eligibles have diabetes.⁷ In MedPAC's claims database, dual eligibles made up 17 percent of all FFS beneficiaries in 2002, and accounted for about 26 percent of FFS program spending. Similarly, in 1999 they represented 19 percent of all Medicaid beneficiaries and accounted for 35 percent of Medicaid expenditures, or \$63 billion.

Few mechanisms exist for coordinating care for these beneficiaries across both payers. Medicare is the primary payer for this group and may benefit more if growth in spending for acute-care services slows. By contrast, Medicaid will benefit more if spending for long-term care services is contained. At issue is whether federal and state governments can or even should coordinate efforts—by contracting with the same organization and using the same performance standards for example. Doing so might prevent dual eligibles from receiving redundant care.

CMS and contractors may also need to coordinate with Medicaid to obtain claims data for both targeting and monitoring care. CMS might be able to better target populations if Medicaid claims data could augment Medicare data. Similarly, contractors might be able to develop a more effective care plan and monitor the care beneficiaries receive if Medicaid claims data were made available to them. For example, verifying when dually eligible beneficiaries fill their prescriptions might help contractors to monitor compliance with their drug therapies. Medicaid claims data would most likely improve the ability of CMS and contractors to set the per member per month payment rate (see Chapter 3).

Coordinating efforts with other Medicare contractors

In at least two instances, Medicare contractors other than those selected for the CCIP may also be providing care coordination services to beneficiaries. The MMA requires sponsors of Medicare Part D prescription drug plans in 2006 to establish drug therapy management programs for beneficiaries with multiple chronic conditions requiring multiple medications. The program is designed to promote the appropriate use of medication by beneficiaries, improve adherence to medication regimens, and detect adverse drug events and patterns of underuse and overuse of drugs. The Secretary is required to issue guidelines for coordinating this program for beneficiaries enrolled in the CCIP.

In addition, CMS has proposed extending efforts by the quality improvement organizations (QIOs) to address the care of patients with multiple comorbidities under their next scope of work (a three-year period beginning August 2005). Under this scope of work, QIOs would:

- assist physician offices in providing chronic care for diseases such as coronary artery disease, congestive heart failure, hypertension, and depression, and also preventive services, such as colorectal cancer screenings; and
- reduce misuse of prescription drugs by helping physicians to adopt electronic prescribing.

Regardless of whether CMS decides to include these new responsibilities in the next scope of work for the QIOs, the QIOs are already working with some physicians to improve management of chronic conditions such as CHF and diabetes. In order to reduce duplication of effort and improve efficiency, it would be useful for CMS to define guidelines for how CCIP contractors should interact with drug plans and QIOs.

How will contractors meet the special needs of Medicare beneficiaries?

Contractors will need to consider the special needs and characteristics that are common among older patients when they implement their interventions in fee-for-service Medicare. For example, contractors must address the needs of:

- older patients who suffer from comorbidities such as dementia and frailty, who often see several physicians or receive care in multiple settings; and

- special populations such as beneficiaries needing end-of-life care.

The Medicare population's high prevalence of multiple chronic conditions should make it particularly well suited for care coordination. Contractors are required to manage all comorbidities, relevant health care services, and pharmaceutical needs. But other characteristics—such as higher prevalence of frailty and dementia, and greater need for end-of-life care—mean that organizations that have typically created disease management programs for healthier, younger populations must now use different strategies.

In the remainder of this section we focus on two types of older persons: Patients with cognitive impairments and patients requiring end-of-life care.

Cognitive impairments

Cognitive impairments such as dementia are comorbidities that contractors will need to consider when designing their programs. MedPAC's Medicare claims data show that about 5 percent of FFS enrollees suffered from dementia in 2002, and people with dementia accounted for about 15 percent of FFS spending in that year which includes care for their comorbidities. That rate of prevalence is probably understated because it is based on Medicare claims: Some beneficiaries may be reluctant to seek treatment at the early stages of mental impairment, or providers may simply attribute it to the aging process.

How might dementia complicate care coordination? Approaches to disease management that are used widely today rely extensively on educating the beneficiary to help manage their own care. For example, patients with CHF are taught to monitor their weight closely and take their medications regularly to avoid acute flare-ups that could lead to hospitalizations. That strategy may not work well for beneficiaries with dementia if they have difficulty understanding or remembering their physician's recommended therapy.

Advocates contend that disease management services can still improve outcomes for beneficiaries with dementia. For people with mild cognitive impairment, such services might promote earlier screening or help to identify reversible factors. For those whose condition is more advanced, contractors might focus their efforts on educating a primary caregiver on how to care for the patient or manage any comorbidities, and suggest techniques for coping with memory loss during the patient's day-to-day activities.

End-of-life care

Patients at the end of life incur high costs. MedPAC's analysis shows that in calendar year 2002, Medicare spending for the 5 percent of beneficiaries who died constituted 18 percent of total Medicare program payments.⁸

One of the biggest challenges for chronic care improvement programs will be identifying beneficiaries at the end of life. It is particularly difficult to predict timing of death with administrative data even for some of the sickest beneficiaries (Buntin et al. 2004). However, guidelines do exist for determining prognosis in some noncancer diseases including the need for hospice or palliative care (Lynn 2001). Even with these additional tools, prognosis is very difficult for diseases like CHF and dementia. Physicians could help contractors identify patients who could benefit from end-of-life services.

Consensus has grown among experts about the components of quality end-of-life care. To the extent that they can be identified prospectively, these beneficiaries can benefit from coordination of services across multiple settings, advance care planning, family and caregiver support, pain management, physical symptom relief, and counseling (Lynn 2001). These services are provided to Medicare beneficiaries through the hospice benefit, but many recipients of hospice care do not receive benefits soon enough to obtain significant advantage from them (see Chapter 6). In addition, many beneficiaries who could benefit from palliative services may not have a clear prognosis or be ready to give up on curative care.

Current care coordination programs do not usually target beneficiaries near the end of life, so they may not be accustomed to providing the services that these beneficiaries need. Ongoing communication with the patient's physician and other caregivers will be critical. Educational materials may need to be less focused on preventive care for a specific condition and more focused on advance planning, family and caregiver support, and pain management. Many of our interviewees agreed upon the need for care coordination for this population but added that most programs were not yet effective in providing services for them. The MMA requires that contractors' care plans include information about hospice care, pain and palliative care, and end-of-life care, but it is not clear how contractors would identify patients who

need this information. Targeting beneficiaries near the end of life and providing appropriate services for them will require collaborative efforts among physicians, care coordinators, and case managers.

Evaluating the effectiveness of chronic care improvement programs

The MMA calls for CMS to evaluate the clinical and financial outcomes of each intervention. In this section, we first discuss the randomized controlled trial design. We then raise key measurement and evaluation issues that the MMA does not explicitly address but that are becoming clearer as CMS begins to implement the CCIP. Specifically, should CMS use a standard set of clinical and financial measures to evaluate effectiveness?

Using a randomized controlled trial design

In recent years, employers and private insurers have been using disease management programs to try to improve quality and control costs during a time of strong upward pressure on health spending (Short et al. 2003). Typically, those programs target beneficiaries with certain conditions and higher-than-average costs, but only if the cost of providing disease management services seems to be offset by reductions in claim costs (Foote 2003). Nevertheless, there is still only limited evidence of the effects of these programs on outcomes and health spending. Studies that attempt to demonstrate improved outcomes or savings have often suffered from serious methodological shortcomings (Fetterolf et al. 2004, Crippen 2002).

Evaluating existing disease management programs has been hampered because:

- few programs have used a rigorous study design to assess the clinical and financial effectiveness of their interventions;
- most programs use a combination of strategies and are not able to measure the relative contribution of each strategy to program outcomes; and
- providers have not reached consensus about which outcomes should be used to assess effectiveness.

If carried out carefully, a randomized controlled trial design and independent evaluations of effectiveness should provide important information to all stakeholders—Medicare, private payers, employers, contractors, physicians and other providers—about the potential of the CCIP to improve beneficiaries’ clinical outcomes and reduce health care spending.

Prior attempts to measure the impact of disease management programs have been complicated by the lack of a control group with which to compare outcomes, and the difficulty in defining a time frame in which to expect measurable results. Most often, existing programs compare outcomes and medical costs after a program has been implemented with benchmark data for the same population from some pre-treatment period. But general improvements in treatment regimens for all patients with a given medical condition can confound the results. In addition, some evaluations have counted savings caused by regression to the mean among beneficiaries who had high costs in the benchmark period. Many of our interviewees recognized these issues and spoke of developing new evaluation methods to address them. For example, one health plan described an evaluation based on comparing medical costs for a client that purchased a disease management program with medical costs for another client that did not.

How many beneficiaries will participate in each program?

The number of beneficiaries who will initially participate in each program is largely driven by the Congress’s intent to use the first phase of the CCIP to evaluate whether this approach is more broadly applicable in Medicare. The law calls for large numbers of people who have targeted conditions to serve as controls in each program, and requires that an independent organization evaluate each program.

The number of beneficiaries in a treatment group may differ among contractors. Key factors that affect the size of treatment groups include the prevalence of targeted conditions within each geographic region and the amount of variation in the outcome variables of interest—such as program spending and clinical characteristics. If the number of participants varies from area to area, the statistical power to detect clinical and financial outcomes may vary. The ability to detect a statistical difference will be greater for larger treatment groups, all else constant.

CMS will enroll beneficiaries who have both a targeted condition and are at high risk for future FFS program spending. This approach reduces the number of participants needed to detect a statistical difference because there is less variation in their spending.

Depending upon how CMS chooses to evaluate programs, mortality rates of people with targeted conditions may become an important factor (see text box, p. 54). CMS's solicitation for bids notes that at the end of each three-year award for the CCIP's initial phase, each contractor will undergo a financial settlement process to ensure that the program achieved 5 percent net savings. If medical claims plus contractor fees for the treatment group are more than 95 percent of medical claims for the controls, the awardee must refund the difference up to 100 percent of its fees. If the treatment group is more expensive than the control, Medicare will still cover the extra medical costs. Under this approach, evaluators will compare total program spending for both groups at the end of three years—no matter how many participants died or survived. But CMS also states that it may require awardees to refund fees based on interim reconciliations and performance monitoring. If CMS uses the approach of comparing average spending in each year, mortality rates would be important for ensuring that one could compare values for sufficiently large numbers of survivors several years after the program's start.

Some organizations contend that CMS should refresh the treatment and control groups periodically during the three-year study period. In other words, CMS would randomly assign new people with the same targeted conditions and similar risk-adjustment scores to replace decedents in both groups, thereby keeping sample sizes sufficiently large over time. However, even with this approach, CMS would likely need to evaluate cost savings separately for the original cohort and for newer entrants. For example, if new participants in a chronic care improvement program were more likely to suffer from acute flare-ups of their condition than beneficiaries who already received one or two years of services, savings from the intervention might appear higher than they would be otherwise.

Using a standard approach and measures to evaluate programs

Evaluation requires standard measures and definitions of savings and quality. CMS has set out some of these:

- Contractors must achieve at least a 5 percent savings target, although they can propose additional savings.
- Contractors must use a core set of measures defined by CMS to assess the quality of diabetes, CHF, and COPD care, the use of preventive services, and the rates of hospital admission and emergency service use. Contractors can propose additional measures of quality, particularly for measuring the quality of care for comorbidities.

The Commission supports CMS's approach of using core quality measures. If contractors do not use a core set of clinical outcome measures and a standardized tool to assess beneficiary and provider satisfaction, it will be difficult to determine whether certain programs are more effective than others.

By requiring use of a core set of measures, CMS will help promote a set of standardized measures for evaluating outcomes of disease management programs, something now lacking. Currently, many different categories of measures are being used, including medical cost savings, return on investment, quality of care, and worker productivity. The industry has recently attempted to define valid indicators to compare programs. In February 2003, one firm and the Johns Hopkins Outcomes Verification Program published a report outlining standard outcome metrics and evaluation methodology for disease management programs (American Healthways and Johns Hopkins Consensus Conference 2003). However, in the same year, the disease management industry was not able to agree on a uniform outcomes methodology (Disease Management News 2004).

CMS's solicitation leaves several open issues concerning how quality and satisfaction will be measured and collected. First, CMS needs to determine how quality performance will be evaluated. Options are improving the care contractors furnish above the enrollees' baseline level, exceeding national averages, improving indicators to levels higher than those for the control group, or some combination. CMS's new ESRD disease management demonstration uses a mixed strategy when linking

How many participants are needed in each treatment group?

The number of beneficiaries that CMS will need to enroll in each program depends on its strategy for evaluating savings. Table 2-5 shows that CMS would need about 4,000 beneficiaries in each Chronic Care Improvement Program (CCIP) treatment group to detect a 5 percent difference in the average value of beneficiaries' three-year sum of program spending. It would also need an equal number of people in the control group. Those are much lower than figures described in CMS's request for proposals because the numbers needed to detect a statistically significant difference between treatment and control groups depends on the amount of variation in spending: the three-year sum of each person's spending varies less, relative to the mean, than does annual spending. This calculation assumes that CMS would compare three-year spending without regard to the number of people who survived to the third year.

If CMS conducts annual reconciliations with contractors to evaluate whether they are achieving savings targets, it may decide to use a different approach. Table 2-6 shows the number of enrollees needed each year to measure a significant difference between average program spending. For example, among beneficiaries who have congestive heart failure (CHF) or complex diabetes, CMS would need to enroll a sample of 14,250 persons during the base year for the treatment group if it wanted to detect a statistically significant 5 percent difference in mean spending three years after the start of the program. It would need an

equal number in the control group as well. Since about 15 percent of fee-for-service enrollees within that CHF or complex diabetes cohort die in a given year, only about 10,210 of the 14,250 participants would be alive at the end of the third year after the program began.

The second set of calculations factor in attrition of each condition group over time, mainly due to deaths in these populations. As the intervention progresses, the number of persons remaining falls. This means that the later the CCIP is to be evaluated, the more people must be chosen to assure adequate sample size in the evaluation period for any given level of statistical precision.

The high mortality rates of these groups raise important issues for evaluating savings under the CCIP. If the program affects the annual mortality rate, it may be difficult to evaluate savings from the program because the treatment and control groups would no longer be equivalent. By the second year, the treatment group would have more people—presumably more acutely ill people—than the control group. Even though the avoidance of deaths in the treatment group would likely reduce first-year costs, it is not clear what effect reduced mortality would have on per capita costs in subsequent years. There may be several ways to evaluate program savings or costs over the CCIP's initial phase, but it seems prudent to also compare the mortality rates of treatment and control groups.

**TABLE
2-5**

How many beneficiaries would CMS need to detect a 5 percent difference in the average three-year sum of spending with 95 percent confidence?

	Average three-year program spending	Number of beneficiaries needed in the first year
CHF or complex diabetes	\$35,840	4,100
COPD	34,950	3,830

Note: CHF (congestive heart failure), COPD (chronic obstructive pulmonary disease). The values shown above describe mean spending and the number of people that CMS would need to enroll in order to make statistical inferences about a difference between spending in treatment and control groups. All values are based on CMS's definitions of conditions and the presence of a moderate to high risk-adjustment score. CMS identifies beneficiaries based on certain diagnoses codes for two or more professional visits on separate dates or (for CHF or COPD) a hospitalization for the condition in one year of claims data. These calculations are for a two-tailed significance test with treatment and control groups of equal size.

Source: Direct Research, LLC, based on a 0.1 percent sample of Medicare fee-for-service enrollees and their claims, linked over the 1996–2002 period.

How many participants are needed in each treatment group? (continued)

**TABLE
2-6**

How many beneficiaries would CMS need to detect a difference in average annual program spending with 95 percent confidence?

	Number of beneficiaries in original group			Surviving number of beneficiaries		
	Year after start			Year after start		
	First	Second	Third	First	Second	Third
To detect a 5 percent difference						
CHF or complex diabetes	9,940	12,760	14,250	9,800	10,780	10,210
COPD	8,500	10,330	14,030	8,420	8,480	9,530
To detect a 7.5 percent difference						
CHF or complex diabetes	4,420	5,670	6,330	4,350	4,790	4,540
COPD	3,780	4,590	6,240	3,740	3,770	4,240
To detect a 10 percent difference						
CHF or complex diabetes	2,480	3,190	3,560	2,450	2,700	2,550
COPD	2,130	2,580	3,510	2,110	2,120	2,380

Note: CHF (congestive heart failure), COPD (chronic obstructive pulmonary disease). The values shown above describe the number of people that CMS would need to enroll in order to make statistical inferences about a difference between spending in treatment and control groups. The surviving number of beneficiaries shows the number who are alive one, two, and three years after the program's start. All values are based on CMS's definitions of conditions and the presence of a moderate to high risk-adjustment score. CMS identifies beneficiaries based on certain diagnoses codes for two or more professional visits on separate dates or (for CHF or COPD) a hospitalization for the condition in one year of claims data. These calculations are for a two-tailed significance test with treatment and control groups of equal size. The required numbers of beneficiaries would be much smaller in the base year than in subsequent years because the variance of spending would exclude that for any decedents or any persons who had no claims data. Numbers in Table 2-6 are larger than those in Table 2-5 because the variance in the sum of spending over three years is smaller relative to its mean than that for annual average spending.

Source: Direct Research, LLC, based on a 0.1 percent sample of Medicare fee-for-service enrollees and their claims, linked over the 1996–2002 period.

Estimates shown in Tables 2-5 and 2-6 reflect an assumption that CMS would need to detect a 5 percent difference in program spending between treatment and control groups. However, the agency will likely need to detect an even greater difference, since programs need to achieve 5 percent net savings after accounting for contractor fees. The magnitude of fees could substantially affect the number of required enrollees, since generally it takes fewer people to detect a larger difference. For example, if CMS allowed a contractor

to aim for a 2.5 percent fee, the contractor would need to achieve 7.5 percent gross savings in average program spending. Under that scenario, CMS would need 6,330 people in the treatment group rather than 14,250 to detect the larger difference at the end of the program's third year. Likewise, if a contractor needed to achieve 10 percent gross savings because it wanted to aim for a 5 percent fee, CMS would need just 3,560 people in the treatment group at the end of the third year. ■

payments to quality. For each of the five measures used, the agency awards one-half of one percent of payments for improving quality and one-half of one percent for exceeding national targets. Using a mixed strategy minimizes the negative aspects of each method. Measuring quality based only on improvements could reward contractors who achieve significant improvement

but remain at a relatively low level of quality. By contrast, setting goals too high might discourage contractors at the low end from trying to improve.

Second, CMS needs to address whether quality will be assessed measure by measure or aggregated across measures. Its solicitation for bids permits contractors to propose methods to aggregate the quality measures. If the

measures are to be aggregated, CMS will need to ensure that contractors use an appropriate weighting methodology. Otherwise, important deficiencies in quality may be obscured.

Third, CMS needs to determine the standard for improving clinical quality. Unlike the savings target, the request for proposal does not call for contractors to achieve a minimum percentage change in quality. Rather, it calls on each bidder to set its projections for quality improvement on a year-to-year basis. CMS could require all contractors to meet at least a minimum quality standard. This would address a concern raised by some policymakers that contractors might compromise quality to meet or exceed savings targets.

Fourth, quality measures need to be measured and collected in a manner to ensure comparability across contractors. CMS or its evaluation contractors will need to audit data to ensure its accuracy and consistency across sites.

Finally, an important task remaining for CMS is to develop instruments to measure beneficiary and provider satisfaction. The agency needs to set a minimal standard for all contractors to achieve in improving satisfaction.

Two additional issues to consider related to the evaluation of the CCIP are the implementation of Medicare's Part D prescription benefit and the generalizability of the results obtained from the evaluations.

During the three-year course of the initial phase, CMS will implement Medicare's Part D prescription drug benefit. CMS plans to include Part D spending in the evaluation of target savings. Will introducing that new benefit confound the CCIP's results? The answer might be no, so long as beneficiaries from the treatment and control groups enroll in Part D at the same rates. Under that scenario, the new benefit would affect spending for both groups equally, and any differences in outcomes could be attributed to the treatment. However, if one group is more likely to enroll than the other, the calculation of target spending may be biased. Contractors may have an incentive to encourage the treatment group to enroll at greater rates than the control group, in order to improve compliance with their drug regimens. CMS and its evaluators should assess the rate of participation in Part D between the study and control groups.

The effectiveness of care coordination interventions at reducing spending and improving quality cannot necessarily be generalized to the entire FFS Medicare population. The initial phase of the CCIP tests care coordination for only three conditions—complex diabetes, CHF, and COPD. Participants will be sicker, on average, than Medicare beneficiaries with these conditions who are not participating in the program. Policymakers should not assume that the savings targets and quality and satisfaction goals achieved in the initial phase can be realized in the second phase if different populations are targeted.

The budget neutrality constraint

The Congress required that the CCIP be budget neutral. The aggregate sum of Medicare program payments for beneficiaries participating in the program and funds paid to contractors should not exceed estimated program payments that would have been made for targeted beneficiaries in the absence of the program. In other words, CMS's payments to contractors need to be offset by other program savings, such as lower inpatient spending. However, for the CCIP's initial phase, the MMA did allow for certain startup costs by authorizing up to \$100 million in net aggregate payments—amounts paid to contractors less any program savings attributable to the chronic care programs—for fiscal years 2004 through 2006.

Will the CCIP maintain budget neutrality? It seems reasonable to expect that contractors should reduce other types of Medicare program spending—particularly for hospitalizations—since one of their major goals is to reduce acute exacerbations of beneficiaries' chronic conditions. Some analysts suggest that contractors could achieve even greater savings than the 5 percent required in CMS's solicitation, particularly since the initial phase targets beneficiaries with CHF—considered the “low hanging fruit” among chronic conditions. Also, the MMA provides a strong incentive for contractors to accomplish program savings targets by requiring them to put administrative fees at risk.

However, savings cannot be guaranteed. Employers and other groups that have used disease management programs have never operated on the scale needed for the Medicare program, nor on populations with the unique medical and social characteristics of the elderly and disabled. Establishing programs for this population may involve significant startup costs for contractors. Case management services are more expensive to provide than the services

typically offered by disease management organizations today. And once CMS begins making monthly payments for CCIP programs, recouping payments from contractors that do not meet performance standards could prove difficult. The Congressional Budget Office estimated that the CCIP would not maintain budget neutrality—it estimated that the program would cost \$500 million over the 2004–2013 period.

Chronic kidney disease and chronic care improvement programs: A case study

This case study focuses on the potential benefits of improved care coordination for renal patients because of MedPAC’s long-standing interest in the quality of renal care. Most recently, we recommended linking payments to physicians and facilities caring for ESRD patients to the quality of care furnished to patients (MedPAC 2004). In the future, MedPAC may examine the potential of care coordination programs to improve quality for other populations with chronic conditions.

CKD includes conditions that affect the kidney, with the potential to cause either progressive loss of kidney function or complications resulting from decreased kidney function. Persons with CKD range from those with decreased kidney function to those with permanent kidney failure—ESRD—who require either maintenance dialysis or a kidney transplant to survive. In most instances, ESRD develops as the consequence of progressive damage to the kidney over a decade or more. The National Institutes of Health (NIH) and the Centers for Disease Control have recognized CKD as a major public health problem because of the increased numbers of those with the disease, their high costs, and the substantial morbidity and mortality experienced by affected patients.

Although CKD is not a threshold condition under the MMA, CKD patients will most likely be among the participants of the program because they suffer from conditions targeted by the law—diabetes, CHF, and COPD. Diabetes is the leading cause of renal failure; about 45 percent of dialysis patients have diabetes, 30 percent have CHF, and 8 percent have COPD. Patients with ESRD will not be among the participants because CMS has excluded them from the CCIP.

Based on our review of the scientific literature, our discussions with providers of care coordination services, and our analysis of Medicare claims data, we find that:

- The ESRD population is growing and is costly.
- Slowing or preventing permanent renal failure may be possible.
- Earlier referral to a renal team may improve patients’ outcomes.
- Coordinated care programs may improve some aspects of care for renal patients, although the impact of such programs on Medicare spending is unclear.

The end-stage renal disease population is growing and is costly

The impetus behind coordinating the care of CKD patients is to delay or prevent new cases of ESRD. The number of new cases of ESRD continues to grow, particularly among diabetics, African Americans, and the elderly. Patients with ESRD, particularly patients on dialysis, are one of the costliest populations for Medicare and have significant morbidity and mortality. Permanent renal failure lowers most patients’ quality of life. Healthy People 2010, a set of health objectives for the first decade of the new century developed by the Department of Health and Human Services, calls for the rate of new cases of ESRD to be reduced by one-third (Office of Disease Prevention and Health Promotion 2004).

The ESRD population comprises about 293,000 patients requiring dialysis and 114,000 patients who have undergone a kidney transplant and have a functioning kidney graft. Dialysis is the process by which wastes and excess fluids are removed from a patient’s body.^{9, 10} Kidney transplantation is preferred over dialysis because it improves both survival and quality of life while reducing long-term costs of care. Dialysis patients, however, outnumber transplant patients, not because of a lack of demand for transplants, but because of the well-documented shortage of kidneys available for transplantation. In 2001, only 15,331 kidney transplants were performed. By contrast, 57,336 patients were awaiting a transplant (United Network for Organ Sharing 2004).¹¹

Left unchecked, the number of ESRD patients is estimated to be more than 650,000 patients by 2010. Incidence rates have increased during the past decade from 223 per

1,000,000 people in 1991 to 334 per 1,000,000 people in 2001. Diabetes accounts for most new cases of ESRD, and diabetics and the elderly are the fastest growing segments of the ESRD population. About half of the nearly 100,000 new cases in 2001 were patients 65 years or older. Other conditions that contribute significantly include high blood pressure and other cardiovascular conditions, and obesity.

ESRD patients are costly to Medicare. Although representing less than 1 percent of beneficiaries, they account for about 6 percent of all Medicare spending. According to the U.S. Renal Data System, average spending per ESRD patient was \$45,000 in 2001. Dialysis patients, with average annual spending of \$52,000 in 2001, were 2.8 times more costly than kidney transplant patients. The high spending of dialysis patients is partly driven by the costs for outpatient dialysis, which account for about 42 percent of total spending.¹² However, because many dialysis patients suffer from and are frequently hospitalized for other chronic comorbidities, spending for inpatient hospital services accounts for about 36 percent of total spending.

Rates of hospitalization and mortality for dialysis patients have remained high and relatively unchanged during the past 10 years. Between 1993 and 2001, hospitalization rates per 1,000 patient years ranged from 2,019 to 2,062. Adjusted annual mortality rates have remained relatively constant during this time, ranging from 236 to 253 per 1,000 patient years at risk (USRDS 2003).

Finally, ESRD patients experience a decline in their quality of life, although transplant patients have higher quality-of-life scores than those treated with dialysis. Women and older ESRD patients have lower scores than do men and younger patients.

Slowing or preventing new cases of end-stage renal disease may be possible

Earlier intervention and better management of CKD patients may, for certain cases, delay or even prevent permanent kidney failure. The NIH, Healthy People 2010, and the renal clinical guidelines developed by the National Kidney Foundation (NKF)—the Kidney Disease Outcome Quality Initiative (K/DOQI)—all conclude that early referral to a renal team is important to reduce the substantial morbidity and mortality associated with ESRD (NIH 2004, NKF 2004).

The first step in slowing or preventing the progression to ESRD is identifying patients with CKD. The K/DOQI recently published a clinical guideline in which CKD is defined according to the presence and absence of kidney damage and the level of kidney function—glomerular filtration rate (GFR)—with higher stages representing more severe kidney damage (Table 2-7). This guideline defines CKD as either having structural or functional abnormalities of the kidney or having a GFR of less than 60 mL/min—stages 3 and 4—for three months or more. K/DOQI recommends that stage 3 patients be evaluated and treated for complications of CKD and that stage 4 patients be prepared for renal replacement therapy.

Populations at risk for CKD include patients with one of the conditions targeted by the CCIP—diabetes. Other at-risk groups include: older persons, persons with hypertension, and minorities. How large is the at-risk population? Using data from the National Health and Nutrition Examination Survey III, Coresh and colleagues (2003) estimated that 14.2 percent (about 2.6 million) of all diabetics have stage 3 and 0.92 percent (about 167,000) have stage 4 CKD. Among persons age 70 and older, 24.6 percent (about 6.3 million persons) have stage 3 and 1.3 percent (about 332,000 persons) have stage 4 CKD.¹³

Screening at-risk populations may be necessary because kidney disease in its early stages is often asymptomatic; thus, many people who would benefit from early intervention are not identified. In addition, some evidence

TABLE 2-7 Stages of chronic kidney disease

CKD stage	Description
1	Kidney damage with normal or elevated GFR (≥ 90)
2	Kidney damage with mildly decreased GFR (60–89)
3	Moderately lower GFR (30–59)
4	Severely lower GFR (15–29)
5	Kidney failure GFR (<15)

Note: CKD (chronic kidney disease), GFR (glomerular filtration rate). GFR is a measure of kidney function and measures the rate at which the kidneys filter the blood of toxins. Normal GFR values in adults are between 100 and 150 milliliters per minute.

Source: Adapted from the National Kidney Foundation’s clinical guideline for chronic kidney disease, 2004.

suggests that CKD is underdiagnosed even when clinical measures are available to identify the disease (Coresh et al. 2003, Kausz et al. 2001, McClellan et al. 1997).

Once CKD is identified, it may be possible to slow or halt the progression of kidney disease to ESRD by improving the care of cardiovascular disease and diabetes. The American Diabetes Association recommends diabetic patients receive hemoglobin A1c testing at least two to four times per year and lipid testing at least annually. Care for some CKD patients did not meet these targets:

- About half of CKD patients with diabetes did not receive two to four hemoglobin A1c tests in 2001.
- 37 percent of CKD patients with diabetes did not receive at least one lipid test in 2001 (USRDS 2003).

Reducing the complications of CKD—such as anemia, bone disease, and malnutrition—may also slow the progression to ESRD and improve quality of care. Opportunities exist to improve the care of CKD complications:

- About 75 percent of patients initiating dialysis did not receive erythropoietin in the pre-ESRD period (USRDS 1999). K/DOQI calls for erythropoietin therapy for CKD patients with anemia.
- A substantial number of CKD patients do not receive appropriate dietary instruction (Pennell 2001). Fifty percent of hemodialysis and 43 percent of peritoneal dialysis patients reported that they had not seen a dietician before starting dialysis.

Prescription of angiotensin-converting enzyme (ACE) or angiotensin-receptor blocker (ARB) therapy in persons with microalbuminuria—the presence of protein in the urine, indicating that the kidneys are not working properly—has been demonstrated to decrease both the progression of kidney disease toward ESRD as well as the incidence of cardiovascular events and death. CMS's request for proposals includes two quality indicators for monitoring the frequency with which contractors test persons with diabetes for microalbuminuria and prescribe either ACE or ARB therapy.

Finally, better management of patients with CKD may lower their risk of mortality due to cardiovascular disease. Cardiovascular mortality is three times greater in patients with CKD than in the general population. CKD patients are 5 to 10 times more likely to die due to cardiovascular disease than to develop ESRD (USRDS 2003). Healthy People 2010 calls for reducing the mortality rate due to cardiovascular disease.

Improving the quality of care for patients progressing to end-stage renal disease

Earlier intervention and better management of CKD patients may reduce the substantial morbidity, mortality, and costs associated with ESRD. More integrated care among primary care physicians and providers with expertise in nephrology—physicians, nurses, dieticians, and social workers—may improve the care furnished to CKD patients. Healthy People 2010 calls for increasing the proportion of CKD patients under the care of informed health care providers 12 months before the start of renal replacement therapy.

Referring patients with chronic kidney disease to a renal team

Many CKD patients are not seen by providers with expertise in nephrology until they are very close to beginning dialysis. Kinchen and colleagues (2002) reported that 30 percent of patients were seen by a nephrologist less than 4 months before dialysis initiation, 22 percent were seen 4 to 12 months before, and 48 percent were seen more than one year before. Potential reasons for late referral include asymptomatic CKD, noncompliance with referrals, and the attitudes of primary care physicians about referring CKD patients to specialists. These researchers also found that referral patterns varied based on patients' demographic characteristics.

Earlier referral to a renal team may lead to better ESRD outcomes. The risk of death was significantly greater among ESRD patients referred to a renal team late (less than 4 months before the start of dialysis) compared to patients referred early (more than 12 months before the start of dialysis) (Kinchen et al. 2002).¹⁴ Other researchers have also found that late referral to a renal team is associated with: (1) a higher risk for unplanned first dialysis, (2) more complications, (3) higher hospital costs

and longer duration of hospitalization in the first three months of dialysis, and (4) greater use of temporary vascular access.

Some care coordination programs promote earlier referral to a nephrology team for patients with CKD as one way to improve quality. MedPAC contracted with Direct Research, LLC, to examine the potential impact of early referrals to nephrology care on the use of services, outcomes, and Medicare spending for CKD patients before and after they started dialysis. This analysis uses Part A and B claims data from 1996 to 2002 for a 5 percent representative sample of FFS beneficiaries.

First, we identified a cohort of incident dialysis patients. The study population is comprised of patients who received at least six dialysis sessions during their initial month of dialysis and whose initial dialysis date from the outpatient dialysis claim matched the start of dialysis date from the Renal Beneficiary Utilization System/Program Management and Medical Information System (REBUS/PMMIS) to within two weeks. So that we could examine the use of services for up to two years before dialysis, we excluded patients starting dialysis in 1996 and 1997. We also excluded patients whose Medicare entitlement was due to ESRD so that we would have at least two years of data before the start of dialysis.¹⁵

Because of this latter exclusion, the study population is older, on average, than all new dialysis patients. In the study population, 16 percent of patients are under age 65, 40 percent are between 65 and 74 years, and 45 percent are 75 years and older.¹⁶ By contrast, among all new dialysis patients in 2001, 50 percent of patients were under age 65, 25 percent were between 65 and 74 years, and 25 percent were 75 years and older. Thus, the results derived from this analysis are not representative of all new dialysis patients.

Next, we classified patients based on when they first saw a provider with expertise in nephrology and when they started dialysis:

- late (on or after the start of dialysis),
- intermediate (within 4 months before starting dialysis or between 4–12 months before starting dialysis), or
- early (more than 12 months before starting dialysis).

Providers with expertise in nephrology are defined as physicians who reported the specialty code of nephrology on at least one Part B claim. Ideally, we would have preferred measuring access to any physician with expertise in nephrology but this information is not available in Medicare claims data. Thus, our results will be affected to the extent that physicians are either under reporting or over reporting nephrology as their specialty.

We examined the use of services during the pre-ESRD period that are recommended in renal clinical guidelines: (1) prescription of Medicare-covered injectable medications, such as erythropoietin, for complications of CKD and (2) outpatient placement of an arteriovenous (AV) fistula.¹⁷ We measured the use of peritoneal dialysis—the most common home dialysis method—as the initial dialysis method because of interest by the Congress and others in promoting home dialysis. We examined outcomes that better care coordination during the pre-ESRD period might improve: (1) hematocrit at dialysis onset, (2) hospitalization in the month prior to starting outpatient dialysis, and (3) mortality in the first and second years following dialysis.

We were not able to examine the rate of kidney transplantation among the study population because this analysis would have led to small, unstable estimates. As noted earlier, the study population is older, on average, than all new dialysis patients and the rate of kidney transplantation among persons 65 years and older is low. About 8 percent of all transplants were received by patients 65 years and older in 2001. MedPAC may, in the future, examine the factors associated with receiving a kidney transplant among all CKD patients. As compared to dialysis, renal transplantation improves survival and quality of life while reducing long-term costs of care.

We also were not able to examine the use of medical nutrition therapy services because Medicare coverage did not begin until January 1, 2002. Included in the Medicare, Medicaid, and SCHIP Benefits Improvement & Protection Act of 2000, this benefit provides nutritional counseling to patients with diabetes or CKD. MedPAC may, in the future, examine use of this service among all CKD patients.

The results presented below are not adjusted for potential differences in the demographic and clinical characteristics of patients in each group. For example, we were not able to adjust for differences in the level of renal function at which dialysis was initiated.¹⁸ Other researchers have shown some differences in their results after they adjusted for potential confounders (Kinchen et al. 2002).

The majority of the study population first saw a nephrologist less than one year before dialysis. About 28 percent of patients did not see a nephrologist until they started dialysis, 17 percent saw one less than 4 months before starting dialysis, 15 percent saw a nephrologist 4 to 12 months before, and 40 percent saw a nephrologist more than one year before. Ten percent of the study population had no record of a claim submitted by a nephrologist either before or after dialysis. Because this analysis uses claims data, we do not know whether these patients were never treated by a nephrologist or whether they were treated by a nephrologist who reported a physician specialty code other than nephrology.

Patients may not be seeing a nephrologist before starting dialysis because CKD has yet to be diagnosed. We determined, however, that 51 percent of the study population had a Part A or B claim indicating chronic renal failure more than one year before starting dialysis, 46 percent in the year before starting dialysis, and only 3 percent on or after starting dialysis.

Our results about the association between earlier referral and use of services and outcomes are generally consistent with those reported by other researchers (Table 2-8). A greater proportion of patients with early referrals were prescribed at least one medication for complications of CKD and had an AV fistula placed compared with late referral patients. The average initial hematocrit of early referral patients was greater than that of late referral patients (31 percent versus 27 percent, respectively); K/DOQI recommends a target hematocrit ranging from 33 percent to 36 percent.

Early referral may have a small, positive effect on peritoneal dialysis use: 2.3 percent of late referral patients chose this modality compared with 5.8 percent of early referral patients. Overall, the use of peritoneal dialysis among all new dialysis patients in the U.S. is 7.8 percent. Our results are lower because the study population is older than all new dialysis patients and use of peritoneal dialysis is inversely related to age (USRDS 2003).

**TABLE
2-8**

Some differences in the use of services based on the timing of nephrology care

Time between first visit to nephrologist and start of dialysis

	Same time or after	Less than 4 months	4-12 months	More than 12 months
Received at least one medication for complications of CKD	4.7%	9.8%	15.2%	17.9%
Average initial hematocrit	27.3%	28.1%	28.1%	31.0%
Use of arteriovenous fistulas:				
5-12 months before dialysis	2.2	0.4	8.1	10.8
1 month before dialysis	9.5	16.1	30.8	29.8
Hospitalized in the month before starting dialysis	83.2	71.2	66.5	64.8
Peritoneal dialysis is initial dialysis modality	2.3	6.2	5.3	5.8
Mortality in the first year after dialysis	29.9	31.3	27.4	24.8
Mortality in the first two years after dialysis	51.6	49.4	49.4	47.9

Note: CKD (chronic kidney disease). To permit for sufficient data, patients starting dialysis in 2002 are excluded from the first year mortality rates; patients starting dialysis in 2001 and 2002 are excluded from the mortality rates for the first two years after dialysis.

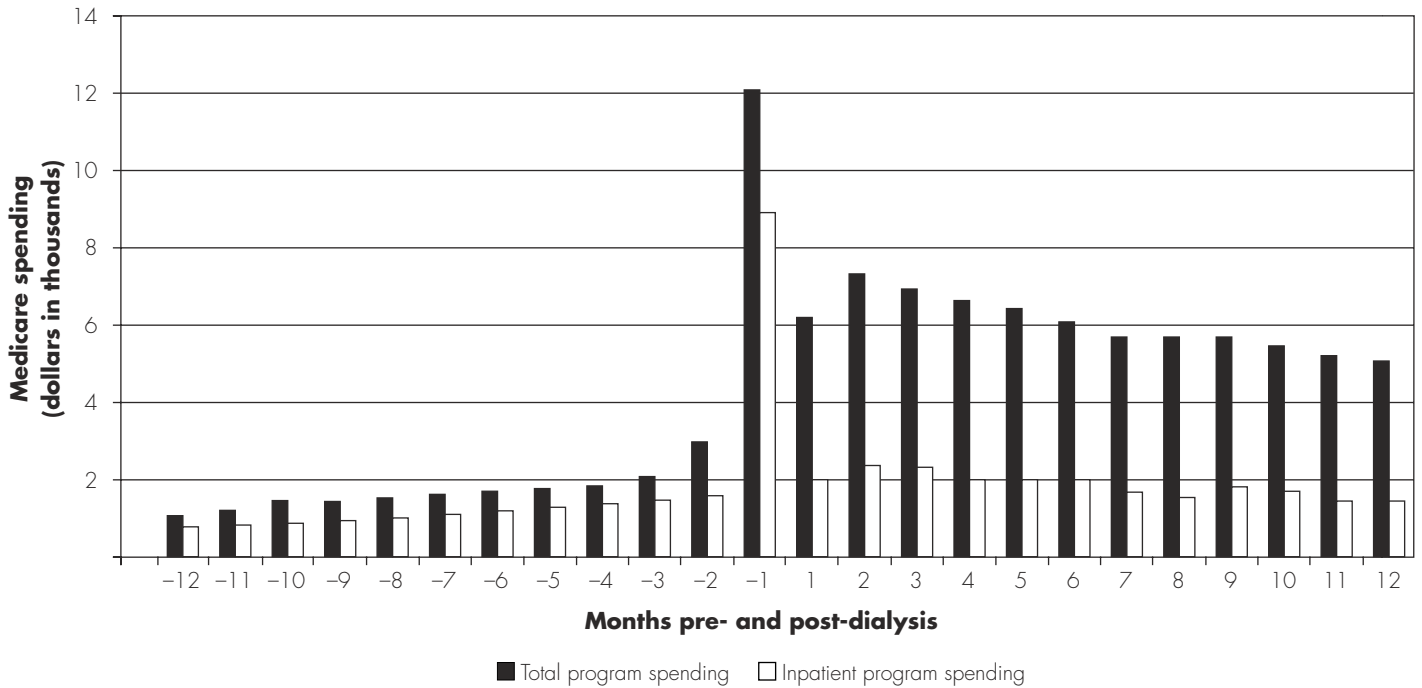
Source: Direct Research, LLC, based on a 5 percent sample of Medicare beneficiaries, their claims, and information from REBUS/PMMIS.

Although hospitalization rates are high in the month before dialysis begins, the rate is lower for patients who saw a nephrologist more than 12 months before starting dialysis. Mortality rates among the study population are also high. Two years after dialysis, 48 percent of patients who were referred early had died compared with 52 percent of patients who were referred late.

CKD patients are costly: average Medicare spending was \$29,804 in the 12 months preceding dialysis and \$61,434 in the 12 months after dialysis begins. Not surprisingly, total Medicare spending increases once patients start dialysis (Figure 2-5, p. 62). However, spending is also high in the month before starting dialysis because a substantial proportion of patients are hospitalized.

FIGURE 2-5

Inpatient spending spikes in the month before dialysis begins



Note: Month 1 is the start of dialysis.

Source: Direct Research, LLC, based on a 5 percent sample of Medicare beneficiaries, their claims, and information from REBUS/PMMIS.

Providers of renal care coordination services told us that they aim to decrease rates of hospitalization by better preparing patients for dialysis.

Inpatient hospital spending modestly differs by when patients first saw a nephrologist (Figure 2-6). Inpatient spending in the year before dialysis averaged \$20,137 for late referral patients compared to \$14,878 for early referral patients; in the year after dialysis began, the difference in average inpatient spending narrowed to \$20,941 for late referral patients compared to \$18,229 for early referral patients. The difference in inpatient spending between early and late referral patients after starting dialysis may be associated with care at the end of life. Nearly all ESRD patients (92 percent) are hospitalized in the last year of life, and 60 percent of ESRD patients die in the hospital (MedPAC 2000).

One of the important reasons to look at patterns of care among CKD patients is to consider chronic care management. While there appear to be opportunities to

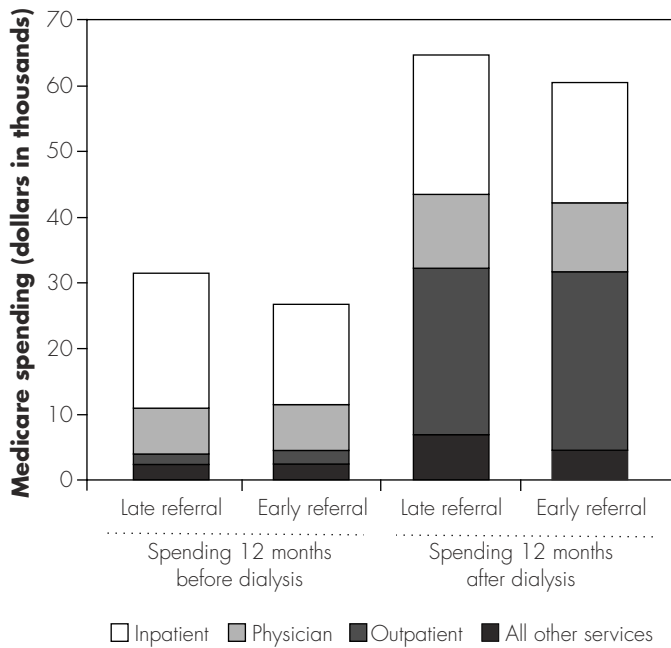
improve quality and reduce spending, it is not clear how care coordination programs would affect Medicare spending once the fees associated with such programs are considered in a spending analysis. Total program spending for early referral patients was 16 percent lower in the year before dialysis and 6 percent lower in the year after dialysis compared to late referral patients. What is unknown is the level and intensity of care coordination services that CKD patients would require and the fees associated with these programs. Some patients would most likely require case management services, which are more expensive to provide than the services typically offered by disease management organizations.

Preparing chronic kidney disease patients for renal replacement therapy

As noted in the prior section, earlier intervention may lead to improved care of complications from CKD and comorbidities, particularly diabetes, lipid abnormalities,

FIGURE 2-6

Inpatient spending is somewhat lower for early referral patients



Note: Late referral patients are those whose first visit to a nephrologist was on or after the start of dialysis. Early referral patients are those whose first visit was more than 12 months before dialysis. The increase in outpatient spending in the one year after dialysis is primarily associated with outpatient dialysis services.

Source: Direct Research, LLC, based on a 5 percent sample of Medicare beneficiaries, their claims, and information from REBUS/PMMIS.

and high blood pressure, and may reduce morbidity and mortality once patients progress to ESRD. Two interventions that may benefit patients are:

- educating CKD patients about the different renal treatment options, and
- surgically placing a permanent vascular access device instead of a temporary access device.

Educating CKD patients about renal treatment options

Better education in the pre-ESRD period gives patients an opportunity to learn about the different ESRD treatment options. Only 25 percent of CKD patients who were ultimately treated with hemodialysis reported that one type of peritoneal dialysis—continuous ambulatory peritoneal dialysis—was discussed with them as a treatment option (USRDS 1997). By contrast, 82 percent of patients who received information about continuous

ambulatory peritoneal dialysis during the pre-ESRD period chose home dialysis. The lack of appropriate education during the pre-ESRD period may have contributed to the decline in the use of peritoneal dialysis from 13 percent of all new dialysis patients in 1991 to 8 percent in 2001 (USRDS 2003).¹⁹

Many CKD patients are not educated about kidney transplantation. For example, among patients under age 60 years, only 60 percent of peritoneal dialysis and 45 percent of hemodialysis patients recalled being informed about kidney transplantation. The lack of knowledge about transplantation is just one of the many factors that affect access to this treatment option. As noted earlier, a limited supply of donor organs is available. Access differs based on race and ethnicity: African Americans are less likely than Whites to be identified as potential candidates, be referred for transplant evaluation, and receive a transplant (Alexander and Sehgal 1998).

Using arteriovenous fistulas Vascular access services are needed by the 90 percent of all dialysis patients who undergo hemodialysis. AV fistulas are considered the best long-term vascular access because they provide adequate blood flow for dialysis, last a long time, and have a complication rate lower than the other access types—AV grafts and venous catheters. However, AV fistulas need more time to mature than grafts and catheters. K/DOQI recommends that a fistula should be allowed to mature for at least one month, and preferably for three to four months. Data from 2001 show that only 29 percent of new dialysis patients had an AV fistula (CMS 2002). Healthy People 2010 targets increasing the proportion of new hemodialysis patients who use AV fistulas.

Care coordination programs may improve the outcomes of renal patients

Care coordination programs offer the potential of improving the quality of care for CKD patients. Some health care organizations and providers have begun to implement programs focusing on the care of CKD patients (Schorr 2003, Yeoh et al. 2003). These programs emphasize:

- Early identification of at-risk patients. Laboratories calculate patients' GFR when physicians order a lab test that measures serum creatinine;²⁰

- Managing CKD and comorbidities to delay or avoid renal replacement therapy;
- Educating patients and families about the role of nutrition, weight management, compliance with prescribed drug regimens, types of renal replacement therapy, and types of vascular access;
- Referring patients to nephrologists and multidisciplinary teams. (One program, for example, refers stage 3 patients with structural damage or with risk factors for developing ESRD and those in stage 4 to renal multidisciplinary teams); and
- Measuring outcomes.

Evidence is lacking on the effectiveness of these programs. MedPAC was unable to locate studies examining the effectiveness of programs targeting patients with CKD in the scientific literature.

Care coordination programs also offer the potential for broadening providers' focus of care from ESRD to all comorbidities and, in doing so, better coordinating care. ESRD patients, particularly dialysis patients, fit the profile of a population that could benefit from coordinated care programs because they suffer from multiple comorbidities, are hospitalized frequently, are prescribed many medications, and incur high costs.

Several private payers, including Aetna, PacifiCare, Empire Blue Cross and Blue Shield, Blue Cross and Blue Shield of Minnesota, and Elderplan have arranged for disease management organizations to provide services for their ESRD members. These programs often offer a range of services including outreach to the primary care physician and nephrologist, initial assessment and ongoing monitoring of patients, and patient education. Providers of ESRD disease management services told us that they too vary the level and intensity of the services by the severity of the illness. Some state Medicaid programs are also contracting with outside vendors to provide ESRD disease management services. Two of the four national for-profit dialysis chains have affiliate organizations offering renal disease management services.

Like programs for other populations, the effectiveness of care coordination programs for ESRD patients has yet to be conclusively demonstrated. One study evaluating a

disease management program showed that hemodialysis patients enrolled in a health plan with a disease management program had 19 to 35 percent significantly better survival rates and 45 to 54 percent fewer hospitalization rates compared with all hemodialysis patients enrolled in FFS Medicare (Nissenson et al. 2001).

Conclusion

Renal patients experience substantial morbidity and mortality and are among the costliest populations for Medicare. Evidence from the literature suggests that earlier intervention and better management of patients with CKD may, in some cases, delay or prevent permanent kidney failure. In addition, MedPAC's analysis of claims data suggests that earlier referral of CKD patients to a nephrologist may reduce some of the morbidity associated with ESRD.

The CCIP will provide opportunities to promote earlier intervention and improve management of CKD. Patients with CKD will undoubtedly be among the program's participants because of the high prevalence of diabetes and CHF in this population. In the initial phase of the CCIP, policymakers should consider including in the evaluation how well each contractor met the special needs of patients with CKD.

As more information becomes available, MedPAC may examine the potential of different approaches to coordinate the care for patients with CKD. Such an effort would include interviewing providers of programs focusing on improving the quality of CKD care and reviewing studies examining the effectiveness of different approaches. It is not yet clear that population-based disease management is the optimal approach because CKD is asymptomatic for many persons. Programs that coordinate the care of CKD patients may need laboratory data for targeting patients.

CMS has excluded patients with ESRD from participating in the CCIP, but not patients with other costly conditions, such as rheumatoid arthritis and multiple sclerosis. Care coordination programs as configured under the MMA might have provided opportunities to improve renal care. Although CMS will be initiating a disease management demonstration for ESRD patients in the near future, not all ESRD patients will be able to participate in this program. ■

Endnotes

- 1 CMS published a request for proposals on April 23, 2004, and applications are due to CMS by August 6, 2004.
- 2 Hierarchical condition category scores are used by CMS as part of its formula for risk adjusting payments to Medicare Advantage plans.
- 3 Since many drugs are prescribed for multiple conditions, prescription data will not always be useful to determine diagnoses.
- 4 In addition, CMS only recognizes outpatient diagnoses from professional (physician) office and emergency room visits and consultations, not from other providers or from other physician services. For example, physician services for procedures, test, and imaging are not counted when flagging the target populations for the intervention.
- 5 The National Kidney Foundation is in the process of developing diabetes- and cardiovascular-related guidelines for patients with chronic kidney disease.
- 6 Interviewees informed us that they periodically reevaluate the risk level of each patient participating in their disease management and care coordination programs. Some patients who are at a higher risk level may shift to a lower risk level. On the other hand, the condition of some patients may worsen during the course of the year. Having claims data may enable contractors to monitor changes in a patient's condition.
- 7 Here we use the term "dual eligible" to refer to people for whom a state has paid their Medicare Part B (or A) premium. This includes those eligible for a state's full package of Medicaid benefits, as well as Qualified Medicare Beneficiaries and Specified Low-Income Beneficiaries.
- 8 Note that the 18 percent share is lower than other figures from studies on care provided at the end of life. Those analyses tend to examine the amount of program spending on beneficiaries during the last 12 months of their lives, rather than for a calendar year (Hogan et al. 2000).
- 9 About 90 percent of all dialysis patients undergo hemodialysis, in which blood from the patient's body is circulated through an external machine and returned to the patient's blood stream. About 10 percent of all patients undergo peritoneal dialysis, a procedure that introduces dialysate into the abdominal cavity to absorb and remove waste products through the peritoneum.
- 10 The estimate of kidney transplant patients includes patients undergoing transplantation in 2001 and patients with a functioning kidney transplant.
- 11 To help address this problem, the Department of Health and Human Services awarded grants totaling \$4.3 million in 2003 to support social, behavioral, and clinical intervention programs to increase organ and tissue donation.
- 12 Outpatient dialysis services include composite rate services, injectable drugs administered during dialysis, physician monthly capitation services, vascular access services, and peritoneal access services.
- 13 Estimates obtained from the American Diabetes Association and the U.S. Bureau of the Census were used to estimate the number of diabetics and persons 70 years or older who have CKD, respectively.
- 14 The median follow-up period for the population was 2.2 years.
- 15 The 1972 amendments to the Social Security Act extended Medicare benefits to people with ESRD who were fully or currently insured or eligible for Social Security, their spouses, and their dependent children. About one-third of ESRD patients are entitled to Medicare on the basis of ESRD alone.
- 16 Sum does not total to 100 because of rounding.
- 17 Vascular access refers to the site on the patient's body where blood is removed and returned during hemodialysis. The AV fistula is the type of vascular access recommended by renal clinical guidelines because it is associated with fewer complications and lasts longer than the other types of vascular access.
- 18 Clinicians are still debating the level of renal function at which dialysis should be initiated. Some clinicians suggest that early dialysis leads to reduced mortality among dialysis patients. Others recommend a strategy of careful management until dialysis becomes inevitable (Kausz et al. 2000).
- 19 Other factors related to the decline in peritoneal dialysis include the medical conditions, preferences, and social circumstances of patients and the preferences of medical personnel. In addition, MedPAC has noted that the rapid growth in the number of dialysis facilities throughout the 1990s has created an incentive to direct patients to in-center treatment so that facilities operate at capacity. Finally, the profitability of separately billable drugs may also provide an incentive for in-center care.
- 20 Creatinine is a waste product from muscles and protein in the diet removed from the body by the kidneys. As kidney disease progresses, the level of creatinine in the blood increases.

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CHAPTER

3

**Dual eligible beneficiaries:
An overview**

Dual eligible beneficiaries: An overview

Dual eligibles are a vulnerable and costly group. They tend to be poor and report lower health status than other beneficiaries, and cost Medicare about 60 percent more than nondual eligibles. Nevertheless, our profile of dual eligibles finds a diverse population, with spending concentrated among a minority of beneficiaries and a significant portion reporting good health and few physical and cognitive limitations.

Coverage and payment policies, which affect how beneficiaries receive their care, are complicated by the intersection of Medicare and 50 separate state Medicaid policies. The Commission finds that current policy toward dual eligibles creates incentives to shift costs between payers, often hinders efforts to improve quality and coordinate care, and may reduce access to care. This chapter provides a foundation for assessing policy alternatives available to the Medicare program for addressing the care needs and costliness of beneficiaries who are eligible for both Medicare and Medicaid.

In this chapter

- Who are dual eligibles?
- What are their spending and care patterns?
- How is their access to care?
- How do coverage and payment policies work for dual eligibles?

Dual eligibles are persons who qualify, in some way, for both Medicare and Medicaid coverage. Medicare covers their acute care services, while Medicaid covers Medicare premiums and cost sharing, and—for those below certain income and asset thresholds—long-term care services and, until 2006, prescription drugs, among other services. We use the term “dual eligible” to encompass all Medicare beneficiaries who receive Medicaid assistance, including those who receive the full range of Medicaid benefits and those who receive assistance only with Medicare premiums or cost sharing.

Dual eligibles as a whole are a particularly vulnerable subgroup of Medicare beneficiaries. By virtue of their eligibility for Medicaid coverage, they tend to be poor and report lower health status than other beneficiaries. Medicaid plays an important role in reducing out-of-pocket spending for this population and potentially improving access to care.

Dual eligibles are more expensive for Medicare than other beneficiaries. About 15 to 17 percent (6.2 to 7.0 million) of Medicare beneficiaries in 2001 were dual eligible, accounting for about 22 to 26 percent of Medicare spending.¹ Total spending—across all payers—for dual eligibles averaged about \$20,840 per person in 2001, more than twice the amount for other Medicare beneficiaries.

Given dual eligibles’ vulnerability and relative costliness, do Medicare’s current eligibility, coverage, and payment policies promote access to quality care for this population? Could their needs be better met? And, are there ways to meet their needs more cost effectively? This chapter provides a foundation for assessing the need for policy alternatives and reports information about dual eligibles that could be used to guide future policy in this area.

Because of MedPAC’s charter to recommend improvements to the Medicare program, we address these questions from the Medicare perspective. This focus should not diminish the significant resources and energy states devote to assisting dual eligibles, however. In 1999, dual eligibles represented 19 percent of Medicaid recipients and accounted for 35 percent of Medicaid spending (Kaiser 2003a). Accordingly, a complete assessment of the impact of current policy and alternative policies must take into account how resources can be aligned across both programs to improve dual eligibles’ access to quality care.

Our profile of dual eligibles, based on analysis of Medicare Current Beneficiary Survey (MCBS) data, finds a diverse population. Although a high proportion have characteristics associated with being poor (e.g., female, minority, poorly educated), they vary greatly in other respects (e.g., living situation, health status, age). We find that over one-third of dual eligibles are under 65, 38 percent have cognitive or mental impairments, 22 percent have multiple physical impairments, and 23 percent are institutionalized. However, a full 40 percent of all dual eligibles have less debilitating physical conditions or no impairments at all.

Medicare spending on dual eligibles is concentrated among a minority of the population. Dual eligibles are more likely to use all types of Medicare-covered services than nondual eligibles, and average Medicare spending is higher for dual eligibles across all services. However, when we consider average Medicare spending on services only for those beneficiaries who actually use services, we find that dual eligibles have lower spending per beneficiary than other beneficiaries for hospital, skilled nursing facility (SNF), and home health services. Dual eligibles are also more likely to receive care in long-term care facilities than other Medicare beneficiaries.

Dual eligibles’ access to care is generally good. We found, from analyzing MCBS and Consumer Assessment of Health Plans Survey (CAHPS) data, that about 86 percent of dual eligibles report having a usual source of care and receiving both immediate and regular care when needing it. However, beneficiaries with other sources of supplemental insurance tend to rate their access more highly. Medicare-only beneficiaries (those with no supplemental insurance) rate their access worse than dual eligibles on some measures and better than dual eligibles on others.

Coverage and payment policies affect how beneficiaries receive their care and, so, influence access to care as well as the quality and cost of the care. Both Medicare and Medicaid (which includes some 50 state programs) have rules and processes for determining which program covers which service and the payment amount for each service. Specifically, we find that the current coverage and payment policies for dual eligibles:

- create incentives to shift costs between payers;
- often hinder efforts to improve quality and coordination of care;

- lead to coverage conflicts that are difficult to resolve;
- may threaten access to care; and
- are inconsistent on whether dual eligibles are considered Medicare beneficiaries first—meaning that Medicare protections should prevail when Medicare and Medicaid program requirements conflict.

Who are dual eligibles?

Dual eligibles are those who meet eligibility requirements for both Medicare and Medicaid and are enrolled in both programs. We explore these technical qualifications before profiling their demographic and health status characteristics. Naturally, many characteristics of the dual eligible population are related to their eligibility qualifications.

What are the criteria for dual eligibility?

Medicare beneficiaries can qualify for Medicaid if they meet certain income and resource requirements or have high health care bills. Each state sets its own eligibility standards and determines the scope of benefits provided to Medicaid beneficiaries, within federal guidelines.

Dual eligibles can be divided into several different categories, each qualifying for a different set of covered benefits (Table 3-1, p. 74). Although identifying which beneficiaries are in which category is important for our understanding of the spending and care patterns of dual eligibles, most data sources that researchers rely upon (e.g., the enrollment data base and MCBS) do not explicitly identify a beneficiary’s eligibility category. Efforts are underway to better link Medicare and Medicaid data, but in the meantime, it is important to understand conceptually the differences between “full” dual eligibles and those who participate only in the Medicare Savings Programs, which offer partial supplemental coverage.

Full dual eligibles

Most dual eligibles qualify to receive full Medicaid benefits. Full dual eligibles are entitled to receive all benefits covered by Medicaid, such as nursing home and other institutional care, home care, dental care, mental health care and therapy, eye care, transportation to and

from providers, and prescription drug coverage.² Medicaid also pays their Medicare Part A (if necessary) and Part B premiums and cost sharing for all Medicare Part A and Part B services.

Beneficiaries have two pathways to receiving full Medicaid benefits. First, they may be eligible if they have incomes less than or equal to 73 percent of poverty (the Supplemental Security Income eligibility level) and assets not in excess of \$2,000 for individuals and \$3,000 for couples. States have the option to set higher asset thresholds and extend full Medicaid benefits to beneficiaries with incomes up to 100 percent of poverty.

Beneficiaries can also receive full Medicaid benefits if their medical expenses are high enough to reduce their net income below a state-specified level. These beneficiaries are considered “medically needy.” Often, beneficiaries become medically needy if they have a chronic illness like diabetes or dementia that leads to significant and overwhelming medical expenses, or if they move to a nursing home. States are not required to offer medically needy programs, but 39 states do. For medically needy beneficiaries, states also have the option of paying the Part B premium.

Two additional programs are available to states to assist low-income beneficiaries: the Special Income Rule for Nursing Home Residents program, known as the 300 percent rule, and the Home- and Community-Based Services Waivers program. The 300 percent rule allows beneficiaries with incomes up to 300 percent of the Supplemental Security Income eligibility income level to receive full Medicaid benefits, Medicare Part B premiums, and cost sharing if they are in an institution.³ The latter program provides Medicaid-covered home- and community-based services to those beneficiaries who would be eligible for Medicaid if they resided in an institution. These beneficiaries might then continue to live in the community with assistance (personal care, for example) rather than in an institution.

Medicare savings programs

Beneficiaries with somewhat higher income and asset levels are eligible for more limited Medicaid coverage. Beneficiaries with income and assets that exceed state requirements for Medicaid but have incomes below 100 percent of poverty and meet an asset test (no more than

**TABLE
3-1**

How do Medicare beneficiaries qualify for Medicaid?

Type of dual eligible	Medicaid benefits	Eligibility criteria	
		Required	Optional
Full dual			
Meets low-income standard	Wrap-around Medicaid benefits, Medicare premiums and cost sharing	Income: ≤73 percent of FPL* Asset limit: \$2,000 (individual) \$3,000 (couple)	Income: 74–100 percent of FPL Asset limit: higher asset threshold
Medically needy (has high medical expenses)	Wrap-around Medicaid benefits, Medicare premiums and cost sharing (extent of coverage may vary by state)	None	By deducting incurred medical expenses from income, individual may spend down to a state-specified level
Medicare savings program			
QMB	Medicare premiums and cost sharing	Income: up to 100 percent of FPL Asset limit: \$4,000 (individual) \$6,000 (couple)	None
SLMB	Part B premium	Income: 100–120 percent of FPL Asset limit: \$4,000 (individual) \$6,000 (couple)	None
QI**	Part B premium	Income: 120–135 percent of FPL Asset limit: \$4,000 (individual) \$6,000 (couple)	None

Note: FPL (federal poverty level), QMB (qualified Medicare beneficiary), SLMB (specified low-income Medicare beneficiary), QI (qualifying individual). These requirements apply for 2003.

* States that elect the so-called “209b option” can set more stringent income and asset limits.

** The QI program is funded under a block grant that was extended through September 31, 2004.

\$4,000 for an individual and \$6,000 for a couple) are eligible to be qualified Medicare beneficiaries (QMBs). Medicaid pays their Medicare premiums and cost sharing.⁴

Beneficiaries with incomes between 100 and 120 percent of poverty are eligible to be specified low-income Medicare beneficiaries (SLMBs). Medicaid pays their Part B premium.

Medicare beneficiaries may also receive benefits through the qualifying individual (QI) program. The Balanced Budget Act of 1997 established the QI program as a capped federal allocation to states, out of which states pay

the Part B premiums for qualifying Medicare beneficiaries. Originally set to last five years, starting in 1998, the QI program was recently extended through September 31, 2004. Because the QI program is subject to an annual federal funding cap, the number of Medicare beneficiaries who may participate in the program is limited.

Some Medicare beneficiaries who previously qualified for Medicare because of a disability but then returned to work may purchase Medicare Parts A and B. If their income is

less than 200 percent of poverty but they do not qualify for any other Medicaid assistance, they may be eligible for the Qualified Disabled and Working Individuals program, through which Medicaid pays their Part A premiums.

Implications of eligibility criteria

Eligibility and benefits offered to dual eligibles can vary greatly by state. Medicare beneficiaries residing in one state might qualify for full wrap-around Medicaid benefits, coinsurance, and cost sharing, while similar beneficiaries in another state might only qualify to have their Medicare Part B premiums paid. These differences in eligibility across states translate into differences in basic health insurance coverage and out-of-pocket spending, which can in turn affect access to needed health care.

Also, even if beneficiaries are eligible for Medicaid benefits, they may not be enrolled in the program, which may limit their use of health care. Seventy-eight percent of those who qualify for the QMB program are enrolled and only 18 percent of those eligible for the SLMB program are enrolled (Moon et al. 1998).⁵ The barriers to program participation are numerous. Beneficiary education about the programs is often underfunded or lacking. Welfare workers, Social Security Administration employees, and community-based organizations may not know enough about the programs to conduct effective outreach, and states, facing increasing budgetary pressures in recent years, may not have the resources to implement or maintain extensive outreach programs. Beneficiaries may choose not to enroll if the state has Medicaid estate recovery requirements. Furthermore, enrollment processes that require long waits in welfare offices, face-to-face interviews, and extensive documentation of income and assets can deter beneficiaries from enrolling. Language and transportation pose further difficulties.

What are the demographic and health characteristics of the dual eligible population?

How do dual eligibles differ from other Medicare beneficiaries? Dual eligibles are more likely to have characteristics that make them more vulnerable—such as fewer resources and poorer health—than nondual

eligibles. However, many other characteristics—such as age, disability level, living arrangement, and health status—vary significantly among dual eligibles.

Overview of the dual eligible population

By definition, dual eligibles are poor: over 60 percent live below the poverty level, and 94 percent live below 200 percent of poverty (Table 3-2, p. 76).⁶ A disproportionate share lack a high school diploma and are African American or Hispanic. They are also more likely to be female.

The dual eligible population is more likely than the rest of the Medicare population to be disabled (under age 65 and eligible for Medicare because of a disability) or at least 85 years old. More than one-third of dual eligibles are eligible for Medicare because they are disabled, and 14 percent are age 85 or older. In fact, dual eligibles are three times more likely to be disabled than the nondual eligible population.

Relative to nondual eligibles, dual eligibles report poorer health status on the MCBS. The majority report good or fair status, but just over 20 percent of the dual eligible population (compared with less than 10 percent of the nondual eligible population) report being in poor health. Dual eligibles are also more likely to have greater limitations in activities of daily living (ADLs)—e.g., bathing and dressing—than nondual eligibles. One-third of dual eligibles have impairments in three to six ADLs. A full 45 percent of dual eligibles do not report any limitations in these activities.

Almost one-quarter of dual eligibles reside in an institution, compared with 3 percent of nondual eligibles. Although a small proportion live with their spouses, one-third of dual eligibles live with family members and non-relatives, and another one-third live alone.

Dual eligibles are more likely to suffer from cognitive impairment and mental disorders, and they have higher rates of diabetes, pulmonary disease, stroke, and Alzheimer's disease than do nondual eligibles (Murray and Shatto 1998, CMS 2002).

The vast majority of dual eligibles have no other supplemental insurance—other than Medicaid—and those who do often obtain such coverage through other public programs (such as the Department of Veterans Affairs or a state-sponsored drug plan).

**TABLE
3-2****Differences between nondual and dual eligible beneficiaries, 2001**

Characteristics	Nondual eligible	Dual eligible
Demographics		
Male	45%	38%
Female	55	62
White, non-Hispanic	84	57
African American, non-Hispanic	7	21
Hispanic	6	15
Other	3	7
<65	10	36
65-74	47	26
75-84	32	24
85+	11	14
Health status and ADLs		
Excellent or very good	43	17
Good or fair	49	62
Poor	8	21
No ADLs	71	45
1-2 ADLs	19	22
3-6 ADLs	10	33
Residence		
Urban (in an MSA)	77	73
Rural (non-MSA)	23	27
Institution	3	23
Alone	28	31
With spouse	55	16
With children, nonrelatives, others	14	31
Education		
No high school diploma	28	62
High school diploma only	31	23
Some college or more	41	15
Income status		
Below poverty	9	62
100-125% of poverty	9	20
125-200% of poverty	24	12
200-400% of poverty	38	4
Over 400% of poverty	21	1
Supplemental insurance status		
Medicare or		
Medicare/Medicaid only	12	91
Medicare managed care	18	1
Employer	36	1
Medigap	26	1
Medigap/employer	5	0
Other	2	7

Note: ADL (activity of daily living), MSA (metropolitan statistical area). We count beneficiaries as dual eligibles if the months they qualify for Medicaid exceed the number of months they qualify for other supplemental insurance. In 2001, poverty was defined as income of \$8,494 for people living alone and \$10,715 for married couples.

Source: MedPAC analysis of Cost and Use file, 2001 Medicare Current Beneficiary Survey.

Subgroups of dual eligibles

Because the heterogeneity of the dual eligible population makes it difficult to identify the typical dual eligible, we identified six subgroups of dual eligibles that share similar health status profiles and reasons for Medicare eligibility. Segmenting the population in this way and examining changes in the composition and spending patterns over time may help policymakers better target policy options to particular groups (Table 3-3).⁷

Both for aged beneficiaries and for beneficiaries eligible for Medicare because of a disability, we identified the following subgroups of beneficiaries with:

- Mental or cognitive disabilities,
- Limitations in two or more ADLs (and no mental or cognitive disabilities), and
- Limitations in fewer than two ADLs (and no mental or cognitive disabilities).

This analysis excludes beneficiaries with end-stage renal disease and is based on pooled MCBS data over two separate three-year periods. We identified beneficiaries with mental or cognitive disabilities primarily by survey responses, diagnosis and other information from Medicare claims, and self-reported prescription drug use. We did not assign those who reported only depression to this category. We determined beneficiaries' difficulty with ADLs based on survey responses.⁸

Among aged dual eligibles, just less than half have fewer than two ADL limitations and about one-third have mental or cognitive impairments. The smallest group of aged dual eligibles consists of those with more than two ADL limitations. About 17 percent of aged dual eligibles were initially eligible for Medicare due to a disability before they were 65.⁹

Dual eligibles who are under 65 and eligible for Medicare because of a disability have a different health status profile than the aged dual eligibles, with the majority (more than one-half) having mental or cognitive impairments. Similar to the aged dual eligibles, however, relatively few of the under 65 disabled dual eligibles have two or more ADL limitations and no cognitive or mental problems.

**TABLE
3-3**

The characteristics of dual eligible beneficiaries are changing

Subgroup	1993-1995	1999-2001
Under 65 and disabled	28.2%	34.4%
Mentally or cognitively impaired	14.4	17.9
Limitations in two or more ADLs	3.9	5.4
Limitations in fewer than two ADLs	9.9	11.1
Aged	71.8	65.6
Mentally or cognitively impaired	21.6	20.7
Limitations in two or more ADLs	18.4	14.8
Limitations in fewer than two ADLs	31.9	30.2

Note: ADL (activity of daily living).

Source: MedPAC analysis of Cost and Use file, 1993-1995 and 1999-2001 Medicare Current Beneficiary Survey.

Overall, among all dual eligibles:

- over 40 percent have less than two ADL limitations and no mental or cognitive impairments,
- about 38 percent have mental or cognitive limitations, and
- 22 percent have difficulty with two or more ADLs but do not have cognitive or mental limitations.

One important subgroup of dual eligibles resides in institutional settings, such as nursing homes. Of these, the majority (60 percent) were aged and mentally or cognitively impaired in 2001, followed by aged with physical impairments (19 percent), and disabled with cognitive or mental impairments (15 percent).

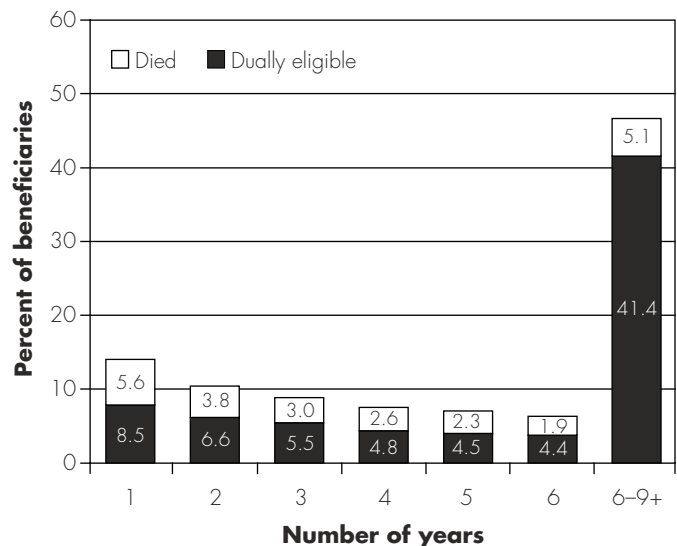
The composition of dual eligibles has changed somewhat in the last decade. A larger percentage of dual eligibles are under 65 and disabled (34 percent compared with 28 percent), and a smaller percentage of dual eligibles are institutionalized (25 percent compared with 29 percent).

Length of dual eligibility

Understanding how long beneficiaries stay dually eligible and the stability of the population over time may help policymakers determine the benefits of targeting care management activities to this population. Using consecutive years of data indicating whether a state Medicaid program paid any portion of beneficiary costs for Medicare Part A, Part B, or both, we found that beneficiaries tended to remain on Medicaid for relatively long periods of time. Of beneficiaries who became dually eligible between 1994 and 1996, nearly half (47 percent) remained dually eligible for more than six years (Figure 3-1). Only 14 percent of those who became dually eligible between 1994 and 1996 were dual eligibles for one year or less. This analysis does not include all medically needy dual eligibles because the data do not allow us to identify all of them.

**FIGURE
3-1**

Beneficiaries who became eligible for Medicaid in 1994-1996 were often still eligible 6-9 years later



Note: Some beneficiaries likely remained dually eligible beyond the nine year time period we analyzed.

Source: MedPAC analysis of 5 percent Denominator files, 1993-2002, from CMS.

What are their spending and care patterns?

Higher Medicare, Medicaid, and total spending for dual eligibles compared to nondual eligibles (Table 3-4) provokes a number of questions. Why are dual eligibles more costly? Are all dual eligibles equally costly or is there variation? What services do they tend to use more of? Answers to these questions may yield insight into how to target policy interventions and evaluate dual eligibles' access to care. This section focuses primarily on Medicare spending.

Why are dual eligibles more costly for Medicare?

That per capita Medicare spending for dual eligibles is higher than for nondual eligibles is not surprising given the criteria for eligibility. Some become eligible because they are sick; others become eligible because they are poor, a characteristic often associated with lower health status. One analysis found that differences in health status explain the majority of the difference in Medicare spending for dual and nondual eligibles, but not all (Liu et al. 1998). Other factors that could contribute to higher spending for dual eligibles include:

- presence of supplemental coverage (i.e., Medicaid),

- socio-economic factors that may lead them to delay care until they require more services in more costly settings,
- lack of an informal care network or environment, and
- separate sources (i.e., Medicare and Medicaid) of coverage that may inhibit coordination of their care.

We look more closely at the sources of Medicare spending (Table 3-5) by comparing the average per capita Medicare payment for dual eligibles and other beneficiaries by service.¹⁰ For each type of service, average Medicare per capita payments are higher for dual eligibles than nondual eligibles. The most striking difference between the two groups is in SNF and hospice services, for which Medicare spends over twice as much on dual eligibles as on nondual eligibles.

Higher average per capita spending for dual eligibles is a function of both a higher proportion of dual eligibles using services than nondual eligibles as well as greater volume or intensity of use among those who do use services. A higher proportion of dual eligibles than nondual eligibles use at least one Medicare-covered service, but the difference is relatively small—92 versus 89 percent. They are also more likely to use each type of Medicare-covered service than nondual eligibles. For example, dual eligibles are more than twice as likely to use SNF services.

Among beneficiaries with payments for each type of service, Medicare spending is significantly higher for dual eligibles in the categories of physician, outpatient hospital, and hospice care, but higher for nondual eligibles in inpatient hospital, home health, and SNF care.

Are all dual eligibles equally costly?

Annual Medicare spending is concentrated among a small number of dual eligibles (Figure 3-2, p. 80). The costliest 5 percent of dual eligibles account for over 40 percent of total Medicare spending for this population, and the costliest 20 percent account for 80 percent of total Medicare spending on dual eligibles. In contrast, the least costly 50 percent of dual eligible beneficiaries account for only 3 percent of Medicare spending on dual eligibles. This wide distribution in annual spending underscores the diversity of the dual eligible population.

**TABLE
3-4**

Dual eligible beneficiaries are more costly than others, 2001

Source of spending	Nondual eligibles	Dual eligibles
Total	\$10,054	\$20,844
Medicare	5,399	8,559
Medicaid	85	8,603
Other	4,570	3,682

Note: Total spending includes Medicare, Medicaid, and out-of-pocket spending in addition to spending from other sources of supplemental insurance and public programs (e.g., the Department of Veterans Affairs, the Department of Defense). We count beneficiaries as dual eligibles if the months they qualify for Medicaid exceed the number of months they qualify for other supplemental coverage. Thus, some nondual eligibles have Medicaid coverage for some portion of the year.

Source: MedPAC analysis of Cost and Use file, 2001 Medicare Current Beneficiary Survey.

**TABLE
3-5**

Differences in spending and service use for nondual and dual eligible beneficiaries, 2001

Service	Nondual	Dual	Percent difference
Average Medicare payment for all beneficiaries			
Total Medicare payments	\$5,399	\$8,559	59%*
Inpatient hospital	2,486	3,974	60*
Physician ^a	1,720	2,278	32*
Outpatient hospital	523	965	85*
Home health	241	338	40*
Skilled nursing facility ^b	322	727	126*
Hospice	98	199	104*
Percent of beneficiaries using service			
Any Medicare service	89.1%	92.2%	3.5%*
Inpatient hospital	15.3	26.8	75.6*
Physician ^a	70.7	90.5	28.0*
Outpatient hospital	51.7	71.6	38.6*
Home health	5.5	8.0	43.9
Skilled nursing facility ^b	3.2	7.7	143.5*
Hospice	1.3	2.5	89.4
Average Medicare payment for beneficiaries using service			
Any Medicare service	\$6,059	\$9,284	53%*
Inpatient hospital	16,281	14,824	-9*
Physician ^a	2,432	2,517	3*
Outpatient hospital	1,012	1,348	33*
Home health	4,348	4,243	-2*
Skilled nursing facility ^b	10,224	9,473	-7*
Hospice	7,405	7,973	8*

Note: ^a Includes a variety of medical services, equipment, and supplies.
^b Individual short-term facility (usually skilled nursing facility) stays for the Medicare Current Beneficiary Survey population.
* Indicates a statistically significant difference between dual eligibles and nondual eligibles, at a 95% confidence level (p<0.05).

Source: MedPAC analysis of Cost and Use file, 2001 Medicare Current Beneficiary Survey, which updates the previous analysis by Liu et al. in 1998.

A similar pattern exists for all Medicare beneficiaries (see Chapter 2). However, because the average Medicare spending on the most costly dual eligibles is higher than on the most costly nondual eligibles, dual beneficiaries are a disproportionate share of the overall most costly beneficiaries. Of the 1 percent of beneficiaries for whom Medicare spending is the highest, one-third are dual eligibles. Similarly, of the costliest 5 percent of beneficiaries, 25 percent are dual eligibles.

On average, total spending (which includes primarily Medicare, Medicaid, and out-of-pocket spending) for dual eligible beneficiaries is more than twice as high as that for nondual eligibles—\$20,840 compared to \$10,050. The distribution of total spending for dual eligibles is similar, but slightly less concentrated, than the distribution of Medicare spending. For example, the top 5 percent of dual beneficiaries account for 27 percent of total spending (compared with 40 percent of Medicare spending).

What type of dual eligibles are more costly?

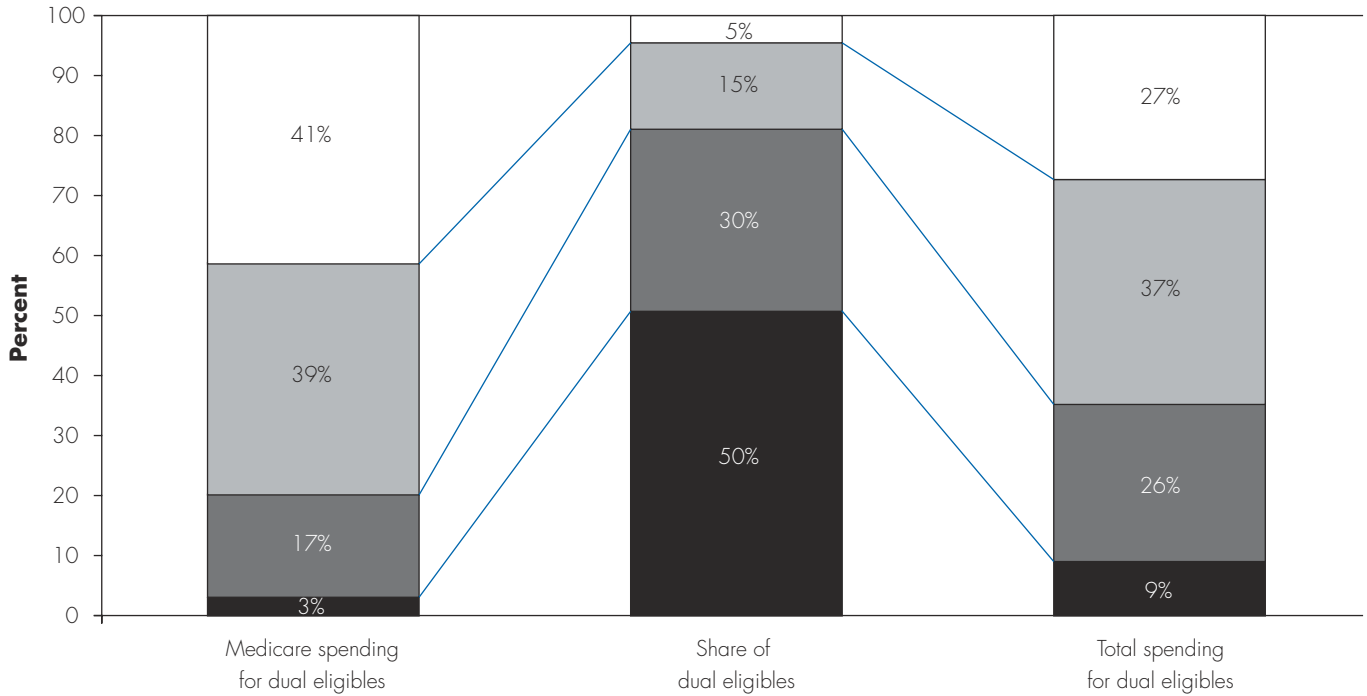
To better understand the underlying diversity of the dual eligible population, we examine spending data using the same subgroup classifications we used earlier in the chapter (page 76). In this analysis, we compare spending patterns among subgroups of dual eligibles as well as across dual eligibles and nondual eligibles (Table 3-6, p. 80).

We find that, on average, the most costly subgroup of dual eligibles for Medicare are aged with mental and cognitive problems (\$12,370), followed by the aged with physical impairments (\$9,603) and the disabled with physical impairments (\$7,299). Not surprisingly, dual eligibles with less than two ADL limitations cost Medicare much less (\$3,425–\$4,415).

Comparing dual eligibles and nondual eligibles, we find that all categories of *disabled* dual beneficiaries are significantly more costly to Medicare than their nondual counterparts. In contrast, Medicare spending for *aged* dual eligibles is about the same as for their nondual counterparts. While Medicare spending on these two populations is relatively close, total spending is much higher for dual eligibles. This disparity reflects the increased likelihood of dual eligibles receiving care in long-term care facilities, which is not covered by Medicare.

FIGURE 3-2

Both Medicare and total spending are concentrated among dual beneficiaries, 2001



Note: Columns may not sum due to rounding. Total spending includes Medicare, Medicaid, supplemental insurance, and out-of-pocket spending.

Source: MedPAC analysis of Cost and Use file, 2001 Medicare Current Beneficiary Survey.

TABLE 3-6 Aged mentally or cognitively impaired dual eligibles are most costly

Subgroup	Medicare spending	
	Dual eligibles	Nondual eligibles
Disabled		
Mentally or cognitively impaired	\$6,405*	\$3,657
Limitations in two or more ADLs	7,299*	4,416
Limitations in fewer than two ADLs	3,425*	2,605
Aged		
Mentally or cognitively impaired	12,370	11,864
Limitations in two or more ADLs	9,603	8,933
Limitations in fewer than two ADLs	4,415	3,992

Note: ADL (activity of daily living).
*Indicates statistically significant difference in spending between dual and nondual eligibles.

Source: MedPAC analysis of Cost and Use file, 1999–2001 Medicare Current Beneficiary Survey.

How is Medicare spending distributed by service for dual eligibles? Has it changed over time?

While Medicare spending for both dual and nondual eligibles living in the community is concentrated on hospital and physician services, the distribution of Medicare spending across services for dual eligibles differs from that of nondual eligibles. A greater portion of Medicare spending is devoted to home health care for dual than nondual eligibles, while a greater portion of spending is devoted to physician care for nondual eligibles, as compared to dual eligibles (Table 3-7).

The distribution of Medicare spending has changed somewhat over time for dual eligibles. The portion spent on home health care declined and the portion spent on physician and outpatient hospital care increased. The portion spent on SNF or inpatient care remained unchanged. Dual and nondual eligibles experienced

**TABLE
3-7**

**Medicare spending by service,
1993-1995 and 1999-2001**

Service type	1993-1995		1999-2001	
	Dual	Nondual	Dual	Nondual
Inpatient hospital	48.7%	52.2%	49.8%	49.1%*
Physician	26.4	28.8	30.8*†	33.3*
Outpatient hospital	7.8	7.6	9.6*	8.4*
Home health	14.4	8.7	6.3*†	4.5*
SNF	2.0	2.0	2.1†	3.4*

Note: SNF (skilled nursing facility).
 * Indicates statistically significant change in the portion of spending for a service between the two time periods.
 † Indicates statistically significant difference in the portion of spending for a given service between the dual and nondual eligible populations.

Source: MedPAC analysis of Cost and Use file, 1993-1995 and 1999-2001 Medicare Current Beneficiary Survey.

similar changes in the distribution of spending, except that the portion spent on SNF care for nondual eligibles increased, while the portion spent on inpatient care for this group decreased.

How is their access to care?

Are dual eligibles able to access the health care they need? This question is particularly relevant for this population because these beneficiaries often possess characteristics that are associated with needing care (e.g., ADL limitations, poor health status) as well as having difficulty obtaining care (e.g., poor, less educated).

Because the question of access is difficult to answer definitively, we examine a number of different indicators. In the previous section, for example, we examined spending patterns over time and found that dual eligibles appear to be accessing fewer of certain types of services than they did before, pointing to possible access problems. However, spending patterns alone do not reveal whether the care beneficiaries are receiving is medically necessary or whether beneficiaries have unmet needs.

Thus, we examine beneficiaries' own evaluation of their access to care and find mixed results. We analyze two surveys, both of which are administered by CMS: the CAHPS and the MCBS.¹¹ Although survey data are limited in that they do not measure the clinical appropriateness of care and can be influenced by factors such as education level, they provide us with an important indication of how beneficiaries perceive their own ability to access care.¹²

The results indicate that most dual eligibles rate their access to care positively, higher in some cases than Medicare-only beneficiaries but generally lower than beneficiaries with other sources of supplemental insurance. Between 75 and 93 percent of dual eligibles rate their access to care highly, depending on the measure of access. This compares with about 83 to 99 percent of beneficiaries with other sources of supplemental coverage—Medigap or employer-sponsored insurance, for example.¹³ Medicare-only beneficiaries may or may not report better access to health care than dual eligibles. The results depend on the aspect of access being measured: Dual eligibles have a slightly more difficult time getting immediate and regular care, but are more likely to have a usual source of care and less likely to delay care due to cost (Table 3-8). Both groups rate their health care and providers highly.

**TABLE
3-8**

Dual eligible beneficiaries report generally good access to care

Question	Percent reporting positively	
	Dual eligible	Medicare only
Do you have one person you think of as your personal doctor or nurse?	84.0%	74.6%
Did you delay seeking medical care because you were worried about the cost?	9.7	22.5
Did you usually or always get care as soon as you wanted when you needed care right away?	88.1	90.3
Did you usually or always get an appointment for regular or routine care as soon as you wanted?	86.5	90.7

Source: MedPAC analysis of the Cost and Use file and the Access to Care file, 2001 Medicare Current Beneficiary Survey; and the 2001 Consumer Assessment of Health Plans Survey.

On some measures, dual eligibles' access to care appears to be relatively good. Dual eligibles report having a usual source of care—a particular doctor or nurse—more often than Medicare-only beneficiaries (84 percent versus 75 percent). Dual eligibles also report that they delay care due to cost less often than Medicare-only beneficiaries (10 percent versus 23 percent). This makes sense, since dual eligibles have little out-of-pocket liability: The majority have Medicaid coverage for both services that Medicare does not cover and the cost sharing associated with Medicare-covered benefits. However, beneficiaries with other sources of supplemental coverage report better access to care on these measures than either dual eligibles or Medicare-only beneficiaries: Between 89 percent and 93 percent have a usual source of care, and between 1 percent and 5 percent delay care due to cost. These differences may reflect differences not only in coverage but also in the underlying characteristics of the populations.

Dual eligibles may have slightly more difficulty accessing immediate and routine care than do Medicare-only beneficiaries. Dual eligibles were less likely than Medicare-only beneficiaries to report that they “usually” or “always” received immediate or routine care when they or their doctor felt they needed it. A higher percentage of beneficiaries with other supplemental coverage (about 93 percent) responded “usually” or “always” to the same questions.

We find conflicting results regarding the broad, overarching question of whether beneficiaries had difficulty getting needed care. Using MCBS data, we find no difference between dual eligibles and Medicare-only beneficiaries. However, using CAHPS, we find that dual eligibles have slightly more problems obtaining necessary health care than Medicare-only beneficiaries. On both surveys, beneficiaries with other sources of supplemental coverage report fewer problems than either of these groups in accessing needed health care.

Both dual eligibles and Medicare-only beneficiaries appear equally able to access a specialist: Between 75 and 77 percent report they are able to see a specialist when needed (compared with 87 percent of those with other sources of coverage). Both groups appear satisfied with their personal doctor, specialist, or overall health care: 78 to 84 percent rate their health care providers or the health care they receive highly.

How do coverage and payment policies work for dual eligibles?

Attempts to coordinate benefits and payments for services used by dual eligibles illustrate the complex interrelationship of the two programs and the challenges involved in managing care, improving access, and containing systemwide costs. The dynamics in the system differ somewhat depending upon whether a dual eligible is in Medicare fee-for-service (FFS) or in a Medicare Advantage (MA) plan (formerly known as a Medicare+Choice plan).

The vast majority of dual eligibles are enrolled in FFS. Unlike other Medicaid recipients, dual eligibles' enrollment in managed care cannot be mandated by states. They are considered to be Medicare beneficiaries first and, as such, are afforded freedom of choice in enrolling in managed care.

In some states, however, dual eligibles' enrollment in MA plans is significant. Eleven percent of dual eligibles in California are enrolled in Medicare managed care, 14 percent in Florida, and 28 percent in Oregon (Walsh and Clark 2002). Other types of Medicare managed care arrangements, such as the Program of All-Inclusive Care for the Elderly (PACE), Evercare, and state waiver plans, are also available to dual eligible beneficiaries, depending on where they live. In addition, recent legislation authorized specialized Medicare managed care plans in order to allow greater regulatory flexibility and encourage development of plans that focus on the dual eligible population, among other special needs populations.

The problem of coordinating benefits

Medicare is the primary insurer for dual eligibles and covers medically necessary acute care services, including physician, hospital, hospice, SNF, and home health services, and durable medical equipment. As the secondary payer, Medicaid generally covers:

- Services not covered by Medicare, such as transportation, dental, vision, and until 2006, most outpatient prescription drugs.
- Wrap-around services, such as cost sharing for services covered by Medicare as well as acute care services that are delivered after the Medicare benefit is

exhausted or if certain Medicare criteria are not met. These services include inpatient hospital, SNF, and home health care.

- Long-term care, including custodial nursing facility care, home and community-based services, and personal care services.

After 2006, Medicare will include a prescription drug benefit. Its design is a significant departure from that of other Medicare benefits for dual eligibles. Whereas Medicare's cost-sharing requirements for all other benefits are uniform regardless of the beneficiary's income, cost-sharing requirements for the drug benefit are dramatically reduced for beneficiaries with low income. The extent of the reduction varies by income and asset level.

Under the new prescription drug benefit, dual eligibles with incomes less than 100 percent of the poverty level pay no premium if they select an average—or lower—cost plan. They also pay no deductible, and institutionalized dual eligibles are not responsible for any copays. Dual eligibles living in the community pay nominal copays, the exact amount of which depends on their income.¹⁴ These subsidies are also available to dual eligibles and other low-income beneficiaries with incomes between 100 and 135 percent of poverty who meet a federal asset test. For those who meet the asset test but have incomes between 135 and 150 percent of poverty, the premium subsidy is adjusted on a sliding scale. Their deductible and coinsurance percentages are also reduced.

Although states can supplement the Medicare drug benefit, they cannot receive federal Medicaid matching funds to do so. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provides an exception to this for states that choose to cover a class of drugs not required under the Medicare drug benefit. In this case, Medicaid programs would be allowed to cover this class of drugs and receive the federal match. Certain situations may motivate states to provide coverage even though they do not receive the federal match. For example, if plan formularies do not include drugs important to some dual eligibles, states may choose to provide supplemental coverage. Also, if not all eligible beneficiaries enroll in the program during the limited enrollment period, states may choose to cover these beneficiaries. However, to the extent that states find that they are unable to provide coverage in

these situations without the federal match, dual beneficiaries may face barriers in obtaining prescription drugs.

As under FFS, Medicare is the primary insurer for dual eligibles enrolled in managed care plans participating in the MA program. Medicaid is the secondary insurer, responsible for covering certain wrap-around benefits and acute and long-term care services not covered by Medicare. However, the boundaries between Medicare and Medicaid coverage are less clear for enrollees in MA plans than in FFS because MA plans can offer additional benefits, such as outpatient prescription drug coverage, preventive services, and vision and dental care—all services that Medicaid often covers. In addition, plans generally have a different cost-sharing structure than FFS Medicare. Plans tend to require less cost sharing at the time of service delivery (though more than Medicaid requires) and may charge a premium in addition to the Part B premium. The benefit structure has evolved as Medicare payment and market dynamics have changed. In the last few years, plans increased cost sharing and premiums, and many reduced the scope of additional benefits they offer. However, with the recent payment increases to plans, premiums and cost-sharing levels may once again decline.

Gray areas of benefit definitions

Defining the boundaries of coverage between the two programs can be imprecise and subjective, particularly when similar services are covered by both programs. Coverage determinations are guided by a combination of factors, including statutory definitions of medical necessity, statutory and regulatory parameters of the benefit, judicial decisions, and the judgment of fiscal intermediary staff and administrative law judges (ALJs).

The two programs have a significantly different coverage mandate in statute. Medicare pays for covered services that are medically “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (Social Security Act Section 1863(1)(A)). Hence, its coverage tends to be oriented toward acute care services. By contrast, Medicaid pays for “necessary medical services and . . . rehabilitation and other services to help . . . individuals attain or retain capability for independence or self-care” (Frye 2003). This emphasis leads to broader Medicaid coverage of durable medical equipment, home care services, and long-term care than Medicare.

In addition, Medicare has specific eligibility criteria for each benefit. For example, to qualify for home health care, beneficiaries must be homebound and need skilled care, and the care must be part time or intermittent and prescribed via a physician's order. To qualify for SNF care, a beneficiary must first have a three-day hospital stay.

These eligibility criteria can be further defined by judicial decisions. Perhaps the best known is the 1988 court case *Duggan vs. Bowen*, in which the court reinterpreted the "part time or intermittent" criteria in a way that allowed more beneficiaries to access home health and increased the number of visits that were covered by Medicare.

Medicare coverage decisions are made by fiscal intermediaries, carriers, and durable medical equipment regional contractor (DMERC) staff who review individual claims. Determining whether someone is homebound or in need of skilled care, for example, can require interpretation of law and regulation, and intermediaries can vary in their interpretation of these definitions. The ALJs provide another layer of review. Intermediary denials of these coverage decisions can be appealed to Social Security ALJs, who, in the past, tended to be more lenient than intermediary staff and reverse some of the intermediaries' decisions (Anderson et al. 2003).¹⁵

Gaps in coverage for dual beneficiaries

Medicaid covers many important services that Medicare does not cover, but neither program covers some services. Medicaid has a core set of required services that each state must cover (e.g., physician, hospital), but about two-thirds of the Medicaid benefit package is offered at the state's option. As a result, significant geographic variation in coverage prevails. Some states do not cover certain services, such as dental, vision, and therapy services; some limit the number of hospital days and prescriptions per month covered; others limit coverage by narrowing their medically necessary criteria. Overall, however, the types of benefits covered are fairly comparable to what many private insurance plans offer.

Given recent state budget pressures, many state Medicaid programs have been reducing or eliminating coverage for optional services. For example, in fiscal year 2004, seven states reduced adult dental services, seven states reduced chiropractic services, and five states reduced vision or eyeglass coverage. Other cuts included podiatric and

psychological services as well as occupational, physical, speech, and mental health therapies (Kaiser Family Foundation 2003b).

In addition, Medicaid may not cover services if they are delivered by non-Medicaid approved providers. This may occur in cases where Medicaid coverage is provided through a managed care plan and a non-network provider delivers care. In addition, some Medicaid programs do not recognize certain types of providers, such as long-term care hospitals or some rehabilitation facilities.

Paying for fee-for-service

When Medicaid coverage wraps around Medicare coverage of a service, Medicare pays providers according to its payment methods and rates. In theory, Medicaid pays the associated cost sharing. However, the extent of a state's liability has evolved since passage of the Balanced Budget Act of 1997 (BBA). The BBA clarified that state Medicaid programs are not required to pay the full cost-sharing amount so long as their payment policies are written in their state plan. States are free to cap their liability so that providers receive no more than the state would have paid if the beneficiary only had Medicaid (Table 3-9). Because so many states' Medicaid payment rates are lower than the total Medicare payment rates (program payment plus coinsurance), and often below the program payment alone, providers caring for dual eligibles frequently do not receive the full coinsurance. In general, providers cannot bill the dual eligible for any portion of the coinsurance unless the state charges a nominal Medicaid copayment for the service.

TABLE 3-9

Illustration of Medicaid payment of Medicare coinsurance for most services

Scenario	Medicare		Medicaid	
	Payment	Coinsurance	Rate	Payment for coinsurance
A	\$80	\$20	\$75	\$0
B	80	20	90	10
C	80	20	≥100	20

Note: A (Medicaid is lower than Medicare payment), B (Medicaid is higher than Medicare but less than combined payment plus coinsurance), C (Medicaid rate is greater than or equal to the combined payment plus coinsurance).

For outpatient mental health services, dual eligibles' liability for cost sharing is a special case and, depending on the state's reimbursement rate, is potentially higher than for other services. Medicare's payment is, in effect, 50 percent of the allowed rate; however, it is technically calculated as 80 percent of 62.5 percent of the allowed amount. The maximum coinsurance a state may pay is therefore calculated as 20 percent of 62.5 percent of the total allowed amount (Table 3-10). As with other services, a state may opt to pay nothing if the Medicaid rate is below the Medicare program payment (i.e., 50 percent of the allowed amount) as long as the policy is stipulated in its state plan. Although not permitted for other types of services, mental health practitioners may bill the Medicare beneficiary for the 37.5 percent not reimbursed by either the Medicare program or the state for outpatient mental health services (Thompson 2003).

The degree of flexibility in Medicaid payment for cost sharing was subject to judicial review and decisions in various states before being clarified in the BBA. Prior to this law, about 12 states are estimated to have limited Medicaid payment of Medicare coinsurance. One study found that, between 1997 and 1999, about 18 states reduced their provider payment rates for dual eligibles and aligned them more closely with Medicare payment rates, thereby limiting Medicare coinsurance payments (Nemore 1999, Thompson 2003). Additional states have likely since amended their state plans to pay a smaller portion of Medicare cost sharing.

Even if Medicaid and dual eligibles do not pay the cost sharing, facilities do not have to fully absorb these amounts. Instead, a portion of this reduction is offset by increased Medicare payments. Medicare pays facility-based providers for uncollected cost sharing, otherwise known as "bad debt." Facility-based providers may be reimbursed by Medicare between 70 and 100 percent of bad debt, depending on the type of facility. Part B providers—such as physicians and other ambulatory care providers—do not receive Medicare payments for bad debt. Bad debt reimbursement is limited for dialysis facilities.

When a dual eligible in FFS Medicare is also in a Medicaid managed care plan, determining wrap-around payment is complicated further. A Medicaid managed care plan may maintain that its payment rate (separate from the FFS rate) is lower than Medicare's payment and therefore it owes the Medicare provider no coinsurance. In addition, in some states, if the service is not provided by a Medicaid plan network provider, the plan is not required to pay the provider. In other states, the plan is expected to pay cost sharing for out-of-network providers (Walsh and Clark 2002).

The implications of coverage and payment rules

The coverage rules, payment rules, and different financing mechanisms of the Medicare and Medicaid programs create a complex environment for dual eligibles to obtain care. While Medicare—as a federal program—is predominantly financed by federal payroll taxes, general revenues, and beneficiary premiums, Medicaid is a joint federal and state program, with states financing up to 50 percent of costs.

Spending

Each program's actions can shift costs from one program to the other. In some cases, this shifting of costs increases systemwide administrative costs.

- *Medicare cost sharing and benefit changes.* If Medicare reduces beneficiary cost-sharing requirements, Medicaid spending usually decreases. Similarly, if Medicare expands its benefit package to include a service already covered by Medicaid, Medicaid savings could result. For example, but for the "clawback" provision of the MMA, states would have saved money by having Medicare expand its

TABLE 3-10

Illustration of Medicaid payment of Medicare coinsurance for outpatient mental health services

Scenario	Medicare		Medicaid		
	Allowed amount	Payment*	Coinsurance**	Rate	Payment for coinsurance
A	\$100	\$50	\$12.50	≤\$50	\$ 0
B	100	50	12.50	>50	≤12.50

Note: A (Medicaid is lower than or equal to Medicare payment), B (Medicaid is higher than Medicare but less than combined payment plus coinsurance).
 *Calculated as 50% of allowed Medicare rate.
 **Per statute, the amount of Medicare coinsurance is calculated as 20% of 62.5% of the total allowed Medicare rate.

coverage for outpatient prescription drugs. In this case, the savings to states are largely eliminated by the requirement that they refund much of the estimated savings to the federal government.

Conversely, if Medicare increases cost sharing or otherwise reduces the scope of a benefit that is also covered by Medicaid, Medicaid spending would increase. For example, recent enactment of a higher Part B deductible or proposals to add a beneficiary copayment for home health services have been estimated to increase Medicaid spending (CBO 2003). In addition, to the extent that increasing Medicare payment rates increases the Part B premium, Medicaid spending for dually eligible beneficiaries also increases.

- *Medicaid payment and Medicare bad debt payments.* Medicare's bad debt payment policy means that Medicare's spending for bad debt payments will rise when states lower their cost-sharing payments.
- *Medicare maximization programs for home health.* Many states have noted the inconsistency of coverage decisions and, facing budget pressures, have undertaken "Medicare maximization programs" to increase the number of decisions requiring Medicare to cover home health services. In their most aggressive form, the state Medicaid program files claims on behalf of beneficiaries and pursues their appeals if denied by the intermediaries. Indeed, the payoff for some states has been well worth the effort. Eight states have adopted this strategy since 1988 (although only five of these states pursue appeals to ALJs), and only one state discontinued its use because the costs turned out to be higher than the returns. Ratios of recovered expenditures to costs incurred under this strategy in Connecticut, New York, and Massachusetts have been between 5:1 and 7:1 (Anderson et al. 2003). The states that adopt this approach tend to be the ones with high Medicaid home care spending.

About 36 other states have adopted less aggressive Medicare maximization strategies, whereby they educate providers on billing techniques that increase the likelihood that Medicare, rather than Medicaid, will pay the claim. Such programs may require providers to submit proof of Medicare denial before Medicaid will pay the claim. This approach generally does not rely on appealing intermediary decisions.

Quality of care

The tension between the two programs over which program will pay may lead to poorer quality of care. Instead of having the incentive to improve the overall efficiency and coordination in the delivery of care, each program has an incentive to maximize payment from the other program. As a result, the incentive of one program to invest in initiatives that would improve quality of care will be undermined if the financial payoff is realized by the other program.

One illustration of this is the disincentive the system provides for state Medicaid programs to finance case and care management services for their dual eligibles. Because these services are primarily intended to reduce hospitalizations covered by Medicare, Medicare would recoup most of the savings. Medicaid programs may choose to provide these services for other reasons, but the current structure of the system provides little incentive for them to do so. (See Chapter 2 for discussion of CMS's new policy on sharing the cost of disease management programs for Medicaid recipients.)

Other care coordination barriers exist as well. One state interested in providing disease management to dual eligibles reports that its Medicaid disease management program has had difficulty identifying Medicare providers caring for dual eligibles because the state does not have access to Medicare claims information. Even when it can identify the providers, the disease management program has had limited success in inducing Medicare providers to cooperate.

Providers have incentives to maximize payment between the two programs in ways that may not best serve the dual eligibles. For example, nursing home providers may have little incentive, at the margin, to avoid hospitalizing dual eligible patients whose nursing home care is paid for by Medicaid. If patients remain in the hospital at least three days (a requirement for SNF care), the hospitalization can trigger a Medicare-covered SNF stay (up to 100 days) that is paid at a higher rate than if the stay were covered only by Medicaid. Offsetting this financial incentive is the requirement that nursing homes report their hospital readmission rates, which are then made available to consumers as one measure of the facilities' quality of care.

Lack of coordination between Medicare and Medicaid may also affect the type of post-acute care patients receive when they are discharged from a hospital and the overall spending for that care. In some cases, dually eligible

patients needing long-term care are discharged to a SNF because the SNF care is covered by Medicare. Eventually, the 100 days of Medicare coverage expire or the patients' needs shift from skilled care to a lower level of care, and Medicaid becomes the primary payer. However, if Medicaid had been the primary payer from the beginning, the patients might have been advised about noninstitutional options at the outset of the stay, potentially leading to a better outcome for the patient and lower costs to Medicaid (Ryan and Super 2003).

Access to care

Payment and coverage rules can affect access to care for dual eligibles in different ways. First, although Medicaid provides many services not available through Medicare, variation in Medicaid benefits across states means that not every dual eligible has access to the same benefits. For example, some states may cover dual eligibles for dental and hearing services; other states may not. Lack of coverage reduces access, particularly for low-income populations.

Second, Medicaid's role as a supplemental insurer in promoting access to care for dual eligibles may be diminished as a result of the BBA clarification that allows Medicaid to pay providers less than the full Medicare cost sharing amount. Because of this, total payments to providers for dual eligibles may be considerably below that for other beneficiaries.

As a supplemental insurer, Medicaid provides financial assistance to dual eligibles by paying beneficiaries' Part B premiums and limiting providers' ability to bill beneficiaries for cost sharing. In addition, Medicaid coverage—on top of Medicare coverage—may improve access to care for dual eligibles by generally paying providers more than they would have received if the beneficiaries had been covered by Medicare or Medicaid alone. Research indicates that physicians segment their potential patient pool based on insurer type and prefer to treat higher-paying patients first. Higher payments, therefore, encourage physicians to treat more dual eligible patients and, conversely, lower payments may discourage providers from caring for dual eligibles (Thompson 2003).

A study of nine states by the Department of Health and Human Services found that lowering the Medicare cost sharing paid by Medicaid decreased the likelihood that a dual eligible would have an outpatient physician visit and reduced the total number of visits the person would have. A 10 percent reduction in cost sharing decreased the

probability of having an outpatient visit by 3 percent. This effect was more significant for outpatient mental health treatment than for other outpatient care. Indeed, the probability of an outpatient mental health visit decreased by 21.3 percent in the study state with the highest payment reduction (Thompson 2003).

Third, conflicting payment and coverage rules may cause complications for providers. For example, a dual eligible who is receiving nursing home care (not SNF care) is eligible for Medicare coverage of durable medical equipment. However, if a nursing home has all of its beds certified for Medicare (which is increasingly the case), the DMERC will assume the patient is covered under the Medicare SNF benefit (which includes full payment for durable medical equipment) and will, therefore, deny the claim. The problem is that the DMERC does not now receive information about the patient's source of coverage, so the only information it has is the certification of the bed.

Another example of the coordination problem stems from state Medicare maximization programs that require home health providers to submit proof of Medicare denial before they can submit a claim to Medicaid for payment. Providers complain that this step delays receipt of payment.

Paying MA plans

In general, MA plans are paid a capitated rate per enrollee based on the rate for the beneficiary's county of residence multiplied by a risk-adjustment factor that is intended to reflect the relative health status of the enrolled beneficiary. CMS has recently implemented a new risk-adjustment method—called the CMS hierarchical condition category model—that pays more accurately for patients' clinical needs. The method of payment for dual eligibles is not different than for other beneficiaries. However, because dual eligibles often have more health problems than nondual eligibles, the payments generated for dual eligibles by the new risk-adjustment formula would likely be higher than for nondual eligibles.

The risk-adjustment method includes an additional adjustment for beneficiaries enrolled in a PACE or demonstration plan—such as Minnesota Senior Health Options and Disability Health Options, Massachusetts Senior Care Options, or the Wisconsin Partnership Program (WPP)—which tend to have more frail dually eligible enrollees. This frailty adjuster, phased-in beginning in 2004, is intended to capture predictable

differences in costliness but with less administrative burden for plans than the previous method.

The frailty adjuster is calculated for each plan based upon a weighted average of the number of limitations in ADLs among each plan's enrolled beneficiaries over 55 and living in the community. The frailty adjustment amount is added to the individual risk score to produce a total risk-adjustment factor. In turn, this factor is multiplied by a base payment amount to produce a total payment amount. Table 3-11 provides an illustration of payment to plans for an aged dual eligible male.

Generally, this additional adjustment results in higher payment for the same frail beneficiary in a PACE or one of the demonstration plans than in a regular MA plan. The intent of this higher payment is to compensate these plans for enrolling such a high percentage of frail beneficiaries, compared with MA plans. In theory, MA plans that enroll a smaller percentage of frail beneficiaries may be better able to offset these beneficiaries' higher costs with payments plans get for much lower-cost beneficiaries.

Cost sharing

Although Medicaid is the secondary payer for dual eligibles enrolled in managed care, Medicaid payment for beneficiaries' cost sharing is inconsistent and complicated by a number of factors:

- States have had difficulty informing plans which beneficiaries are dually eligible, so MA plans may not be aware that a beneficiary is also Medicaid eligible. As a result, the plan bills the beneficiary for cost sharing rather than billing Medicaid. Beneficiaries who are billed are often unaware that they are not liable for the expense and may pay the premium or cost sharing (or avoid care).
- The state may claim that the plan payment to the provider for cost sharing exceeds Medicaid payment for the same service and that Medicaid is therefore not required to pay.
- Physicians and other Medicare providers in the MA network may not be participating Medicaid providers and may not have billing systems compatible with Medicaid.

Payment for cost sharing may be further complicated by variations in state policy. Although most dual eligibles are in Medicare plans that are supplemented by Medicaid

FFS, some beneficiaries are in Medicaid health maintenance organizations (HMOs) for their Medicaid-covered services. States may allow, encourage, or forbid enrollment in Medicaid managed care if the beneficiary is in an MA plan; the rules may even vary by market area within a state. In particular, complications arise if beneficiaries receive care from providers that are not in the Medicaid HMO's network. Similarly, if Medicare provides a service that requires preauthorization from the Medicaid HMO, but fails to obtain that preauthorization, the HMO, depending on the state, may not be required to pay the associated cost sharing (Walsh and Clark 2002).

Furthermore, states are not required to pay MA plan premiums on behalf of their dual eligibles (Walsh and Clark 2002). This policy has become more significant recently given the decline in zero premium options that were available in many areas in the early- to mid-1990s. Some states, including California and Texas, have negotiated with plans so that they pay premiums in exchange for an MA benefit package that includes services, such as prescription drugs, that Medicaid would otherwise have to cover.

Special managed care programs for dual eligibles

Several programs integrate the financing and delivery of care for the full range of health care needs of dual eligibles and thereby avert some of these coordination-of-benefit issues. By aligning incentives, this integrated payment approach is also intended to facilitate coordination of care for dual eligibles. The following three programs combine Medicare and Medicaid capitated payments to integrate care for the dual eligible population.

PACE The Program of All-Inclusive Care for the Elderly serves frail elderly beneficiaries, age 55 and older, who meet states' standards for nursing home placement and reside in areas served by the PACE organizations. Most enrollees are dually eligible.

These plans receive separate capitated payments from Medicare and Medicaid. Until now, the Medicare rate was equal to 2.39 times the Medicare county rate amount for MA plans, but, as noted earlier, this adjustment is being replaced with a frailty adjuster based on limitations in ADLs among enrollees in the plan. The PACE plan negotiates the Medicaid rate with the state Medicaid agency. Separate contracts mean that plans still have to deal with two payers and the inefficiencies that result.

**TABLE
3-11**

Payments to PACE or demonstration plans are often higher than to MA plans

Plan	Base rate	Individual risk score	Frailty adjustor	Total risk adjustment factor	Total payment
Medicare Advantage	\$550	1.18	0	1.18	\$649
PACE or demonstration (with average of 3–4 ADL limitations)	550	1.18	.34	1.52	836

Note: ADL (activity of daily living), PACE (Program of All-Inclusive Care for the Elderly), MA (Medicare Advantage). This example is based on a male age 65 or older. Frailty factor varies between -.14 and 1.09 depending upon the weighted average number of ADLs with which enrollees have difficulty.

PACE plans feature a comprehensive medical and social service delivery system, a multidisciplinary team that provides services in an adult day health center setting, and in-home and referral services in accordance with participants’ needs. The BBA allowed states to implement nonprofit PACE plans without applying for a federal waiver. For-profit PACE plans still must apply for a waiver.

An evaluation of the PACE program found that its enrollees had much lower rates of home health use and inpatient hospitalization and higher rates of ambulatory care than a comparison group. The differences persisted after two years of enrollment, but to a smaller extent. PACE enrollees also reported better health status and quality of life, and, holding other factors constant, they showed a lower mortality rate. Those with the most ADL limitations experienced the most marked decreases in hospital use, decreases in nursing home days, and improvements in self-reported quality of life (CMS 1998).

State demonstration waivers Several state programs operate under the Medicare demonstration authority, including:

- Minnesota Senior Health Options and Disability Health Options, in which Medicare and Medicaid each pay a capitated rate for their respective benefits, including home- and community-based care and nursing facility services (except for those provided beyond 180 days, which are paid on an FFS basis). Enrollment is offered to dually eligible seniors and disabled persons—both those that qualify for nursing home care (“nursing home certified”) and those that do not—as a voluntary option to Minnesota’s mandatory managed care program.

The state oversees a single contract with plans to provide Medicare and Medicaid services. It is therefore able to create a single point of accountability, avoid regulatory duplication, and resolve differences between Medicare and Medicaid. It has merged enrollment processes, membership materials, grievance procedures, and data reporting requirements. However, reflecting CMS’s stance against granting states control over Medicare funds, Medicare and Medicaid capitation payments are always pooled at the plan and not the state level (Miller and Weissert 2003).

- Wisconsin Partnership Program, in which four community-based organizations enter into a Medicaid managed care contract with the Wisconsin Department of Health and Family Services and a Medicare contract with CMS. They receive monthly capitated payments for each participant, from which they pay for all participant services. WPP serves both seniors over 55 and physically disabled dual eligibles. Qualifying beneficiaries must be nursing home certified.

Evercare This demonstration plan largely serves a dual eligible population. In Texas, an Evercare plan accepts capitated payments from both Medicare and Medicaid and offers an integrated product that manages the full range of long-term care services.

The Evercare model provides case management for nursing home residents to reduce the need for hospital and emergency room care. Evercare employs a cadre of nurse practitioners who work cooperatively with residents’ primary care physicians. The physicians are paid more

generously than under FFS Medicare. Evaluations have found that Evercare resulted in reduced hospitalizations compared with control groups and that care is at least comparable with what is available in the FFS environment (Kane et al. 2003, 2002). It currently operates in 11 states and has 24,000 enrollees, about 75 percent of whom are dually eligible.

The implications of payment rules for MA

Coordination of benefits is confusing and threatens the protection intended by dual coverage

As noted above, Medicaid payment of MA plan cost sharing is inconsistent. Many beneficiaries are confused about their benefits and, so, cannot be effective advocates for themselves when they are inappropriately billed for cost sharing. As a result, many dual eligibles are paying for MA plan cost sharing. This situation undermines the protection that Medicaid coverage was intended to provide if, as a result, beneficiaries spend more out-of-pocket and avoid needed care.

MA plans that charge premiums may be a less viable option for dual eligibles

States are not required to pay the MA plan premium on behalf of dual eligibles, and after three consecutive months of nonpayment, plans may disenroll a beneficiary. Plans can elect to charge a premium but not collect it from some members, such as dual eligibles. While nothing prohibits plans from doing this, they are not allowed to advertise that they do. Thus, the policy may keep dual eligibles from enrolling in plans that charge a premium.

If MA enrollment does not provide added value to dual eligibles in terms of enhanced benefits or improved quality, then policies that discourage enrollment of dual eligibles in MA plans may be acceptable. On the other hand, if dual eligibles are disadvantaged by not having the option to enroll in an MA plan, policymakers may want to consider policies that encourage more states to allow dual eligibles to enroll in plans with premiums. (At a minimum, it would appear that QMBs who were not also eligible for full Medicaid benefits would particularly benefit from enrollment if plans covered non-Medicare services.)

Opportunities to integrate benefits for dual eligibles are limited

A variety of factors limit the ability of managed care plans to integrate care effectively. First, the failure of Medicaid programs to notify plans promptly of accurate enrollment information may limit access to benefits. For example, dual eligibles are able to access additional durable medical equipment, home health, pharmacy, and long-term care benefits, but only if plan staff, providers, or beneficiaries are aware of that coverage (Walsh et al. 2003).

Second, having beneficiaries enrolled in one managed care plan for Medicare benefits and another for Medicaid benefits raises a variety of problems for coordination of care. For example, a Medicaid HMO often has no opportunity to provide case management or direct its members to in-network providers. Similarly, the Medicare HMO does not have an incentive to manage beneficiaries' care to avoid long-term care spending.

Third, case studies suggest that even when beneficiaries are enrolled in Medicare and Medicaid managed care plans (but not an integrated plan) offered by the same managed care organization, coordination of care is challenging. Beneficiaries have two separate membership cards and different points of contact for their Medicare and Medicaid benefits. Plans may not be equipped to coordinate across the requirements of the two programs. Also, most Medicaid managed care plans are not responsible for long-term care services. Additional coordination with state long-term care agency personnel is necessary (Walsh et al. 2003).

Integrated financing and care delivery have unrealized potential

Many of these coverage and payment issues are generally alleviated if the dual eligible is enrolled in the same plan for both Medicare- and Medicaid-covered services, and if that plan is committed to integrating benefits. This integration can occur under the various Medicare and Medicaid integrated plans (e.g., PACE, WPP) as well as, in rare instances, in MA plans that also participate in Medicaid. However, these integrated plans serve only a small fraction of dual eligibles. Recent legislation authorizing specialized plans partly addresses this limitation by removing regulatory barriers for plans that would like to offer a product exclusively to dual eligibles. But, for MA plans that prefer to serve a more diverse population, barriers still exist. ■

Endnotes

- 1 The range in the estimated number of dual eligibles reflects differences in whether someone is counted as a dual eligible if Medicaid was their predominant source of supplemental coverage for the year or if they had just one month of Medicaid coverage in a year. The analyses in this chapter are based on the former, which corresponds to the lower figure.
- 2 Beginning in 2006, prescription drug coverage will be included in the Medicare benefit package. (This is discussed in the section, “Coverage and coordination of benefits.”)
- 3 Beneficiaries in nursing homes qualify for this benefit if they have incomes less than or equal to 300 percent of the Supplemental Security Income level and have assets no greater than \$2,000 (individual) or \$3,000 (married).
- 4 In states that have opted to provide full Medicaid benefits up to 100 percent of poverty, beneficiaries may be QMBs who also receive Medicaid coverage for the wrap-around benefits.
- 5 Participation among those who are only eligible for the QMB program (and not for full Medicaid coverage) is likely lower than 78 percent.
- 6 The federal poverty level was \$8,494 for people living alone and \$10,715 for married couples in 2001.
- 7 The definitions of the subgroups of dual eligibles draw directly upon the approach developed by Sandy Foote and Chris Hogan in their analysis of the Medicare disabled population (Foote and Hogan 2001).
- 8 Beneficiaries were assigned to subgroups using a hierarchy that first assigned beneficiaries to the mental and cognitive impairments category based on diagnosis codes as well as prescription drug use. These people may also have physical limitations. The other two categories include all beneficiaries who do not have a mental or cognitive impairment.
- 9 This finding is based upon a separate MedPAC analysis of the 5 percent Denominator file for 2001.
- 10 This analysis updates work by Liu and others based on 1993 MCBS data (Liu et al. 1998).
- 11 CAHPS was originally developed for use with private health plans by a consortium including Harvard Medical School, RAND, Inc., and Research Triangle Institute, with support from the Agency for Healthcare Research and Quality and CMS. It was subsequently adapted for surveying beneficiaries in Medicare Advantage plans and fee-for-service Medicare. It does not include institutionalized beneficiaries. CMS has administered CAHPS to between 168,000 and 178,000 fee-for-service beneficiaries annually since 2000. With response rates of 70 to 80 percent, the CAHPS surveys are the largest surveys of Medicare beneficiaries.
- 12 One bias that can affect survey responses is socially desirable response set bias, which is the tendency of respondents to answer in a way that they perceive to be consistent with societal norms rather than based on their own personal experience. Another possible bias is acquiescent response set bias, which is the propensity of respondents to agree with a question regardless of its content. Studies have shown that survey participants with lower income or education levels exhibit these biases (Ross et al. 1995, Ross and Mirowsky 1984, Ware 1978), and older respondents have also been shown to acquiesce or respond in a perceived socially desirable way (Klein 1972, Ross et al. 1995).
- 13 The exception is beneficiaries with public supplemental insurance, such as that from the Department of Veterans Affairs: These beneficiaries do not rate their access to care as significantly different than dual eligibles.
- 14 Those with income below 100 percent of poverty level pay \$1 per generic and \$3 per brand name drug. Those with income over 100 percent of poverty pay \$2 per generic and \$5 per brand name drug.
- 15 The MMA requires that the ALJ function be transferred from the Social Security Administration (SSA) to the Department of Health and Human Services for Medicare appeals by October 2005. This change addresses criticism that SSA ALJs were not sufficiently knowledgeable about Medicare.

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CHAPTER

4

Purchasing strategies

Purchasing strategies

To understand what steps other purchasers are taking to increase the value of their health care spending, this chapter describes the strategies they use and begins to consider whether they might be applicable to the Medicare fee-for-service program. These strategies are intended to reduce spending while maintaining or improving quality. Some examples are measuring and reporting resource use and quality to providers, encouraging beneficiaries to make more cost-conscious health care decisions, using hospitalists, and aligning financial incentives across settings. In response to the growth of imaging services, purchasers are using additional strategies, including enforcing safety standards for imaging equipment, limiting the type of providers qualified to deliver a service, and reviewing appropriateness of claims. Evaluating the feasibility and value of particular strategies for Medicare fee-for-service, however, requires consideration of the program's ability to administer these strategies effectively and the potential impact on beneficiaries and the health care delivery system.

In this chapter

- Strategies used by innovative purchasers
- Purchasing strategies for imaging services
- Purchasing strategies for Medicare

As cost pressures intensify, policymakers may be increasingly interested in ways to improve the efficiency of the health care that Medicare beneficiaries receive—that is, to reduce spending while maintaining or improving quality. Private health plans available to beneficiaries under Medicare Part C were created to allow Medicare to take advantage of the efficiency-enhancing management tools available to private sector payers. Some policymakers may decide that health plans are the vehicle for improving the efficiency of beneficiaries' care and that the current fee-for-service system should remain unfettered. Other policymakers may want to support innovation by private plans and at the same time improve the efficiency in fee-for-service Medicare to constrain spending growth.

The majority of beneficiaries—about 86 percent—are enrolled in fee-for-service Medicare. Even with the recent legislation that encourages enrollment in managed care plans, both CMS and the Congressional Budget Office project that the majority of beneficiaries will remain in the traditional program for years to come.

Fee-for-service Medicare, which reimburses individual providers for each medical good or service rendered to a beneficiary, poses challenges for program administrators seeking to improve program efficiency. Although Medicare has been able to use its statutory authority to control payment rates to levels that are, in some places, below private sector rates, efforts to implement efficiency-enhancing strategies in the permanent program are limited by Medicare's size, statute, and limited administrative resources, among other factors. At times, these limitations have been overcome: Medicare has implemented prospective payment systems, selectively contracted with facilities for organ transplant services, and implemented coding edits subsequently adopted by private insurers.¹ Furthermore, CMS has run or attempted to launch a number of innovative demonstration programs to improve the efficiency of health care delivery.²

On the whole, however, Medicare's current approach to purchasing services and goods in fee-for-service may fall short in several ways. For example, in many cases, current policy:

- *Provides insufficient incentives for providers and beneficiaries to supply and consume, respectively, the optimal amount of health care.* Furthermore, mechanisms for identifying or penalizing inefficient

providers or inefficient use of services are limited. MedPAC analysis, along with a growing body of research, shows that greater use of health care services does not necessarily produce better outcomes (MedPAC 2003). Thus, in some areas of the program, fewer services could be delivered without compromising quality. Similarly, Medicare does not encourage beneficiaries to weigh costs and benefits in making health care decisions, seeking preventive care or making lifestyle changes. Indeed, for many beneficiaries, supplemental coverage insulates them from the financial implications of their decisions.

- *Does not encourage providers to coordinate care efficiently.* Although Medicare's prospective payment systems provide incentives for providers to minimize their own costs, it pays for different types of services separately. As such, care is fragmented and providers have little incentive to increase efficiency by better coordinating care across services and over time.
- *Sets prices that inaccurately reflect costs of providing goods or services efficiently.* Obtaining timely, accurate knowledge of efficient providers' costs is difficult, though some information is available through cost reports and surveys. As a result, for some services (e.g., certain types of medical equipment), Medicare payment does not closely align with costs (GAO 1998).

What strategies could be considered to improve the incentives and slow spending growth? To begin to answer this question, MedPAC staff surveyed private purchasers and insurers about their strategies to improve efficiency. These purchasers face many of the same cost pressures as Medicare, but may have greater agility and flexibility in experimenting with innovative strategies. They operate on a smaller scale than Medicare and are not nearly as constrained by statute or public scrutiny.

MedPAC found a community of purchasers, insurers, and consultants exploring new and revisiting old ideas to slow spending growth.

First, nearly all of those we interviewed are interested in checking growth in the volume of services. Many are measuring provider efficiency to encourage providers to

reconsider their practice styles and adjusting cost-sharing requirements to induce consumers to temper their demand for care. We focus in greater detail on these strategies, reflecting heightened interest in them among both the Commission and the purchasing experts we consulted.

Second, purchasers reported using strategies that encourage greater productivity in delivering certain services. To the extent that improved productivity lowers costs, the price paid for services could be reduced. Thus, a third overarching type of strategy is aimed at paying prices that better reflect the cost of the service. These pricing strategies range from competitive bidding to tiering to lowering payment when multiple services are performed during an encounter.

Given our interest in the appropriate use of imaging services, MedPAC conducted a focused examination of private sector purchasing strategies for those services. We found that private sector purchasers, concerned about the quality and maintenance of imaging equipment, are imposing and enforcing safety standards. In addition, they are restricting payment for imaging services to those delivered by certain specialties, such as radiology and cardiology, to constrain the proliferation and poor quality of services by some nonradiologists. Finally, we found that private purchasers are applying coding edits to detect improper billing and limit spending.

At the conclusion of the chapter, we take a first step in assessing these strategies for application to Medicare fee-for-service. We consider the extent to which Medicare policy already includes aspects of them and review aspects of Medicare and current law that might affect implementation of such strategies.

A few caveats are in order. First, because we sought out innovators in the field, the accounts of the various purchasers in this chapter are neither representative of the larger marketplace nor are they inclusive of all potential strategies. Second, this chapter is a snapshot in time; it does not fully explore the evolution of the various strategies, many of which purchasers have experimented with for decades. Third, we include the strategies reported to us regardless of their potential applicability to Medicare.³ As discussed at the end of the chapter, many

factors must be considered in such an evaluation, and it is likely that all strategies discussed in this chapter are not equally pertinent to Medicare.

Strategies used by innovative purchasers

In the next section, we report on a range of strategies to reduce spending while maintaining or improving quality. Our summary is largely based upon our interviews with health plans (including one integrated delivery system), large employer purchasers (including one coalition), a public employee purchaser, and benefit consultants, supplemented by a review of the literature. In this chapter, we define purchasers as both health plans and employers.

Modifying the volume of services

These purchasing strategies aim to encourage providers to deliver appropriate care and discourage delivery of inappropriate care. In addition, they try to temper beneficiary demand and direct patients to providers who tend to use fewer services without reducing quality of care.

Identifying efficient providers and promoting efficient care patterns

Nearly all of the private purchasers we spoke with are considering or implementing strategies to identify efficient providers—that is, those that use the fewest resources to provide quality care. Most seek to direct patients to those providers and encourage less efficient providers to improve. The success of this approach largely hinges on the ability to measure efficiency as well as quality. Our interviewees all acknowledged that the science behind each is evolving, but has not been mastered.

Research shows that efficient care can be compatible with high-quality care (MedPAC 2003). Hospitals and physicians in the 10 percent of communities that spend the least per capita achieve this result by providing fewer specialist physician tests, visits, minor procedures, nonsurgical hospitalizations, and admissions to the intensive care unit. And while the volume of care is lower in those communities, the quality of care, patient health status, and patient satisfaction with care is the same as or higher than in the other communities that spend more. Researchers estimate that if hospitals and physicians in

other communities adopted similarly efficient patterns of service use, per capita Medicare spending would be 30 percent less (Fisher et al. 2003).

Purchasers seeking to encourage appropriate utilization often first profile providers by measuring their performance on efficiency and, ideally, quality measures. Some compare price only, which may not accurately reflect the overall resources used to provide care. Then, the purchaser uses at least one of three types of incentives to change beneficiary and provider behavior to improve efficiency: information-based, financial, or participation incentives.

Profiling providers One way to measure providers' relative efficiency or quality is through profiling and creating a report card for providers. The following are among the key design issues in profiling.

Selecting providers to profile Experience varies among those with whom we spoke. Some profile either physicians or hospitals. Some do both. Of those profiling physicians, some focused more attention on specialists than primary care physicians (PCPs), and some focused on a subset of specialists. Others included PCPs.

One reason for focusing on specialists is that they are more likely to be responsible for high-cost tests, procedures, or treatments associated with a particular episode of care. In addition, specialists more frequently have an adequate sample of similar cases. It can be more difficult to assign patients' health care costs to a PCP because in many instances the PCP is not in control of the full spectrum of care patients receive.

Another difference among purchasers seeking to measure performance was whether to focus on group practices or individual physicians. Group performance was the focus in areas where physician groups dominate the market. In other areas of the country, purchasers profiled individual physicians.

Of those plans also measuring hospital performance, some looked at only particular high-cost services, such as transplants and cardiac care. Others assessed overall performance.

Selecting measures of physician efficiency The measures vary, but most profilers use measures based on claims data rather than more costly chart or peer review methods. A preponderance of plans indicated that they were using

software tools designed to measure physicians'—particularly specialists'—costs associated with an episode of care. In general, this software measures actual total costs of an episode of care, compares it with expected costs, and produces a score for each physician. The tools adjust for differences in the case mix of each provider's patients. Some interviewees viewed measuring the episode of care as an improvement over other measures that reflect unit costs only (e.g., length of stay or price of procedure), and thus fail to capture costs associated with redoing a procedure, high complication rates, or poor patient management.

The adequacy of episode-based measurement tools is controversial. Some purchasers and providers believe that current measures are not sufficiently refined and may inaccurately attribute legitimate cost differences to an inefficient practice style. This could occur if classification rules assigned cases with serious comorbidities to only moderate risk categories. If measures inadequately account for such case-mix differences, providers might avoid more complicated patients, creating access problems or unfairly penalizing those who take harder cases.

Others believe that while not perfect, the current episode-based measures are sufficiently accurate. These purchasers believe it is important to start measuring and incorporate improvements over time, rather than wait for a more refined measurement system.

Purchasers reported using other types of measures as well:

- Referral patterns and use of generic drugs, particularly for primary care physicians.
- Frequency with which surgeons are selecting candidates that meet the selected criteria for certain surgeries (e.g., hand and back). This approach requires chart review to verify that clinical findings are consistent with recommended criteria for these surgeries.
- Use of ambulatory surgical centers instead of outpatient departments for certain types of surgery.

Selecting measures for hospital efficiency One large insurer reported measuring hospital performance as the basis for designation as a regional center of excellence for cardiac, orthopedic, and cancer care. The insurer uses a range of quality standards, including Leapfrog Group

standards and training standards for specialists in intensive care (intensivists), as well as efficiency measures.⁴ It measures total costs of an episode of care beginning 3 months before to 12 months after the hospitalization, and is able to track failed therapy rates. This insurer also designates national centers of excellence for transplants. The measures for transplant centers tend to mirror Medicare criteria, which focus on mortality data and years of life after the procedure and are used to select which hospitals Medicare pays for transplants.

Obtaining sufficient data for profiling To begin to identify efficient providers, purchasers must, at a minimum, have enough claims data to evaluate providers in the area. Because care is concentrated in a relatively small number of hospitals, obtaining this data for hospital services is less problematic than for physicians. Even large insurers find that in some market areas they have less confidence in their profiling results or may not profile at all because of insufficient data. To improve their access to claims data, several public or self-insured purchasers require their third-party administrators to share claims data for their full book of business with the purchaser.

Nearly all the purchasers we spoke with are interested in getting Medicare claims data—the largest single source of claims that exists—to assist them in profiling providers. CMS is currently considering the issue and has concerns about protecting beneficiaries’ privacy, the reliability of the physician identification numbers, and the ability of the data to be used for profiling of primary care physicians.⁵ The purchasers we spoke with felt strongly that beneficiaries’ privacy could be protected in this exchange.

Pairing efficiency measures with quality measures Virtually all those interviewed indicated that the efficiency measures should be paired with quality measures to reflect value. Interviewees indicated varying levels of success in relating the two. One used data on adherence to evidence-based practice standards to identify quality providers; some have used the Leapfrog Group standards on the use of specially trained inpatient physicians, electronic prescribing systems, and volume of services.⁶ Others look at complication rates for proceduralists. Still others indicated that they were looking for better ways to measure and reflect quality differences among providers. Some of these measures are considered efficiency-only measures (e.g., number of referrals), while others (e.g., infection and complication rates) reflect the intersection of

quality and efficiency measurement. (MedPAC’s June 2003 report provides further discussion of quality measures.)

Managing provider relations In general, plans report mixed provider response to measuring performance. Plans that have long been measuring physician performance that are also in areas with group practices (some of which accept capitation) report few issues. Others acknowledge some resistance, particularly among those who do not compare with their peers favorably. Many note that physicians are more likely to be receptive to measurement and feedback if they feel that it would help their patients receive better care, the measures are transparent and fully disclosed, and it is clear that the measures are evidence based and consistent with good medical practice. One plan involved physicians in the development of measures and sought continued feedback in meetings with providers on their implementation. Several interviewees noted that when plans used the profiling data as a basis for financial incentives for efficiency, providers responded better to positive incentives (e.g., bonuses) rather than negative ones (e.g., withholds).

Changing behavior to contain costs Profiling can contain costs if it influences the way beneficiaries use care, the way providers deliver care, or the proportion of care delivered by more efficient providers.

Disseminate information to enrollees and providers Information-based strategies offer providers and patients the information to make cost-effective decisions about health care services without direct financial consequences. Nearly all the purchasers we spoke with plan to or already feed the profiling data back to participating providers and to the public (usually on the Internet and in marketing materials). Indeed, movement on releasing provider report cards appears to be gathering momentum. Recently, a group of 28 large employers announced that they are teaming up to develop scorecards to help employees choose their doctor based on cost and quality information (Landro 2004).

A number of purchasers we spoke with found that when providers received quality and efficiency data, performance improved. One insurer that disclosed performance on quality indicators to enrollees as well as providers found that some enrollees immediately began shifting to better-performing providers and that about 3 percent of enrollees continue to shift each year.

Others were less persuaded that feeding the information back, in the absence of other incentives, would induce much change. One purchaser, while intent on releasing the profiling information publicly, acknowledged that enrollees do not always use this information effectively. Yet, the purchaser felt obliged to provide it when available. One also noted that beneficiaries may not know how to interpret efficiency data; beneficiaries may assume that higher use is always better.

Create payment incentives Payment incentives generally seek to induce patients or providers to use cost-effective care by creating stronger rewards or penalties around care decisions. Beneficiary cost sharing, for example, could be adjusted depending upon the relative efficiency of the provider chosen. Providers' payment could vary with provider efficiency. Some interviewees felt that it was best to adjust both the beneficiary cost-sharing and the provider payment. These incentive options are illustrated in arrangements known as tiered networks, centers of expertise, and shared savings strategies.

Tiered networks. Tiered networks are arrangements in which providers—generally physicians and hospitals—are assigned to specific tiers; beneficiary cost-sharing requirements then vary depending on the tier of their selected provider. Assignment to a tier may be based on profiling criteria that can range from blunt measures such as unit prices, average costs, and structural characteristics (e.g., a hospital's teaching or sole community facility status), to more sophisticated longitudinal, risk-adjusted efficiency scores and indicators of quality.

In general, providers have the incentive to be in the preferred tier to increase or retain volume of patients. In some cases, providers in preferred tiers accept discounted payments in exchange for higher volume that may result from being on the preferred tier—but this generally works when the preferred tier is exclusive (similar to some arrangements with centers of expertise discussed below) or when strong beneficiary incentives guarantee higher volume. In other cases, providers in preferred tiers may get a higher base payment rate, such as an increment to fee schedule payments, because they can deliver more efficient care or higher quality (e.g., fewer referrals to specialists or better outcomes). In some plans, providers not initially assigned to the preferred tier may be

ultimately assigned to it if they are willing to accept lower payments (which, by definition, improves one aspect of their efficiency rating).

Once providers are assigned to tiers, plans give enrollees a financial incentive to use lower-cost providers in the preferred tier. Often enrollees must pay higher copayments or coinsurance when they use nonpreferred providers. The differential in cost sharing does not capture most of the differences in cost across hospital tiers, and as such, is not intended to insulate health plans from hospital or physician cost variation. Instead, it informs and sensitizes the patient, who was previously insulated from and indifferent to the cost implications of care (Robinson 2003). (The text box opposite provides one example.)

A variation on this design is multiple networks of providers sorted into tiers. Networks in more efficient tiers have lower premiums, which can be further adjusted based on the level of cost-sharing associated with out-of-network care. Another type of tiering is achieved by plans and purchasers moving away from requiring a flat cost-sharing amount (i.e., a copayment) for services to a percentage of the cost of the service (i.e., coinsurance). This method exposes beneficiaries to the price variation among providers, which can be considerable (given, for example current estimates of \$1,000 variation in hospital costs per day). Newer benefit designs with coinsurance rates as high as 40 percent for hospitalizations and 50 percent for certain outpatient services expose beneficiaries to even more of the cost difference (Robinson 2003).

Whether tiering improves providers' efficiency or beneficiaries' cost-effective decision making is uncertain:

- The magnitude of the cost differential needed to affect beneficiary choice is not known.
- Patients may not know about the differential at the time they need care. Patients may rely more on physician recommendations (which rarely take price into account) than cost differences.
- Tiering of hospital products may not target the source of inefficiency if cost effectiveness of different departments varies significantly within the hospital.
- Purchasers may want to support and maintain relationships with institutions with special missions (e.g., teaching and treating uninsured), which may increase costs (Robinson 2003).

Tiering providers: An example

Several state agencies, including those in Minnesota, Wisconsin, and Washington, have introduced benefit programs for state employees that include tiered networks.

The Minnesota Advantage Health Plan, which covers about 130,000 lives (state, college, and university system employees, dependents, and retirees), is now in its third year of operation. The tiered plan design links the risk-adjusted costs of primary care clinic systems with the level of out-of-pocket cost sharing that enrollees pay at the point of service. To obtain the information needed to assign providers to tiers, the state built a comprehensive claims data warehouse, including all the health and pharmacy claims for their covered population. Based on analysis of the data, the Department of Employee Relations assigns providers to one of four tiers (the fourth tier was added in 2004), based on their risk-adjusted cost profile. Data from the warehouse also support wellness programs and risk and disease management initiatives for target conditions including asthma, diabetes, and heart disease (Haugen 2003). The benefit is administered by three insurance carriers, each of which develop provider networks that serve state employees (State of Minnesota 2004).

Enrollee cost sharing creates clear incentives to use providers in the better-rated tiers. The deductible for Cost Level 1 plan providers in 2004 is \$30 for individuals and \$60 for families; for Cost Level 4, the annual deductible is \$500 for individuals and \$1,000 for families. Cost sharing for office visits, inpatient stays, lab costs, and outpatient therapy copayments also vary across tiers. Maximum out-of-pocket liability, prescription drug benefits, and hospice and nursing home benefits are the same for all the tiers; no cost sharing is required for preventive services (State of Minnesota 2004).

Early assessments of the program suggest that it has lowered costs. Following the initial adoption of the model, discussions with several clinics that had been assigned to the higher-cost tiers led to the renegotiation of their reimbursement rates, which reduced their costs sufficiently to be reassigned to more favorable tiers. Enrollees seem to understand the plan, and most (75 percent in 2002) are in the lowest cost tier. Initial estimates suggest that in the first two years of the program, the state and its employees saved \$33 million in premiums compared with estimated costs if the previous health benefits plan had remained in place unchanged (Haugen 2003). ■

- Experience in implementing these plans has been mixed. Some plans facing hospitals or provider groups with strong market leverage exclude very few providers from their preferred network. Other plans encountered such provider resistance that they had to drop the idea, and some plans operated in communities with too few providers to make it a viable strategy. (Mays et al. 2003)

Nevertheless, some suggest that tiering has great promise. Success can be achieved by redirecting patients away from only a small minority of providers—those that are vastly more inefficient than others and may even be considered bad actors. One consultant noted that while encouraging all patients to use marginally more efficient providers

could generate savings, significantly more savings could be achieved if persistently costly patients could be redirected from inefficient to more efficient providers.

The availability of more usable and accessible information for consumers improves the effectiveness of tiering. More purchasers are sharing provider report cards with consumers (see earlier discussion on profiling). However, tiering may not work for all types of providers. Primary care providers, for example, may be less interested than other providers (e.g., specialists) in being in the preferred tier. If their practices or facilities are full, providers may not value the increased volume of patients that the preferred tier promises.

Centers of expertise. Centers of expertise (or excellence) differ from tiered networks in that differential cost sharing or payment only applies to certain types of procedures or care, rather than to the broader spectrum of care. Insurers and purchasers tend to use a centers-of-expertise approach for high cost procedures, such as transplants or cardiac, orthopedic, and cancer care.

Two key implementation questions emerged in our interviews. First, how can the purchaser increase patient volume at the designated centers of expertise? One of the obstacles plans face is the reluctance of patients who have an established relationship with a physician unaffiliated with the center to change their physician. One plan has attempted to overcome this problem by promoting its program on its nurse telephone line that offers decision support to patients. Another obstacle can be patients' anxiety about the distance of the regional center from home. Some plans have addressed this concern by paying for the families' hotel stays.

Second, how can plans foster continued competition after the initial designations are made? Successful centers of expertise can expect to have increased patient volume and name recognition. To the extent that this outcome results in the "winner" increasing capital investment in both equipment and space, other facilities with less capacity may be at a disadvantage in future competition. On the other hand, as evidenced by the growth in specialty hospitals, volume can shift quickly, particularly as physicians change their referral patterns. One plan we interviewed acknowledged the concern of maintaining a competitive environment, and hopes to resolve it by making annual designations and naming different hospitals as centers of excellence for different procedures.

Expenditure targets and shared savings. Some plans we spoke with reward providers who are more efficient than others by paying them a bonus, refunding the portion of payments withheld at initial payment for services, or increasing payment rates for care provided in the next contract cycle. In effect, this approach sets an expenditure target and shares the savings with more efficient providers, which in turn, encourages maximum efficiency. Plans tend to pair this approach with quality measures to address incentives to stint on care. For example, plans reported measuring physicians' adherence to clinical standards in caring for diabetic, asthmatic, and cardiac patients, as well as their performance in delivering preventive care services.

Basing payment on expenditure targets can be desirable for providers. For example, one integrated delivery system (IDS), Intermountain Health Care, found that by implementing techniques and a care protocol that improved cardiac medications and reduced admission rates for congestive heart failure patients, the hospital lost more revenue than it saved in costs. Thus, even though the more efficient processes (which also lead to higher quality) produced systemic savings, they lost money for the IDS. In response, the IDS used actuarial data to negotiate with purchasers to create expenditure targets for groups of physicians and nurses who routinely work together. They identified populations for certain clinical programs (e.g., cardiovascular) and compared actual costs with actuarially expected costs. If actual costs were below predicted levels, the savings were shared among the hospital, physicians, and the purchaser (James 2002).

The Buyers Health Care Action Group provides another example. Expenditure targets were set quarterly for care systems, or groups of providers, for episodes of care, including hospitalizations. Providers were paid a higher amount if they kept costs below targets and a lower amount if they exceeded the targets (Christianson and Feldman 2002).

Use of exclusive contracting Under this approach, insurers or purchasers do not contract with providers that fail to meet their efficiency and quality criteria. The result is a smaller network of providers from which enrollees can receive covered health care and no coverage for out-of-network care. Some plans indicated that they were planning to respond to employers' interest in offering an exclusive network product.

The experience of Pitney Bowes, a large employer in southern Connecticut, offers some insight into the potential and challenges of exclusive contracting. In the mid-1990s, the company offered employees two health plans: a point-of-service plan and an exclusive provider organization (EPO) plan, which excluded the 100 least efficient physicians identified through profiling. During the two-year experiment, Pitney Bowes' health care costs rose much more slowly than costs in the state of Connecticut as a whole. One published evaluation (Cave et al. 1995) found that more than two-thirds of the savings came from steering enrollees to the more efficient providers in the EPO. Nevertheless, the program was

discontinued after its third year when the physician group that comprised the EPO was sold and the new owner decided not to continue the contract.

Pay only for appropriate care, regardless of provider efficiency

Another strategy that can moderate the volume of services provided is to pay for only medically necessary care. Under this strategy, purchasers can either inform providers that certain care does not meet standards of evidence-based care or deny payment for care delivered outside these standards. Two approaches stand out:

- *Preauthorization for services* requires patients or providers to obtain approval from the health plan for coverage for a nonemergency procedure. Managed care plans used this tool widely in the 1990s. In the backlash, many have reevaluated its use and have implemented more targeted preauthorization requirements. For example, one plan requires preauthorization only for those procedures that they are unlikely to cover.

Plans continue to assess the role of preauthorization, however. Some plans experienced a dramatic increase in volume after lifting pre-authorization requirements, particularly with imaging services, and responded by reinstating some of their requirements (Draper 2004).

- *Coding edits* can identify when care is inappropriate or should not be covered. A coding edit might, for example, reject claims for more than a target number of ultrasounds for pregnant women. Most plans we spoke with buy a commercial product that applies coding edits, and one plan stated that it generated a 5 percent savings. (See discussion under imaging services, p. 107.)

Encourage beneficiaries to take greater responsibility

More recently, purchasers have turned to strategies intended to encourage beneficiaries to assume greater responsibility for their health and reduce their demand for inappropriate care. First, purchasers have increased beneficiaries' financial stake in their care, both when they choose among plans and when they choose among providers at the point of service. Such strategies are often considered examples of consumer-driven benefit design.

Second, purchasers have invested in programs that inform beneficiaries about ways to stay healthy and treatment options when they are sick. Third, many have implemented care management programs that encourage patients to manage their chronic conditions (see discussion in Chapter 2).

Increasing beneficiaries' financial stake in their care is being pursued in a number of ways. First, more purchasers and plans are increasing beneficiaries' choice of providers or network of providers, and giving them financial incentives to receive care from efficient or less costly providers (discussed under tiered networks). In part, this is a reaction to the managed care era when cost sharing was low and utilization was controlled by requiring referrals from primary care providers and other techniques. While increased cost sharing has been shown to induce patients to cut back on both appropriate and inappropriate care, research is inconclusive about the effect this response has on health outcomes for people over 65 (Rice and Matsuoka 2003).

Second, some employers and plans are offering enrollees high deductible plans, combined with a health reimbursement account (HRA), catastrophic insurance, and web-based medical information tools to assist in making better medical decisions. The HRA is an account from which consumers draw to make health care purchases. When the account is exhausted, enrollees must typically pay out of pocket until the annual deductible is met, after which the plan becomes a traditional major medical plan. Employers may fund the HRA with pretax dollars, which may be rolled over to the following year if they are not spent (Gabel 2002).

Purchasers also report that providing enrollees with more information on treatment options can produce savings. For example, one interviewee noted that when patients are shown a video that graphically describes their treatment and surgical options, fewer of them opt for more invasive surgery. Similarly, Humana has a tool that identifies patients who are currently using a high-cost drug and could possibly switch to one of two lower-cost drugs. Through an interactive voice response system, a computer calls patients and explains that the person can save money by taking a substitute drug. Humana found that 19 percent of these automated calls prompted patients to move to a lower-cost drug (Trude and Grossman 2004).

Wellness programs reduce demand by improving the health and well-being of employees or enrollees. Programs often include activities such as health appraisals and screenings, quarterly newsletters, targeted mailings, and 800 numbers. It is estimated that more than 80 percent of businesses with 50 or more employees and more than 70 percent of Fortune 500 firms have employee wellness programs (Pennsylvania Health Care Cost Containment Council 2001). Tracking the financial success of corporate wellness programs is challenging, but the joint General Motors and United Auto Workers wellness program was found to reduce both health care costs and absenteeism (McGlynn et al. 2003).

One large health plan developed a program that provides concrete rewards for consumers practicing healthier lifestyles. Consumers can earn points, or credits, for completing health risk assessments, enrolling in a disease management program, attending weight reduction programs, or completing an online nutrition education program. Plan members with enough credits are eligible for prizes and discounts on health promotion products (Ho and Pacificare Health Systems 2004).

Changing the costs of production

Another set of purchaser strategies encourages providers to change the cost of producing each unit of service. Some savings can be achieved by improving productivity within a site of service, while others may result from aligning payment incentives across service areas. These strategies may reduce the volume of care. However, when payment is for a bundle of services—such as with hospital inpatient stays—volume may not decline, but the individual services making up the bundle might. Ideally, prices could be adjusted to reflect the decline in resources comprising the bundle. The following are two examples of strategies that improve productivity within a site.

Add hospitalists and intensivists

Hospitalists and intensivists are physicians who focus their clinical efforts on the management and treatment of hospital and intensive care unit patients. Generally, a hospitalist or intensivist relieves primary care providers of their inpatient responsibilities, freeing up their time to see more patients outside the hospital. Studies have found that the use of hospitalists is associated with reduced lengths of stay and lower hospital costs. (Gregory et al. 2003,

Diamond et al. 1998). One study found that this occurred without increasing the readmission rate or cost shifting to subacute providers (Gregory et al. 2003). Among those we interviewed, one executive called hospitalists “amazingly effective” and felt they that were continually learning how their role could be leveraged to improve efficiency.

Reengineer processes of care

One IDS executive also reported using techniques of the manufacturing industry to review their process for delivering care. These techniques include asking front-line employees to participate in redesign, measuring many aspects of performance (e.g., waste, wait times, organizational barriers to improvement), and improving inventory management. For example, by mapping a typical pneumonia visit, the IDS staff found that many steps, such as the requirement that patients walk to a separate laboratory to get blood drawn, could be eliminated (Wysocki 2004). Other facilities have adopted this approach as well, reducing medication errors, emergency room wait times, infection rates, and nursing turnover (Gabor 2004).

The following are some examples of strategies intended to improve productivity across sites.

Pay differentially

One plan increases surgeons’ payments if they select a less costly site (e.g., ambulatory care center versus a hospital outpatient department) in which to perform the surgery.

Promote sharing of savings

Our interviewees reported three types of arrangements that encourage productivity improvements by sharing the savings among stakeholders (e.g., plans, purchasers, providers, beneficiaries). In each of these arrangements, plans should measure quality to mitigate incentives to skimp on care.

- Insurers measure providers’ costs across an episode of care and pay efficient providers a higher rate or bonus payments. This technique can be used to promote appropriate use of services (discussed earlier) as well as to reduce costs associated with units of service. For example, to the extent that the cost of implantable devices (one source of growing costs cited by

interviewees) is factored into the total episode cost, physicians may be inclined to review their use of such devices.

- Insurers pay a bundled payment for an episode of care that is divided between the various services associated with the episode by the contracting entity (such as a hospital or IDS). Our interviewees adopted this approach only when paying centers of excellence for transplant and certain other services.
- Hospitals could give physicians a percentage of any reduction in the hospital's costs for patient care attributable to the physicians' efforts. This arrangement, known as gainsharing, is now prohibited for Medicare-covered care by the Office of Inspector General (see text box below).⁷

One IDS executive opposed to the prohibition noted that when he had pressed one of his cardiologists about the potential overuse of costly drug-eluting stents, the cardiologist responded that the additional cost was not his problem; it was the hospital's. The executive firmly believes that he could achieve

systemwide savings if he were allowed to pay physicians a portion of the savings gained from collaborating with the hospital to reduce costs.

Paying a price that reflects costs

An additional type of strategy is to pay a price that more closely reflects the cost of delivering the service. Some plans discussed pricing strategies. Two purchasers reported using competitive bidding for laboratory and specialty pharmacy services as well as durable medical equipment. One plan reported significant cost savings from using this approach; another indicated that it was worthwhile but noted it required more time and resources to issue a formal request for proposal than more typical price negotiations.

A number of plans indicated that they adjust their prices if multiple services are performed at a single encounter, paying the full price for the first (or primary service) and then a fraction of the price for the second or third service.

Tiered networks (discussed earlier) are also a type of pricing strategy. Plans or purchasers can accept the price offered by a provider and, based on that price, assign the

Gainsharing prohibitions in the Medicare fee-for-service program

The Office of Inspector General (OIG) has ruled that gainsharing violates the civil monetary penalty provision that broadly prohibits any hospital from knowingly making a payment directly or indirectly to physicians as an inducement to reduce or limit services to Medicare (or Medicaid) beneficiaries under the physician's care. Congress exempted such arrangements between health plans and providers from the prohibition and gave the Secretary regulatory authority to oversee these arrangements (OIG 1999).

The OIG acknowledges the potential positive aspects of gainsharing arrangements by citing a variety of ways savings can be generated without adversely affecting quality: substituting lower cost but equally effective medical supplies, items, or devices; reengineering hospital surgical and medical procedures; reducing use of medically unnecessary ancillary services; and reducing unnecessary lengths of stay. However, the OIG finds that gainsharing arrangements pose a high

risk of abuse. In addition to concerns about stinting on patient care, the OIG notes the possibility that hospitals may use gainsharing to enhance payment to high-referring physicians.

The OIG's first opinion left little leeway for providers to tailor an acceptable arrangement that would not be either in violation or liable to prosecution. A later advisory opinion offers insight into conditions under which the OIG will use its prerogative to not enforce the civil monetary penalties provision, even if it is technically unlawful. The opinion found that a hospital that identified specific cost-saving techniques, measured savings in ways that avoided creating adverse incentives, and measured quality of care would not be prosecuted. The approach exemplified in this opinion may still present obstacles if providers feel that by specifying the measures so distinctly and publicly, they are more vulnerable to malpractice suits. ■

provider to a tier that requires higher beneficiary costsharing. Indeed, providers may respond to the threat of being placed in an unfavorable tier by lowering their price. Hospital and physicians, as well as providers of radiological services or other services, may do this.

Purchasing strategies for imaging services

Given questions about use of imaging services covered by Medicare, the Commission looked specifically at private sector strategies aimed at ensuring appropriate and safe use of imaging services. Use of imaging varies widely among geographic areas, raising questions about overuse and underuse of the services (MedPAC 2003). For example, a recent article described the rapid growth of imaging services in Syracuse, New York, where the number of magnetic resonance imaging machines has grown by over a third over three years, and the number of scans increased 23 percent (Abelson 2004). The story describes concerns about quality and duplication of capacity.

In addition, the volume of some imaging services has grown rapidly in recent years. From 2001 to 2002, for instance, volume growth per beneficiary for some imaging—magnetic resonance imaging, computed tomography, nuclear medicine, and heart echography—ranged from 13 to 17 percent (MedPAC 2004). Purchasing strategies might be a way for Medicare to address these issues.

To learn more about purchasing strategies, the Commission heard from a panel of experts about strategies used by private insurers to purchase imaging services. The panel included representatives from two private health plans and an executive from a firm that manages radiology benefits for multiple health plans.

In their presentations to the Commission, panelists acknowledged that advances in imaging technology are expanding the ability of physicians to diagnose and treat disease. They also expressed some concerns, including:

- proliferation of imaging equipment;
- lack of familiarity with new imaging modalities among nonspecialist physicians;

- self-referral, including ordering of imaging studies by physicians who furnish the studies with equipment in their offices;
- direct-to-consumer marketing of imaging services and associated questions about the need for demand management;
- defensive medicine in response to physician concerns about professional liability;
- repetition of imaging studies; and
- poor quality of imaging equipment in some settings.

In adopting their purchasing strategies, private insurers are working to control growth in the cost and utilization of imaging services while ensuring access to appropriate care.

Some of these strategies are similar to ones that we heard about during interviews with health plans, purchasers, and benefit consultants. Private insurers have just adapted them to emphasize the efficiency of imaging services. For instance, private insurers are profiling individual physicians or groups of physicians to compare patterns of imaging utilization among peers. The results are used to benchmark performance and provide information to physicians and enrollees to help them make cost-effective decisions. In addition, profiling results are used to design payment incentives for physicians who provide cost-effective care.

Private insurers are also using preauthorization to reduce utilization of imaging services that is inconsistent with practice guidelines. The strategy is viewed as an educational tool to help ensure that physicians are aware of practice guidelines.

To emphasize imaging services in their beneficiary education programs, private insurers make beneficiaries aware of their treatment options. In addition, the insurers provide information on the risks of exposure to radiation.

The panel discussed other strategies, including:

- coding edits, which are rules used during claims review to either detect improper billing codes or adjust payment for multiple imaging services on the same claim;
- safety standards for imaging equipment; and

- privileging, which includes certification of those who can bill for imaging services.

These strategies have features designed to address cost growth and the other concerns specific to imaging.

In starting to consider these strategies, we compared them to current policies of the federal government. We find the government already pursues some of these strategies, such as coding edits; could relatively easily implement others, such as promoting beneficiary education about the use of imaging; and cannot pursue others, such as tiering, under current law.

Coding edits

According to the panel, private insurers often use Medicare’s coding edits. Known as Correct Coding Initiative (CCI) edits, these edits detect two forms of improper billing: unbundling and billing for mutually exclusive services.⁸ Unbundling occurs when a claim includes two related billing codes and one code is defined as a component of the other code. Billing for mutually exclusive services includes billing for two services not typically furnished to the same patient. In all cases, CCI edits consider pairs of billing codes and detect instances in which both codes are not payable. Savings due to these edits totaled \$333 million in 2002 (compared with total program spending of \$45 billion), according to the CMS contractors who process claims. Savings may be larger than this, however, if providers know the coding edits and choose not to submit bills that would be edited.

Consistent with a MedPAC recommendation, CCI edits are transparent. They are made public and shared with the medical community and the American Medical Association’s Correct Coding Policy Committee for review and comment before their implementation (MedPAC 2000).

Private insurers supplement the CCI edits with ones that are more extensive. Some of these compare billed services with practice guidelines. Others result in payment adjustments when multiple imaging services are billed on the same claim.

In adjusting payments for multiple imaging services, private insurers usually pay the full amount for the first service but a reduced amount for each additional service. This strategy is based on the premise that there are efficiencies when multiple services are provided during one patient encounter. Medicare has a similar policy, but it

applies to surgical services only. For instance, under the physician fee schedule, Medicare pays the full fee schedule rate for the most expensive surgical service, but a discounted rate for the other services.

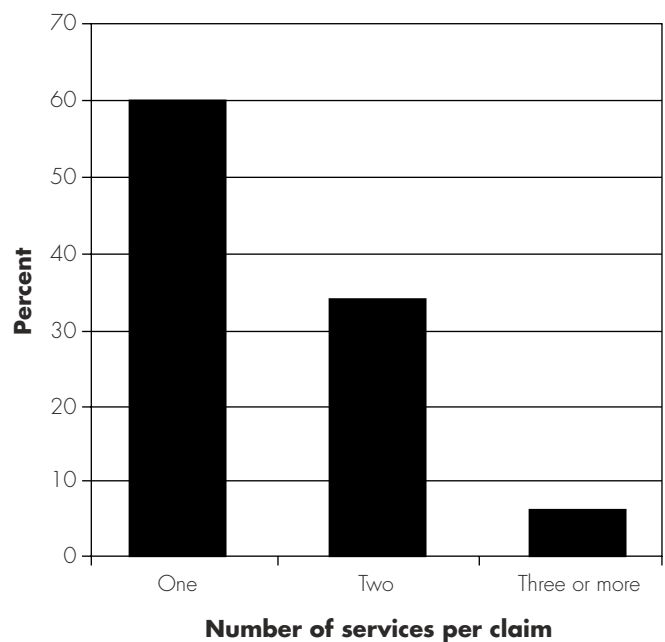
How often do claims submitted to Medicare include multiple imaging services? We have not analyzed the issue fully, but claims data for services billed under the physician fee schedule show that, for computed tomography (CT)—one type of imaging—about 40 percent of claims with any CT services include two or more CT services (Figure 4-1). Among these, CT of the abdomen and CT of the pelvis are the services that are billed together most frequently. When this occurs, the physician receives full payment for both services.

Safety standards for imaging equipment

Private insurers have implemented standards for imaging equipment in response to concerns about safety and technical quality of outpatient imaging facilities. To accomplish this, they inspect facilities periodically and assess:

FIGURE 4-1

Among claims with any CT services, 40 percent included two or more CT services, 2002



Note: CT (computed tomography).

Source: MedPAC analysis of claims data for 1 percent of Medicare beneficiaries.

- availability of equipment necessary to provide services,
- maintenance and safety of equipment,
- qualifications of staff,
- technical quality of radiographic and other images,
- procedures for ensuring quality control, and
- storage and management of records.

Performance is compared to standards developed by the American College of Radiology and other organizations.

In general, private insurers find that facilities comply with established standards. This can vary, however. Research has shown failure rates approaching 50 percent, depending on the type of practitioner operating the facility (Table 4-1). Such results may understate failure rates because they exclude facilities that withdraw from the market in anticipation of inspections (Verilli et al. 1998).

In some cases, facilities fail inspections because of the age of their imaging equipment. This problem can arise because facilities sometimes acquire used equipment from a hospital, for example, and continue to use the equipment beyond its useful life. The result for patients can be greater exposure to radiation than would occur with newer technology. In other cases, inspections reveal use of the incorrect type of equipment for a given imaging study. For

instance, one inspection found use of dental equipment for x-rays of toes. Problems such as these raise questions about the extent to which some imaging facilities are achieving a minimum level of safety for their patients.

When private insurers implement safety standards for outpatient imaging facilities, their activities are similar to oversight of mammography facilities by the Food and Drug Administration (FDA). Under authority of the Mammography Quality Standards Act of 1992, the FDA establishes quality standards for mammography equipment and personnel. To enforce these standards, the agency annually inspects and certifies over 9,000 mammography facilities.

CMS is also engaged in such quality assurance efforts. Under authority of the Social Security Act, CMS establishes conditions of participation for entities meeting the definition of “provider of services,” such as hospitals, skilled nursing facilities, and home health agencies. Conditions of participation are primarily structural requirements believed to ensure that providers can safely furnish quality health care (MedPAC 2000). They include standards for nurse staffing, radiologic services, laboratory services, medical records, infection control, discharge planning, and other aspects of health care delivery. Other entities, not defined as providers of services, are also subject to such standards—known as conditions of coverage. Those entities include renal dialysis facilities, ambulatory surgical centers, and portable x-ray suppliers.

Under authority of the Clinical Laboratory Improvement Amendments, passed in 1988, CMS also establishes quality standards for clinical laboratories. These laboratories are in physician offices, hospitals, skilled nursing facilities, and other locations.

To enforce conditions of participation, conditions of coverage, and quality standards for laboratories, CMS relies on others for inspections as part of the agency’s survey and certification program. In some cases, state survey agencies conduct the certification surveys. In other cases, the surveys are conducted by private accreditation organizations, such as the Joint Commission on Accreditation of Healthcare Organizations. As long as the private organizations’ standards meet or exceed CMS’s standards, providers receiving private accreditation are deemed in compliance with the CMS standards.

TABLE 4-1

Outpatient imaging failure rates vary by specialty

Practitioner or physician specialist	Number of sites inspected	Failures	
		Number	Percent
Chiropractor	144	70	49%
Podiatrist	49	22	45
Family or general practitioner	72	31	43
Internist	20	8	40
Urologist	14	5	36
Surgeon	12	3	25
Orthopedist	43	7	16
Obstetrics and gynecology	41	3	7
Radiologist	77	1	1

Source: Orrison and Levin 2002.

MedPAC has recommended ways to improve the survey and certification process (MedPAC 2000). The Commission has recommended more frequent updates of conditions of participation and more frequent surveys of providers. The Commission has also recommended adequate levels of funding for survey and certification activities and sanctions that reflect the scope and severity of deficiencies found during surveys.

Physicians, and the services provided in their offices, are not subject to federal safety standards other than those for mammography and clinical laboratory services. Upon meeting the statutory definition of “physician,” physicians can furnish diagnosis, therapy, and other services within

the scope of medical practice for the state in which they are licensed.⁹ States often regulate imaging services in physician offices through radiologic health initiatives.

Independent diagnostic testing facilities are another important source of imaging services (see text box below). CMS has established certain requirements for them, but they are not subject to survey and certification or other rigorous enforcement mechanisms.

Privileging

Privileging is another strategy private insurers have used to achieve efficiency and ensure quality. Privileging programs restrict payment for some imaging services to

Independent diagnostic testing facilities

Independent diagnostic testing facilities (IDTFs) are entities—independent of a hospital or physician office—in which nonphysician personnel furnish diagnostic procedures under physician supervision. An IDTF is considered to be independent of a physician’s office if it:

- primarily bills for diagnostic tests rather than physician services (such as evaluation and management), and
- provides diagnostic tests primarily to patients whose conditions are not being treated by physicians in the practice.

A radiology practice that provides both the technical component and professional component (i.e., the test interpretation) of a test at the same location is not required to enroll as an IDTF.

Prior to 1998, freestanding diagnostic centers were classified as independent physiological laboratories, which were largely unregulated by either CMS or states. CMS and the Office of Inspector General (OIG) found evidence of fraudulent behavior by these entities and potential safety problems (HCFA 1997, OIG 1998). To address these issues, CMS created the IDTF category in 1997. IDTFs have certain requirements,

which do not apply to physician offices that provide diagnostic services:

- They must have at least one supervising physician who oversees the quality of the testing, the proper operation and calibration of the equipment, and the qualifications of nonphysician staff.
- The nonphysician staff must be licensed by the state or certified by a national credentialing body.
- The beneficiary’s treating physician must order all procedures performed by an IDTF in writing.
- They can only perform procedures that are approved in advance by their carriers.

Before enrolling IDTFs in Medicare, carriers must verify through document review and a site visit that the IDTF actually exists, the requirements above are met, and the equipment it uses is properly maintained and calibrated. However, enforcement of the standards is not rigorous: IDTFs are not subject to periodic survey and certification unless they wish to begin furnishing new types of services or if they open a new practice location. Under these circumstances, the carrier must perform an additional site visit. ■

physicians in certain specialties, such as radiology and cardiology. In addition to addressing the quality of imaging services, privileging counteracts problems that private insurers perceive with self-referral and proliferation of imaging equipment.

Medicare data illustrate the extent to which imaging services are provided by physicians in different specialties (Figure 4-2). Radiologists account for almost half of spending for imaging services furnished to Medicare beneficiaries. Cardiology also accounts for a relatively large proportion of spending for imaging. Still, much of the rest of spending is for services furnished by physicians in other specialties.

One effect of privileging is that it can reduce repeats of imaging studies. Studies are sometimes furnished by physicians or other practitioners who are not well-qualified to do so. The panel cited one example where podiatrists were interpreting MRIs. When this occurs, repeat studies are sometimes ordered. Privileging can prevent the problem by limiting payment to those most qualified to furnish imaging services.

In implementing their privileging programs, private insurers have found that certain operational details are important. For instance, privileging requires accurate

information on physician specialty and, for nonphysicians, type of practitioner.¹⁰ In addition, private insurers must waive privileging requirements in some rural areas to ensure access to care.

These privileging programs are not unlike some current Medicare policies. For example, chiropractors are permitted to bill Medicare for only one type of service: manual manipulation of the spine to correct a subluxation (dislocation). When chiropractors furnish other services, such as imaging, Medicare does not cover the services.

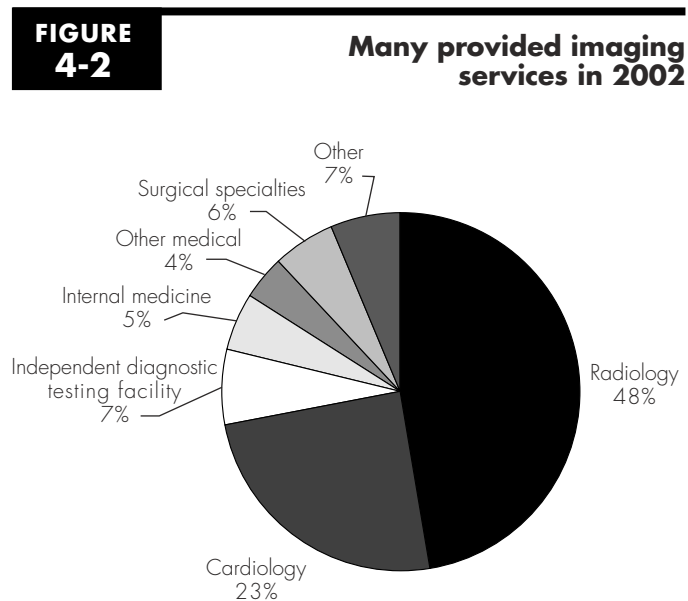
Privileging is also similar to Medicare coverage of power operated vehicles (POVs), also known as scooters. Under a campaign called Operation Wheeler Dealer, CMS will not cover a POV, unless it is ordered by a physician with a specialty in physical medicine, orthopedic surgery, neurology, or rheumatology (CMS 2003a). The campaign is a response to rapid growth in spending for the vehicles and evidence of rampant fraud and abuse in Harris County, Texas (CMS 2003b).

Restrictions on self-referral are another way to limit who can provide certain services, including imaging. Under the so-called Stark I and Stark II laws, physicians cannot refer Medicare (or Medicaid) patients to entities with which they, or members of their family, have a financial interest. The entities covered by the laws include those that provide radiology services as well as other services, such as clinical laboratory services, physical therapy, and home health. Certain types of referrals are exempt, including those within group practices.

Self-referral also includes a physician directing patients to imaging equipment within his or her practice (Kouri et al. 2002), but the Stark laws do not restrict this form of self-referral. In some respects, privileging is a private insurer response to this limitation of the Stark laws.

Next steps

Should Medicare do more to emulate private insurers' strategies for purchasing imaging services? The answer to this question depends on the administrative feasibility—for both Medicare and the physicians and other providers who furnish services—of more closely aligning Medicare policy with the strategies of private insurers. It also depends on the effectiveness of those strategies for making the purchasing of imaging services more efficient. MedPAC plans to address these issues during the coming year.



Note: Other includes multispecialty clinic, portable x-ray supplier, and nuclear medicine.

Source: MedPAC analysis of physician claims data for 100 percent of beneficiaries.

Purchasing strategies for Medicare

In response to rising health care costs, insurers and employers in the private sector, as well as a growing number of public programs, have introduced strategies designed to promote efficiency in health care delivery. CMS has demonstrated a strong interest in value-based purchasing, and has introduced a variety of new programs. Notable examples are Medicare hospital and nursing home quality review and improvement programs, the development and dissemination of comparative information on provider quality for consumers, and the implementation of demonstration programs designed to test methods for improving the quality and effectiveness of health care in the fee-for-service program.

The purchasing strategies we have reviewed vary considerably. Some are variations or enhancements to systems or methods already present in some form in Medicare, such as consumer education and outreach programs or claims administration techniques like coding edits. Medicare contractors such as the quality improvement organizations (QIOs) are like their private sector counterparts in using profiling to review utilization and quality and educate providers about their performance. CMS has also developed data for consumers to use in comparing providers on measures of cost (as well as quality of care) for the new prescription drug cards and Medicare health plans. The introduction of some purchasing strategies, however, has been constrained by statute.

Recent legislative reforms have removed some significant barriers to implementing new purchasing strategies, but Medicare remains unique in the characteristics of its enrollee population, its legal complexity, and its size. Determining whether particular strategies should be pursued, or the manner in which strategies might be implemented successfully, will require careful analysis.

The statutory and regulatory context

The Medicare statute provides the basic structure for Medicare contracting; regulations that implement the statute and program policy shape how the program actually does its work. When Medicare was enacted in 1965, the legislation clearly reflected concern about government influence on the practice of medicine. The

law specified that the program be administered by private entities that would, under contract, operate the program like large group insurance companies, and it set out basic criteria limiting the program's authority to affect health care. The first sentence of the Medicare title of the Social Security Act states,

“Nothing in this title shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.”

The second sentence is designed to preserve beneficiaries' access to their choice of providers. It states,

“Any individual entitled to insurance benefits under this title may obtain health services from any institution, agency, or person qualified to participate under this title if such institution, agency, or person undertakes to provide him such services.”

Broadly, these provisions—noninterference and beneficiary freedom of choice—provide a starting place for examining Medicare purchasing strategies. The context for interpreting these provisions, however, has changed over time. As Medicare has grown to be a major part of the health care system, policymakers have recognized that decisions about Medicare coverage and payment affect the American health care system in many ways.

The introduction of private plan options has also recast the role of the Medicare program. Private plans—primarily HMOs and preferred provider organizations—contracting with Medicare can use financial and management incentives to encourage providers to manage care more efficiently and effectively. Private plan options coexist with fee-for-service Medicare, and the same standards of coverage and beneficiary grievances and appeals apply across Medicare fee-for-service and private plans.

Despite the expansion of Medicare’s role as a purchaser, however, implementing some strategies would require changes to Medicare law. Ongoing work commissioned by CMS is examining what changes would be needed to implement specific purchasing strategies, including:

- developing cost and/or quality profiles of providers that would form the basis of selective contracts;
- establishing differential payments related to meeting performance standards;
- reducing cost sharing for beneficiaries obtaining services from “preferred” providers;
- increasing covered services for beneficiaries obtaining services from “preferred” providers; or
- steering beneficiaries to providers through advertising and education campaigns.¹¹

This analysis examines how federal antitrust provisions and other laws affecting providers’ ability to form networks or establish other financial arrangements, data privacy law, and specific provisions of the Medicare statute and regulations could affect purchasing strategies. State law also may affect these strategies. Although federal law generally preempts state law on matters pertaining to Medicare, state law governing risk-sharing arrangements and provider participation in health plans (such as any willing provider laws) can, in effect, determine what types of provider organizations operate in local markets—and therefore are available to participate in Medicare. State policy regulating the licensing and certification of health care facilities and professionals also affects the availability of services and how they are used in local markets.

Medicare law would need to be changed to allow some purchasing strategies. For example, provisions governing fee-for-service Medicare do not currently permit differential beneficiary cost sharing.¹² Certain types of gain-sharing strategies or productivity bonus arrangements may not be permissible for fee-for-service providers under current anti-kickback provisions of federal or state law. It also appears that fee-for-service Medicare cannot increase covered services for beneficiaries who obtain care from preferred providers under current law.

Purchasing strategies that are not generally permissible under the statute may be allowable under fee-for-service demonstration programs, but this is not always clear.

Different cost-sharing designs or augmented benefits might be permissible under demonstration authority, although there have been challenges to the designs proposed for some demonstrations (including a cataract care demonstration project and the Medicare Competition Pricing Demonstration).

Medicare may not currently have statutory authority to undertake any profiling activity that identifies or creates categories of “preferred providers.” Legal challenges might center on the validity, or arbitrariness, of the measures and standards that CMS might use to categorize providers. A strategy that centered on categorizing individual practitioners as “preferred” or “more efficient” might also be challenged by practitioners not receiving the designation if the strategy did not allow for due process under the law.

Although the Medicare statute does not explicitly direct the Secretary to develop provider profiles, the authority to profile provider performance related to quality of care could be implied from provisions establishing the Medicare Peer Review Organizations (now called QIOs). The 1982 amendments to Medicare law that created the review organizations defined their functions to include the review of the quality of institutional and practitioner services and gave the Medicare program a broad authority to carry out the statutory provisions. The regulations implementing the QIO program charge them with examining whether “the quality of services meet professionally recognized standards of care.” As part of the work they perform under contract with CMS, QIOs undertake national and local projects designed to improve quality of care for targeted conditions or diagnoses. These studies use CMS claims, medical records, and other data. QIO projects generally include profiling of provider practice and treatment variations, educational interventions designed in collaboration with providers, and feedback to providers on performance improvements (CMS 2003c).

CMS may seek to expand QIO profiling activities. The framework for the next contractor scope of work includes a section describing possible activities focused on developing QIOs’ role in increasing the efficiency of care. Under the new contracts, for example, CMS has indicated that it may ask QIOs to make the QIO Clinical Data Warehouse a resource for partnerships to publish and

improve performance measures. Another section of the proposed framework lays out activities designed to expand QIOs' ability to "impact quality and costs." Examples include aligning QIO efforts with private sector programs to reduce inappropriate use of services, pharmaceuticals, and technology, and developing programs to prepare physicians for performance measurement using information technology (CMS 2003d).

CMS's contracting authority

Law and regulations governing Medicare's contracting authority define some of its options as a purchaser. Like other federal entities, CMS must follow the requirements of federal procurement regulations. These regulations are designed to ensure fair competition among eligible entities. In practice, the requirements can limit agencies' ability to move quickly to develop or amend contracts and restrict ways in which contracts can be constructed.

When Medicare was created, however, the statute included more extensive limits on the program's ability to engage in the contracts necessary to administer the program. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) substantially restructured the Secretary's authority to contract for Medicare administrative services, removing requirements for the nomination of contractors by eliminating the distinction between Part A and Part B contractors, and ending special procurement provisions. New contracts will be competed under the general federal procurement process rules (unless there are specific Medicare statutory provisions that conflict with the federal procurement rules).

Under these reforms, all of the functions of the current fiscal intermediaries and carriers processing Part A and Part B claims are assumed by new entities called Medicare Administrative Contractors (MACs). The Secretary will be able to renew MAC contracts for up to five years. The legislation calls for the Secretary to enter into new contracts with fiscal intermediaries without regard to the former nomination process no later than October 1, 2005. The full transition to the MAC contracts is to begin after October 1, 2005, and be completed by September 30, 2011.

The statute requires the Secretary to develop contract performance requirements addressing claims processing efficiency, customer service, provider education, and other activities, and to develop standards for assessing whether

contractors meet these requirements. In developing performance standards, the Secretary must consult with beneficiary and provider organizations and organizations performing other Medicare functions. The Secretary must make the performance measures public, and include beneficiary satisfaction levels. The contractors do not, however, have to perform all of the claims administration, utilization review, education and outreach, and other functions associated with Medicare claims administration. The Secretary can design contracts that focus on specific activities. Previous legislation permitted this approach for only two services, durable medical equipment and home health; the MMA reforms will allow CMS to apply this approach to other types of services.

The new provisions governing Medicare contracting could provide opportunities for new purchasing strategies in at least two ways. First, the pool of contractors should expand, allowing organizations with special expertise in areas related to particular services or provider groups, or who have developed innovative approaches to claims management and review, medical review, provider profiling, and other activities, to compete as Medicare contractors. This flexibility may also provide some opportunity for CMS to review the various activities of the other contractors, including the program integrity contractors and the QIOs. It might be possible, for example, to use Medicare administrative data to develop more comprehensive analyses of provider profiles, focusing on variations in service volume, quality, or effectiveness of care. Second, the Secretary has been directed to incorporate performance measures and incentives into contracts. This could provide more impetus for contractors competing for Medicare business to devise strategies to inform providers about effective practice or to devise more effective claims screening protocols.

Next steps

Innovative purchasing strategies that are emerging in the private sector and in other large public systems suggest that there are ways Medicare can be a better purchaser of health care. There may also be opportunities for fee-for-service Medicare to take a more active role in the development and evaluation of purchasing strategies that could increase the efficiency and effectiveness of health care overall. There is, however, no clear consensus about how actively Medicare, directly or through its contractors, should manage purchasing decisions in the fee-for-service program.

Three broad questions arise in evaluating whether the Medicare fee-for-service program should pursue specific purchasing strategies:

- How would purchasing strategies affect Medicare beneficiaries?
- How would the purchasing strategy affect the delivery system that serves beneficiaries?

- Can the Medicare program administer the strategy effectively?

The Commission plans to take up these issues as it considers policy options over the course of the next year. ■

Endnotes

- 1 Coding edits are rules invoked during computerized claims processing to detect improperly coded claims for payment.
- 2 Various Medicare demonstrations have experimented with alternative strategies to improve efficiency, including the centers of excellence, competitive bidding, group practice, and disease management demonstrations.
- 3 Others have considered applicability of private sector strategies to Medicare (Berenson 2003, Etheredge 2003).
- 4 The Leapfrog group is a consortium of public and private organizations, organized by the Business Roundtable, that promotes programs designed to help large purchasers of health care initiate programs to advance quality of care and improve patient safety.
- 5 RTI International has prepared a report for CMS examining a range of issues related to selective contracting, physician profiling, and other purchasing strategies. The draft report, *Environmental scan for: Selective contracting practices with efficient (qualified) physicians and physician group practices; profiling techniques; incentive payments and barriers to selective contracting*, has not yet been revised to reflect CMS comments, nor has it been accepted by CMS in final form.
- 6 Recent research has raised questions about the ability of volume of services to serve as a proxy for hospital quality. One study found that the positive relationship between quality and high volume of coronary artery bypass graft surgeries was not observed in patients younger than 65 years or in those at low operative risk (Peterson et al. 2004).
- 7 CMS recently initiated a demonstration in New Jersey to test the impact of a gainsharing arrangement on Medicare spending. Before it was implemented, however, three hospitals that were not chosen to participate in the program sued the Secretary. The District Court of New Jersey halted the demonstration because of concerns that it violated the 1986 Federal civil monetary penalty statute (Albert 2004).
- 8 These edits apply to all physician services, not just imaging services.
- 9 This same principle applies to other professionals, including dentists, optometrists, podiatrists, and chiropractors.
- 10 Chiropractor is one type of nonphysician practitioner billing some private insurers for imaging services.
- 11 This discussion of legal issues surrounding the introduction of purchasing strategies in fee-for-service Medicare draws on the CMS draft report, prepared by RTI International, described in endnote 5.
- 12 Different cost-sharing arrangements are explicitly permitted for Medicare Advantage private plans.

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CHAPTER

5

**Defining long-term
care hospitals**

R E C O M M E N D A T I O N S

5A The Congress and the Secretary should define long-term care hospitals by facility and patient criteria that ensure that patients admitted to these facilities are medically complex and have a good chance of improvement.

- Facility-level criteria should characterize this level of care by features such as staffing, patient evaluation and review processes, and mix of patients.
- Patient-level criteria should identify specific clinical characteristics and treatment modalities.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1

.....
5B The Secretary should require the Quality Improvement Organizations to review long-term care hospital admissions for medical necessity and monitor that these facilities are in compliance with defining criteria.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1

Defining long-term care hospitals

Rapid growth in the number of long-term care hospitals (LTCHs) and in Medicare's spending highlights the need for more information about these facilities and the care beneficiaries receive in them. Using qualitative and quantitative methods, we find that LTCHs' role is to provide post-acute care to a small number of medically complex patients. We also find that the supply of LTCHs is a strong predictor of their use and that acute hospitals and skilled nursing facilities are the principal alternatives to LTCHs. We find that, in general, LTCH patients cost Medicare more than similar patients using alternative settings but that if LTCH care is targeted to patients of the highest severity, the cost is comparable. We conclude that continued growth in LTCHs and the financial incentives presented by multiple Medicare prospective payment systems make a new, clearer definition of LTCH care imperative. Thus, the Commission recommends that long-term care hospitals be defined by facility and patient criteria that ensure that patients admitted to these facilities are medically complex and have a good chance of improvement.

In this chapter

- What are long-term care hospitals and how does Medicare pay them?
- How did we study long-term care hospitals?
- What role do long-term care hospitals play in providing care?
- Where are clinically similar patients treated in areas without long-term care hospitals?
- How do Medicare payments and outcomes compare for LTCH patients versus those in other settings?
- What criteria can we use to better define LTCHs and the patients most appropriate for this type of care?
- Technical methodology section

Prior to this study, little was known about long-term care hospitals (LTCHs), a category of Medicare providers exempted from the prospective payment system (PPS) for acute hospitals in 1983. The rapid growth in the number of LTCHs and the corresponding increase in Medicare spending, combined with the concentration of these facilities in some parts of the nation and the lack of them in other parts have raised a number of questions, such as:

- What role do long-term care hospitals play in providing care?
- Where are clinically similar patients treated in areas without long-term care hospitals?
- How do Medicare payments and outcomes compare for LTCH patients versus those in other settings?

For MedPAC's June 2003 report to the Congress, we studied patients with the 11 most common diagnoses in long-term care hospitals, using descriptive analysis and controlling for diagnosis related group (DRG) and severity of illness (MedPAC 2003). We found that patients in market areas with LTCHs had similar acute hospital lengths of stay whether they used these facilities or not. Patients who used LTCHs were three to five times less likely to use skilled nursing facility (SNF) care, suggesting that SNFs and long-term care hospitals may be substitutes. We also found that Medicare pays more for patients treated in LTCHs, compared with similar patients not treated in them. We concluded that more research was needed to answer the three questions above.

In this chapter, we report the results of our subsequent research, both qualitative and quantitative, designed to answer the questions about LTCHs. We then turn to the question of what criteria Medicare can use to better define long-term care hospitals and the patients most appropriate for treatment in them.

What are long-term care hospitals and how does Medicare pay them?

To qualify as long-term care hospitals for Medicare payment, facilities must meet the conditions of participation for acute hospitals. Currently, the only other requirement is that LTCHs must have an average Medicare length of stay (LOS) greater than 25 days.

The number of LTCHs has grown rapidly from 105 facilities in 1993 to 318 in 2003, or 12 percent annually. Recently, the pace of growth has doubled—22 new LTCHs were certified by Medicare in the first six months of fiscal year 2004 compared with the same number of facilities in all of fiscal year 2003.

Medicare spending for LTCHs has grown even more rapidly than the number of LTCHs, at 15 percent per year. Spending has almost quintupled from \$398 million in 1993 to \$1.9 billion in 2001. CMS estimates that Medicare spending for LTCHs will be \$2.8 billion in 2004. This estimate, however, does not take into consideration the growth in LTCHs since 2001 and the consequent increases in LTCH cases. For example, the number of LTCH cases increased by 24 percent from 2001 to 2002.

Medicare is the predominant payer for long-term hospital care, particularly for newer LTCHs. In 1997, Medicare paid for 71 percent of LTCHs' discharges (Liu et al. 2001). For long-term care hospitals established after September 1993, Medicare paid for 80 percent of discharges.

In fiscal year 2003, the method of payment for LTCHs changed from a cost-based system to a prospective payment system. Under the old cost-based system, LTCHs had incentives to keep their total costs slightly below their facility-specific payment limit (established in their base year and updated annually) in order to qualify for limited bonuses. Payments were not adjusted for changes in the mix of patients over time. Under the PPS, Medicare pays LTCHs predetermined per discharge rates based primarily on patients' principal diagnoses. Each discharge is assigned to one of 518 case-mix categories, and each case-mix category has its own payment rate that reflects the expected costs of treatment. While the payment system now accounts for case-mix differences, it does not account for differences in the severity of patients within each case-mix category. As a result, similar to other PPSs, LTCHs have an incentive to admit patients with the least need for resources among those with the same diagnosis.

Long-term care hospitals are usually the most costly post-acute care setting. In fiscal year 2004, for patients with the most common LTCH diagnoses, Medicare rates for LTCHs range from 0.9 to 4.4 times as much as estimated rates for inpatient rehabilitation facilities (IRFs), and about 3 to almost 12 times as much as estimated rates for SNFs (Table 5-1).

**TABLE
5-1**

Payments usually are higher for long-term care hospitals than for other post-acute settings, fiscal year 2004

Per case payment for post-acute setting

Principal diagnosis	Long-term care hospital	Inpatient rehabilitation facility*	Skilled nursing facility**
Tracheostomy with ventilator 96+ hours	\$115,463	\$ 26,051	\$ 10,051
Respiratory system with ventilator	74,689	26,051	7,897
Major joint and limb replacement, lower extremity	67,104	17,135	6,165
Skin graft and wound debridement	48,595	N/A	8,111
Amputation	44,983	33,245	9,590
Hip fracture	44,633	18,487	10,618
Stroke	31,496	34,196	8,905
Skin ulcers	34,704	N/A	8,111
Septicemia	34,340	N/A	8,974
Osteomyelitis	29,563	N/A	10,410

Notes: N/A (not applicable).

*For inpatient rehabilitation facilities, payments are for the case-mix group with the lowest functional status and the most comorbidities. This seemed to be the most conservative comparison to LTCHs.

** For skilled nursing facilities (SNF), payments are estimated based on the actual average length of stay by diagnosis (for the first SNF admission after hospital discharge) times the per diem rate for the case-mix group to which patients with that diagnosis are most likely to be assigned.

Source: Federal Registers 2003a, 2003c, 2003e; MedPAC analysis of 2001 claims from CMS.

LTCHs are unevenly distributed across the country (Figure 5-1, p. 124). Some areas have many LTCHs; other areas have none. Using multivariate regression analysis, we determined that presence of an LTCH in a market area is not related to the proportion of sickest patients. The uneven distribution and lack of a clinical relationship to LTCH location raises two questions: First, what role do LTCHs play if they are present in some areas and not others? Second, where are clinically similar patients treated in areas without any of these facilities?

How did we study long-term care hospitals?

We used both qualitative and quantitative approaches to answer our key questions regarding the role that LTCHs play, where patients in areas without LTCHs are treated, and the differences in Medicare payments and outcomes for patients who use LTCHs compared with those treated in other settings. We used:

- Structured interviews with 34 physicians, hospital administrators, nurses, and discharge planners to

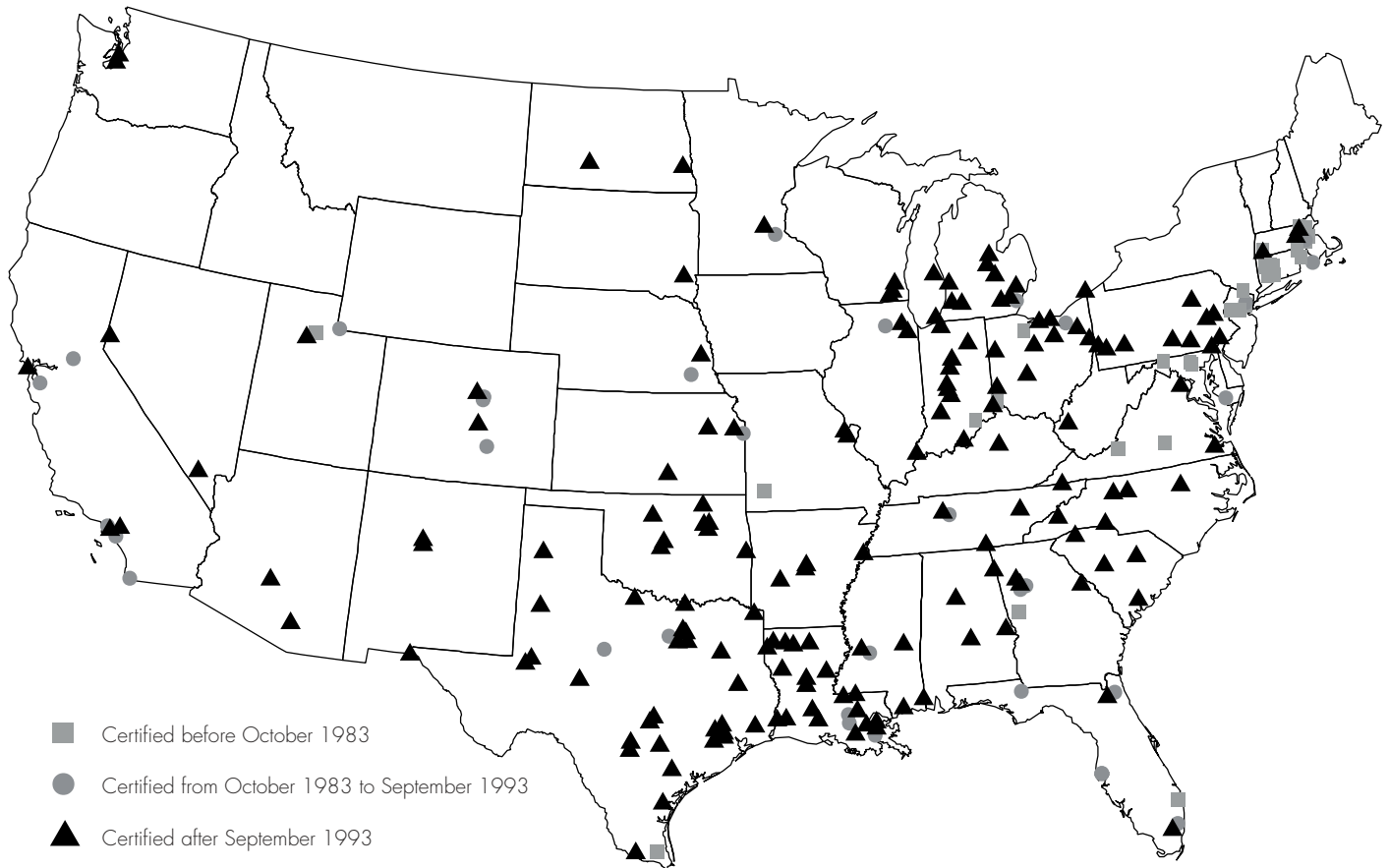
understand how LTCH-type patients are treated in markets with and without LTCHs. Researchers from NORC and Georgetown University conducted these interviews in four markets (two with and two without LTCHs).

- Site visits to LTCHs in three cities. Physicians from 10 LTCHs presented clinical cases of patients treated in their facilities to MedPAC staff, Commissioners, and a physician consultant.
- Quantitative analyses that included both market-level analyses to compare characteristics of patients treated in markets with and without LTCHs, and patient-level analyses to examine the impact of LTCH use on Medicare spending and outcomes.

The unit of analysis for the quantitative research is the beneficiary’s episode of care. Episodes begin with admission to the acute hospital and end with either readmission to the acute hospital, 61 days without Medicare acute or post-acute care services (Medicare’s definition of a spell of illness), or death.

**FIGURE
5-1**

Location of long-term care hospitals, 2003



Source: Online Survey, Certification, and Reporting System from CMS.

In addition to the full data set with 4.3 million episodes that we used for most of our analyses, we also created two subsamples of episodes for patients most likely to use LTCHs to see whether the coefficients of interest differ for the types of patients who are frequently admitted to these facilities.

- The first subsample (226,000 episodes) includes patients who had a high probability (the top 5 percent) of using an LTCH based on their clinical characteristics. Although these patients have the highest probability of using an LTCH, their likelihood of using an LTCH is still relatively small.
- Our second subsample (20,000 episodes) consists of patients with an acute hospital diagnosis of tracheostomy with at least 96 hours of ventilator

support. In this chapter we refer to these individuals as tracheostomy patients. This group is the most strongly associated with using LTCHs.

We used the full sample and two subsamples to evaluate how LTCH use affects the following dependent variables:

- acute hospital length of stay,
- discharge destination following acute hospital stay,
- Medicare spending for acute hospitals,
- Medicare spending for post-acute care, including spending for LTCHs,
- Medicare spending for the episode of care (Part A services and home health care),

- readmission to acute hospitals, and
- mortality 120 days after acute hospital admission.

We used several approaches to control for severity of illness. First, we controlled for clinical variables available in administrative data. Second, we used an instrumental variable approach to control for unmeasured severity of illness or “selection bias,” which might arise if physicians refer sicker patients to LTCHs from the acute hospital (McClellan et al. 1994). More information about our methodology is found in the last section of this chapter.

What role do long-term care hospitals play in providing care?

Physicians and LTCH administrators told us that long-term care hospitals provide post-acute care and that most patients are transferred from acute hospitals. Analysis of episodes supports these statements—about 80 percent of LTCH patients are transferred from acute hospitals.

LTCHs provide post-acute care to a small number of medically complex patients who are more stable than patients in an intensive care unit (ICU) but may still have unresolved underlying complex medical conditions. Fewer than 1 percent of Medicare beneficiaries discharged from acute hospitals are transferred to LTCHs. Many of these patients require ventilator support for respiratory problems, have failure of two or more major organ systems, neuromuscular damage, contagious infections, or complex wounds needing extended care. LTCH clinicians maintain that they admit patients who have a good prognosis for improvement, which is why they extensively screen patients before admission.

The use of LTCHs is associated with certain diagnoses, severity levels, and the proximity of the facility. Having a diagnosis of tracheostomy is the single strongest predictor of LTCH use, although individuals with tracheostomies represent only 3 percent of LTCH patients. Diagnoses other than tracheostomy also predict long-term care hospital use—respiratory system diagnosis with ventilator support, acute and subacute endocarditis, amputation, skin graft and wound debridement, and osteomyelitis. Having the highest severity level, regardless of diagnosis, almost quadruples the probability of LTCH use.

Living near an LTCH increases a beneficiary’s probability of using such a facility. For example, living in a market area with an LTCH quadruples the probability of LTCH use. Being hospitalized in an acute hospital with an LTCH located within the hospital also quadruples the probability that a beneficiary will use a long-term care hospital.

Where are clinically similar patients treated in areas without long-term care hospitals?

Using quantitative and qualitative analyses, we find that acute hospitals and SNFs are the principal substitutes for long-term care hospitals in areas without LTCHs. In qualitative studies, physicians told us that some patients without access to LTCHs stay longer in the acute hospital and others go to the relatively few SNFs equipped to handle patients with multiple complex illnesses or needing ventilator support. Our empirical results support that assertion.

Acute hospitals Our multivariate analyses support the finding that patients who use LTCHs have shorter acute hospital lengths of stay than similar patients who do not use these facilities. For all acute hospital patients, those who use LTCHs have an acute hospital LOS that is seven days shorter than those who do not. For patients in the top 5 percent probability of using an LTCH, patients who use long-term care hospitals have an acute hospital LOS that is nine days shorter. Shorter hospital lengths of stay for similar patients who use LTCHs suggest that long-term care hospitals substitute for at least part of the acute hospital stay.

Patients similar to those treated in LTCHs are sometimes treated in acute hospital step-down units—units created to step down from ICUs—instead of LTCHs. Some of these units specialize in patients with pulmonary conditions. Interviewees told us that acute hospitals with step-down units may be better equipped to handle patients requiring extended acute care than hospitals without these units. In acute hospitals without step-down units, patients may occupy a critical care or intensive care bed for a longer period, or be transferred to a medical floor.

Skilled nursing facilities Our multivariate results, controlling for severity of illness and other factors, indicate that freestanding SNFs are the principal

alternative to LTCHs, in areas both with and without these facilities. Overall, 24 percent of patients in the top 5 percent probability of using an LTCH use freestanding SNFs; 15 percent of patients with tracheostomies use freestanding SNFs. In both groups, the use of LTCHs is associated with a one-third reduction in the probability of freestanding SNF use. The sharp decrease in probability of use of skilled nursing facilities by long-term care hospital users suggests that SNFs and LTCHs are substitutes.

Our qualitative results on SNFs as an alternative to LTCHs are mixed. During structured interviews, physicians told our contractors that some SNFs are adequately equipped to handle ventilator-dependent patients or others requiring a high level of care, and that these SNFs are the principal alternative to LTCHs. These SNFs offer a level and intensity of care that some respondents thought comparable to that offered in LTCHs. Long-term care hospital clinicians, however, are adamant that treatment provided in SNFs is not as intensive as care provided in LTCHs.

Other settings Beneficiaries in areas without LTCHs are not necessarily excluded from using LTCH services. A few beneficiaries living in areas without LTCHs traveled to an LTCH in 2001. Six percent of patients with tracheostomies who lived in areas without LTCHs used a long-term care hospital (Table 5-2).

Our qualitative and quantitative results are mixed about whether IRFs sometimes substitute for long-term care hospitals. In one market, physicians told our contractors that IRFs actively weaned patients from the ventilator; in another, they said that IRFs only admitted patients who had already been weaned from the ventilator. Quantitative analysis indicates that 7 to 8 percent of patients with the highest probability of using LTCHs (top 5 percent) used IRFs in market areas with and without long-term care hospitals. Among tracheostomy patients who live in areas with LTCHs, 5 percent used IRFs; in areas without LTCHs, 7 percent of patients with tracheostomies used IRFs.

How do Medicare payments and outcomes compare for LTCH patients versus those in other settings?

When LTCH care is not targeted to patients who are most likely to need this level of care, patients who use long-term care hospitals are more costly to Medicare than similar patients using alternative settings. Our multivariate analysis supports this finding. Patients using LTCHs save Medicare money in the acute hospital, principally because of shorter lengths of stay and lower outlier payments; the same patients, however, cost Medicare more money for post-acute care and for the total episode. The cost

TABLE 5-2

Discharge destinations for acute hospital patients, 2001

Type of patient	Long-term care hospital	Freestanding skilled nursing facility	Hospital-based skilled nursing facility	Inpatient rehabilitation facility	Home health care	No post-acute care	Died
Market areas with long-term care hospitals							
All patients	1%	10%	4%	4%	10%	66%	5%
Patients in top 5% probability	4	20	9	8	9	29	20
Patients with tracheostomies	23	11	4	5	4	21	32
Market areas without long-term care hospitals							
All patients	0%	11%	3%	3%	10%	67%	5%
Patients in top 5% probability	0	25	8	7	10	29	20
Patients with tracheostomies	6	17	5	7	6	20	39

Note: Top 5% probability refers to patients in the top 5% probability of using a long-term care hospital. Patients with tracheostomies refers to patients with 96+ hours ventilator support. Percentages may not add to 100 due to rounding.

Source: MedPAC analysis of 2001 claims from CMS.

differences narrow considerably when LTCH care is targeted to patients who are most likely to need this level of care. For example, among patients in the top 5 percent probability of using an LTCH, we find that patients using LTCHs cost Medicare more than patients using alternative settings, but the difference is not statistically significant. For patients with tracheostomies, total episode spending was lower for those who used an LTCH compared with those who did not.

To account for the fact that episodes did not include the cost of readmission to the acute hospital, we compared LTCH users and nonusers without a readmission (about 80 percent of patients) and found similar results. LTCH users cost Medicare more for the total episode compared with patients who used alternative settings. Among patients in the top 5 percent probability of using an LTCH, we found a positive but statistically insignificant difference in total episode spending between LTCH users and nonusers.

Among all patients, LTCHs do not save Medicare money. However, among the most severely ill patients (those with the top 5 percent probability of using an LTCH), Medicare's costs for patients who use LTCHs are comparable to costs for those who use other settings. Among patients with tracheostomies, those who use LTCHs save Medicare money. This finding suggests that LTCH use is best targeted to those patients who need and can benefit from the level of care provided in this setting.

Two caveats apply to our findings on Medicare payments because they are based on actual Medicare spending in 2001. First, acute hospital high-cost outlier payments were unusually high in 2001 (CMS 2003d). As a result, we may be overstating the amount that LTCHs reduced Medicare's spending on outlier payments. Second, 2001 preceded changes in the financial incentives and rates that occurred with the LTCH PPS implementation in 2003. Consequently, Medicare PPS spending for LTCH patients in the top 5 percent and for LTCH patients with tracheostomies may be significantly higher than actual payments in 2001 because of the combination of the PPS rates and improvements in coding. If PPS payments are higher than pre-PPS payments, our findings of savings to Medicare for tracheostomy patients will be overstated. Unfortunately, we cannot be sure how PPS payments compare with pre-PPS payments because coding changes prevent us from being able to model PPS payments accurately. In 2001, LTCHs' payments were unaffected by diagnosis, so coding was incomplete. Now, coding is

likely more complete, but LTCHs may still have difficulty with accurate coding (CMS 2004).

Patients treated in LTCHs tend to have fewer acute hospital readmissions—a measure of outcomes—than patients treated in other settings. Patients using LTCHs were readmitted 26 percent less frequently than similar patients in alternative settings. This finding was not unexpected—LTCHs are acute hospitals and thus can deal with most problems patients might have in-house.

We are unable to reach any conclusions about mortality, another possible outcome measure. In contrast to the results for Medicare payment and readmission, the results for death within 120 days of acute hospital admission conflict, depending on the model used. With ordinary least-squares regression analysis, we find little difference in the death rate for LTCH patients and similar patients treated in alternative settings. With instrumental variable regression analysis, we find that long-term care hospital patients have a higher death rate than patients using alternative settings. Finally, with another method to control for selection bias (the Heckman model), we find that LTCH patients have a lower death rate.

What criteria can we use to better define LTCHs and the patients most appropriate for this type of care?

Our qualitative and quantitative research findings suggest that Medicare should use more precise criteria to ensure that LTCHs treat only appropriate patients. In general, beneficiaries treated in long-term care hospitals cost Medicare more than patients treated in alternative settings; however, if LTCH care is better targeted to those patients who appear to be most suitable for LTCH care, the costs to Medicare are more comparable.

Before proceeding with the discussion of criteria, it is worth reiterating a couple of points. The role of LTCHs is still unclear—especially because some areas of the nation have them and some do not. In the absence of LTCHs, clinically similar patients are principally treated in acute hospitals or in freestanding SNFs that are equipped to handle patients requiring a high level of care.

Criteria that limit the types of patients treated in LTCHs may help avoid some of the problems that may result from current payment incentives, growth of the LTCH industry,

and high payment rates. First, the financial incentives of the acute and long-term care hospital PPSs are likely to encourage facilities to selectively retain and admit certain types of patients to minimize their costs. Acute hospitals have a financial incentive to transfer patients as quickly as possible if they are likely to become high-cost outliers (to avoid losses on these patients). LTCHs have an incentive to admit patients with a given diagnosis who are likely to require the fewest resources. Second, as the number of LTCHs grows, facilities may find it increasingly difficult to find patients who truly require LTCH-level care; this would lead to an increase in lower severity patients being cared for in LTCHs and higher Medicare spending. Finally, LTCH care is costly. The per case base rate is \$37,000 and payments can be as high as \$115,000 per case for the most complex patients.

Therefore, to ensure that patients treated in LTCHs are indeed those for whom this care is the most appropriate and that Medicare is a prudent purchaser, MedPAC supports the adoption of criteria that would delineate the types of patients who are appropriately treated in this setting and more distinctly define these facilities.

LTCH staff adamantly maintain that other post-acute settings cannot substitute for long-term care hospitals and that LTCHs are different in many ways from other settings, especially SNFs. According to their clinicians, long-term care hospitals:

- have sicker patients who are more likely to improve.
- frequently use admission criteria to determine whether patients require an LTCH level of care.
- have active daily physician involvement with patients.
- have licensed nurse staffing of 6 to 10 hours per day per patient (much higher than other post-acute care settings).
- frequently employ specialist registered nurses.
- employ physical, occupational, speech, and respiratory therapists.
- have respiratory therapists available 24 hours per day.
- have multidisciplinary teams that prepare and carry out treatment plans.

The challenge will be to develop criteria that describe the level of care required by LTCH patients so that their needs

are clearly distinguishable from those of less resource-intensive patients who should be treated in other less costly settings. LTCH criteria should focus, to the extent possible, on patients and their care needs, rather than on facility characteristics. The Commission supports the eventual adoption of a common patient assessment tool and classification system across all post-acute settings and the longer term goal of integrating all post-acute payment policies (MedPAC 2001b). However, we recognize that common instruments are not ready to be applied across all settings. Until they are, a combination of facility and patient criteria should be used to distinguish this level of care from other post-acute care settings.

LTCH criteria should meet several goals. The criteria should:

- be feasible to administer and monitor, for both CMS and providers.
- establish clear expectations for providers and hold them accountable for their actions.
- encourage high quality care and require LTCHs to provide information about the quality of care furnished to patients.
- incorporate financial incentives for LTCHs to admit appropriate patients.
- be consistent with payment policies for other providers.

In the next two sections, we present examples of facility- and patient-level criteria that Medicare could use to meet these goals. It is possible that there are additional criteria that might target LTCH care and meet the goals.

Facility criteria

Facility-level criteria should delineate features of the care provided in LTCHs. Some examples include a patient evaluation and review process, a patient assessment tool, and the availability of physicians.

Patient review process These reviews would ensure that all patients treated in LTCHs require this level of care. For example, each LTCH could be required to establish a patient review process that screens patients prior to admission, validates within 48 hours of admission that the cases meet admission criteria, periodically (weekly, for example) evaluates patients throughout their stay, and assesses the available options when patients no longer

meet the continued stay criteria. Documentation of these reviews in the medical records would facilitate monitoring, as would a clear and uniform patient review process.

Standard patient assessment tool This criterion would ensure consistency in the assessment process. For example, LTCHs could use a uniform tool to conduct patient reviews. The patient assessment instrument would need to be a reliable and valid clinical tool appropriate for this level of care. Though most LTCHs already use assessment tools—for example, the Acute Physiology and Chronic Health Evaluation III (Knaus et al. 1991)—all facilities should use the same tool that emphasizes clinical and functional assessments of patients. Such a tool should also facilitate measurement of outcomes by allowing for comparisons of admission and discharge scores.

Level of physician availability Physicians' presence and their active involvement with patients are key aspects of the care that differentiates long-term care hospitals from SNFs. Medicare might distinguish between LTCHs and SNFs by requiring that physicians be involved and available to LTCH patients on a daily basis, but the Secretary would need to determine whether physician availability should be on a 24-hour basis. Consulting physicians, who are frequently part of the treatment team in LTCHs, should be on call and capable of being at the patient's side within a moderate period of time (e.g., an hour).

Average Medicare length of stay greater than 25 days The length of stay criterion, the only criterion currently in place for LTCHs, is intended to ensure that patients require a high level of resources. Without other criteria, however, the length of stay criterion does not prevent SNF-level patients from being treated in LTCHs at much higher costs to Medicare. Over time, as patient criteria clearly delineate the types of patients appropriate for treatment in LTCHs, CMS could reevaluate use of this criterion.

Multidisciplinary team treatment Requiring multidisciplinary teams of professionals, including physicians, to prepare and carry out treatment plans would encourage a team-based focus on patient care. Given the nature of their patient populations and depending on the mix of patients, we would expect LTCHs to have a diverse mix of staff with specific expertise, such as wound care specialists; respiratory therapists capable of rescuing

patients; physical, occupational, and speech therapists; and individuals capable of providing end-of-life counseling. LTCHs could be required to include specific disciplines on staff or create individualized treatment plans for each patient within 24 hours of admission.

Patient criteria

Patient-level criteria would identify specific clinical characteristics and treatments required by patients cared for in LTCHs. All of these criteria would be intended to ensure that the patients admitted to LTCHs require an intensive level of resources and have a good chance of improvement.

National admission and discharge criteria National admission criteria could be required for each of the major categories of patients treated in LTCHs, including respiratory, infectious disease, other medically complex, wound care, rehabilitation, ventilator-weaning, and cardiovascular or peripheral vascular patients. Because these criteria would be specific to each of the most common case types, they would need to be as detailed and clinically relevant as possible. Uniform criteria would ensure consistency in the types of patients being treated at LTCHs. Admission criteria currently exist, such as the InterQual® Long-Term Acute Care Criteria (McKesson Health Solutions 2004). A requirement that patients who do not meet the admission criteria be admitted to a different level of care could reinforce such criteria.

The admission criteria could include the following components:

- The clinical characteristics of the patients, such as specific heart, blood pressure, or respiratory insufficiency rates; open wounds; third degree or necrotic wounds; specific gastrointestinal or hematologic conditions that require frequent blood product replacement; or active infection requiring prolonged treatment. The clinical characteristics would vary by major patient category.
- The need for specific treatments, such as continuous or frequent intravenous fluid or medication administration; telemetry or pulmonary monitoring; pulse oximetry; total parenteral nutrition or enteral feeding; continuous gastrointestinal suction; complex wound care; chest tubes; or ventilator support. The treatments would also vary by major patient category.

Discharge criteria would ensure that patients are medically ready for discharge to less intensive and medically appropriate alternative care settings. For example, separate discharge criteria could be developed for each of the major categories of patients treated in LTCHs and be specific to the discharge destination. In developing these criteria, it would be necessary to ensure that they do not encourage unbundling of care that could be provided in LTCHs and that would create additional costs for Medicare.

Minimum staffing per patient per day A minimum staffing requirement would ensure that LTCHs provide an intensive level of care that is comparable to a step-down unit (from ICU-level care) in a hospital and would reinforce the notion that long-term care hospitals treat medically complex patients who cannot be treated in SNFs. For example, LTCHs could be required to admit only patients who need at least 6.5 hours per day of licensed nurse staffing. Another example might allow substitution of respiratory or physical therapy for licensed nurse hours. Nurse aides' and other unlicensed providers' hours would not be counted toward meeting a staffing requirement.

Patient mix and severity These criteria are directed toward ensuring that LTCHs treat only medically complex cases. For example, one requirement could be that a high share (for example, 85 percent) of a facility's patients must be classified into broad diagnosis categories—such as complex medical, complex respiratory, cardiovascular, ventilator-dependent, or extensive wound care—and that a large share (e.g., 85 percent) of an LTCH's patients demonstrate a high level of severity of illness at admission. When the criteria are first implemented, the shares of patients required to be in the diagnosis categories and required to have a high level of severity of illness might be lower than the proportions eventually envisioned. These lower shares would give LTCHs time to adjust and give CMS time to improve measurement. However, these criteria should become more aggressive over time. The objective is that facilities should be dominated by the treatment of patients appropriate for LTCHs as defined by the criteria. As the required share of severely ill patients increases, it will be necessary to take into consideration coding improvements that LTCHs are likely to make and compensate for them. Otherwise, changes in coding practices might be mistaken for increases in the share of severely ill patients that LTCHs treat.

Facilities that specialize (have a high percentage of patients) in rehabilitation or psychiatric care would not be

long-term care hospitals, but could be converted to rehabilitation or psychiatric facilities and be paid according to their respective PPSs. The Commission believes that a few LTCHs have unique circumstances that have arisen out of historical missions for their communities. These few LTCHs may require special treatment. However, we do not envision special treatment for any long-term care hospital entering the Medicare program.

The Commission's recommendation to better target the patients treated in long-term care hospitals, found below, should not be taken as a blanket endorsement of LTCHs and their role in the post-acute care continuum. The rapid growth in long-term care hospitals, the opportunities for profit, and the fact that patients get care in other settings in markets where LTCHs do not exist all raise concerns for the Commission. The growth and incentives of the LTCHs within hospitals are of particular concern. The Commission considered recommending a moratorium on long-term care hospitals within hospitals, but decided against it at this time. The Commission may reconsider this option in the future depending on continued expansion of this industry, analyses of payments and costs, as well as CMS's administrative actions.

RECOMMENDATION 5A

The Congress and the Secretary should define long-term care hospitals by facility and patient criteria that ensure that patients admitted to these facilities are medically complex and have a good chance of improvement.

- **Facility-level criteria should characterize this level of care by features such as staffing, patient evaluation and review processes, and mix of patients.**
- **Patient-level criteria should identify specific clinical characteristics and treatment modalities.**

RATIONALE 5A

LTCHs are currently defined only by a Medicare average length of stay greater than 25 days. We found that when LTCHs' admissions are not targeted, their patients cost Medicare more than similar patients cared for in alternative settings. The rapid growth in the number of long-term care hospitals, the uneven distribution of LTCHs, and the opportunity for LTCHs to profit from admitting patients with lower severity of illness means that, to be a prudent purchaser, Medicare needs to better define LTCHs and patients appropriate for LTCH care.

IMPLICATIONS 5A

Spending

- The specific spending implications of this recommendation are unknown. CMS will need to develop and implement specific criteria. If the criteria are stringent, Medicare spending for LTCHs will likely decrease.

Beneficiary and provider

- If the criteria are stringent, LTCHs would target their services to more clinically appropriate patients. This may result in some beneficiaries being treated in alternative settings. In areas with high numbers of LTCH beds per beneficiary, some facilities may close. It could also result in LTCHs admitting patients from a larger group of acute hospitals and from a broader geographic area (i.e., expanding their catchment areas).

Compliance issues

The Secretary will need to monitor the compliance of LTCHs with facility- and patient-level criteria. Currently, long-term care hospitals that are out of compliance with the Medicare 25-day average LOS requirement lose their LTCH status and are paid as an acute care hospital. Data submitted to the fiscal intermediaries (cost reports or LOS data supplied by LTCHs that are out of compliance) are used to monitor the LOS requirement. In addition, the Quality Improvement Organizations (QIOs) examine 116 long-term care hospital cases a month to assess medical necessity and to confirm coding.

One option for monitoring compliance with LTCH criteria would be for CMS to require the QIOs to review all LTCH admissions for medical necessity. Another option would be to expand the monthly QIO review to include a statistically representative sample of medical records from each LTCH. Data from such a sample would yield timely information at less cost than a full review. Regardless of the option selected to conduct these reviews, the QIOs will either need additional funds or a change in their scope of work. In addition, CMS will need to develop policies for the treatment of LTCHs out of compliance with the criteria. CMS will need to establish policies about the timing and process by which it will determine that a facility will no longer be paid under the LTCH PPS, as well as the opportunities and processes for appeals.

RECOMMENDATION 5B

The Secretary should require the Quality Improvement Organizations to review long-term care hospital admissions for medical necessity and monitor that these facilities are in compliance with defining criteria.

RATIONALE 5B

LTCHs' compliance with the new criteria will need to be monitored. QIOs are already reviewing LTCH claims for medical necessity and having them monitor compliance would be an appropriate expansion of their role. The QIOs may need either additional funding or a change in their scope of work to appropriately accomplish these tasks.

IMPLICATIONS 5B

Spending

- We expect Medicare spending for QIOs to increase unless there is a change in their scope of work.

Related policy considerations

Refinements to the LTCH payment policies should be consistent with Medicare's longer-term goals for payment policy. These goals include improving quality and promoting patient care in the most appropriate and cost-effective setting.

Quality

In the future, consistent with Medicare's goals for all settings, payments should be tied to improvements in quality of care and maintenance of high quality of care (MedPAC 2004). For example, the Secretary could develop quality indicators for LTCHs, including those that measure improvement in health status from admission to discharge, and require facilities to report their performance on these indicators to CMS. Measures might include rates of ventilator weaning, wound healing, endocarditis cures, emergency department use, avoidable readmissions to short-term acute care hospitals, and mortality, as well as patient safety indicators.

For example, ventilator weaning success rates could serve as a quality indicator. Weaning success rates would reinforce the idea that LTCHs should work aggressively with patients to wean them off ventilator support. A study would be needed to determine how such an outcome should be measured, reported by facilities, and tracked by QIOs. Weaning success rates might be appropriate for tying payments for long-term care hospitals to quality incentives.

Payments for SNFs and acute hospitals

Long-term care hospital payment policies cannot be considered in isolation. Although criteria may ensure that LTCHs treat patients requiring a higher level of care, they would not address shortcomings in other payment systems that likely have encouraged the growth in the number of LTCHs. The classification systems currently used in the SNF and acute hospital PPSs may result in LTCHs treating patients who could be more appropriately treated in these other, less expensive settings. Refinements to the payment policies for SNFs and acute hospitals could ensure that payments more accurately reflect patients' resource needs, thereby encouraging providers to make placement decisions based on the clinical characteristics of the patient, rather than financial considerations.

MedPAC has already recommended that CMS develop a new classification system for SNFs (MedPAC 2004). A new SNF PPS classification system could better target payments to medically complex patients in SNFs and away from the provision of therapy services. Such refinements could make SNFs financially neutral to treating medically complex patients who could be appropriately treated in this lower-cost setting (e.g., wound care, AIDS, ventilator-dependent patients.)

Further study will be needed to determine how the acute hospital PPS contributes to the growth of LTCHs and what changes could be made to better align the incentives. For example, a classification system for acute hospitals that reflects the severity of patients within DRGs might improve the accuracy of payments and make these hospitals more financially neutral to keeping patients longer in this setting. Not only could a more accurate classification system increase payments for the most severely ill patients and decrease the likelihood of care being unbundled to LTCHs, it might lower the number of outliers. Furthermore, acute hospitals that receive increased payments for the sickest patients might establish ICU step-down units that could effectively treat these cases. One result could be slower growth of LTCHs.

Other characteristics of the acute hospital PPS may also have encouraged the development of LTCHs. The current outlier policy—both the fixed losses (\$30,150 beginning April 2004) imposed on every outlier case and the share above the fixed-loss threshold Medicare pays—may encourage those hospitals with an LTCH nearby to transfer cases that are likely to become outliers.

Conversely, the policy may disadvantage hospitals that do not have an LTCH nearby. Adjusting the outlier threshold or the share above the threshold that Medicare pays might make hospitals less inclined to transfer cases they could appropriately treat themselves.

The transfer policy may also need refinement to more accurately reflect the types of patients most frequently transferred to LTCHs. Our analysis indicates that, of the 11 DRGs most frequently transferred to LTCHs, 5 are not included in the current transfer policy.

LTCHs within hospitals

The interrelated nature of the payment policies for acute and long-term care hospitals is most evident in the increasing number of LTCHs within hospitals (see text box). Since implementation of the PPS, the number of LTCHs has increased by almost 50 percent (CMS 2004). Virtually all of these new facilities are LTCHs within hospitals. CMS maintains that these LTCHs may increase their host hospitals' ability to profit from the acute hospital PPS. The acute hospital can simply shorten the stays of certain patients (who could have remained in the acute hospital under the original DRG payment) and transfer them to its in-house LTCH, thus generating two discharges and increasing Medicare's costs (CMS 2003e). CMS plans to issue new regulations to prohibit such practices. We agree with the concerns expressed by CMS and look forward to publication of the new regulations, which we will review.

Technical methodology section

In this section we present more information about our methods. In creating the data set, we constructed 5.5 million episodes—100 percent of the episodes for beneficiaries admitted to acute hospitals in the first six months of 2001. After exclusions, we had a data set of 4.3 million episodes. We excluded 1.2 million patients who were unlikely to be transferred to an LTCH because they had a very short LOS, defined as less than or equal to the 10th percentile of the LOS for their all patient refined DRG (APR-DRG). About 100,000 additional episodes were excluded because of missing data.

We defined two subpopulations and performed separate analyses on them. The first subpopulation consists of individuals in the top 5 percent probability of using an

More on long-term care hospitals within hospitals

The number of long-term care hospitals (LTCHs) located within acute hospitals has grown at almost three times the rate of long-term care hospitals in general—35 percent per year between 1993 and 2003 compared with 12 percent. By 2004, LTCHs within hospitals made up one-half of all long-term care hospitals. The growth of these long-term care hospitals is important for several reasons. First, our analyses suggest that admission to an acute hospital that hosts an LTCH within it is a very strong predictor of long-term care hospital use. Second, CMS maintains that LTCHs within hospitals may increase the host hospitals' ability to profit from the acute hospital prospective payment system by shortening the length of stay (LOS) and profiting from a per case payment based on a longer LOS. Host hospitals may more quickly transfer patients to LTCHs within hospitals and increase Medicare's costs by generating two discharges. In the absence of LTCHs within hospitals, these patients might have remained in the acute hospital under the original diagnosis related group payments.

On average, LTCHs within hospitals are smaller than freestanding long-term care hospitals—36 beds compared with 111 beds. They also have stronger relationships with one acute hospital—LTCHs within hospitals received 61 percent of cases from their most frequent referrer compared with freestanding LTCHs' 42 percent of cases received from one acute hospital.

LTCHs within hospitals are subject to few restrictions. They are required to have a separate governing body, chief financial officer, chief medical officer, and medical staff. In addition, they currently must meet one of the following three criteria:

- perform basic functions independently from the host hospital,
- incur no more than 15 percent of total inpatient operating costs for items and services supplied by the host hospital, or
- have an inpatient load of which at least 75 percent of patients are admitted from sources other than the host hospital.

CMS requires that LTCHs within hospitals report to their fiscal intermediaries that they are co-located with acute hospitals. However, these long-term care hospitals currently are not required to report the provider number, name, or address of the co-located acute hospital. Such a reporting requirement would help CMS and researchers monitor these facilities to understand referral patterns and patient mix, especially if the reporting were recorded in the Provider of Services file. ■

LTCH (between 3.4 and 33 percent). The cutoff value (3.4 percent) represents the 95th percentile of predicted probabilities (most observations have predicted probabilities below 1 percent). The second subpopulation consists of individuals assigned to the tracheostomy APR-DRG (004, defined as tracheostomy with ventilator for 96 or more hours or primary diagnosis except for face, mouth, or neck diagnoses).

Post-acute spending includes payments for all care in SNFs, IRFs, LTCHs, and for home health services during the episode. Total spending includes payments to acute hospitals in addition to post-acute spending. Spending for

readmissions to the acute hospital are not included in the total episode spending, nor is any spending for physician or outpatient services. All spending is standardized for the effects of the wage indexes.

To control for clinical characteristics, we assigned patients to APR-DRGs using acute hospital diagnoses and derived severity of illness and risk of mortality scores (3M 1998). We combined these with other clinical variables—age, prior hospitalization, critical care unit (CCU) days, and ICU days—to determine the probability of LTCH use. Patients in the top 5 percent are much more likely than the general population to have high severity levels (3 or 4),

high mortality risk scores (3 or 4), ICU use, prior hospitalizations, and the following diagnoses: tracheostomy, amputation, endocarditis, skin graft, skin ulcers, or osteomyelitis.

We defined patients' proximity to an LTCH according to the Dartmouth Atlas (Wennberg et al. 1999).

Beneficiaries' zip codes link patients to hospital service areas (HSAs) and hospital referral regions (HRRs) (Center for the Evaluative Clinical Sciences 2003). There are 3,253 HSAs without LTCHs and 183 with LTCHs. To control for supply of post-acute care services, we also calculated SNF and IRF beds per acute hospital discharge by HSA.

To control for patients' socioeconomic status, we used the following variables by patients' county of residence from the 2001 Area Resource File (HRSA 2001): five-year infant mortality rate, percentage of persons with four years of college, percentage of persons with income below federal poverty level, and per capita income. To control for different rates of Medicare service use, we calculated a ratio of per capita total service use by county (MedPAC 2001a). This index includes all types of Medicare spending and is a measure of general practice patterns. Characteristics of acute hospitals include ownership, ratio of interns and residents to beds, and presence of an SNF, IRF, or LTCH within the hospital.

We used an instrumental variable approach to control for unmeasured severity of illness (selection bias) (McClellan et al. 1994). This approach consists of constructing a proxy for LTCH use that represents the odds of using an LTCH. We modeled these odds as a function of patient characteristics and instruments that are thought to be correlated with using an LTCH but not correlated with the severity of illness variables. The instruments include whether:

- an LTCH operates in the beneficiary's HSA,
- an LTCH operates in the beneficiary's HRR, and
- the patient is discharged from an acute hospital that has an LTCH within the hospital.

The intuitive idea of these instrumental variables is that patients in close proximity to a long-term care hospital will have a higher probability of using an LTCH. We then test whether patients with a high probability of using LTCH services because an LTCH is nearby have different outcomes than those who have a very low probability of using LTCHs because they are farther away.

We used two-stage least squares to estimate the instrumental variable model. Most episodes had predicted probabilities below 1 percent. The predicted probability of LTCH use was calculated for all observations using a logit model that includes clinical factors (i.e., APR-DRGs, APR-DRG severity level code, APR-DRG mortality risk code, prior hospitalization, ICU use, and CCU use) and demographic factors (age group and sex). The coefficients were calculated among individuals living in hospital service areas with LTCHs.

We used a second method for controlling for selection bias (unmeasured severity) (Heckman 1979). Rather than avoid the sample selection problem by using a proxy for LTCH use, this method creates a new variable that is used to adjust for unmeasured severity. The model has strong untestable assumptions regarding the distribution of the error terms and should be used with great caution (Duan et al. 1983). We use the Heckman model as a second check on our instrumental variable approach. We also conduct ordinary least-squares regressions. ■

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CHAPTER

6

**Hospice care in Medicare:
Recent trends and
a review of the issues**

Hospice care in Medicare: Recent trends and a review of the issues

In this chapter

- What is the Medicare hospice benefit and how has its use changed over time?
- Hospice payment policy and issues

The Medicare hospice benefit is designed to provide palliative care to beneficiaries with terminal illnesses who are approaching the end stages of their lives. Its use has grown considerably in the last several years with matched increases in Medicare spending. The hospice payment system—based on fixed daily rates—has not changed since the benefit was established in 1983. As MedPAC has recommended previously, an examination of the services hospices currently provide is needed to assure that payments accurately account for efficient provider costs. With improved data on the services hospices provide, this evaluation could examine payment refinements related to case mix, length of hospice enrollment, care settings, geographic variation, as well as hospice eligibility. Also, to encourage hospice quality improvement, Medicare needs to establish and collect quality measures for public reporting. Finally, a restructuring of Medicare’s payment arrangement to Medicare Advantage plans could encourage plans to continue their care coordination activities after patients elect hospice care.

End-of-life care is an important issue for the Medicare program because most Americans are Medicare beneficiaries when they die. Many clinicians, policymakers, and consumers have called for greater focus on the quality of care delivered to dying patients and their families (IOM 1997).

Medicare offers a benefit—the hospice benefit—that is specifically targeted to Medicare beneficiaries with a terminal illness. Medicare’s hospice benefit covers a broad set of palliative services for beneficiaries whose physicians have determined that, if their illness runs a normal course, they are expected to die within six months. To elect the hospice benefit, beneficiaries must forgo curative treatment for their terminal condition.

Although in earlier years, observers were concerned about low use of this benefit, in the last five years, use of Medicare’s hospice benefit has increased rapidly, signaling the improved awareness and appreciation of the benefit by physicians, hospitals, patients, and their families. In the last couple of years, CMS has also promoted the availability of the benefit to providers and beneficiaries. Medicare spending on hospice has grown from \$1.9 billion in 1995 to an estimated \$5.9 billion in 2003.

The Commission has recommended that the Secretary of the Department of Health and Human Services (HHS) collect and disseminate information on the quality of hospice care and refine the payment system to ensure that payments reflect the costs of efficient providers while ensuring quality of care (MedPAC 2002, 1999). This chapter reviews these recommendations, examines ways to refine payments, and considers ways for hospices to account for the services and the quality of care they provide to this vulnerable population.

What is the Medicare hospice benefit and how has its use changed over time?

Medicare’s hospice benefit offers a broad array of palliative care services, including counseling and other psychological services, to beneficiaries with a terminal illness. Started in 1983, use of the hospice benefit has grown rapidly over the last several years with an expansion in the types of patients enrolling in hospice care. The supply of hospice provider organizations has also increased. Medicare spending on the hospice benefit has more than doubled since 2000.

Hospice services and providers

The Medicare hospice benefit covers the following services for palliative care:

- skilled nursing care
- medical social services
- physician services
- patient counseling (dietary, spiritual, and other)
- short-term inpatient care
- medical appliances and supplies
- drugs and biologicals for pain control and symptom management
- home health aide services
- homemaker services
- therapy (physical, occupational, and speech)
- inpatient respite care (providing a limited period of relief for informal caregivers by placing the patient in an inpatient setting like a nursing home)
- family bereavement counseling
- any other item or service listed in a patient’s care plan as necessary for the palliation and management of the terminal illness

The Medicare hospice benefit has always covered prescription drugs for palliative purposes. Even though recent legislation added coverage for prescription drugs to Medicare (starting in 2006), hospices will still be required to cover drugs for palliative care. Thus, beneficiaries in hospice care will continue to be covered for symptom management of their terminal illness through the hospice benefit. Drugs for conditions unrelated to their terminal illness could be covered through the optional Medicare drug benefit.

Hospice services are furnished most often in the patient’s home—the place where most beneficiaries report that they would prefer to die (Ratner et al. 2001). Hospice services may also be provided in nursing facilities and other inpatient settings. Providers deliver hospice care based on the patient’s care plan. Hospices may decide not to admit patients if they believe they do not have the resources to care for them.¹

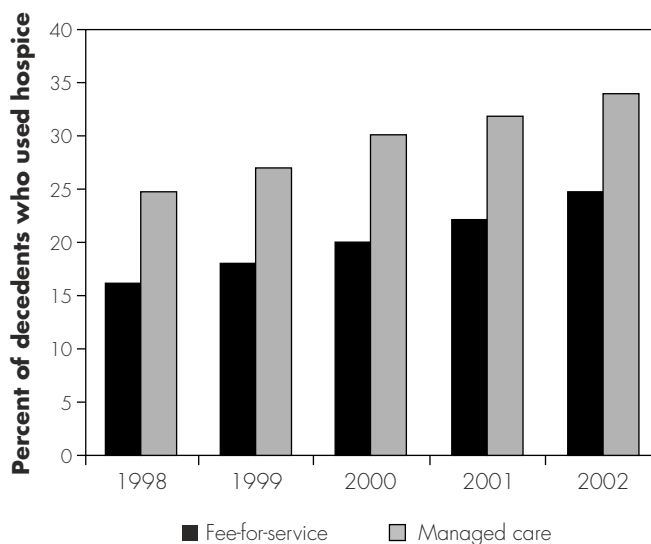
Beneficiary liability for hospice services is minimal. Hospices may charge a 5 percent coinsurance for each drug furnished outside of the inpatient setting, but the coinsurance may not exceed \$5 per drug. For inpatient respite care, beneficiaries are liable for 5 percent of Medicare's respite care payment per day.²

Hospice services can continue as long as patients are certified as eligible. Both the hospice medical director and the patient's attending physician (if he or she has one) must complete the initial certification of terminal illness. The initial benefit period is 90 days, which may be followed by another 90-day benefit period. Subsequently, a beneficiary may qualify for an unlimited number of 60-day benefit periods. The medical director of the hospice must recertify that the patient is terminally ill at the beginning of each benefit period. Beneficiaries may change their hospice provider once in each benefit period. At any time, beneficiaries may discontinue their hospice care, in which case they revert back to their full Medicare coverage.

For hospice coverage, beneficiaries have the choice of any certified hospice provider that agrees to admit them. Several types of agencies provide hospice care to Medicare beneficiaries (Table 6-1). Half of all hospice agencies are freestanding. The remaining half are owned

FIGURE 6-1

Hospice use has grown and remains higher for decedents in managed care



Source: MedPAC analysis of 5 percent enrollee database from CMS, 2003.

by other types of providers, namely, home health agencies, hospitals, and skilled nursing facilities.³ Most hospice agencies are not-for-profit organizations, but for-profits have grown to over a third of the industry.

TABLE 6-1

Trends in the mix of hospice type and ownership have continued

	2001	2002	2003
Hospice type			
Freestanding	42%	46%	50%
Home health agency based	33	29	27
Hospital based	24	24	23
SNF based	1	1	1
Ownership			
Not for profit	59	58	56
For profit	31	33	36
Government	8	8	8
Other	2	1	1

Note: SNF (skilled nursing facility). Some columns do not total 100 percent due to rounding.

Source: MedPAC analysis of unpublished data from CMS.

Hospice use trends

CMS data show continued acceleration in use of the hospice benefit and associated spending increases. From 1998 to 2002, the percentage of beneficiaries using hospice before they died grew from 16 percent to 25 percent in fee-for-service and from 25 percent to 34 percent in managed care (Figure 6-1). While 60 percent of beneficiaries who died of cancer used hospice, growth has been substantial among patients with noncancer diagnoses and among patients in nursing homes (MedPAC 2002).

In addition to these growth trends, a provision in the recently passed Medicare Prescription Drug, Improvement, and Modernization Act of 2003 is likely to increase hospice use even further. This provision allows hospice physicians to bill Medicare for hospice consultation sessions, which may be used to evaluate a beneficiary's eligibility and need for hospice services. This session may also be used to discuss hospice care options and referrals.

Length of enrollment

In most cases, a beneficiary's length of enrollment is determined by the number of days a beneficiary lives after electing the hospice benefit. Between 2001 and 2002 the average length of enrollment for a beneficiary in hospice care increased from 50 days to 55 days (Table 6-2) but the median remained 16 days. This suggests that a consistent subset of the hospice population has short lengths of stay, while longer lengths of stay for the remaining beneficiaries drove up the average. In fact, from 1998 to 2002, more than 25 percent of beneficiaries dying in hospice stayed less than a week. The number of days at the 90th percentile, however, has grown. Thus, long stays are getting longer. The increased prevalence of nursing home residents in hospice care may be a factor in this long-stay trend.

Demographic differences

Growth in the use of hospice has occurred among beneficiaries in each age, race, and sex group. Examining hospice use among age groups, we see that growth among the oldest decedents has been fastest (Figure 6-2).

Between 1998 and 2002, the share of beneficiaries age 95 or older who died while in hospice care rose from 12 percent to 23 percent.

This trend is consistent with findings that hospice use has increased considerably among beneficiaries in nursing facilities and beneficiaries with noncancer diagnoses. From 1992 to 2000, use of hospice by beneficiaries in nursing facilities grew from 11 percent to 36 percent (Hogan 2002). Over this same period, the percentage of new hospice patients with noncancer diagnoses rose from 24 percent to 49 percent (MedPAC 2002).

TABLE 6-2

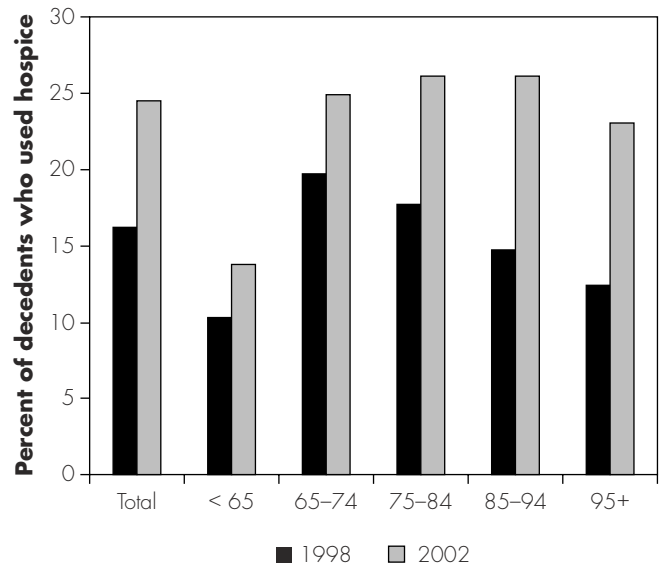
Long stays in hospice are getting longer but short stays persist

	Length of stay (in days)			
	Mean	25 th Percentile	Median	90 th Percentile
1998	52	6	18	123
1999	51	6	17	129
2000	51	6	16	130
2001	50	6	16	133
2002	55	5	16	147

Source: MedPAC analysis of 5 percent enrollee database from CMS, 2003.

FIGURE 6-2

Growth in hospice use is greatest among older decedents



Note: Excludes beneficiaries in managed care.

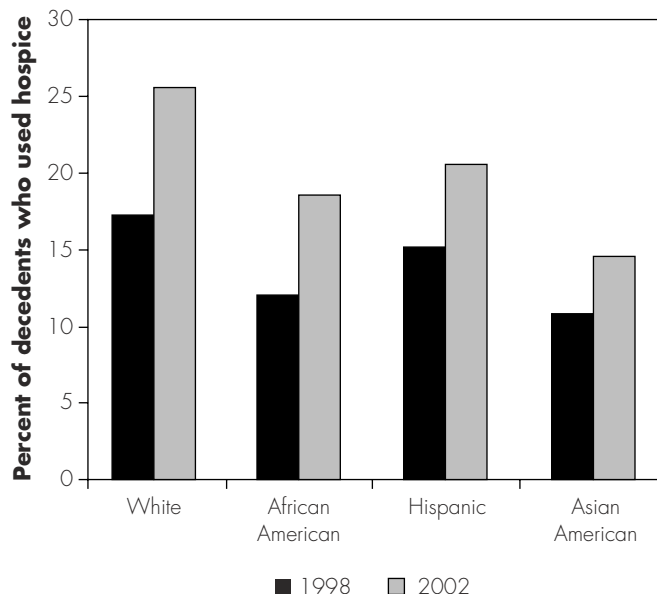
Source: MedPAC analysis of 5 percent enrollee database from CMS, 2003.

Hospice use also has increased for beneficiaries of each race, but white beneficiaries tend to use the hospice benefit more than beneficiaries of other races (Figure 6-3). This finding is consistent with earlier research. Some have attributed lower use of hospice among minorities to factors such as differences in culture and heritage affecting views of death, differences in religion, socialization, and education, as well as disparities in access to care for health services in general (Crawley et al. 2000, Mahoney 2000).

Beneficiaries with end-stage renal disease (ESRD) also have low enrollment in the hospice benefit, despite their high mortality rates (Hogan 2002). For hospice patients with ESRD, ESRD may or may not be their terminal diagnosis. If ESRD is their terminal diagnosis, then dialysis needed on a palliative basis is considered a covered hospice service and would be paid for through the per diem hospice rate. If, however, ESRD is not their terminal diagnosis, then Medicare would continue to cover their dialysis outside the hospice benefit, and their hospices would not be liable. The high cost of ESRD care (with and without dialysis) and confusion among agencies

FIGURE 6-3

Hospice use has increased among all races



Note: Excludes beneficiaries in managed care. Figure does not show "other" or unidentified race.

Source: MedPAC analysis of 5 percent enrollee database from CMS, 2003.

regarding its coverage in and out of the hospice benefit likely contribute to low enrollment of this population in hospice care.

Use of hospice by managed care enrollees

Consistently, beneficiaries in managed care plans use hospice more often than those in the fee-for-service program during their last year of life (Figure 6-1, p. 141). Previous research has also found greater use of hospice among Medicare decedents in managed care, even after controlling for age, sex, race, Medicaid status, and ESRD status (Riley and Herboldsheimer 2001). Higher use of the hospice benefit by managed care enrollees may reflect a variety of factors, including patient preference for care and financial incentives for managed care plans to refer patients to hospice (see discussion later in this chapter).

One might expect that the higher use of hospice by beneficiaries in managed care plans reflects earlier referrals to hospice, but beneficiaries in managed care plans have, on average, shorter lengths of enrollment. In 2002, the mean length of enrollment for managed care

enrollees in hospice was 50 days compared with 55 for fee-for-service hospice users. Both populations had similar median lengths of stay.

Hospice agency trends

The number of Medicare-certified hospice agencies increased by 8 percent between 2001 and 2003. Not-for-profit programs remain the largest share of the industry (56 percent), but for-profit facilities have seen the most rapid growth, shown in Tables 6-1 (p. 141) and 6-3. In particular, for-profit hospices grew in number by 25 percent, significantly more than facilities with other types of ownership. The number of freestanding agencies grew 29 percent—considerably more than their provider-based counterparts, which all experienced single-digit change between 2001 and 2003. According to CMS, similar trends have emerged in the first several months of 2004. The strong growth in the number of for-profit hospices may suggest that the financial environment for providing hospice care may be attractive for some providers.

Hospice volume within agencies has grown as well. Hospice volume is measured roughly by the total number of days an agency's patients were enrolled in the hospice

TABLE 6-3

The number of freestanding and for-profit facilities has increased the most

	Number of hospice facilities			Percent change 2001-2003
	2001	2002	2003	
All hospices	2,266	2,323	2,454	8%
Hospice type				
Freestanding	949	1,067	1,222	29
Home health agency based	744	677	653	-12
Hospital based	553	560	562	2
SNF based	20	19	16	-20
Ownership				
Not for profit	1,340	1,339	1,384	3
For profit	706	762	883	25
Government	187	188	189	1
Other	35	34	34	-3

Note: SNF (skilled nursing facility).

Source: MedPAC analysis of unpublished data from CMS.

benefit. Thus, hospice volume may grow in size through increases in patient census as well as increases in patients' lengths of stay. Between 2001 and 2003, the number of high-volume hospice agencies increased, while the number of low-volume hospice agencies declined.⁴ Analysis from cost reports reveals that most high-volume agencies are freestanding, while most low-volume agencies are hospital based.

Medicare spending trends on hospice and end-of-life care

Consistent with increases in the number of users and the average length of hospice enrollment, Medicare spending for hospice care has increased. CMS's Office of the Actuary projected spending to grow from \$3.5 billion in 2001 to \$5.9 billion in 2003, a 30 percent annual increase (Figure 6-4). In relative terms, total Medicare spending for hospice services is now close to that for dialysis services (including drugs) for beneficiaries with ESRD.

It is well known that spending is disproportionately high at the end of life—when people are often the sickest. Medicare spending in the last year of a beneficiary's life is about six times higher, on average, than annual spending for beneficiaries who do not die—a ratio that has been consistent over the last two decades (Hogan 2002). Chapter 2 also examines this distinction with regard to

disease management analyses, finding that Medicare spending for beneficiaries is usually higher in the last year of life.

Soon after the hospice benefit began in 1983, results from the National Hospice Study suggested that hospice would save money for the Medicare program (Mor and Kidder 1985). Indeed, the structure of the hospice benefit—restrictive eligibility, waiver of curative care, and caps—was originally intended to reassure policymakers that it would not add substantially to Medicare's cost (Moon and Boccuti 2002).

Recent analysis finds that in the last year of life, beneficiaries who had hospice care incurred Medicare spending that was 4 percent higher, on average, than beneficiaries who did not elect hospice care, but this comparison varied by diagnosis (Campbell et al. 2004). Other recent work reports similar findings (Moon and Boccuti 2002, Hogan 2002), but the Campbell study further addresses selection differences (including the propensity to use hospice) and matches decedents who used hospice to those who did not. Among decedents with cancer, the study finds that Medicare spends 10 percent less on those who elect hospice care in the last year of life compared to those who do not. Among those with all other diagnoses, hospice use correlates with higher Medicare spending, particularly for those with dementia. Although a number of differences characterize the typical patterns of service use for cancer and noncancer decedents, the key distinction is that hospice decedents without cancer tend to use more intense hospital inpatient services before they enter hospice, and have more expensive hospice stays.

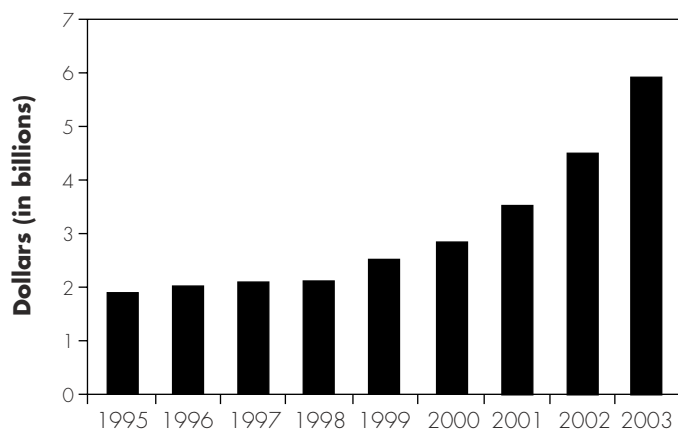
These findings do not call into question the important value of the benefit to Medicare beneficiaries, but they may disappoint those who hope that hospice saves Medicare money, on average. The rise in hospice use suggests a growing demand for the benefit, which underscores the need for Medicare to ensure that hospice payments reflect the efficient provision of quality patient care for all types of patients.

Hospice payment policy and issues

The method Medicare uses to pay hospices is fairly basic and has not been altered since the benefit began in 1983. Hospices can provide many different services within a patient's care plan, but we have limited data on what

FIGURE 6-4

Recently, Medicare spending for hospice services has increased sharply



Source: CMS Office of the Actuary.

services are actually provided, what level of services different patients need, and how the different settings of care may affect providers' costs.

This section reviews improvements that researchers and the Commission have previously recommended regarding payment and data needs for hospice services, and discusses the continued special treatment of hospice within the Medicare Advantage program. This section also reviews the most recent evidence on Medicare program expenditures associated with hospice use, suggesting that hospice use is associated with savings for some types of patients but increases in the aggregate (Campbell et al. 2004).

How does Medicare pay for hospice care?

Medicare makes daily (per diem) payments to hospice agencies for each day a beneficiary is enrolled in the hospice benefit. The payment structure is based on four levels of care, with the vast majority of care provided in just one category—routine home care. The daily payments are constant, regardless of patient case mix or the services provided. For enrolled beneficiaries, hospice agencies may receive daily routine home care payments even for days when no services are provided.

Hospice payments were calculated based on information from a Medicare demonstration project completed in the early 1980s. Although payments have been updated annually based on the hospital market basket index, the set of services included in the payment has not been examined or recalibrated to reflect possible changes in patterns of hospice care and associated costs.

Hospice payment categories

The four hospice payment levels, listed below, vary according to expected input cost differences:

- **Routine home care.** Patients receive hospice services at home or in a nursing facility but do not receive continuous care, as defined below. This category accounts for 95 percent of patient days in hospice care (NHPCO 2004). Medicare's national daily payment for this level of care is \$118 in fiscal year 2004.
- **Continuous home care.** Patients receive continuous nursing care at home, and sometimes receive home health aide or homemaker services. Continuous home care is paid on an hourly basis. It is furnished only

during periods of crisis and only as required to allow patients to stay home. Continuous home care accounts for 1 percent of patient days in hospice care (NHPCO 2004). Medicare's national daily payment for 24 hours of care at this level is \$689 in fiscal year 2004.

- **General inpatient care.** Patients receive care in an inpatient facility—a hospital, skilled nursing facility, or unit in a hospice facility that meets many standards of an inpatient facility—to control pain or manage acute symptoms that cannot be managed in another setting. General inpatient care accounts for 4 percent of patient days in hospice care (NHPCO 2004). Medicare's national daily payment for this level of care is \$525 in fiscal year 2004. From this amount, the hospice is responsible for paying the inpatient facility.
- **Inpatient respite care.** Patients receive short-term care at a facility (including any of the inpatient settings for general inpatient care listed above) to relieve family caregivers who need a short period of relief. Payment is limited to no more than five consecutive days per benefit period, but there is no lifetime limit on availability of respite care. Inpatient respite care accounts for less than 1 percent of patient days in hospice care (NHPCO 2004). Medicare's national daily payment for this level of care is \$122 in fiscal year 2004. From this amount, the hospice is responsible for paying the facility.

When a Medicare beneficiary elects hospice, and is certified as eligible, the hospice provider can begin to bill Medicare for services. Medicare pays for only one type of service per day; if the patient is not receiving continuous home care, general inpatient care, or inpatient respite care, the hospice provider bills for routine home care for each day of the hospice election.

Hospice caps

Hospice has two fixed annual caps. One cap is an absolute dollar amount; the other limits the number of days of inpatient care. The caps are not applied on a patient-by-patient basis; rather, the caps are based on agency-level aggregate averages. The caps are calculated from November 1 through October 31 of a given year, rather than on the traditional October to September fiscal year. The two caps are described in more detail below:

- An agency's total Medicare payments may not exceed an annual cap, which is calculated based on the total number of beneficiaries served in the year. For the

2003 cap year, the quotient of total payments over total number of beneficiaries cannot exceed \$18,661.

- An agency's inpatient care days (either general or respite and regardless of setting) may not exceed 20 percent of its total patient care days in the cap year.

Although most agencies do not reach the caps, those that average long lengths of stay are more likely to exceed the total payment cap than are agencies that average shorter lengths of stay. A review of industry investor reports indicates that some agencies do, indeed, reach the total payment cap due to long average lengths of stay, and thus have billed Medicare for more than \$18,661 per enrolled beneficiary, on average, in the 2003 cap year. The total payment cap is not adjusted for geographic differences in wage levels, although the hospice payment rates are. Thus, a hospice in a high-wage area, theoretically, could reach the cap more quickly than one in a lower-wage area.

Update mechanism

Hospice payments and the cap amount are updated every year in two ways: Per diem payments are increased each year based on the hospital market basket index, and the hospice caps are increased by the medical expenditure category of the consumer price index for all urban consumers. In some previous years, Medicare statutes have called for updates to the per diem payments of less than the full market basket increase. But since 2003, automatic updates have been the full market basket increase.

Payment policy issues for hospice care

The hospice payment system generates little information on the services delivered and the types of patients who receive services. In its May 2002 report to the Congress, MedPAC called for the Secretary of HHS to evaluate hospice payments to ensure that they are consistent with the costs of providing appropriate care (MedPAC 2002). The Commission also recommended that the Secretary research differences in the care and resource needs of hospice patients and determine whether a case-mix adjusted payment system for hospice care is feasible, including studying ways to establish a high-cost outlier policy. Other researchers have recommended some additional modifications to hospice payment policy.

Possible changes to hospice payment policy cited by MedPAC and others (Huskamp et al. 2001, Lynn and Adamson 2003, Virnig et al. 2004) include adjustments for:

- patient case mix
- outliers
- length of hospice enrollment
- setting (home or nursing home)
- geographic area (urban or rural)
- eligibility requirements
- quality of care

Case-mix and outlier adjustments

Adopting case-mix adjustments could help Medicare pay more accurately for hospice services. Although hospice providers report their costs in cost reports and submit claims, these data are not enough to calculate patient-level case-mix adjustments or to identify outliers. Additional data are needed. To develop the case-mix adjustment system for home health agencies, for example, CMS had contractors conduct a detailed analysis of home health claims, visits, cost reports, and data from the Outcome and Assessment Information Set (OASIS), which provides functional status measures. For hospice, case-mix adjustment could be based on a similar instrument or, more crudely, on diagnosis.

Data on hospice costs could also be used to determine the need for outlier payments. If there is a need to compensate hospices for extraordinary covered expenses, then cost analyses, which account for case mix, could help establish the parameters for outlier payments.

Hospices report that their costs for drugs are rising (as is the case for other providers that purchase drugs), but little is known about the types, mix, intensity, or acquisition costs for drugs hospice patients use. Some hospices may be using formularies to help manage their drug costs, but no data are available to understand how these work.

Recent research found that some hospices deny admission to patients with high expected service costs (Lorenz et al. 2004). Specifically, 63 out of 100 California hospices surveyed said that they denied admission to individuals for one or more reasons. These reasons included that the patient lacked a caregiver at home, or was receiving total parenteral nutrition, tube feedings, radiotherapy, chemotherapy, or transfusions. Representatives of

hospices corroborated these findings with MedPAC staff, stating that agencies that do not feel they have enough resources to care for costly patients can, and sometimes do, deny their enrollment. Case-mix adjustments are designed to help correct this problem by directing higher or lower payments to agencies based on expected patient care costs. Without case-mix adjustment, the financial incentives of a fixed daily payment system encourage providers to admit the patients with the lowest daily costs.

Length of hospice enrollment adjustments

The number of days a patient receives hospice care is an important issue. The longer the hospice enrollment, the greater the opportunity for dying beneficiaries to receive a comprehensive program of palliative care, including multiple counseling visits. As noted earlier, at least 25 percent of hospice beneficiaries are in hospice for less than a week (Table 6-2 on p. 142). Long hospice stays generally incur lower average daily costs for the agency than short hospice stays, because the first and last days usually require more intensive services. In a previous report, MedPAC noted that if costs for short hospice stays are considerably higher than Medicare's payments, then higher per diem payments for the first and last days of a short hospice stay might be needed (MedPAC 2002).

A preliminary review of 2002 cost report data shows that patients at for-profit agencies have longer lengths of stay, on average. Hospice enrollment periods for patients receiving care from for-profit hospices averaged 73 days—over 50 percent higher than those in not-for-profit facilities (48 days).

Representatives of the hospice industry and investor reports state that cancer patients often have shorter lengths of stay in hospices than those with other terminal diagnoses, such as chronic heart failure and chronic obstructive pulmonary disease. If noncancer patients average longer lengths of stay, then Medicare makes a higher number of per diem hospice payments for them than for cancer patients, on average. Because noncancer patients are the fastest growing population of hospice patients, the financial impact of this distinction is becoming more significant (MedPAC 2002).

With some adjustments, the per diem payment system is better suited for hospice care than a per case payment system; per diem payments do not penalize agencies when patients remain in hospices for more than the average

number of days, as would per case payments. However, the variance in average daily costs by length of stay may not be reflected in the current per diem payments.

Payment adjustments by patient residence

Patient costs may differ depending on whether patients reside at home or in a nursing home, or in an urban or rural area. When a hospice beneficiary eligible for Medicaid lives in a nursing home, Medicaid pays the hospice at least 95 percent of the Medicaid nursing home rate in the state. The hospice, in turn, contracts with the nursing home and pays for the patients' room, board, and other nursing home services unrelated to the patients' terminal condition. Drugs for palliative treatment of the terminal condition are covered under the hospice benefit, but other drugs unrelated to the terminal condition may be covered by the Medicaid payment.

Costs for providing hospice care in nursing facilities may be lower than in patients' homes. Investor reports note that hospice workers providing services in a nursing home are able to visit multiple patients at the nursing home, thereby reducing time and transportation costs. Studies conducted by the Department of Health and Human Services' Office of Inspector General (OIG) highlighted a number of issues regarding Medicare beneficiaries receiving hospice benefits while residing in nursing homes (OIG 1997). The OIG found that these Medicare beneficiaries received hospice-specific services less often than those outside nursing homes, and that the covered services for general nursing home care and hospice care may overlap. To address these issues, the OIG recommended that the Secretary of HHS seek legislation to modify Medicaid or Medicare payments for hospice patients in nursing facilities. CMS and hospice associations have since issued guidance on the appropriate care for hospice patients in nursing homes.

Hospices in rural and urban areas may also have different cost structures. Although the rate of hospice use has increased faster in rural areas than in urban areas, the rate of use in rural areas remains lower (MedPAC 2002). Many factors may contribute to this discrepancy, including differences in hospice supply, hospice demand, and hospice input costs. Medicare hospice payments are usually lower for rural hospices than urban hospices to adjust for wage differences, as in other Medicare sectors.⁵ Payments are not, however, adjusted for other cost factors that may relate to urban and rural differences. For

example, rural hospice providers likely face high transportation costs due to greater distance between patients' homes (MedPAC 2002). Hospices in some urban areas may also face high transportation costs related, instead, to traffic and security needs. Other research has noted that rural hospices have less ability to employ economies of scale because they are typically smaller than urban hospices (Virnig et al. 2004).

Recent Medicare legislation established a small demonstration project to examine hospice care for rural patients in inpatient facilities of 20 or fewer beds. Eligible beneficiaries for these facilities will be limited to those who lack an appropriate caregiver at home and who are unable to receive home-based hospice care. The cap on the number of inpatient days is waived under this demonstration.

Eligibility requirement adjustments

The requirement that beneficiaries have a six-month terminal prognosis, if the disease runs its expected course, may arbitrarily exclude beneficiaries who could appropriately benefit from hospice care. This constraint may be particularly problematic for patients with chronic and eventually fatal illnesses. Because prognoses for noncancer diagnoses can be difficult to determine, physicians may err on the side of being too conservative or too optimistic about their patients' life spans (Austin and Fleisher 2003). Thus, the timing of hospice referrals can be challenging under the prognosis requirement. Perhaps in recognition of this difficulty, Aetna and Kaiser Permanente—two large insurers—have recently initiated palliative care options for patients with prognoses of 12 months or less to live (McLaughlin 2004).

Medicare addresses some of the difficulties with determining a prognosis by allowing physicians to recertify patients for hospice care, even if their patients lived longer than expected (provided that their terminal illness still carries a reasonable prognosis of six months or less to live). Researchers have noted that many patients could benefit if hospice eligibility were determined by acuity level or diagnosis, rather than by time constraints (Lynn 2001). We are not aware, however, of any research that has attempted to quantify how changes in eligibility for hospice care would affect beneficiary access or Medicare spending.

Quality of care issues

MedPAC has recommended that Medicare implement financial incentives for providers to furnish high quality care (MedPAC 2004). This recommendation could eventually extend to hospice providers as well, once quality data are routinely collected. MedPAC also recommended in 1999 that the Secretary of HHS make end-of-life care a national quality-of-care improvement priority for Medicare (MedPAC 1999). Although some Quality Improvement Organizations (QIOs) have developed special projects to improve end-of-life care (in nursing homes, for example), this initiative is not a national QIO priority. Furthermore, QIOs' recent scopes of work do not include working with hospices to improve the care they provide. CMS has not initiated a process to review hospice quality measures to establish a core set of quality measures for public reporting.

Medicare does not require hospice agencies to conduct ongoing quality improvement, as it does other providers, such as hospitals. Conditions of participation for hospice providers do not require quality assessment or quality improvement programs, which generally create an expectation for continued improvement and often specify areas to be improved.⁶ However, most hospices do conduct quality assessment, because it is a typical requirement for accreditation sought outside of Medicare. Therefore, if Medicare were to add a quality assessment requirement in its conditions of participation, accredited agencies likely would not face a significant burden.

A critical foundation for quality incentives and quality improvement is that providers submit data on common measures of quality. In 1999, MedPAC recommended that the Secretary of HHS sponsor projects to develop and test measures of the quality of end-of-life care for Medicare beneficiaries. We cataloged a number of such initiatives. One example is the Toolkit of Instruments to Measure End-of-Life Care—a project funded by the Robert Wood Johnson Foundation—that reviews a variety of quality measurement tools in each of 10 different aspects of end-of-life care (CGHCR 2004).

Many members of the hospice industry have worked to develop a voluntary measurement process. For example, the National Hospice and Palliative Care Organization (NHPCO) has sponsored research to identify measurement tools along three domains of care: self-determined life closure, safe and comfortable dying, and effective

grieving. The organization also has developed a survey instrument to assess family satisfaction with hospice care. Member hospices voluntarily collect information on bereaved families' perceptions, reports of care, and satisfaction with the deceased person's hospice experience. These hospices can also provide their results to prospective patients and their families.

Additional measures not captured on NHPCO's survey may be useful, as well. One is the management of pain, for which there are many instruments, including OASIS for home health. A second is the percentage of beneficiaries dying at home—a setting for death that most people prefer.

Developing quality measures for public reporting should be a priority for the Medicare hospice program. One approach CMS could take is to contract with a research firm to develop a quality measure set, which was the approach used for home health care. Another alternative is to task the QIOs with developing and testing measures. This approach was used to develop the hospital quality measures that are now being reported through a voluntary public-private initiative. Neither effort would require the development of an exhaustive set of measures to capture all the domains of quality hospice, nor more broadly, end-of-life care; these could be brought into the measure set over time. Some measures developed as part of this work could also apply to other parts of the program, reflecting the fact that most Medicare beneficiaries die without enrolling in hospice. To reinforce the process of measure development, CMS could also revise the hospice conditions of participation to require a process for quality improvement.

Data needed to refine the hospice payment method

To assess payment adequacy and quality issues described above, more data are needed. Data on the types of services different patients use could be collected nationally by requiring hospice providers to report the information on claims forms or in cost reports. Alternatively, the data could be collected from a sample subset of providers. Some combination may be appropriate so that basic data on service use is provided by all hospices, while more detailed documentation on patient cost and service delivery could be collected from a sample. Any data collection effort should balance the need for information with the burden placed on providers and CMS.

How does Medicare pay for hospice beneficiaries in Medicare Advantage?

Medicare Advantage plans are not required to offer the Medicare hospice benefit, but their enrollees may elect hospice care outside their plan under the same eligibility rules as beneficiaries in fee-for-service Medicare. Beneficiaries who elect hospice care do not need to disenroll from their Medicare Advantage plan, but they may do so if they wish.⁷

When Medicare Advantage enrollees elect hospice care, Medicare reduces its monthly capitated payments for those beneficiaries because plans are no longer financially liable for all Medicare-covered services used by beneficiaries in hospice care. That is, for hospice patients who are enrolled in Medicare Advantage plans, fee-for-service Medicare pays for the hospice care as well as care unrelated to the terminal condition. Plans continue to be liable, however, for non-Medicare benefits that they offer to their enrollees (such as vision or dental care). Medicare's reduced capitated payment is meant to cover this liability.

The following example illustrates this payment arrangement: Medicare pays \$700 per member per month to a given plan. The plan spends \$650 to cover all Medicare-covered services and uses the remaining \$50 to cover vision and dental care (non-Medicare-covered services) at no additional cost to enrollees. If an enrollee elects hospice, and chooses to stay in the managed care plan, Medicare will reduce its payment to the plan for that beneficiary to \$50 per month so the plan can continue to cover the patient's vision and dental care. For Medicare-covered services unrelated to the terminal condition, plans (or individual providers and suppliers) may bill Medicare on a fee-for-service basis. As with all Medicare beneficiaries, hospice agencies bill Medicare directly for providing hospice care.

Payment policy issues for hospice beneficiaries in Medicare Advantage

The current payment arrangement for hospice beneficiaries enrolled in Medicare Advantage plans works against the goal of fully integrated health care delivery through private plans. Generally, under Medicare Advantage, the Medicare program pays a capitated amount to care for the full array of Medicare services. Because the program does not pay separately for each type of service (e.g., hospital, physician), plans have incentives to coordinate all care, and to choose the most effective

setting to improve quality and lower costs. By contrast, beneficiaries electing hospice are moved out of the managed care payment system for all Medicare-covered services, which discourages plans from continuing efforts to coordinate their care.

The policy raises two further concerns. It explicitly pays plans to offer non-Medicare-covered services to hospice enrollees, which it does not do for any other set of beneficiaries. The policy is also administratively complex; the capitation payments made to plans for the non-Medicare services must be figured separately for each plan depending on its adjusted community rate proposal.

The payment arrangement for hospice beneficiaries enrolled in Medicare Advantage plans establishes a financial incentive for plans to direct patients to hospice care; it allows plans to eliminate their financial liability for Medicare-covered services to their sickest (and usually most expensive) enrollees—those with terminal illnesses. Data presented earlier in this chapter show higher use of the hospice benefit by decedents in Medicare Advantage plans, consistent with these incentives. Some research indicates that the higher use is appropriate, particularly among beneficiaries with cancer (McCarthy et al. 2003).

It is unclear why the Congress opted to exclude the hospice benefit from the earlier risk-contracting program, then from the Medicare+Choice program—now referred to as the Medicare Advantage program. Efforts to ensure beneficiary access to hospice care may have been a consideration. Also, hospice may have been treated

differently from other Medicare benefits because of the uncertainty of the cost of hospice care in 1983, the same year that the risk-contracting program was started. At that time, few hospice providers existed and data on their costs were largely unavailable (Riley and Herboldsheimer 2001).

Although removing managed care plans' financial liability for hospice care may increase use of these important services, it may discourage plans from developing chronic disease management programs that provide palliative care. In the past, some managed care plans may have been reluctant to develop innovative end-of-life and chronic care management programs for fear of attracting terminally ill enrollees who would raise plans' costs (Raphael et al. 2001). Recent research has suggested that, although risk-adjustment addresses some of these concerns, the current risk-adjustment measures could be improved to compensate plans more accurately when delivering care to people with terminal illnesses (Buntin et al. 2004).

Ideally, if Medicare Advantage plans were liable for hospice beneficiaries' full spectrum of care, they would be more likely to coordinate care across settings and potentially employ chronic care disease management protocols for appropriate beneficiaries. Indeed, some commercial plans have such innovations in place for the broad populations they enroll, as described in the text box opposite. ■

A broader perspective: End-of-life care

Many clinicians, policymakers, and consumers have called for improvements in care delivered to dying patients and their families (IOM 1997). MedPAC has made similar recommendations with respect to the Medicare program (MedPAC 1999). End-of-life care analysis often draws the distinction between palliative and curative care, but the division between the two is not always clear-cut. Palliative care at the end of life focuses on controlling symptoms of disease such as pain; it also concentrates on allowing patients to maintain function. Services to address emotional, spiritual, and social concerns with death and dying are also features of palliative care. Curative care, by contrast, focuses on curing disease. Elements of each type of care are often present in the course of a patient's illness, sometimes simultaneously. Because physicians are often unable to make absolute prognoses, palliative care may be desirable in conjunction with curative treatment.

Concerned that patients and their physicians face difficult choices between palliative and curative care, Aetna and Kaiser Permanente—two large insurers—have recently started programs which allow patients with terminal illnesses to receive a combination of both (McLaughlin 2004). Another example is the Palliative Care Option developed by Regence BlueShield, which has looser eligibility requirements than the Medicare hospice benefit. Started as a program for children, the plan is intended to have a broader appeal than the Medicare hospice benefit, potentially decreasing costs for emergency room visits and hospital care and improving patient and provider satisfaction with managed care.

Many researchers have called for Medicare to encourage the provision of palliative care that is not tied so tightly to prognosis (Lynn et al. 1998). They point out that as patients become ill and transition toward death, the need for curative care gradually declines and the share of services devoted to palliative care gradually rises; there is no fixed point in time when all care should shift from curative to palliative.

Organizations have been experimenting with different approaches to end-of-life care. For example, a national initiative supported by the Robert Wood Johnson Foundation has explored a variety of hospital-hospice partnerships in palliative care (CAPC 2001). Some of these ventures focus on increasing the use of Medicare's hospice benefit through a variety of approaches ranging from professional education to developing specialized units. Others have developed new nonhospice palliative care services. Another initiative supported by other foundations provides funds to support the training of physicians in the principles of palliative care (PDA 2003). Still another initiative has funded community-oriented palliative care (UHFNY 2004).

People concerned about better care for the dying have raised concerns about whether the services covered in Medicare outside the hospice benefit support quality end-of-life care, particularly considering that most beneficiaries are not in hospice when they die (Moon and Boccuti 2002). Some have called for broader Medicare coverage outside the hospice benefit, including coverage of outpatient drugs, transportation, and nonskilled home care (Raphael et al. 2001). Covering more types of palliative care services for beneficiaries who are very ill but who have not yet been given a six-month prognosis could improve their quality of life; however, such additional benefits would likely raise Medicare spending.

Recent legislation addresses some of the perceived barriers for Medicare to provide end-of-life care outside the hospice benefit. Coverage of outpatient drugs is one important area; the chronic care initiative is another (see Chapter 2). The chronic care initiative may be one way to address concerns that hospice care is not well accessed by beneficiaries with chronic illnesses that have less predictable prognoses, and by beneficiaries who do not necessarily wish to forgo all curative care. ■

Endnotes

- 1 Hospices may not apply separate admission criteria based only on payer status (e.g., Medicare versus private insurance).
- 2 Beneficiary coinsurance for respite care may not exceed the Part A inpatient hospital deductible, which is \$876 in 2004.
- 3 The term “freestanding” means that the agency is not owned by another type of provider; it does not refer to an actual freestanding building. Freestanding agencies commonly provide hospice services to patients residing at home or in a nursing facility.
- 4 Information on hospice volume is from CMS data reported in the *Federal Register* (vol. 66, no. 188, p. 49475; vol. 67, no. 169, p. 56113; vol. 68, no.189, p. 56507).
- 5 Wage adjustments are based on the location of the patient, not the hospice agency.
- 6 Hospices are, however, required to have a quality assurance program in place. Such programs usually review processes of care, but do not focus on outcome measures or improvements.
- 7 If beneficiaries decide to remain in their plan, they must continue to pay their premiums, if applicable.

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CHAPTER

7

**Information technology
in health care**

Information technology in health care

Information technology (IT) has the potential to improve the quality, safety, and efficiency of health care. Diffusion of IT in health care is generally low (varying, however, with the application and setting) but surveys indicate that providers plan to increase their investments. Drivers of investment in IT include the promise of quality and efficiency gains. Barriers include the cost and complexity of IT implementation, which often necessitates significant work process and cultural changes. Certain characteristics of the health care market—including payment policies that reward volume rather than quality, and a fragmented delivery system—can also pose barriers to IT adoption. Given IT’s potential, both the private and public sectors have engaged in numerous efforts to promote its use within and across health care settings. Additional steps could include financial incentives (e.g., payment policy or loans) and expanded efforts to standardize records formats, nomenclature, and communication protocols to enhance interoperability. However, any policy to stimulate further investment must be carefully considered because of the possibility of unintended consequences.

In this chapter

- What is health information technology?
- Quality and health information technology
- Current status of health information technology
- Efforts to encourage faster diffusion

By providing new ways for providers and their patients to readily access and use health information, information technology (IT) has the potential to improve the quality, safety, and efficiency of health care. However, relatively few health care providers have fully adopted IT. Low diffusion is due partly to the complexity of IT investment, which goes beyond acquiring technology to changing work processes and cultures, and ensuring that physicians, nurses, and other staff use it. In addition, certain aspects of the market—such as payment policies that reward volume rather than quality and the fragmentation of care delivery—do not promote IT investment, and may hinder it. Because of its potential, policymakers need to better understand how information technology is diffusing across providers, whether action to spur further adoption is needed, and if so, what steps might be taken. Any policy to stimulate further investment must be carefully considered because of possible unintended consequences—such as implementation failures due to organizations’ inability to make the necessary cultural changes. This chapter is a first step in increasing our understanding of the current state of IT in the health care industry. The Commission will continue to work on this issue.

Despite considerable attention to the topic, much remains unknown about the role of IT in the health care setting. What types of IT are being used? What is the link between use of IT and quality improvements? How much investment have hospitals and physicians already made in information technology, and in what kinds? What factors drive IT investments (e.g., financial returns, quality improvement goals, other factors)? What factors hinder IT investments and implementation (e.g., work flow changes, lack of compatibility with other IT, costs)? What current steps are being taken by public and private entities to encourage further diffusion of IT? What additional actions might make sense?

Delivering quality health care requires providers and patients to integrate complex information from many different sources. Thus, increasing the ability of physicians, nurses, clinical technicians, and others to readily access and use the right information about their patients should improve care. The ability for patients to obtain information to better manage their condition and to communicate with the health system could also improve the efficiency and quality of care. This potential to improve care makes broader diffusion of IT desirable.

However, further research is needed to better understand what types of IT applications are most useful for improving care in different settings and what circumstances are necessary to ensure successful implementation. Current studies show that some technologies lead to better care. However, the evidence base is narrow, coming primarily from select institutions that developed their own systems, and may not represent the average facility.

The health care system generally uses less IT than other industries, but surveys indicate that providers are increasing their investments. The extent of IT and the types of IT deployed vary by setting and institution. The prevalence of IT in any setting largely reflects the strength of the drivers and barriers to investment. For many organizations, quality and process improvements are primary drivers. For others, gains in efficiency motivate investment. Yet, the cost and the complexity of IT implementation, including necessary organizational and workflow redesign, pose considerable barriers, as does uncertainty regarding the stability of the IT industry.

The larger health care market poses additional barriers to investment in IT. Payment systems that tie reimbursement to the volume of services delivered, for example, may penalize providers who improve quality in ways that result in fewer units of service. To the extent that IT investments lead to reduced volume, many who make the investment will not reap all of the benefits. Systems that integrate care across settings tend to be more advanced users of IT because they are able to capture some of these efficiencies. In addition to barriers posed by payment systems, a fragmented delivery system leads to redundant investments by multiple providers who lose the benefit of economies of scale. Although this aspect of our delivery system is a barrier to adoption, widespread use of IT could help providers coordinate care across settings, overcoming some of the problems of fragmentation.

Both the private and public sectors have engaged in numerous efforts to promote use of IT within health care institutions and across care delivery settings. Activities include developing and promoting industry-wide standards; funding research to investigate the impact of IT on quality; providing incentives that encourage investment in IT; giving grants to those investing in IT; and developing strategies to improve the flow of information across providers. Additional activities to promote diffusion

could include changes to payment policy, institution of loan or grant funds, and requirements to adopt specific technologies.

What is health information technology?

In general, IT allows health care providers to collect, store, retrieve, and transfer information electronically. However, more specific discussion of IT in health care is challenging due to the lack of precise definitions, the volume of applications, and a rapid pace of change in technology.

Similar terms can be used to define different products, and the exact functions of a system will depend on the specifics of its implementation in a given setting. Both the terms and the functions also change over time. For example, computerized provider order entry (CPOE), which can minimize handwriting or other communication errors by having physicians or other providers enter orders into a computer system, can apply only to prescription drugs, or may also include additional physician orders, such as x-rays or other images, consultations, and transfers. For electronic health records (EHRs, also known as electronic medical records, automated medical records, and computer-based patient records, among other names), multiple definitions exist, depending on the constellation of functions that are included (Brailer and Tarasawa 2003).¹ They can be used simply as a passive tool to store patient information or can include multiple decision support functions, such as individualized patient reminders and prescribing alerts.

When purchasing IT, providers must consider multiple functions and literally hundreds of applications offered by numerous vendors. In general, the various IT applications fall into three categories:

- administrative and financial systems that facilitate billing, accounting, and other administrative tasks;
- clinical systems that facilitate or provide input into the care process; and
- infrastructure that supports both the administrative and clinical applications.

Table 7-1 provides examples of IT applications in hospitals and physicians' offices; the accompanying text box (p. 160) provides definitions for various clinical systems and other terms used in IT discussions.

**TABLE
7-1**

Examples of health information technology for hospitals and physicians

Type of information technology	Applications
Hospitals	
Administrative and financial	Billing General ledger Cost accounting systems Patient registration Personnel and payroll Electronic materials management
Clinical	Computerized provider order entry for drugs, lab tests, procedures Electronic health record Picture archiving and communication systems for filmless imaging Results reporting of laboratory and other tests Clinical decision support systems Prescription drug fulfillment, error-alert, transcriptions Electronic monitoring of patients in intensive care units
Infrastructure	Desktop, laptop, cart-based, and tablet computers Servers and networks Wireless networks Voice recognition systems for transcription, physician orders, and medical records Bar-coding technology for drugs, medical devices, and inventory control Information security systems
Physicians	
Administrative and financial	Billing Accounting Scheduling Personnel and payroll
Clinical	Online references (drug compendia and clinical guidelines) Receiving lab results and other clinical information online Electronic prescribing Computerized provider order entry Clinical decision support systems Electronic health record E-mail communication with patients
Infrastructure	Desktop and laptop computers Handheld technology Servers and network

Note: Applications listed are examples and not exhaustive.

What is health information technology?

The following technologies and terms are often included in discussions of information technology in health care:

- **Electronic health record (EHR):** EHRs were originally envisioned as an electronic file cabinet for patient data from various sources (eventually integrating text, voice, images, handwritten notes, etc.). Now they are generally viewed as part of an automated order-entry and patient-tracking system providing real-time access to patient data, as well as a continuous longitudinal record of their care.
- **Computerized provider order entry (CPOE):** CPOE in its basic form is typically a medication ordering and fulfillment system. More advanced CPOE will also include lab orders, radiology studies, procedures, discharges, transfers, and referrals.
- **Clinical decision support system (CDSS):** CDSS provides physicians and nurses with real-time diagnostic and treatment recommendations. The term covers a variety of technologies ranging from simple alerts and prescription drug interaction warnings to full clinical pathways and protocols. CDSS may be used as part of CPOE and EHR.
- **Picture archiving and communications system (PACS):** This technology captures and integrates diagnostic and radiological images from various devices (e.g., x-ray, MRI, computed tomography scan), stores them, and disseminates them to a medical record, a clinical data repository, or other points of care.
- **Bar coding:** Bar coding in a health care environment is similar to bar-code scanning in other environments: An optical scanner is used to electronically capture information encoded on a product. Initially, it will be used for medication (for example, matching drugs to patients by using bar codes on both the medications and patients' arm bracelets), but other applications may be pursued, such as medical devices, lab, and radiology.
- **Radio frequency identification (RFID):** This technology tracks patients throughout the hospital, and links lab and medication tracking through a wireless communications system. It is neither mature nor widely available, but may be an alternative to bar coding.
- **Automated dispensing machines (ADMs):** This technology distributes medication doses.
- **Electronic materials management (EMM):** Health care organizations use EMM to track and manage inventory of medical supplies, pharmaceuticals, and other materials. This technology is similar to enterprise resource planning systems used outside of health care.
- **Interoperability:** This concept refers to electronic communication among organizations so that the data in one IT system can be incorporated into another. Discussions of interoperability focus on development of standards for content and messaging, among other areas, and development of adequate security and privacy safeguards. ■

Source: Adapted from deliverable submitted to MedPAC by Abt Associates.

Quality and health information technology

One of the primary motivators for adopting many clinical health IT applications is the belief that they improve the quality of patient care. Yet, further research is needed to better document and understand the link between IT and

quality, including the types of quality problems information technology can be used to solve and implementation strategies to ensure that quality objectives are met.

Quality health care relies on physicians, nurses, patients and their families, and others having the right information at the right time and using it to make the right decisions.

Yet the health information needed to make these decisions changes frequently; the guidelines and clinical evidence continually evolve, as does knowledge about the condition of the patient. IT may provide a tool to store, integrate, and update this information base.

Beyond improving care in individual settings, health IT also has the potential to address the problems presented by a fragmented delivery system. Most patients receive care from many disparate providers. The primary means of coordination is often through discussion with the patients about what other services they have received and what the other providers thought about their conditions. Information technology used across settings could create a “virtual” integrated delivery system without requiring formal mergers or affiliations.

The Commission stated in its June 2003 report to the Congress that health IT was one of the more important system changes necessary to improve quality (MedPAC 2003). While the potential is clear, the evidence linking quality with various IT applications is less so.

In 2000, the Institute of Medicine (IOM) released a report focusing on patient safety estimating that 44,000 to 98,000 people die in U.S. hospitals annually as a result of medical errors. Many of these errors involve medications. In a subsequent report, the IOM identified IT as one of the four critical forces that could significantly improve health care quality and safety (IOM 2001). Partly in response to these reports, the Leapfrog Group, a group of large employers committed to patient safety improvements, made hospital adoption of CPOE a major goal for large employers and health plans. These influential external forces linking IT to improved quality and patient safety have contributed to a widespread belief that adoption of IT in health care will improve quality and safety.

In this section we present findings from a literature review done for MedPAC by Abt Associates on the relationship between health IT applications and quality. We find evidence that various forms of health IT improve or have the potential to improve quality. However, because many of these findings were based on the experiences of a few organizations without subsequent evaluation of the unique circumstances that may have led to their success, the results may not be generalizable to other organizations. Two large academic medical centers with a strong commitment to the use of health IT conducted many of the studies of CPOE. Each developed its own system. Studies

have not critically analyzed how these systems were implemented. Implementation issues such as work flow disruption, physician involvement, and ease of use have tremendous impact on whether health IT is effective.

Some studies have shown that use of CPOE can reduce the frequency of medication errors. However, 9 out of the 11 formal analyses took place at one of two advanced institutions. CPOE significantly reduced (by 55 percent) serious medication errors (Bates et al. 1998). Of the 11 most rigorous studies, at least 1 study showed that CPOE improved quality and safety through one of the following actions:

- reducing medication errors, including adverse drug events;
- decreasing dosage errors;
- prescribing certain medicines more precisely; or
- prescribing with improved accuracy by faculty and residents (Oren et al. 2003).

Although more limited in the types of errors it can prevent, bar coding is probably the most proven technology of those we discuss. Bar coding prevents errors at the patient’s bedside by averting the administration of the wrong drug when other levels of review have failed. Studies document that bar coding reduced ambulatory and inpatient medication error and the number of adverse drug events (Oren et al. 2003, Bates and Gawande 2003, GAO 2003). One study at a Department of Veterans Affairs hospital showed that bar coding of medications reduced the kind of medical errors bar coding could prevent by 85 percent (McVicar and Valdes 2003).

The types of computer-based clinical decision support systems (CDSS) vary widely—from preventive care reminders to notification of potential drug interactions. Therefore, the types of technology studied vary widely. A 1998 review of the literature on the impact of 68 computer-based clinical decision support systems showed a beneficial impact on processes of care in 43 out of 65 studies and a positive impact on patient outcomes in 6 out of 14 studies (Hunt et al. 1998).

Two studies of clinical decision support systems focused on aspects of the medication system. One found that computerized reminders improve by 100 percent the use of “corollary orders,” that is, orders for other

pharmaceuticals or tests that would ensure appropriate dosage (Overhage et al. 1997). Another studied a broad range of CDSS and found improvements in types and doses of drugs (Teich et al. 2000). In a review of the evidence on CPOE and CDSS, researchers found that one important issue in ensuring successful implementation of either is that the threshold for alerts must be set so that physicians do not receive so many “false alarms” that the information is ignored (Kaushal and Bates 2001).

Electronic health records are often implemented with CPOE and decision support efforts; therefore, it is difficult to evaluate separately their impact on quality. However, an electronic health record has the potential to make health information more available to providers and patients when they need it. The availability of lab and radiology reports, patient-specific histories, and clinical reminders, along with other functions such as CPOE and bar coding, have the potential to improve quality.

The quality benefits of investment in IT are often achieved after tremendous efforts and some initiatives have failed. A recent study of the effect of computerized guidelines for managing heart disease in primary care found that sophisticated reminders from an EHR failed to improve adherence to accepted practice guidelines or outcomes for patients with heart disease (Tierney et al. 2003). A Department of Veterans Affairs hospital that is the test site for a new computer software program recently reported surgery delays and other problems with its new computer system (De La Garza 2004). Even when implemented, CDSS might not be used because of physician workload or limited training for rotating staff (Patterson et al. 2004). Other research has shown that automated systems are also subject to errors: U.S. Pharmacopeia reported that 10 percent of medication errors it studied resulted from computer-entry errors (Armstrong 2003).

IT can be a tool for improving quality and safety, but is not the only one and is often used by providers as part of a broader effort. In 2001, the Agency for Healthcare Research and Quality (AHRQ) determined that 14 safety practices had greater strength of evidence regarding their impact and effectiveness than any practice which relied on IT. They include such low-cost items as appropriate provision of nutrition, with a particular emphasis on early enteral nutrition in critically ill and surgical patients, and use of maximum sterile barriers while placing central intravenous catheters to prevent infections (AHRQ 2001). This is not to say that these practices are superior to IT; ideally, organizations would pursue them all.

Current status of health information technology

The degree of IT use varies by health care setting: Pharmacies are generally advanced users, while other settings such as physician offices or nursing homes are further behind. The kind of technology used also varies by setting. For example, in home health, the use of technology that allows patients to monitor their own vital signs from their home and communicate results to the agency could increase the ability to address a problem before a patient requires acute care. In both home health and nursing home settings, use of handheld computers to complete documentation and capture patient assessment information can increase efficiency and provide more information to care givers. IT and the Internet have also had a significant impact on consumers. Numerous websites have made health information more available to patients, thereby strengthening their role in care decisions. The Internet also helps consumers choose providers by allowing insurers and others (including Medicare) to post information on providers including, in some instances, comparative quality information.

This section provides detailed information on two settings—hospitals and physicians’ offices—that have received considerable policy attention. Further MedPAC work may focus on other settings, such as post-acute care, as well as on the impact of IT and the Internet on consumers. This section also looks at linking health care providers through an information infrastructure, or “interoperable” systems that allow communication among the IT applications used by different providers.

Information technology in hospitals

Relatively little is known about the level of diffusion of IT in hospitals and strategies hospitals take when making IT investment decisions. Much of the existing information about IT diffusion comes from voluntary surveys, some of which are conducted on the Internet. Therefore, the results may not be representative and may be biased toward more advanced users of IT. Given the evolving state of the technology and limited availability of nationally representative surveys, varying estimates of IT diffusion exist. The following discussion draws on a literature review on hospital IT investments conducted for MedPAC by Abt Associates. It also draws on interviews Abt Associates conducted with hospitals that have made significant investments in IT, and some that have not, to

better understand IT investment decisions (Abt Associates 2004a and 2004b).

Diffusion of information technology in hospitals varies with the type of technology. Of the three major categories shown in Table 7-1 (p. 159), diffusion is greatest in administrative and financial applications such as patient registration, billing, and payroll. Clinical applications, such as computerized provider order entry for drugs or other items (e.g., lab work) and electronic health records, are less diffused. Infrastructure technologies build the base that other technologies work from, and include both widely diffused technologies, such as e-mail and telecommunications, and those that are less common, such as wireless connections and voice recognition. Infrastructure investments also include maintaining secure information systems that comply with federal security rules.

Estimates of the use of CPOE vary, but several studies report that 5 to 6 percent of hospitals currently have a system (Leapfrog Group 2004, Devers and Liu 2004). Others argue that these studies may have stringent definitions that lead to low estimates of CPOE use (iHealthBeat 2003). Estimates of the use of EHRs in hospitals are similarly low (Glaser 2002). Other types of clinical IT—such as picture archiving and communications systems (PACS) that allow digital storage and retrieval of x-rays, MRIs, and other images—have diffused more widely. About 15 percent of all hospitals were estimated to have PACS in 2002, with most academic and large hospitals having this technology. In a more recent survey of hospital executives, 49 percent indicated that they had PACS or were implementing it (Morrissey 2004).

For each type of clinical IT, academic medical centers and large hospitals are more likely to be advanced users. Providers who are part of integrated systems delivering inpatient and outpatient services are also more likely to have the necessary financial support and a clearer need to ensure smooth flow of information across their systems. Those who are part of multiple hospital systems (about half of all hospitals according to the American Hospital Association Guide 2003–2004) probably benefit from IT support offered by the larger organization. They may also be motivated to adopt IT to facilitate information flow across system members.

Clinical applications, particularly CPOE and EHR, may not diffuse rapidly for a number of reasons. They are

relatively new. They are costly, complex, and difficult to implement in stages. They require significant changes in work processes and culture for nurses, pharmacists, other allied health professionals, and physicians to be successfully implemented. Finally, achieving the benefits of these technologies for improvements in quality of care appears to hinge on the same factors that pose a risk to successful implementation. As discussed below, the financial return to investment for these technologies is uncertain.

Though not widely diffused now, many organizations are planning to implement clinical systems in the near future. The Healthcare Information and Management Systems Society (HIMSS) has conducted a survey in each of the past three years. The most recent web-based survey (conducted November 2003 through January 2004) included 307 respondents out of nearly 2,000 chief information officers or directors of information systems at health care facilities who were asked to participate. Most of the respondents work for health care systems and hospitals; some 86 percent came from an organization led by a hospital (HIMSS 2004a).

The HIMSS survey respondents reported that in the next year, upgrading security protocols and reducing medical errors and promoting patient safety will be priority issues for their IT departments (Figure 7-1, p. 164). Specific applications they think most important for the next two years include bar coding, EHR, and clinical information systems (Figure 7-1, p. 164).

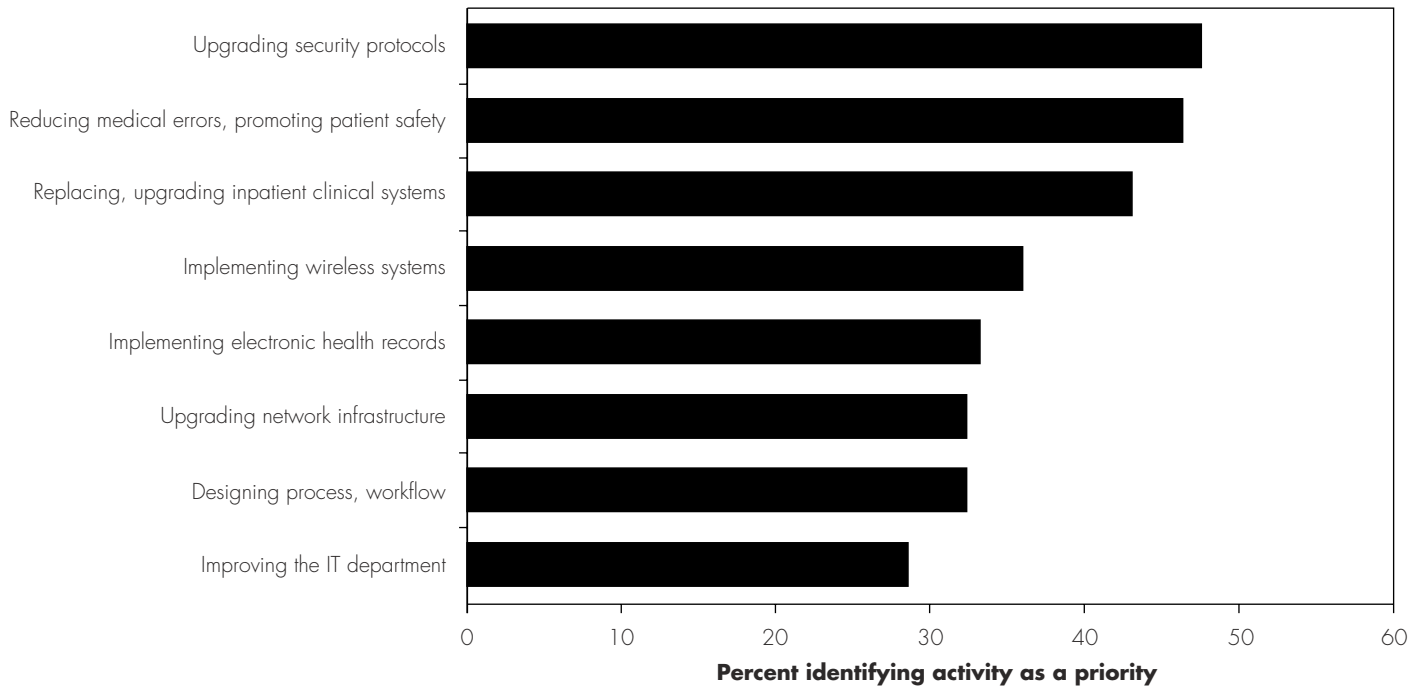
A recent survey of hospital investment priorities by the Health Care Financial Management Association indicated that IT is as high a priority as capital construction. Among IT applications, this survey suggested a different ordering of priorities than other surveys. The survey of 460 hospital and system chief financial officers showed that 72 percent anticipate investing in PACS, 64 percent in CPOE, and 61 percent in other major information technology. The same survey found that overall capital spending is expected to rise 14 percent annually for the next five years, compared with 1 percent annual increases from 1997 to 2001 (HFMA 2004).

Many systems and hospitals have recently announced IT plans. For example, Kaiser Permanente, an integrated system, is investing \$1.8 billion to put in place a fully operational EHR. Catholic Health West recently announced its intention to implement various forms of health IT for all of its 41 hospitals.

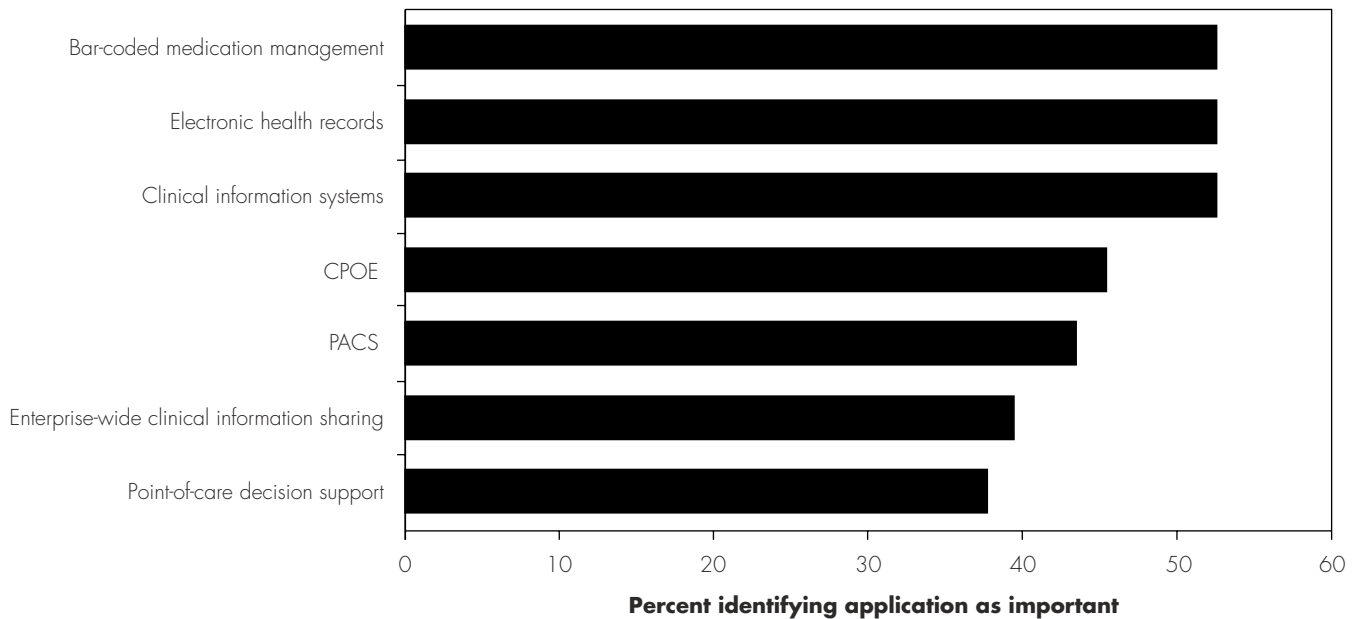
**FIGURE
7-1**

Information technology priorities for hospitals

Hospital and health care executives name security and safety as top priorities for 2004



Hospital and health care executives name bar coding and other clinical applications as most important for 2004-2005



Note: CPOE (computerized provider order entry), PACS (picture archiving and communications system).

Source: Healthcare CIO Results: Final Report, Leadership Survey, Healthcare Information and Management Systems Society, February 23, 2004.

Drivers of adoption

Hospitals consider both financial return on investment and nonfinancial benefits when making IT investment decisions. Return on investment varies by the type of IT. Technologies that pay for themselves tend to diffuse more widely. Studies dating back to the 1980s have shown that electronic billing and claims submission rapidly pay for themselves and generate additional savings by decreasing the costs of creating bills and speeding reimbursement. These technologies are practically universal. Hospitals have also been quick to adopt other kinds of technology that produce revenues, such as imaging equipment.

Little economic literature addresses the question of the impact of IT on hospital financial performance. One study offers preliminary results indicating that investment in IT leads to increased volume in nonprofit hospitals and reduced length of stay in for-profit hospitals. The same study found that the longer the health IT investment, the greater the effect (Parente and Van Horn 2002). Some reports suggest returns on investment or anticipated savings for several specific clinical applications. Voice recognition software can pay for itself by lowering transcription costs. PACS can lower costs for acquiring and storing films by storing digitized radiology images, and may reduce the workload among radiology staff (Wiley 2003). One study suggests an 18-month payback period (Baldwin 2002).

Most of the hospitals with advanced IT systems interviewed by Abt used PACS: Of the 12 total, 10 had it in place, 1 was implementing it, and the last had put out a request for proposals. Most of the hospitals had performed return on investment calculations and predicted positive returns, which most realized. Recent diffusion estimates suggest that PACS, at least, is becoming more common, perhaps in part because the financial return is evident. However, one of the smaller hospitals interviewed that was less advanced in its use of IT purchased PACS despite predicting a negative return on investment. The projected lack of return was due primarily to a low volume of imaging in the facility.

The literature provides scant evidence of return on investment calculations for CPOE and EHR and we see lower diffusion of these technologies. Regarding CPOE, six of the interviewed hospitals have the system or are implementing it, five plan to have it within one to three years, and only one had no plans to pursue it. In general, hospitals reported that patient safety and quality of care,

rather than financial returns, motivate their investments in CPOE and EHR. None of these hospitals had conducted or planned to study return on investment for CPOE.

Calculating return on investment for clinical IT can be challenging. The costs of CPOE and EHR can be difficult to measure because they require investment not only in the technologies themselves, but also in changing work processes, significant staff training, and ongoing system support (Darves 2004). Quantifying some of the benefits for these applications, such as improved care processes and workflow, can be difficult. Reductions in costs stemming from reduced medical errors, shorter stays, or efficiencies in care delivery can also be hard to measure.

Furthermore, the financial returns from some quality improvements may accrue not to the hospital investing in the technology, but to other parties. For example, a hospital might invest in CPOE and, through successful implementation, prevent an adverse drug event that would have resulted in another hospital admission. The hospital loses revenue from the avoided admission, and the purchaser of care gains. In this example, the hospital improves care and the patient is clearly better off.

Closed systems of care, in which a single entity serves as both the insurer and the provider of care, will reap all of the financial benefits from health IT. This may explain why closed systems, such as the Veterans Health Administration or staff model HMOs, are generally more advanced users of IT systems. One national health system, the National Health Service (NHS) in England, has recently committed to a large-scale implementation of IT (see text box, p. 166). The head of that effort recently noted that the NHS is able to do some things, such as negotiate big discounts from IT vendors, that could not be easily duplicated in the United States (AHA News Now 2004).

The nonfinancial benefits hospitals consider when making IT investment decisions include clinical efficiencies and improved quality, patient and provider satisfaction, image and public relations, and employee morale. A focus on improved quality of care by the Institute of Medicine, the Leapfrog Group, and others has fueled interest in CPOE, in particular, as well as EHRs, other pharmacy systems, and lab systems. Those hospitals interviewed by Abt that had more advanced IT systems indicated that patient care and safety were major drivers for adopting clinical IT. Consumer expectations and possible discounts on

England plans for national information technology system

England's government has begun contracting with information technology (IT) firms to implement a National Programme for IT (NPfIT) within the National Health Service (NHS), the public agency that provides health care. The program consists of four parts:

- electronic patient records, which will include a central data repository of patient information available to all health care providers;
- electronic scheduling of appointments for consultations and hospitalizations that will be available to referring general practitioners and, eventually, patients;
- e-prescribing, which will allow electronic prescriptions filled by physicians to flow to both the pharmacy and the Prescription Pricing Authority that manages payments; and
- improved broadband communications networks to facilitate communication across the National Health Service.

The NPfIT has an ambitious agenda that seeks to implement the world's largest health care IT system by the year 2010. Because the health system in England is closed, with the government employing staff, it can implement a system that covers all patients and providers. However, implementation will require coordination among the national health authority, regional health authorities, and local health care

providers, some of whom have already invested in their own IT systems.

The NHS plans for the first element, electronic scheduling, to be available in some locations by the summer of 2004, with full implementation by the end of 2005. The NHS will phase in the national database of electronic patient records by 2010. The NHS targets having 50 percent of prescriptions handled electronically by 2005 and 100 percent by 2007.

Funding for the NPfIT includes \$17 billion from the national government, with additional funds coming from local health authorities. The central funding currently covers only the cost of the technology, and not the training and work process changes that will be needed to implement health IT at the local level.

Supporters of the system predict significant improvements in efficiency and quality of care, as patient information will be accessible to all providers at any time. The system will also include decision-support functions, such as clinical guidelines or prompts for drug allergies. Supporters also claim that significant discounts can be obtained from IT contractors because of the size of the endeavor and the centralized procurement process. Others have noted the need for greater attention to the availability of local funds for implementation and training. Additional concerns include the need to involve stakeholders during design, ensure data quality, and implement adequate security and privacy safeguards. ■

Sources: Parliamentary Office of Science and Technology 2004, NHS 2004, Naik 2003, Dodge 2004.

malpractice insurance premiums for reduced medical error rates have been cited as drivers of adoption (Scalet 2003). In addition, declining prices for IT technologies should facilitate IT use.

Standards and regulations set by state and federal governments or accrediting agencies can also spur investment in IT. Electronic transaction standards put in

place through the Health Insurance Portability and Accountability Act of 1996 (HIPAA) should facilitate adoption of IT by removing some innovation barriers and providing guidance for future investments, steering hospitals away from applications that will not meet the standards. Currently, hospitals are working to comply with HIPAA requirements to ensure the security of their information systems (HIMSS 2004a). The recent

requirement by the Food and Drug Administration (FDA) for pharmaceutical companies to include bar codes on their products within two years is likely to stimulate investment in bar coding in the near future (FDA 2004).² However, the adoption of bar coding in hospitals may depend on the extent to which manufacturers put bar codes on single doses of their medications, rather than putting them on a package containing multiple doses (Hawryluk 2004).

Barriers to adoption

While many factors push hospitals to invest in IT, others pose barriers. Investment in IT is costly and must compete with other priorities, including investment in bricks and mortar, as well as in technologies with more direct application to clinical care and greater certainty for increased revenues, such as new imaging equipment (Morrissey 2004). The availability of capital for investment in IT depends, of course, on hospitals' ability to access capital in general, which may be easier for some hospitals (e.g., those with good financial performance, for-profits, members of chains) than others. Recent estimates of the percentage of hospital operating budgets spent on operating IT systems indicate that 2 to 3 percent is the industry average (Morrissey 2004, HIMSS 2004a). Capital expenditures on IT generally consume a larger share of capital budgets, although the percentage varies with each hospital's investment cycle.

Cost poses another barrier to adoption. The costs of implementation and ongoing maintenance vary by the size of the hospital, as well as by the functions to be installed. A full clinical IT system that includes CPOE and an EHR will cost tens of millions of dollars; CPOE on its own was estimated to cost about \$8 million for a 500-bed hospital (First Consulting Group 2003). Installing bar coding is expected to cost around \$1 million for the average hospital (Hawryluk 2004). In addition to the costs of IT, hospitals may perceive lack of reimbursement for specific IT investments as a barrier.

The costs of implementing IT go beyond purchasing the technology to providing training and systems support, which case studies indicate are crucial for success. Deriving benefit from IT generally requires changing work processes, which can be more challenging than the purchase and installation of the technology itself (Darves 2004, First Consulting Group 2003). New applications must also integrate with existing systems, which makes implementation more complex and can further increase costs. For example, applications providing considerable

depth of support for a given department, such as PACS for radiology, may not communicate easily with an existing patient registration system.

Nearly every study of clinical IT implementation and adoption cites physician reluctance as a major hurdle to broader investment and overcoming it as a key to project success. A number of large-scale investments, including the one at Cedars-Sinai Medical Center in Los Angeles, have failed due to a lack of physician acceptance. With the exception of pharmacy settings, there is little consistent evidence that IT systems save time for providers. In some instances, the literature suggests the reverse: Systems such as CPOE add to clinicians' workloads because information must now be entered into a computer. EHRs require even greater levels of physician acceptance than CPOE (Darves 2004, GAO 2003). The need for changes in work process and culture suggest that hospitals may not be able to move quickly when making IT investments because they can manage only a limited amount of change at a time. The need to maintain full operations while undertaking systems changes provides an additional challenge. Given the importance of culture and physician acceptance for implementation of clinical IT, hospitals that employ a large share of their physicians may find it easier to implement because they have more control over how their physicians work.

Earlier we noted that federal and state regulations like HIPAA can drive investment in IT. They may also slow adoption of some types of IT, however, if IT funds and the attention of hospital executives must be directed to specific technologies over others. The HIPAA transaction rules require investments in IT supporting transactions, potentially at the expense of other investments. The HIPAA privacy and security requirements may also increase the complexity of the design of IT systems that share patient information.

In the latest HIMSS survey, respondents were asked to identify the most significant barrier to implementing IT. Lack of financial support was cited most often; however, it was chosen by fewer than one in four respondents (23 percent). Respondents also considered the following to be significant barriers:

- vendors' inability to deliver products effectively (14 percent);
- difficulty in providing quantifiable benefits or return on investment from IT (13 percent); and

- difficulty achieving end-user acceptance (11 percent), among others.

Very few respondents (3 percent) considered lack of common data standards to be a significant barrier (HIMSS 2004a). The hospitals interviewed by Abt highlighted the following as possible barriers to successful implementation of IT: cost, physician culture or reluctance, the need for concomitant changes in workflow and processes, retraining, poor quality of vendor offerings, and integration with existing systems.

Information technology in physicians' practices

Like hospitals, physicians are more likely to use IT for administrative functions (such as billing, claims submission, and scheduling) than for clinical functions (such as electronic health records, clinical decision support, access to formularies or other references, or computerized provider order entry). Physicians must also invest in infrastructure to support their IT applications.

Data on the use of IT by physicians and their staffs are limited. This section reports the results of three surveys of the current and planned use of IT in physicians' offices. For clinical IT, estimates of physicians' use of EHRs in their offices vary across surveys. Brailer and Terasawa (2003) suggest that 20 to 25 percent is a reasonable estimate of current diffusion. This estimate is higher than those generally quoted for hospitals, perhaps because the EHR is only one of many technologies hospitals are pursuing. A longitudinal record of patients' care may be more relevant in an outpatient clinic or office setting, where physicians coordinate care across settings.

The Center for Studying Health System Change (HSC) included questions on use of IT in its latest physician survey. Although the information is somewhat dated—it was conducted in 2000 and 2001—it is nationally representative of all physicians. HSC asked about use of IT in the practice, not by the physician himself or herself. In addition, HSC did not gather information on the frequency or intensity of IT use. The survey found that adoption of IT varied by the application:

- 77 percent of physicians accessed the Internet,
- 53 percent obtained information on treatment alternatives and clinical guidelines,
- 32 percent obtained information on formularies, and

- 11 percent used IT to write prescriptions (Reed 2004).

This survey compares IT use by practice and personal characteristics of the physician. Physicians in group and staff model HMOs, practices with 50 or more physicians, and medical schools were most likely to use IT. Those in solo or small group practice were less likely to do so. By specialty, surgeons were less likely to be in practices that use IT than primary care physicians or those in medical specialties (Reed 2004). Some very large physician group practices, such as Harvard Vanguard Medical Associates in Boston, the Marshfield Clinic in Wisconsin, and Geisinger Healthcare in Pennsylvania, have developed and operated EHRs for 10 years or more.

The Healthcare Information Management Systems Society surveyed physician and practice managers and executives in 2003 on the use of IT in ambulatory settings. Only 16 percent of the respondents (compared with about 35 percent of physicians nationwide) were in a practice with 1 or 2 physicians. Given that physicians in larger groups are more likely to use IT, respondents likely represent physicians that use IT more than the national average (HIMSS 2004b).

The survey found widespread use of handheld technology, but significantly lower use of EHRs and e-mail for communicating with patients. The majority of survey respondents indicated that physicians have personal digital assistants or some other form of handheld technology (71 percent), used most commonly as a portable drug reference. Less common uses include scheduling, e-prescribing, better documenting care to facilitate billing (“charge capture”), dictating, and accessing information in an EHR. Sixty-two percent reported that they did not have an EHR, while small shares indicated that one was present in all departments within their organization (24 percent), or in some departments (15 percent). Only 17 percent indicated that they or physicians in their organization communicate with patients about clinical issues via e-mail. Reasons for not doing so included legal concerns, HIPAA privacy concerns, and, to a much lesser extent, lack of reimbursement.

A recent survey by Modern Physician/Pricewaterhouse Coopers (436 respondents) suggests increases in the use of IT by physicians. The survey was conducted online, however, which may bias the results toward users of IT. Forty-one percent of respondents indicated that their organizations have invested in an EHR, with investment

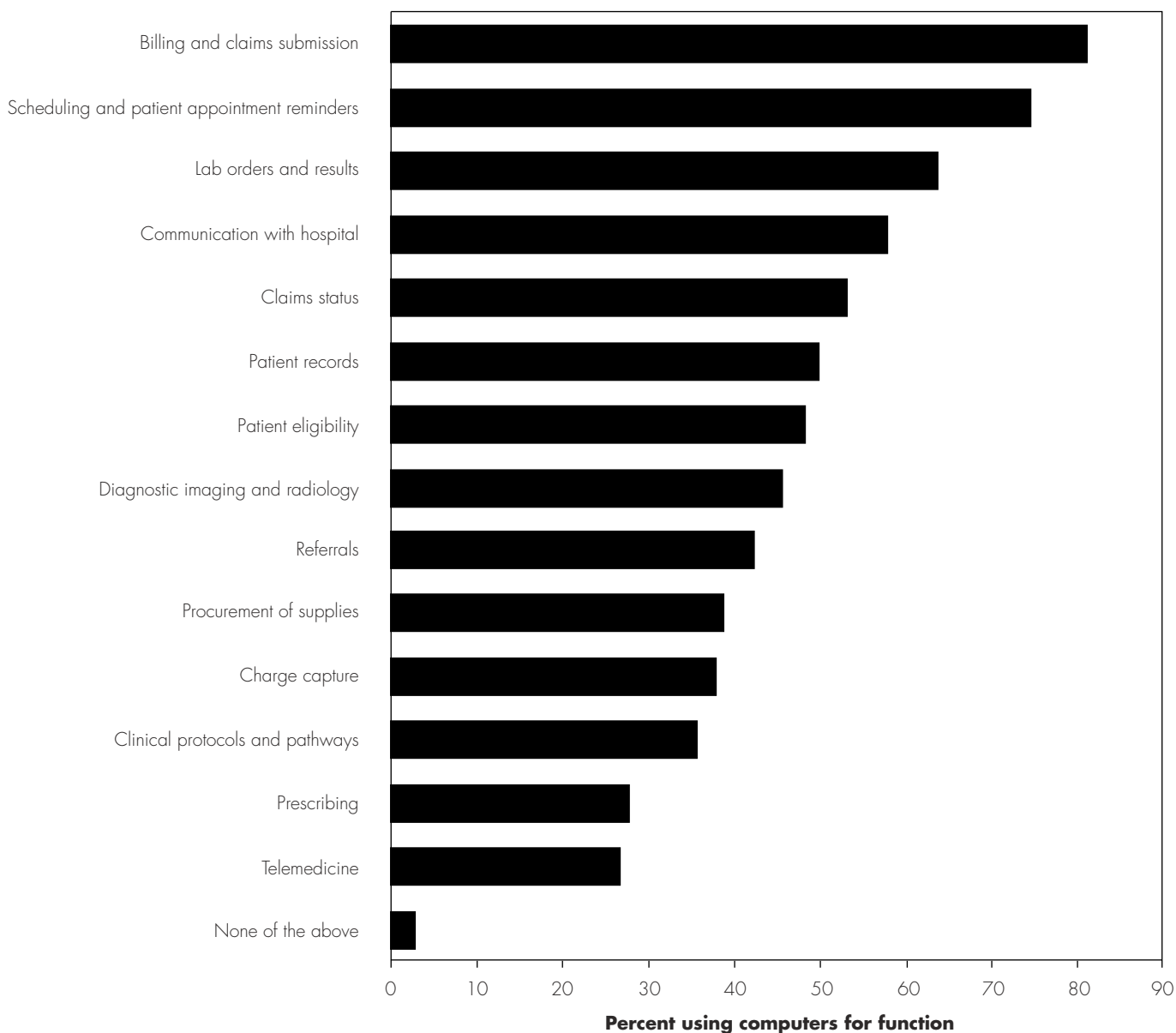
more likely in hospital-affiliated practices (61 percent) than in independent group practices (37 percent) (Versel 2003). This echoes the findings by HSC, where practice type was a predictor of IT use.

Physicians also reported using computers more for administrative functions than for clinical functions

(Figure 7-2). The most common uses included billing or claims submission and scheduling or patient appointment reminders. Placing lab orders or getting results by computer was also common. Small shares of respondents reported that physicians used computer-based systems to access clinical protocols or pathways, write prescriptions, or conduct telemedicine.

FIGURE 7-2

Physicians use computers more for administrative than clinical functions



Note: The survey asked, "What do your physicians use computer-based systems for?" Charge capture means better documenting care to facilitate billing.

Source: Modern Physician/PricewaterhouseCoopers survey of executive opinions on key information systems issues, Modern Physician, November 2003.

Drivers of adoption

As is the case with hospitals, a variety of motives influence physicians' use of IT. Financial returns are certainly one consideration. We found few studies, however, on the return on investment for physician use of IT. One might conclude that the widespread use of IT for administrative and financial functions (e.g., billing and accounting) indicates that these systems do bear a financial return, or are at least useful for practice management.

The evidence of a link between larger practice size and greater use of clinical IT suggests that having a larger revenue base or more complex practice with greater management capabilities allows larger groups to better support the sizeable investments needed to implement information systems. In addition, economies of scale reduce the per physician cost of investing for larger groups. Finally, larger groups may also have more need for IT to communicate within the practice.

Although clinical systems require up-front financial investment, some argue that physicians can benefit financially from the increased documentation of care, leading to fewer rejected claims and enhanced revenues (CITL 2003, Versel 2003). For EHRs, savings also accrue from reduced transcription and medical records management costs, as physicians enter information directly into the EHR and can retrieve information more efficiently (Miller and Sim 2004).

A qualitative study of 30 physician organizations that had EHRs found that the financial returns were uncertain, and depended on the extent to which physicians used the EHR (Miller and Sim 2004). The study found that "the path to quality improvement and financial benefits lies in getting the greatest number of physicians to use the [EHR] (and not paper) for as many of their daily tasks as possible." Some of the practices realized no financial gains, but a few realized gains of more than \$20,000 per physician per year. Physicians rarely used all the capabilities of the EHR, and most combined paper processes with the EHR.

A recent study looked at the value of CPOE in ambulatory settings and estimated that nationwide adoption could improve patient outcomes and save money for the health care system as a whole by avoiding adverse drug events and related hospitalizations, and by suggesting cost-effective use of medications, lab tests, and radiology (CITL 2003). These savings will not all accrue to the

providers implementing the system. However, the study projected that physicians could increase revenues through the use of IT by reducing the cost of rejected claims by at least \$10 per outpatient visit.

Both financial and nonfinancial incentives encourage physician use of IT. In a recent survey, physicians indicated that improving business performance, improving the clinical quality of care, and managing growth in the size of the physician practice motivated the adoption of IT (Versel 2003). Moving to an EHR can decrease storage costs for medical records; increase access, security, and efficiency of medical records; and improve documentation. Rooms previously used for storing paper records may be converted to patient exam rooms. In addition, some insurers are providing discounts on malpractice when physicians have IT systems because they provide better documentation of the care provided (Scalet 2003).

Advances in technology or financing arrangements may further spur use. Open source software that has no licensing requirements can lower the cost of technology. In addition, some specialty organizations have negotiated discounts from vendors for their members. Alternatively, application service providers have begun to promote arrangements in which they own and maintain the software and store data for physicians, who pay a monthly access fee (Chin 2004).

Barriers to adoption

Many barriers slow physician adoption of IT. The costs of investing in IT can be significant, the financial return is not certain, and any financial benefits will not necessarily all accrue to the physician practice bearing the costs. Most current payment policies do not include incentives for use of IT. The small size of many practices makes the start-up and maintenance costs of IT systems difficult to manage. Costs vary tremendously with the characteristics of the practice and the applications involved. In one study, the average cost of an EHR varied from \$16,000 to \$36,000 per physician (Miller and Sim 2004). Even if cost is not an issue, the complexity of the technology, limitations in the products currently on the market, and the time it takes to complete implementation pose barriers. Implementing and supporting IT applications requires skills that have not traditionally been part of a medical practice. In addition, physicians must make significant changes to both office and physician workflow and take time away from seeing

patients to learn how to use IT (Brailer and Terasawa 2003, Miller and Sim 2004).

Beyond the financial and technological concerns, the use of electronic systems for clinical reminders may not agree with some physicians' clinical practice styles, which may rely primarily on their knowledge and experience. In addition, use of computers may be seen as interrupting the physician-patient relationship by drawing away from the personal interaction. These systems may add to a physician's workload, rather than alleviating it, particularly in the initial implementation (Brailer and Terasawa 2003, Miller and Sim 2004).

Linking health care providers through information technology

For information technology to become widespread, individual providers must adopt it. Once that happens, connecting them electronically could bring additional benefits. Health care today involves considerable sharing of information among providers such as physicians' offices, hospitals, imaging centers, and clinical laboratories, as well as among providers and payers. A health care information infrastructure would provide the networks and standards to allow providers within a community to share information electronically. In addition, patients could use it to access their medical records or other health care information from all providers. A primary focus of those advocating a health care information infrastructure is development of standards for messaging so that one IT system can communicate with another.

Few systems allow communication among providers today, although some cities are sharing information across emergency departments. Two communities have moved to have a more comprehensive ability to share information. In Indianapolis, an intranet connecting some hospitals to facilitate sharing of clinical information is under development. In California, Santa Barbara County has a central system collecting radiology, pharmacy, and lab reports that can be accessed by providers, payers, and laboratories (Broder 2004).

Some see a health care information infrastructure as a key building block to encourage investment by providers and increase its value. The goal is interoperability—the ability for information to flow among settings of care. The information infrastructure would consist of standards and networks that allow electronic communication among

providers, so that, for example, the electronic record created during a hospital stay is accessible to the primary care physician, or even becomes part of the electronic record maintained by the primary care physician. Interoperability could increase the usefulness of implementing IT and decrease the risk of investing in a system that might quickly become obsolete. The health care information infrastructure has been a major focus of the Department of Health and Human Services (HHS) and a number of private initiatives, such as the eHealth Initiative and projects at the Markle Foundation.

A study to be released in 2004 suggests that standardized health care information exchange could reduce national health care spending by automating how providers share data (CITL 2004). Currently, telephone, fax, and mail are most often used for communication among health care providers. Patients themselves also serve as a conduit of information among providers. Electronic communication could reduce repeat tests and expenses for administrative tasks. However, the low diffusion and riskiness of investment in IT suggest that interoperability is many years off. If providers do not have IT systems in place, an information infrastructure will have limited use. However, having an infrastructure in place may provide an incentive for further adoption.

Efforts to encourage faster diffusion

In the previous sections, we find that current levels of clinical IT diffusion are relatively low but increasing, and that rates of adoption vary by type of provider and technology. Barriers to adoption are multifaceted and complex, making investment in health IT a risky proposition for many providers. A primary driver of adoption of IT, the need to improve quality is compelling. We find potential for IT to improve quality and patient safety, but further evidence is needed. The question is not whether to push for further adoption, but how, and how fast. The implementation experience of those providers who have adopted various forms of IT suggest that caution is warranted to ensure effective, broad implementation.

Market forces that inhibit faster diffusion of health information technology

Research comparing diffusion of IT in different industries has identified two key criteria for broad diffusion: 1) the external market must reward the product of IT, and 2) the

organization must be capable of sustaining its commitment to IT and continually respond to changing needs of the users of the IT (Givens 2003). Certain attributes of the health care market may impede faster diffusion:

- Quality, a main reason for investing in IT, is not rewarded. While awareness of the problem is growing, payments for health care do not distinguish between providers who furnish a higher quality product and those who produce a lower quality product. Rather than rewarding higher quality, most fee-for-service payment systems emphasize volume of services. The current system rewards volume by paying every time a procedure or service is provided, regardless of its quality. This approach encourages adoption of technology that supports provision of a billable service, such as an MRI, over technology that might improve the quality of many services. This approach also leads providers to try to see as many patients as possible rather than ensuring that every patient receives the best care possible. Clinical IT applications sometimes add time to patient interactions with physicians, thus causing physician resistance to using IT, even though giving orders or having information available electronically could lead to higher quality care.
- The financial rewards may bypass the purchaser of IT. If a physician group invests in an IT system to better manage the care of their patients with chronic conditions, lower levels of hospitalization can result. But unless the change results in additional office visits, only the payer benefits financially; the physician group does not. If a hospital invests in CPOE to reduce adverse drug events, it could lead to fewer complications and readmissions—leading to cost savings for the payer, but lower payment for the hospital. Integrated delivery systems that combine insurance and service delivery functions are capable of capturing savings from the use of IT and tend to be more sophisticated users.
- The fragmented nature of health delivery also impedes further adoption. Without organized delivery systems, it is difficult for individual providers to adopt health IT applications capable of communicating across systems of care.

These broader market factors operate on top of the barriers to adoption noted previously, including the complexity of

implementation. The IOM recognized these complexities in its Crossing the Quality Chasm report.

“The challenge of applying information technology to health care should not be underestimated. Health care is undoubtedly one of the most, if not the most, complex sectors of the economy. The number of different types of transactions (i.e. patient needs, interactions, and services) is very large. Sizable capital investments and multi-year commitments to building systems will be required. Widespread adoption of many information technology applications will require behavioral adaptations on the part of large numbers of patients, clinicians, and organizations.”

The complexity and implementation costs are further exacerbated by the impression that vendors’ products do not necessarily perform as anticipated. On the recent HIMSS survey, the second most important reason given for not investing in IT was “vendors’ inability to effectively deliver products.”

Over time, the market may naturally ease some of these barriers. Development of improved products could reduce the hesitation to invest. Physician acceptance may accelerate with more user-friendly versions and experience. In the long term, adoption of uniform standards also should help providers share information across settings of care and make investment decisions less risky.

However, market barriers such as fragmentation and misaligned payment systems are fundamental problems. Current public and private efforts are attempting to correct for many of these, but more changes may be needed to create conditions necessary for health IT to become broadly available to providers and the patients they treat.

Public and private efforts

The initiatives described in this section, in one form or another, attempt to either strengthen the drivers of health IT or lower the barriers. Numerous public and private initiatives have generally focused on one or more of the following (Table 7-2):

- developing or adopting standards,
- providing incentives for providers to use health IT, or
- giving grants for research and implementation.

**TABLE
7-2**

Public and private health information technology initiatives

Standards	Incentives	Grants
<p>Public</p> <ul style="list-style-type: none"> • Transactions, privacy, security, and provider, plan, and employer identifiers (HIPAA) • HHS adoption of standards for federal agencies and EHR functionality initiative • E-prescribing standards (MMA) • IOM work to encourage use of IT in health care • Commission on Systemic Interoperability (MMA) 	<ul style="list-style-type: none"> • Physician incentives through Medicare demonstration and Medicare Advantage plans (MMA) • FDA requirement for manufacturers to barcode pharmaceuticals 	<ul style="list-style-type: none"> • Matching grants for e-prescribing (MMA) • AHRQ research on value of IT and implementation strategies
<p>Private</p> <ul style="list-style-type: none"> • Health Level 7 efforts to create functional model of EHR • Numerous private sector standards development efforts for administrative functions, prescriptions, labs, and clinical terminology • Physicians' and standard-setting groups' development of standard definitions and terminology for a continuity of care record. 	<ul style="list-style-type: none"> • Leapfrog efforts to encourage CPOE • Plan and purchaser inclusion of physician use of IT as a quality measure • AAFP effort to create affordable open-source architecture for small practices 	<ul style="list-style-type: none"> • Markle Foundation grants to eHealth Initiative • Regenstrief and Santa Barbara community grants

Note: HIPAA (Health Insurance Portability and Accountability Act of 1996), HHS (Department of Health and Human Services), EHR (electronic health record), IOM (Institute of Medicine), IT (information technology), MMA (Medicare Prescription Drug, Improvement, and Modernization Act of 2003), FDA (Food and Drug Administration), AHRQ (Agency for Healthcare Research and Quality), CPOE (computerized provider order entry), AAFP (American Academy of Family Physicians).

Several organizations, both public and private, are also attempting to coordinate the various stakeholders to ensure as focused an effort as possible. HHS is leading the National Health Information Infrastructure (NHII) initiative to coordinate public and private efforts to create a national infrastructure.

Private sector organizations, such as the eHealth Initiative and its affiliate, Connecting for Health (a group made up of a broad set of public and private sector stakeholders), and the National Alliance for Health Information Technology (a group made up of leaders from all health care sectors) are also funding strategic collaboration.

Standards development and adoption

Developing and adopting standards can help ensure a smooth flow of health information across providers.³ The Congress and HHS have focused on this need in the past few years.

Through HIPAA, the Congress required HHS to develop standards for transactions, such as billing and claims attachments, and required a standard policy related to the privacy and security of health information. These efforts created a base for standardizing health data more broadly. The privacy and security rules, for example, made discussions of broad sharing of patient information possible. However, while HIPAA required the development of standard ways to move administrative data, it did not address standardization of clinical data.⁴

Current HHS efforts are focused on adopting standardized clinical messaging mechanisms and terminology. In this arena, the public sector has been a catalyst to stimulate development and adoption, and the private sector has, for the most part, developed the standards.

The Department of Health and Human Services has taken a lead role to ensure that standards are adopted within the federal agencies and more broadly. Working with numerous private sector organizations and with other

federal agencies such as CMS, the Department of Veterans Affairs (VA), AHRQ, and the Department of Defense, it has broadly defined its goal as developing the NHII. The initiative is defined as “the technologies, standards, systems, values, and laws that enable health information to be appropriately and safely shared among all relevant health decision-makers to promote improvements in health and healthcare.” HHS’s goals include faster adoption of clinical IT in provider settings, and across providers and government agencies.

These goals require standard terms and messaging formats. HHS initiatives include:

- Giving providers the rights to use the Systemized Nomenclature of Medicine (SNOMED). HHS has obtained the rights to the comprehensive standard medical vocabulary of SNOMED and will make it available at no charge. Prior to this policy, providers had to pay for the rights to use this system for classifying clinical information.
- Working with the Health Level 7 (HL7) group, a private sector standards development organization, to define the functions of an electronic health record. As a first step, HHS asked the IOM to define the key capabilities of an EHR. The IOM defined five primary and five secondary uses of an electronic health record system upon which HL7 is basing its work.
- Adopting standards for use in electronic interactions within the federal government. Through the Consolidated Health Informatics (CHI) initiative, HHS is working with other federal agencies to adopt certain private sector standards for government agencies, such as CMS, the VA, DoD, and the Centers for Disease Control and Prevention (CDC). Through this effort, the federal government is hoping to prompt the private sector to standardize clinical and messaging terminology and logic. The CHI initiative set out to identify all aspects of health care delivery that may need to have standards and seek private sector organizations that already developed standards. CHI initiative staff analyze the standards’ utility with advice from private sector experts. The CHI initiative is focused on 24 clinical domains. Five standards were adopted by the federal government in March of 2003 (Table 7-3). On May 6, 2004, the Secretary announced that HHS had adopted 15 more standards for the electronic exchange of information across agencies.

**TABLE
7-3**

**Standards adopted by the
Consolidated Health
Informatics initiative**

Source of standard	Type of information
Health Level 7	Order entry, scheduling, admitting, discharge, and transfer
Joint Committee of the ACR and NEMA	Imaging information (DICOM)
National Council on Prescription Drug Programs	Drug ordering between retail pharmacies and health care providers
Institute of Electrical and Electronics Engineers	Information exchange between medical devices and the computer systems that receive the information (IEEE 1073)
Regenstrief Institute	Lab test result names (LOINC)

Note: ACR (American College of Radiology), NEMA (National Electrical Manufacturers Association), DICOM (Digital Imaging and Communications in Medicine), LOINC (Logical Observation Identifiers Names and Codes).

The MMA calls for further adoption of standards. To encourage use of e-prescribing in the new Medicare prescription drug benefit, the MMA required the Secretary to adopt standards for such transactions. The MMA also established a Commission on Systemic Interoperability. This commission is to study the best strategy, including a “timeline and prioritization for such adoption and implementation,” to create a nationwide system of interoperability of IT. The provision requires the commission to consider the costs and benefits of standards, both financial and qualitative; the current demand on industry resources to implement the MMA and other electronic standards, including those in HIPAA; and cost-effective and efficient ways for industry to implement the standards.

External incentives for use of health information technology

The primary driver of adoption—the relationship between IT and quality improvement—may be strengthened by grants for research on the value of health IT, but also by purchaser and plan expectations and incentives for high

quality care. The concept the Commission adopted in its June 2003 and March 2004 reports to include incentives for quality improvement in the Medicare payment system is one approach to encouraging use of IT. By rewarding a quality product, Medicare, in its purchaser role, could provide incentives for providers to adopt the technology necessary to improve quality. Other strategies include increased payment for use of certain forms of health IT and increased reporting on quality measures. Many organizations find that reporting on quality measures requires an information system to track and report data.

Our research found a variety of private sector models in which incentives for quality either directly or indirectly encouraged further diffusion of health IT. CMS has begun to explore some of these models through demonstrations. The MMA also included incentives for e-prescribing. These types of incentives are aimed at strengthening the drivers of health IT adoption by creating an external incentive for investment.

One way in which purchasers and plans are encouraging health IT use is by including measures of provider IT adoption in the quality indicators they use to reward providers. For example, the Leapfrog Group, an organization made up of large purchasers, has included the adoption of CPOE as one of its key patient safety goals. As a result, hospital adoption of CPOE has become a priority for some health plans. One health plan—Empire Blue Cross Blue Shield—in concert with several large employers gave direct bonuses to hospitals for implementing the Leapfrog goals, including CPOE. In Seattle, Boeing is charging employees no copay for using hospitals that meet Leapfrog Group standards, including use of CPOE. In other hospitals, patients will have to pay 5 percent of their bill (Freudenheim 2004). The Bridges to Excellence initiative by several large employers has physician use of certain IT tools as one measure of physician quality. CMS is also considering such an approach in its Doctors Office Quality project.

A less direct approach to encouraging diffusion is to reward the outcome of implementing health IT, for example, higher quality. The relationship between rewarding providers for higher quality and implementation of IT is not proven. However, collecting and analyzing the data necessary to measure quality performance, and implementing process improvement, is easier with IT. Further, because an IT system can track patients and send physicians automatic reminders, physicians with IT can

identify patients who need certain diagnostic or preventive services.

Some private sector organizations are giving IT to providers. Anthem Blue Cross Blue Shield and Wellpoint are purchasing computers and certain software for many of the physicians in their networks. These plans expect to benefit from the purchase. While this practice does not appear widespread, a recent regulatory clarification may make it easier in the future. CMS recently issued a final rule implementing certain provisions of the Stark II Law which allows doctors to receive “technology items or services” to encourage them to participate in community-wide health information systems.

Mandating use of a specific technology is yet another approach. This has not been done directly. However, the FDA’s recent regulation requiring pharmaceutical manufacturers to place bar codes on their products points in this direction. While the rule does not require hospitals to purchase and use the technology necessary to read the codes on the pharmaceutical products, the FDA hopes the availability of the coding will encourage hospitals to do so. In addition, the Joint Commission on Accreditation of Healthcare Organizations recently proposed adding a requirement for bar coding in future hospital accreditation standards.

Grants for research and implementation

Public and private sector grants are funding research on the value of IT and implementation models for community-wide or provider-setting adoption. The Agency for Healthcare Research and Quality is allotting \$10 million in fiscal year 2004 to create a better research base on the value of implementing IT. The request for applications seeks information to allow stakeholders to make more informed decisions regarding adopting and using IT. AHRQ also has \$7 million available for assisting health care systems in planning successful health IT implementation and \$24 million for organizational and community-wide implementation.

The President’s budget request for 2005 calls for \$50 million more for hospital information technology grants through AHRQ. In addition, the MMA authorized \$50 million in 2007 and such sums as necessary in 2008 and 2009 for matching grants for physicians to purchase the software and hardware necessary to e-prescribe.⁵

The private sector has also used grants to fund efforts to encourage further diffusion. Some of these efforts are national collaborations around diffusion and community-level initiatives. The Markle Foundation has identified diffusion of health IT as a priority and funded a variety of efforts to identify strategies to encourage diffusion. In 2002, the Foundation convened and funded Connecting for Health, a group of more than 100 public and private stakeholders to work on data standards, privacy, and security issues, and to spur national efforts to create a national health information infrastructure. In 2004, the Robert Wood Johnson Foundation is acting as a partner with the Markle Foundation to fund Phase II, which will look at community-wide exchange of information, information sharing with patients, and adoption of data exchange standards.

The Healthcare Collaborative Network (HCN) is supported by Connecting for Health, the eHealth Initiative, and IBM. The HCN is a national demonstration project designed to show the feasibility of an electronic infrastructure. It involves the electronic exchange of lab results, prescriptions, and clinical procedures among several major delivery systems, including New York Presbyterian, Vanderbilt University Medical Center, and Wishard Memorial Hospital. Several government agencies—CDC, FDA, and CMS—are also involved.

To support community-level projects to exchange information electronically, the Foundation for the e-Health Initiative, with \$3.86 million in funding from the Health Resources and Services Administration's office for Advancement of Telehealth, will be giving grants to several communities for seed funding and other support for individual communities who are using IT to drive quality improvements.

In addition to these national efforts, local private sector groups have provided funding for two of the most well-known community-level initiatives. The Regenstrief Institute worked with hospitals in Indianapolis to create a secure platform to share patient information and is currently expanding its efforts to a broader group of providers. In Santa Barbara, the California Healthcare Foundation provided seed money to create a system for sharing patient information among a variety of providers and public health organizations.

Potential additional action

Over time, these efforts may speed adoption of health IT. Providers who have already implemented IT successfully did so over a lengthy time period and used a step-by-step approach. But significant barriers remain for many providers, and the market forces encouraging adoption are weak. Current efforts may need to be expanded or new strategies developed to stimulate broader diffusion of health IT.

Several legislative proposals, information technology experts, and research groups, such as the IOM, have suggested other ways to encourage faster adoption of IT.⁶ Options include:

- **Payment policy.** Purchasers and plans can encourage the adoption of IT by: 1) paying more to providers who adopt certain forms of information technology or 2) paying more for the quality product that may result when information technology is used. The private sector is using some of these payment options. However, as yet, the government has not chosen to adopt them.
- **Loan funds.** To provide the necessary investment funds, some have suggested establishing a health technology loan fund or regional funds. The concept, outlined in a paper written by The Health Technology Center, and widely discussed, described a revolving fund that would be administered at the state level with matching state and federal dollars (The Health Technology Center 2003). These types of funds could also be funded by private foundations. The state-level affiliates would decide how the loans would be distributed, including the types of information technology appropriate for support and the amounts and terms of the loans. These loans could also be used to leverage investment from capital markets.

While loans would address the cost barrier, it would be important to ensure that those who qualified for the loans had the capacity to implement and continue to support the health IT. We found through our analysis that organizations often took a step-by-step approach to implementation, beginning with limited applications, and broadening the functions used over a period of several years. To do so required strong leadership, clear strategies for retraining all levels of personnel, and a commitment to redesigning the care

process without disrupting clinical care. Loan recipients will need this level of commitment and infrastructure for implementing health IT. Without such an infrastructure, the IT projects funded may fail, thus leading to further concern that implementing health IT is too risky. Because of the need to learn more about successful implementation strategies, loans might need to be tied to some evaluation strategy.

Loans would also need to be well targeted to organizations that cannot afford health IT on their own. As our analysis shows, health organizations of all types are beginning to adopt a wide variety of IT applications. In addition, some applications may be encouraged over others to ensure a step-by-step approach.

- Grants. The federal government and private foundations are already using grants to spur further diffusion, but these efforts could be expanded. Federal grants could encourage further private sector investment. The proposal discussed above for establishing loan funds also envisions some grants. In designing grant programs, strong criteria for evaluation would allow learning from the grantees' lessons that could be applied more broadly. In addition, the projects should be designed so that once the grant funding ends, the project can be self-

sustaining. In the long term, health IT must be sustained through market forces. It would also be important to target funds to those who are unable to invest on their own.

- Requirements to adopt specific technology. The Medicare program or private payers could also require providers to adopt certain types of technology, such as CPOE for hospitals. Alternatively, the government or other payers could require organizations to perform the types of functions for which IT is often used. For example, CMS could require physicians to keep track of preventive services given to diabetic patients through electronic patient registries or paper records. Over time, the provider may find adoption of IT to track patients more efficient.

Our review shows that IT use in health care is growing, but providers do experience barriers. Implementation is difficult, making the risk of investment high. Many public and private organizations support increased use of health IT, but more may be necessary. MedPAC will continue to monitor diffusion efforts, including assessing diffusion in settings other than hospitals and physician offices and looking at the impact of IT on consumers. We will also analyze in more depth potential public actions to encourage diffusion, including efforts within the Medicare program. ■

Endnotes

- 1 The Institute of Medicine identified the following core care delivery-related capabilities as necessary for an EHR that promotes patient safety: patient health information and data, results management, order entry, decision support, electronic communication and connectivity, patient support, administrative processes, and reporting and population health management. Few, if any, EHRs currently in use have all of these capabilities (IOM 2003).
- 2 The two-year implementation period allows for some exceptions.
- 3 While standards adoption is critical in the long run, in the short term, standards adoption could create switchover costs for some providers and slow purchasing decisions that are dependent on standards yet to be introduced.
- 4 HIPAA did require the National Committee on Vital and Health Statistics (NCVHS) to make recommendations on some forms of clinical coding. NCVHS has discussed whether to move from ICD-9-CM coding to ICD-10-CM. HIPAA also required and the Secretary adopted standards for pharmacy information.
- 5 For these funds to be used, the Congress will need to appropriate them in this year's budget.
- 6 The IOM has published a variety of reports on encouraging diffusion of health IT and the importance of health IT to quality delivery of health care. One specific proposal included in a report on graduate medical education was to base some of the distribution of indirect medical education funds on hospital adoption of IT.

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A P P E N D I X

A

**Review of CMS's preliminary
estimate of the physician
update for 2005**



Review of CMS's preliminary estimate of the physician update for 2005

Medicare's payments for physician services are made according to a fee schedule that assigns relative weights to services, reflecting resource requirements. These weights are adjusted for geographic differences in practice costs and multiplied by a dollar amount—the conversion factor—to determine payments. Thus, the conversion factor is a key element of the payment system. If it changes, there is a proportional change in the payment rates for all of the more than 7,000 services represented in the fee schedule.

The conversion factor is updated annually, based on a formula in law that is designed to control spending while accounting for factors that affect the cost of physician services. The Centers for Medicare & Medicaid Services (CMS) issues a final rule on the update in November of each year and implements the update on January 1 of the following year. To help the Congress and others anticipate the update, the Balanced Budget Refinement Act of 1999 (BBRA) requires CMS to prepare, by March 1 of each year, a preliminary estimate of the next year's update. The BBRA also requires MedPAC to review that estimate in the Commission's June report. This appendix fulfills the requirement that we review the estimate of the update for 2005.

In passing the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the Congress amended the update formula for physician services and required an update for 2005 of no less than 1.5 percent. CMS has estimated the update for 2005—based on the

formula but without the MMA minimum—at -3.6 percent. Thus, because of the statutory requirement for a minimum update, CMS concludes that an update of 1.5 percent is likely. MedPAC agrees that a 1.5 percent update is the most likely scenario. It is unlikely that the figure will be higher than 1.5 percent, because such an increase would require a large decrease in the volume of physician services, which is very unlikely based on historical trends.

In reviewing CMS's estimate, our purpose is not to assess the adequacy of the update.¹ Instead, the review that follows is limited to the technical issues involved in CMS's estimated update based on the statutory formula.

Calculating the update

Calculating the update is a two-step process. First, CMS estimates the sustainable growth rate (SGR). The SGR is the target rate of growth in spending for physician services and is a function of projected changes in:

- input prices for physician services,²
- real gross domestic product (GDP) per capita,³
- enrollment in traditional fee-for-service Medicare, and
- spending attributable to changes in law and regulation.

For 2005, CMS's preliminary estimate of the SGR is 4.6 percent (Table A-1).

**TABLE
A-1****Preliminary sustainable
growth rate, 2005**

Factor	Percent
Change in input prices	2.6%
Change in traditional Medicare enrollment	-0.2
Change in real GDP per capita	2.2
Change due to law and regulations	0.0
Sustainable growth rate	4.6

Note: GDP (gross domestic product).

Source: Gustafson 2004.

Second, CMS calculates the update, which is a function of:

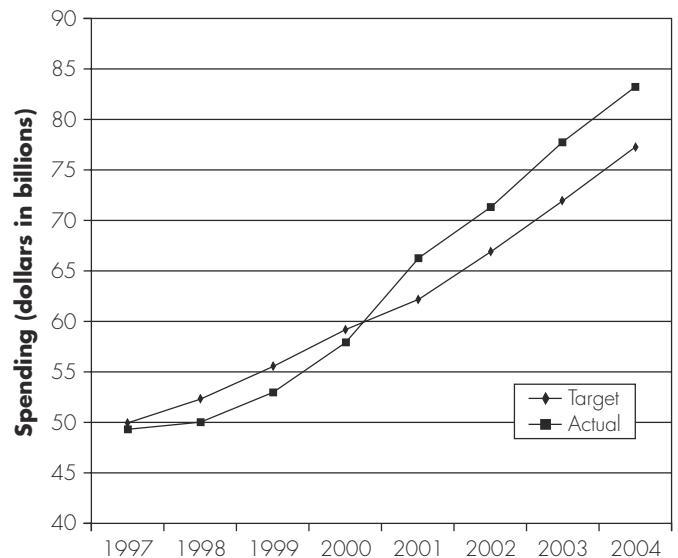
- the change in input prices for physician services,⁴
- a legislative adjustment required by the BBRA,⁵ and
- an update adjustment factor that increases or decreases the update as needed to align actual spending, cumulated over time, with target spending determined by the SGR.

Of these factors, the update adjustment factor has the largest effect on the update estimate for 2005 (Table A-2). For 2005, the figure is -7.0 percent, which is the maximum negative adjustment permitted under current law.⁶ The factor is negative because actual spending for physician services started to exceed the target in 2000 and is projected to stay above the target at least through 2004 (Figure A-1). When this adjustment is combined with the

**TABLE
A-2****Estimate of the update for
physician services, 2005**

Factor	Percent
Change in input prices	2.8%
Update adjustment factor	-7.0
Legislative adjustment	0.8
Update	-3.6

Source: Gustafson 2004.

**FIGURE
A-1****Estimated actual spending for
physician services to exceed
target through 2004**

Source: Office of the Actuary 2004 and Gustafson 2004.

other factors that determine the update for 2005—a change in input prices of 2.8 percent and a legislative adjustment of 0.8 percent—the result is an update of -3.6 percent.

Reviewing CMS's estimate

For the 2005 SGR, MedPAC anticipates no changes in CMS's estimates that will be sufficient to alter the update. The estimate of the change in input prices, as measured by the Medicare Economic Index (MEI), is similar to changes in the MEI for earlier years.⁷ The change in real GDP per capita of 2.2 percent equals the 10-year moving average of real GDP estimates from the Bureau of Economic Analysis, adjusted for population growth (BEA 2004).

On issues related to the other two factors in the SGR—enrollment and spending due to changes in law and regulation—CMS's estimates may be somewhat less certain. CMS assumes a decrease in fee-for-service enrollment of 0.2 percent. This is different from the enrollment projection from the Congressional Budget Office (CBO), which is an increase in fee-for-service enrollment of 0.9 percent for 2005. A decrease could

occur, but only if there is a shift in enrollment from Medicare fee-for-service to Medicare Advantage.⁸ CMS's ability to project the magnitude of any such shift should improve as we gain further experience with Medicare Advantage. This experience is critical because of the importance of enrollment growth in determining the SGR, and therefore, the target for spending over time.

As to changes in spending due to law and regulation, CMS estimates no changes for 2005 because of offsetting provisions in the MMA. Under the law, several new benefits will start in 2005: a preventive physical for new beneficiaries, cardiovascular screening blood tests, and diabetes screening tests. In addition, spending will increase because of incentive payments for physician services furnished in physician scarcity areas and health professional shortage areas. The total increase in spending—the incentive payments plus the new benefits—will equal \$230 million, according to CMS's estimates.

By contrast, other requirements in the MMA will result in a decrease in payments—payments for administration of drugs covered by Medicare Part B—in 2005. The decrease will occur because of a drop in the size of a transitional adjustment in 2005, compared to 2004. The adjustment will drop from 32 percent to 3 percent, as a percentage of payments for drug administration under the physician fee schedule. CMS estimates that this decrease will equal \$200 million and will almost fully offset the increases in spending due to the new benefits and the incentive payments.⁹

In reviewing CMS's estimate of the law and regulations factor for the SGR, we learned from CBO that they do not independently calculate this factor. However, CBO agrees that the cost-increasing and cost-decreasing provisions in the MMA approximately offset each other.

MedPAC cannot assess the magnitude of these estimates. Nevertheless, we judge that the estimates, and the difference between them, are not large enough to change the update for 2005.

The remaining issues concern CMS's estimates of actual spending. Data on actual spending are nearly complete through the first three quarters of 2003 but are less complete for the last quarter of that year. Therefore, the estimate of actual spending in 2003 may increase or decrease somewhat before CMS issues a final rule on the update in November 2004. The uncertainty regarding 2004 estimates is greater than for 2003 because CMS currently has no information on actual spending for that year. The agency has responded to this uncertainty by using stochastic projection techniques to analyze variation in the update adjustment factor (Office of the Actuary 2004). Under a range of possible scenarios for growth in real GDP per capita and growth in the volume of physician services, the analysis shows a 95 percent probability that the update adjustment factor will equal the maximum negative adjustment of -7.0 percent.

A maximum negative adjustment has such a high probability because a different outcome would require an uncharacteristic decrease in spending for physician services in 2004. An update of 1.5 percent for 2004 has already occurred. Without a sudden shift of enrollment from Medicare fee-for-service to Medicare Advantage, the only way for spending to fall is through a substantial decrease, at least 4 percent, in the volume of physician services per beneficiary. Such a decrease is very unlikely, however, based on historical trends. Since 1999, for example, volume has increased at an average annual rate of about 5 percent per year. For this reason, MedPAC agrees with CMS's conclusion that the update for 2005 is likely to equal the MMA minimum of 1.5 percent.

Endnotes

- 1 MedPAC recommended an update for 2005 of 2.6 percent (MedPAC 2004).
- 2 For the SGR, physician services include services commonly performed by a physician or performed in a physician's office. In addition to services paid for under the physician fee schedule, these services include diagnostic laboratory tests and drugs covered under Medicare Part B. To estimate this factor, CMS uses a weighted average of the Medicare Economic Index (MEI), a measure of changes in input prices for physician services, the change in payment rates for laboratory services legislated by the Congress, and a weighted average of the change in payment rates for Part B-covered drugs.
- 3 As required by the MMA, the real GDP per capita factor in the SGR is measured as a 10-year moving average.
- 4 For the update, physician services include only those services paid for under the physician fee schedule.
- 5 This adjustment maintains the budget neutrality of a technical change in the calculation of the update intended to reduce year-to-year changes in the conversion factor.
- 6 Without this limit, CMS estimates that the adjustment would equal -10.0 percent.
- 7 Historical changes in the MEI are published by the CMS Office of the Actuary (2004).
- 8 For 2005, CBO projects an overall increase in Medicare Part B enrollment of 1.4 percent.
- 9 There is a difference of \$30 million between the spending increases and the spending decrease. This difference is not large enough to appear in the SGR as a change in spending due to law and regulation because it is less than 0.1 percent of spending for physician services.

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A P P E N D I X

B

**Beneficiaries' financial
resources and liability
for health care costs**

Beneficiaries' financial resources and liability for health care costs

As part of its mandate, MedPAC is charged with monitoring Medicare beneficiaries' access to care. Access to care has many dimensions. The extent of health insurance is an important one. Health insurance enables access to care by reducing cost to patients at the point of service. Medicare beneficiaries all have health insurance, but the Medicare benefit package does not cover all services and, like most forms of insurance, requires cost sharing for most of the services it covers.

Many Medicare beneficiaries obtain supplemental coverage to pay for Medicare cost sharing and services Medicare does not cover. Different forms of supplemental coverage are not equally comprehensive, and some require premiums. Medicaid coverage is the most comprehensive and does not require payment of a premium (see discussion of dual eligibles in Chapter 3). Coverage offered to retirees by previous employers and unions (called employer-sponsored insurance or ESI) and coverage offered by Medicare managed care plans has typically been relatively comprehensive and available at relatively modest premiums—but this varies greatly by ESI plan or Medicare managed care plan. Medigap, a common form of supplemental coverage, provides virtually complete coverage of cost sharing for Medicare-covered services, but very limited coverage of other health services.

This appendix provides an overview of the relationship between Medicare beneficiaries' out-of-pocket spending (defined as the sum of beneficiaries' payments for premiums, cost sharing for covered services, and spending

on noncovered services) and their financial resources. If we find that some beneficiaries have very high out-of-pocket spending relative to resources, this might raise some concerns about whether these beneficiaries have sufficient protection from their Medicare coverage and whether access to care may be a problem for them.

MedPAC analysis of access to care has found that beneficiaries with the most comprehensive types of supplemental coverage tend to report the best access to care. Further, those beneficiaries without supplemental coverage are the most likely to report delaying services that they believed they needed due to cost (MedPAC 2004).

The relationships among financial resources, out-of-pocket spending, and supplemental coverage are complex. For example, Medicare beneficiaries' supplemental coverage tends to vary with characteristics such as age and sex (MedPAC 2004), which are in turn related to resources (Aizcorbe et al. 2003). Further, beneficiaries with the most comprehensive coverage tend to use more health care services (Atherly 2001).

Measuring the relationship of out-of-pocket spending to financial resources

The analysis presented in the following pages compares beneficiaries' out-of-pocket spending to their financial resources for different groups and over time. The data are

for 2001 and earlier, so they do not reflect the changes to benefit design under Medicare or supplemental coverage that were required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). These changes, particularly coverage of drugs under a new Part D, should reduce overall out-of-pocket spending among beneficiaries.

Much of our analysis uses the Medicare Current Beneficiary Survey (MCBS). When using the MCBS, we exclude beneficiaries in Medicare managed care plans and those living in institutions. Excluding beneficiaries in managed care plans results in a more accurate portrayal of out-of-pocket spending because their health care expenditures tend to be underreported relative to beneficiaries in traditional Medicare. We exclude institutionalized beneficiaries because the MCBS does not have data on the premiums they paid for supplemental coverage, and data on their prescription drug expenditures are unreliable.

Out-of-pocket spending

Out-of-pocket spending is the sum of beneficiaries' own spending on:

- cost sharing for services covered by Medicare,
- services not covered by Medicare,
- the premium for Part B Medicare, and
- premiums for any insurance that supplements Medicare.

A MedPAC analysis of 2000 data found that among noninstitutionalized beneficiaries in traditional Medicare, 40 percent of out-of-pocket spending was for noncovered services, 31 percent was for supplemental premiums, 17 percent was for Part B premiums, and the remainder—12 percent—was for cost sharing on Medicare services (MedPAC 2003a). Of the out-of-pocket spending on services (covered and noncovered), prescription drugs had the largest share, comprising 18 percent of total out-of-pocket spending.

Resources

For this analysis we generally compare beneficiaries' out-of-pocket spending to their income, although we provide

some information on overall assets. We cannot use asset information in our analyses of out-of-pocket spending because available data sources do not permit this comparison.

However, assets are a vital part of beneficiaries' financial circumstances. Therefore, we analyze beneficiaries' assets in the first figure in this appendix, before analyzing financial liability. If we were able to include assets as well as income in our analysis, we would show lower shares of resources going to out-of-pocket spending.

Measuring financial liability

We estimate beneficiaries' financial liability (out-of-pocket spending relative to income) using two related but distinct measures. The first takes out-of-pocket spending as a share of income. The second calculates how much income remains after subtracting out-of-pocket spending (income net of out-of-pocket spending). Making the comparison using the second measure allows us to separate changes over time in the magnitude of growth in the two amounts. It does not always tell the same story as the first measure.

For example, take a person whose income rose from \$10,000 to \$15,000 over 5 years and whose out-of-pocket spending rose from \$1,500 to \$2,500 (both in real dollars). Using the first measure, out-of-pocket spending as a share of income, the beneficiary's situation appears to have worsened—it rose from 15 percent to 17 percent. But using the second measure, the beneficiary is better off in the later period, as his income net of out-of-pocket spending has risen from \$8,500 to \$12,500.

We based both measures of financial liability on beneficiaries' annual income and annual out-of-pocket spending. We used annual data because that is what is available in existing databases. However, for many people, out-of-pocket spending in the year of our analysis is much higher than their out-of-pocket spending in prior and subsequent years. Consequently, data over a much longer period than one year would yield a more accurate picture of a beneficiary's out-of-pocket spending relative to income and less variation in our measures of financial liability.

Data sources

The database we used the most in our analysis is the Cost and Use file of the 2001 MCBS. The MCBS is a beneficiary-level file with data on beneficiaries' income and very detailed information on their expenditures on health care. We are concerned, however, about underreporting of income and beneficiaries' prescription drug expenditures on the MCBS, so we made adjustments to those variables (see text box).

We also used a second database—the Consumer Expenditure Survey (CES)—which includes data on household income, assets, and out-of-pocket spending. However, the assets data are missing for a high proportion of households. Although the CES has poor assets data, it has reliable data on income and out-of-pocket spending over a long time frame. Therefore, we used the CES to analyze the change over time in out-of-pocket spending relative to income among beneficiary households.¹

Relationship of this to previous work

Several studies analyze beneficiaries' financial liability from out-of-pocket spending on health care services and insurance (Gross et al. 1997, Lee 1998, Maxwell et al. 2001, Maxwell et al. 2000, MedPAC 2000 and 1999, and Moon et al. 1996). The analysis presented here extends the work in those studies along several dimensions, analyzing these issues:

- The variation in financial liability across beneficiaries.
- The change over time in beneficiaries' financial liability from out-of-pocket spending on services and insurance.
- The impact on beneficiaries' financial liability of different supplemental coverage, focusing on reported declines in ESI as a source of supplemental coverage among future retirees.
- The effect of economic and demographic characteristics on beneficiaries' financial liability.

Data and methods

Our analysis uses two databases, the Cost and Use file of the Medicare Current Beneficiary Survey (MCBS) and the Consumer Expenditure Survey (CES). The MCBS includes data on individual beneficiaries, while the CES includes household data. Because of this difference, estimates of the same variable—such as out-of-pocket spending as a share of income—are different between the two databases.

The MCBS also has a general problem of underreporting income and prescription drug expenditures. Working with researchers at the Congressional Budget Office, we adjusted MCBS income amounts on the basis of beneficiaries' age, marital status, and income reported on the MCBS. The intent was to adjust the MCBS income amounts so that in the aggregate they match income amounts on the Current Population Survey (CPS). We caution, however, that the adjusted income amounts still may be too low because the CPS is believed to have

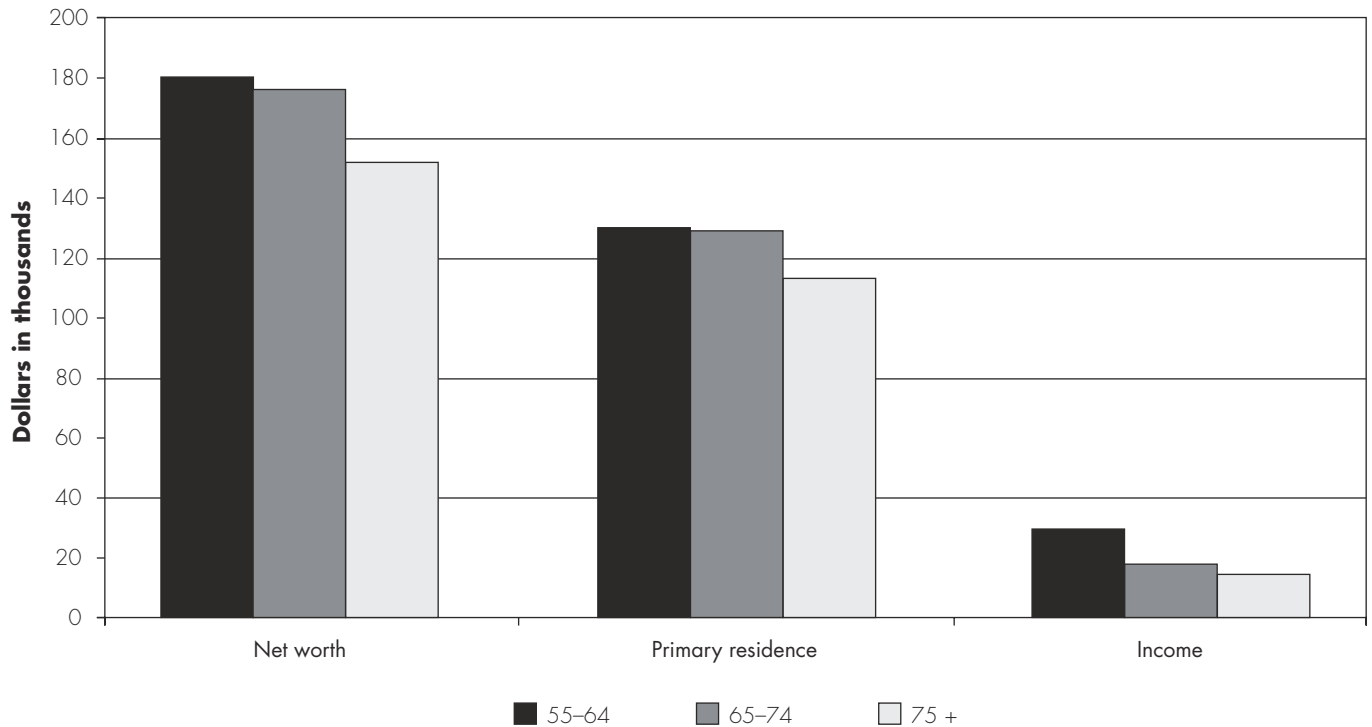
underreported income—but to a lesser extent than the MCBS.

We adjusted MCBS prescription drug expenditures using a method developed by a CMS researcher (Poisal 2004). The intent was to adjust MCBS drug expenditures so they match drug expenditures reported by the pharmacies that dispensed the drugs. Adjustments were based on the beneficiaries' reported level of drug expenditures. In general, the adjustment was greater the higher a beneficiary's reported drug expenditures.

An additional issue regarding income is that the MCBS reports income for married beneficiaries as joint income with their spouses. However, health care spending is reported at the individual level. Therefore, when we use MCBS data, we divide each married beneficiary's income by 1.26, the ratio of the poverty line for two-person elderly households to the poverty line for single-person elderly households. ■

**FIGURE
B-1**

**Median family net worth, primary residence assets,
and income by age of household head, 2001**



Note: "Primary residence" includes only families who have equity in a primary residence.

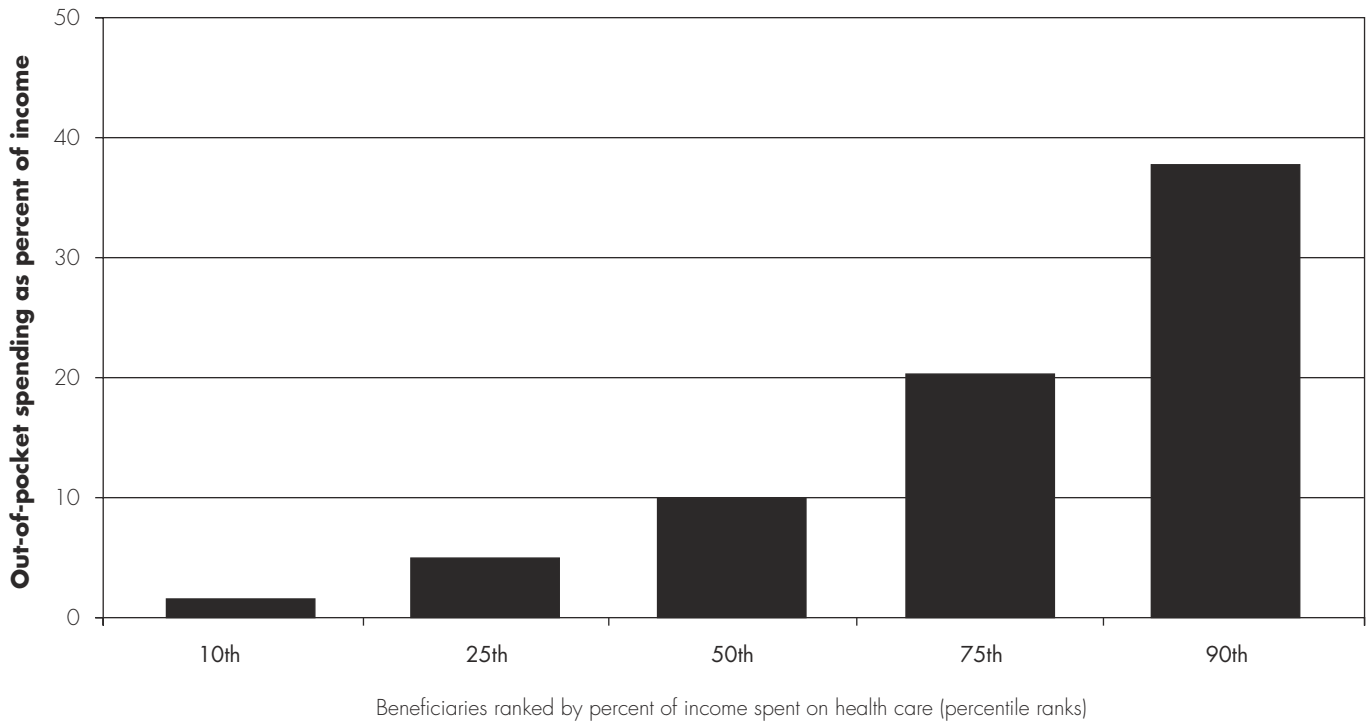
Source: Net worth and primary residence are from the Federal Reserve Board 2001 Survey of Consumer Finances. Income is from the 2001 Consumer Expenditure Survey.

Data from the Survey of Consumer Finances indicate that net worth (assets minus liabilities) tends to be lower among families with older heads of household (Figure B-1). In 2001, the median family with a household head age 65 to 74 had a net worth of \$176,000. Median net worth declined to \$151,000 for households headed by someone age 75 or older. Much of the wealth held by elderly households is in their primary residence. For example, among households headed by someone age 65 to 74 the median equity in their primary residence was \$129,000 in 2001.

We mentioned earlier that shortcomings in the data prevent us from using assets (or net worth) in evaluating beneficiaries' financial liability from health care costs. Instead, we rely strictly on beneficiaries' income. Among families with a household head age 55 or older, income tends to be much lower than net worth. But, a common characteristic of income and net worth is that both tend to be lower among families with older household heads.

**FIGURE
B-2**

Out-of-pocket spending on health care varies widely among beneficiaries, 2001



Note: Sample size is 9,653. Out-of-pocket spending includes out-of-pocket spending on services, the Part B premium, and premiums for supplemental insurance. Analysis is only beneficiaries living in the community who are not enrolled in a Medicare managed care plan.

Source: MedPAC analysis of Cost and Use file, 2001 Medicare Current Beneficiary Survey.

Financial liability from out-of-pocket spending varies widely among beneficiaries (Figure B-2). In 2001, out-of-pocket spending was 10 percent of income for the median (middle) beneficiary. Also, it was 2 percent of income for the beneficiary at the 10th percentile and 37 percent of income for the beneficiary at the 90th percentile.

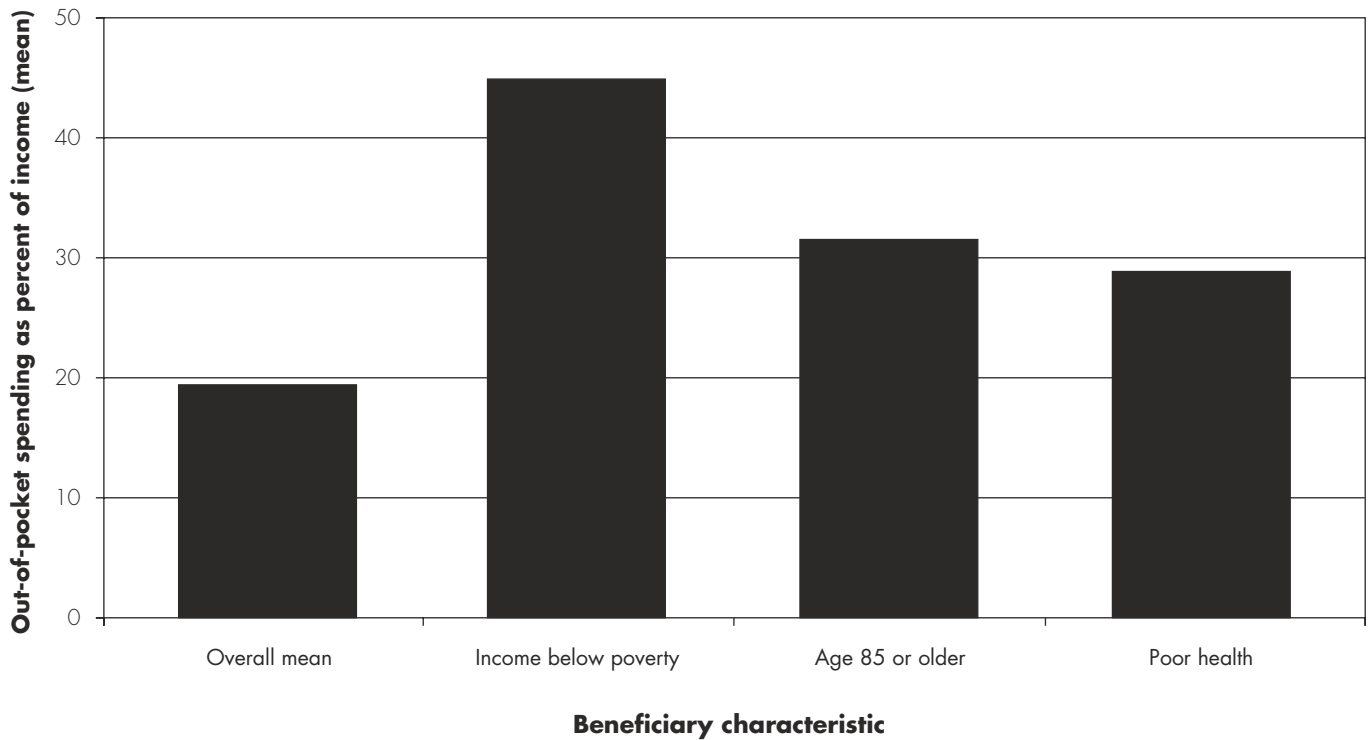
Financial liability from out-of-pocket spending is also likely to vary widely on a geographic basis. MedPAC analysis indicates wide variation across states and regions in the amount of health care services beneficiaries use (MedPAC 2001, 2003b). It is likely that beneficiaries in the states and regions with the highest service use per

beneficiary also tend to have relatively high out-of-pocket spending and financial liability.

Because of the wide variation in financial liability, it is difficult to pinpoint the financial liability faced by the “typical” beneficiary. Many researchers have used the mean of out-of-pocket spending as a share of income. We estimated a mean of 20 percent, but it may not provide a meaningful representation of the typical beneficiary. The mean of 20 percent is twice as large as the median value of 10 percent. Moreover, nearly three-fourths of beneficiaries spend less than 20 percent of their income on health care.

**FIGURE
B-3**

Out-of-pocket spending as a percentage of income is higher for certain beneficiaries, 2001



Note: Sample size is 9,653. Out-of-pocket spending includes out-of-pocket spending on services, the Part B premium, and premiums for supplemental insurance. Analysis is only beneficiaries living in the community who are not enrolled in a Medicare managed care plan.

Source: MedPAC analysis of Cost and Use file, 2001 Medicare Current Beneficiary Survey.

Our analysis of MCBS data indicates higher out-of-pocket spending as a share of income tends to be associated with certain characteristics (Figure B-3). These characteristics include:

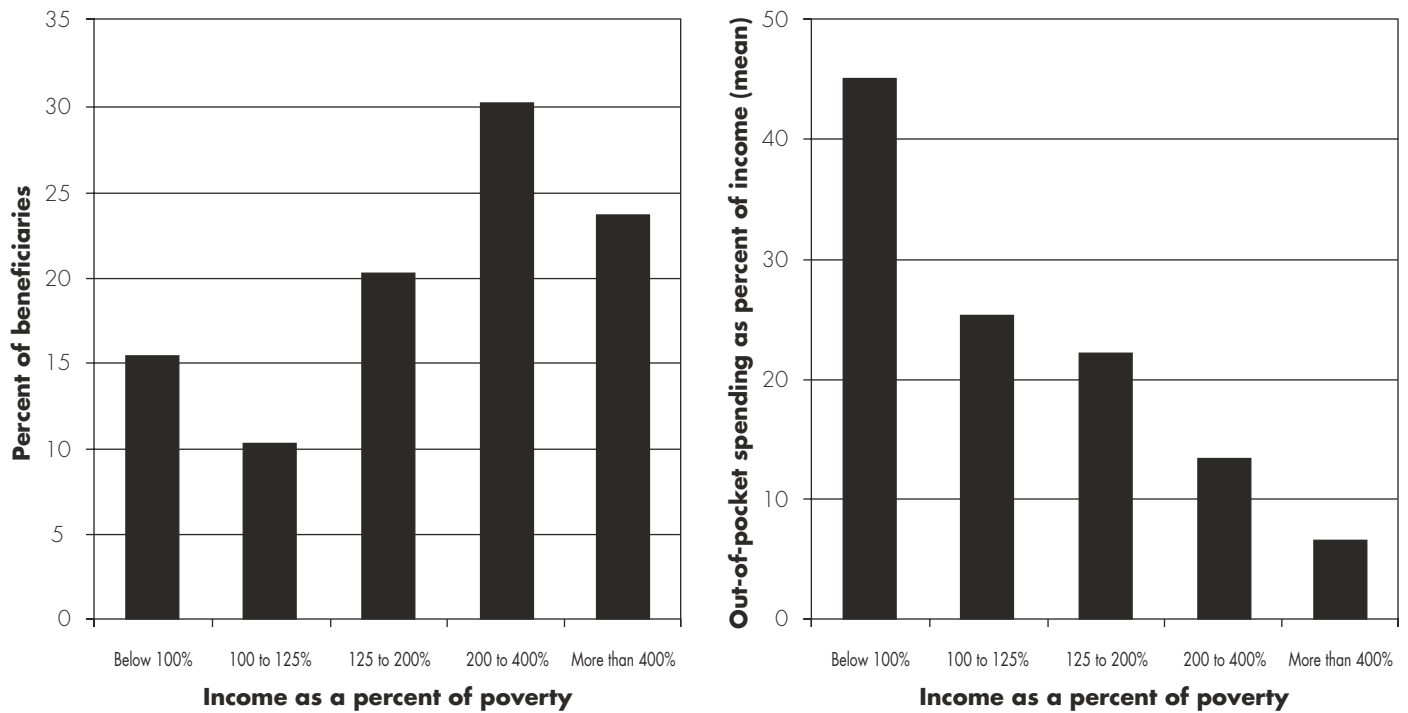
- income below poverty

- age 85 or older
- poor health status

In addition, other research shows that rural-dwelling beneficiaries spend a larger share of income on health care than their urban counterparts (Caplan and Brangan 2004).

**FIGURE
B-4**

Out-of-pocket spending as a percentage of income is substantially higher for low-income beneficiaries, 2001



Note: Sample size is 9,653. In 2001, the poverty level for people age 65 or older was \$10,715 for married couples and \$8,494 for people living alone. Out-of-pocket spending includes out-of-pocket spending on services, the Part B premium, and premiums for supplemental insurance. Analysis is only beneficiaries living in the community who are not enrolled in a Medicare managed care plan.

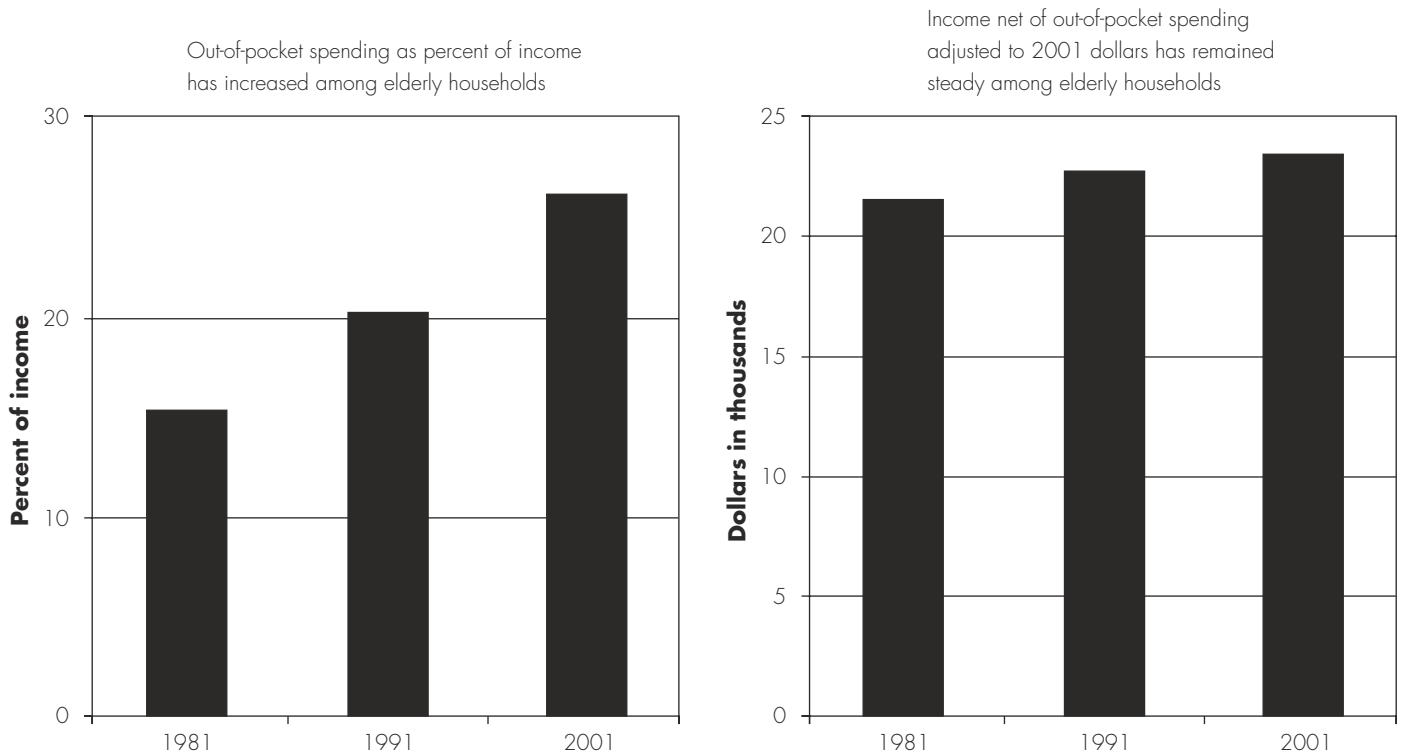
Source: MedPAC analysis of Cost and Use file, 2001 Medicare Current Beneficiary Survey.

Fifteen percent of beneficiaries report income below the poverty line.² An additional 10 percent report income between 100 and 125 percent of the poverty line. Among these lower-income beneficiaries, out-of-pocket spending as a share of income is high relative to higher-income beneficiaries (Figure B-4).

Out-of-pocket spending as a share of income averaged 45 percent among beneficiaries with income below the poverty line. In contrast, it averaged only 7 percent among beneficiaries with income greater than 400 percent of the poverty line.

**FIGURE
B-5**

Financial liability due to health care spending among households with elderly members, 1981–2001



Note: Sample size is 3,734 in 1981; 4,543 in 1991; and 6,429 in 2001. Out-of-pocket spending includes out-of-pocket spending on services, the Part B premium, and premiums for supplemental insurance. Analysis is only households with at least one person age 65 or older.

Source: MedPAC analysis of 1981, 1991, and 2001 Consumer Expenditure Survey.

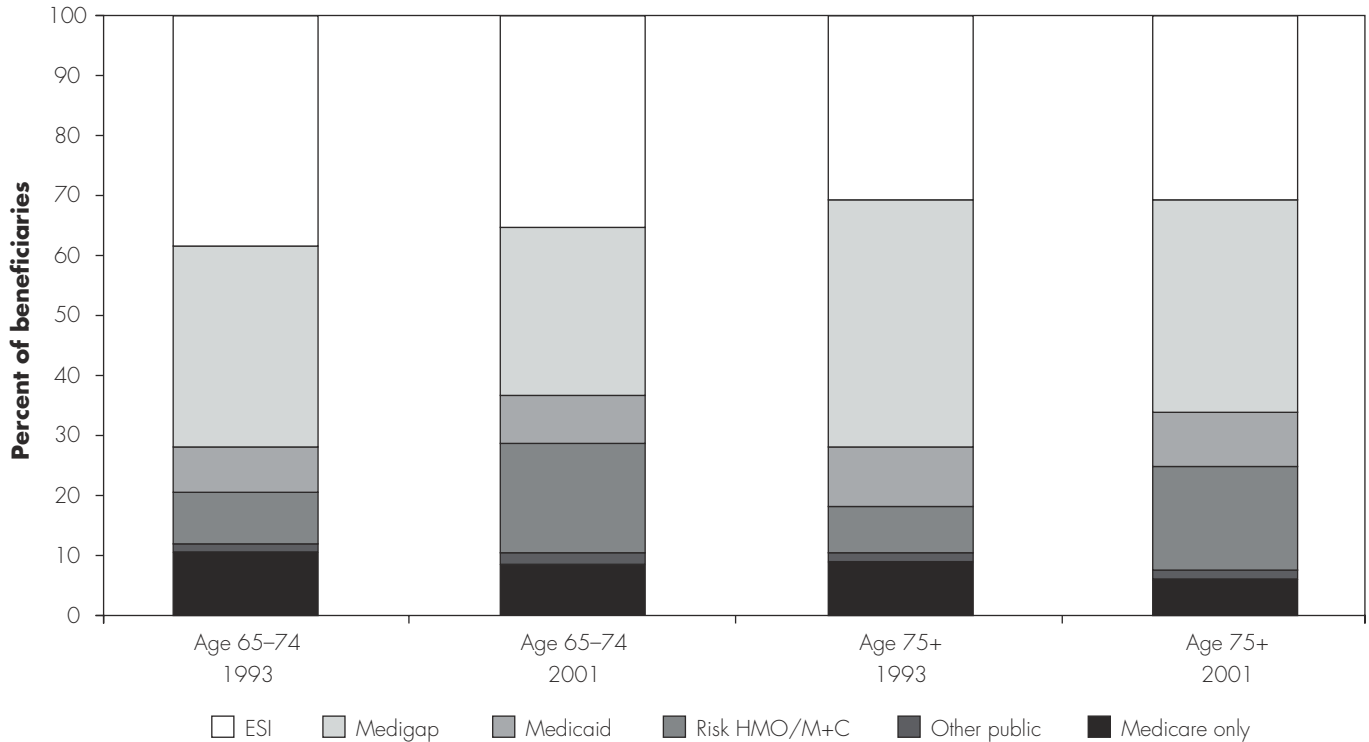
Is beneficiaries' financial liability getting better or worse? Our analysis of the Current Expenditure Survey produced mixed results; the answer depends on the measure (Figure B-5). On the one hand, from 1981 to 2001, out-of-pocket spending as a share of income increased substantially among elderly households (those with at least one member age 65 or older). This result reflects out-of-pocket spending increasing at a faster rate than income. From 1981 to 2001, average income among elderly households increased by 13 percent in real terms, while out-of-pocket spending increased in real terms by 58 percent. We

adjusted all dollar amounts to 2001 levels using the consumer price index.

On the other hand, an alternative measure of financial liability—*income net of out-of-pocket spending*—presents a different picture. After adjusting dollars to 2001 levels, the average income net of out-of-pocket spending among elderly households stayed nearly constant from 1981 to 2001, increasing by 8.8 percent (0.4 percent per year). This reflects the fact that income increased by a larger magnitude than out-of-pocket spending, even though income increased by a smaller percentage.

**FIGURE
B-6**

Employer-sponsored insurance has declined as a source of supplemental coverage among younger beneficiaries



Note: Sample size is 4,223 for age 65-74 in 1993; 4,379 for age 65-74 in 2001; 4,962 for age 75+ in 1993; 5,256 for age 75+ in 2001. ESI (employers-sponsored insurance), M+C (Medicare+Choice). Analysis is of beneficiaries living in the community only.

Source: MedPAC analysis of Cost and Use files, 1993 and 2001 Medicare Current Beneficiary Survey.

Medicare requires beneficiary cost sharing in the form of deductibles, coinsurance, and other mechanisms, and does not cover some services. In addition, Medicare does not have an annual limit on beneficiaries' out-of-pocket spending. In response, most beneficiaries have supplemental insurance. The most common type of supplemental insurance is employer-sponsored insurance (ESI) through previous unions or employers, held by 33 percent of beneficiaries in 2001.

ESI is, in general, the most comprehensive supplemental insurance in the private sector. In addition to providing coverage of Medicare deductibles, coinsurance, and catastrophic costs, many employer-sponsored plans are designed to wrap around Medicare, covering deductibles and coinsurance for covered services and additional services not covered by Medicare, leaving beneficiaries

with significantly less out-of-pocket spending than they would otherwise have.

Although it has been the most prevalent source of supplemental coverage, the availability of ESI has started to decline. Among beneficiaries age 65 to 74, the percentage with ESI had a small decline from 1993 to 2001 (Figure B-6). This result, however, hides the magnitude of the downward trend in availability of ESI. Between 1988 and 2003, the number of employers with more than 200 employees offering ESI fell from 66 percent to 38 percent (KFF and HRET 2003). In many instances, these changes affected new hires rather than those already in the workforce, so the impact of the reductions will affect future retirees much more than current beneficiaries.

**TABLE
B-1****Many large firms have eliminated health benefits for future retirees, and many more plan the same change**

	Percent of large firms	
	2001-2002	2003
Eliminated health benefits for future retirees	13%	10%
Somewhat likely to eliminate health benefits for future retirees over next 3 years	22	20

Note: Large firms have at least 1,000 employees.

Source: Kaiser Family Foundation and Hewitt Associates, 2004 and 2002.

The decline in the availability of ESI coverage for future retirees is evident in recent surveys of large firms (with more than 1,000 employees). Over the 2001–2002 period, 13 percent of large firms eliminated subsidized health benefits for future retirees (Table B-1). In 2003, an additional 10 percent of large firms eliminated such coverage. Moreover, about 20 percent of large firms in recent years said they are at least somewhat likely over the next three years to eliminate subsidized health benefits for future retirees (KFF and Hewitt Associates 2004 and 2002).

In addition to firms terminating health benefits for future retirees, many have recently required retirees to pay 100 percent of the premium for ESI coverage. Over the 2001–2002 period, 14 percent of large firms made this

change, and an additional 11 percent made the change in 2003. Also, 26 percent of large firms said they are somewhat likely to implement this policy over the next three years.

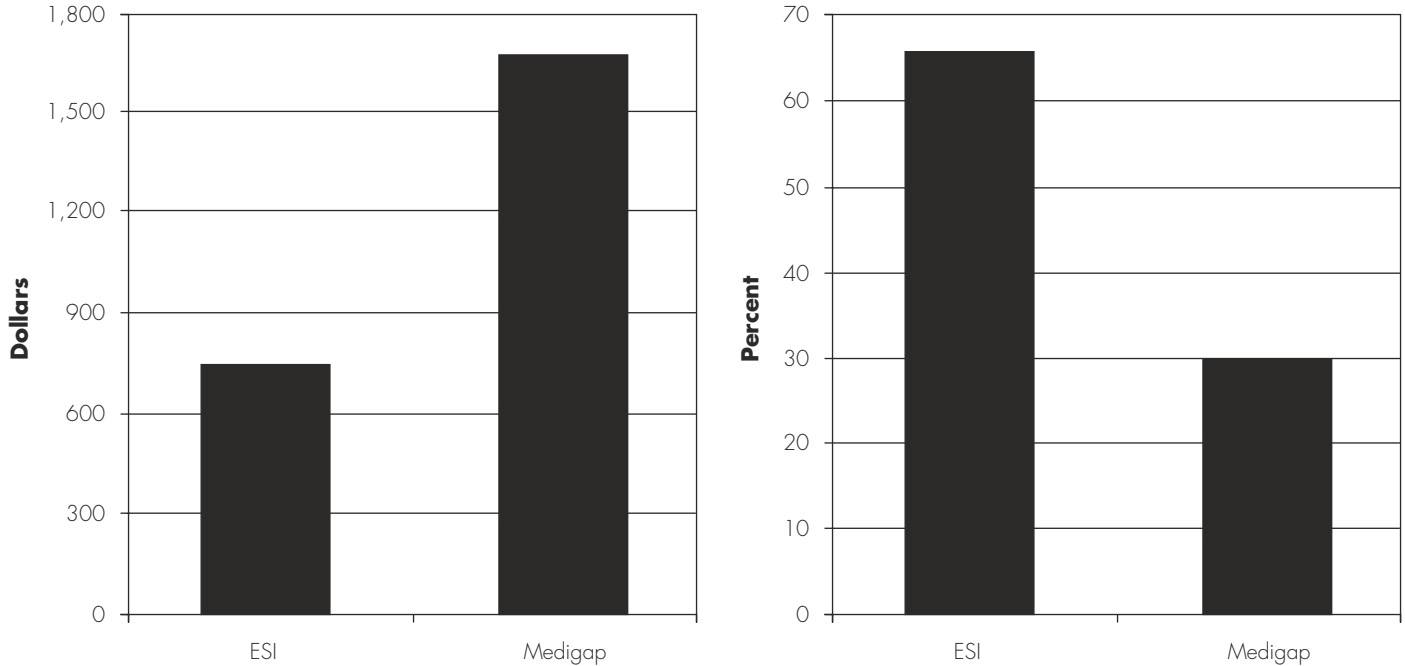
Finally, the Equal Employment Opportunity Commission recently voted to allow employers to offer health benefits to retirees under age 65 but reduce or eliminate benefits to retirees age 65 or older. Currently, employers have to offer the same coverage to all retirees. If the vote is allowed to stand, its effect on the prevalence of ESI among beneficiaries is unclear. Some employers may continue to offer ESI to 65 and older retirees that is less generous than the coverage for under-65 retirees. Alternatively, employers may eliminate altogether ESI coverage for 65 and older retirees (Pear 2004).

**FIGURE
B-7**

**Employer-sponsored insurance has lower beneficiary premiums
and is more generous than Medigap**

On average, beneficiaries with ESI pay less out of pocket for premiums

ESI pays a higher percent of health care costs not paid by Medicare



Note: ESI (employer-sponsored insurance). Sample size is 3,509 for ESI; 3,279 for Medigap. Analysis is only beneficiaries living in the community who are enrolled in ESI or Medigap plans.

Source: MedPAC analysis of Cost and Use file, 2001 Medicare Current Beneficiary Survey.

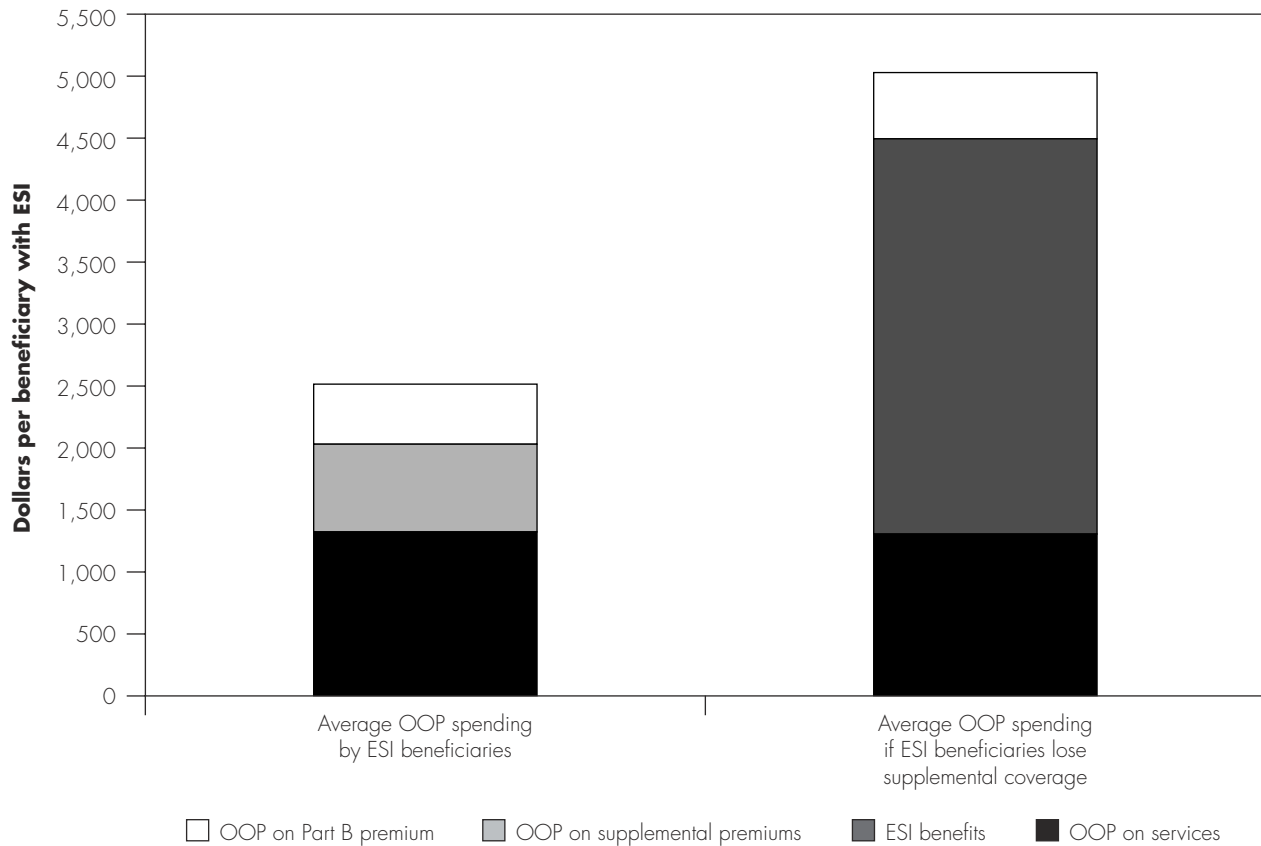
To the extent that the prevalence of ESI is declining, beneficiaries' out-of-pocket spending will likely increase, which could adversely affect access to care. One option for the future retirees whose firms have dropped their ESI coverage is to purchase a Medigap plan in the individual market.

On average, beneficiaries with ESI pay less out of pocket for premiums than beneficiaries with Medigap (Figure B-7). Also, ESI tends to be more generous. For

beneficiaries with ESI, supplemental insurance pays 65 percent of the costs not paid by Medicare, while Medigap pays 30 percent of costs not paid by Medicare. As a result, the future retirees whose firms have dropped their ESI coverage may pay more out of pocket for services and premiums if they obtain a Medigap plan. A recent study indicates that beneficiaries with Medigap need to save much more than do beneficiaries with ESI to pay for all health care costs in retirement (Fronstin and Salisbury 2003).

**FIGURE
B-8**

Out-of-pocket spending for beneficiaries with ESI would be higher if they had no supplemental insurance and did not change service use



Note: ESI (employers-sponsored insurance), OOB (out-of-pocket). Sample size is 3,509. Analysis is only beneficiaries living in the community who are enrolled in ESI plans.

Source: MedPAC analysis of Cost and Use file, 2001 Medicare Current Beneficiary Survey.

For future retirees whose firms have dropped ESI coverage, another option is to go without any supplemental insurance in traditional Medicare (Medicare only). Their out-of-pocket spending could be much higher under Medicare-only coverage than under ESI. In Figure B-8, the column on the left shows average out-of-pocket spending by ESI beneficiaries, and the column on the right shows average out-of-pocket spending if all ESI beneficiaries became Medicare only and did not change their service use.

In 2001, ESI beneficiaries averaged \$2,567 in out-of-pocket spending—\$1,319 on services, \$734 on supplemental premiums, and \$514 on Part B premiums. If these beneficiaries did not have any supplemental insurance, they would not pay any supplemental

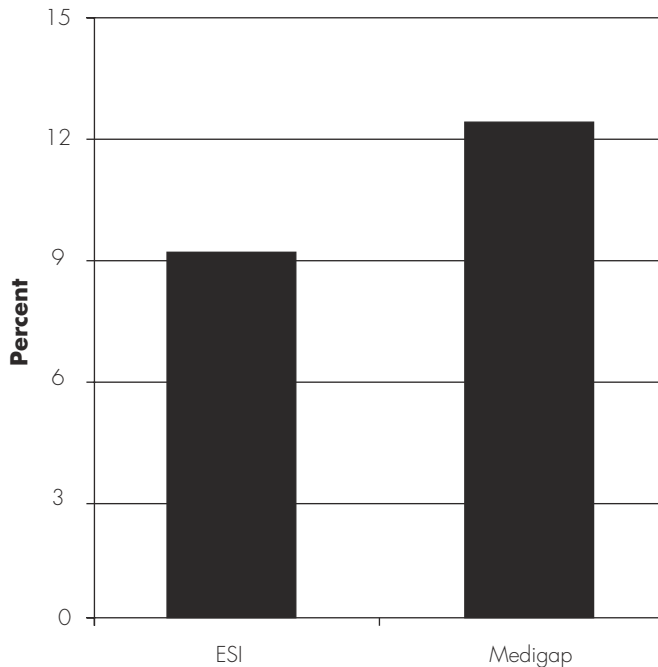
premiums, but they would still pay out of pocket for services and Part B premiums. In addition, they would have to pay out of pocket for the \$3,221 in benefits they currently receive from their ESI.³ On net, they would face an additional \$2,487 in out-of-pocket spending.

Having Medicare-only coverage in lieu of ESI would likely induce beneficiaries to reduce their use of services in response to their exposure to the cost sharing, which would reduce the impact on their out-of-pocket spending. However, in all cases beneficiaries would have a greater likelihood of catastrophic losses from health care expenses. If a beneficiary has out-of-pocket spending that is high relative to their income, they may qualify for Medicaid as “medically needy.”

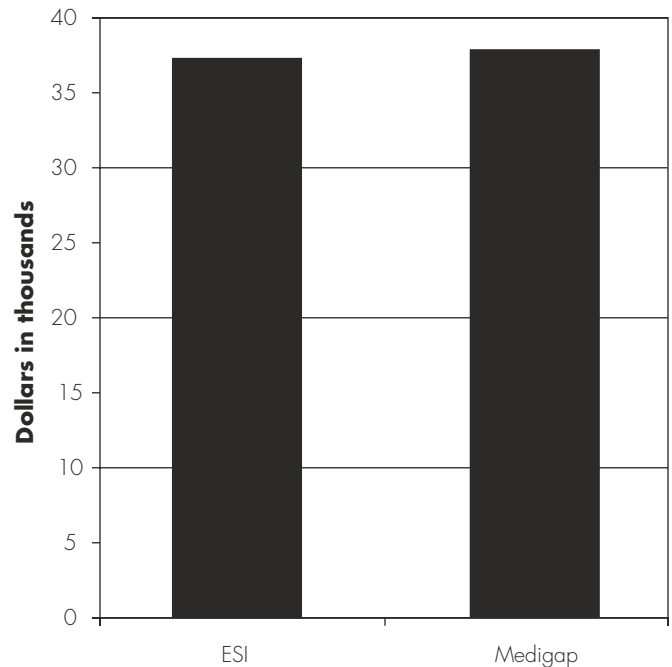
**FIGURE
B-9**

Among male beneficiaries, financial liability varies by supplemental insurance

Men age 65–69 with ESI pay a lower percent of income out of pocket than those with Medigap



Among men age 65–69, income net of out-of-pocket spending is similar for those with ESI and those with Medigap



Note: ESI (employer-sponsored insurance). Sample size is 365 for ESI; 227 for Medigap. Analysis is only beneficiaries living in the community who are enrolled in ESI or Medigap plans.

Source: MedPAC analysis of Cost and Use file, 2001 Medicare Current Beneficiary Survey.

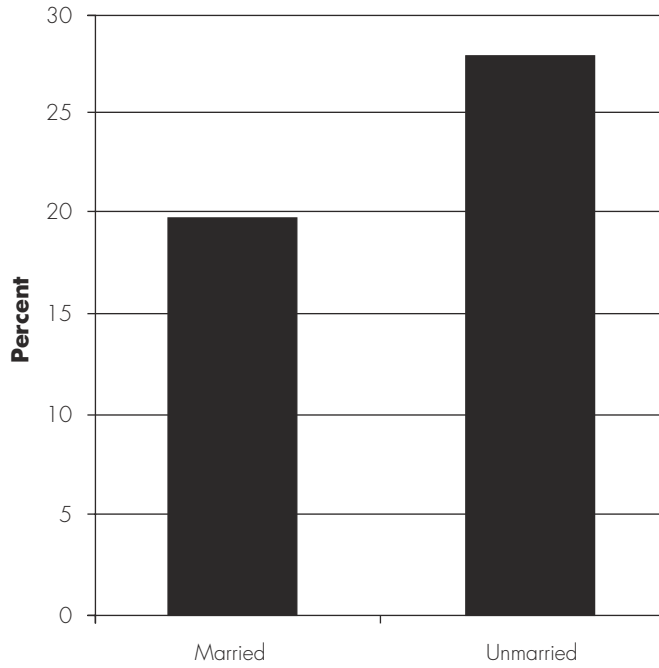
Our analysis has focused on the “big picture,” examining financial liability of broad Medicare populations. Over the next five pages, we narrow our focus and look at the financial liability of some “typical” beneficiaries. Our purpose is to investigate how demographic characteristics affect beneficiaries’ financial liability. Specifically, we examine the significance of age, marital status, gender, and supplemental insurance on financial liability.

Figure B-9 compares financial liability under ESI and Medigap for men age 65 to 69. The diagrams show how financial liability differs in this age cohort between those with ESI and those with Medigap. On average, out-of-pocket spending as a percentage of income is lower among those with ESI. But, because we find that 65- to 69-year-old men with ESI have lower average incomes, income net of out-of-pocket spending is nearly equal for those with ESI and those with Medigap.⁴

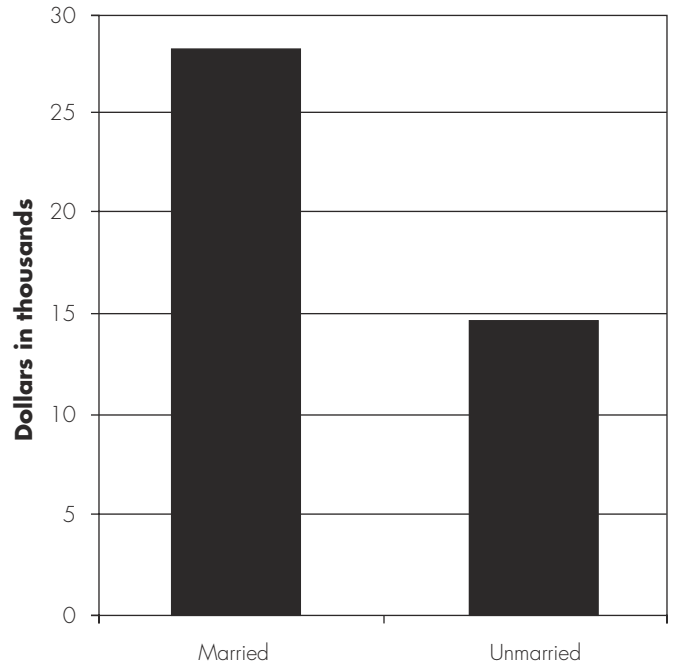
**FIGURE
B-10**

Among female beneficiaries, financial liability varies by marital status

Women age 75–84 who are married pay a lower percent of income out of pocket than those who are unmarried



Women age 75–84 who are married have higher income net of out-of-pocket spending



Note: Sample size is 632 for married; 1,173 for unmarried. Analysis is only beneficiaries living in the community who are women age 75–84 and are not enrolled in a Medicare managed care plan.

Source: MedPAC analysis of Cost and Use file, 2001 Medicare Current Beneficiary Survey.

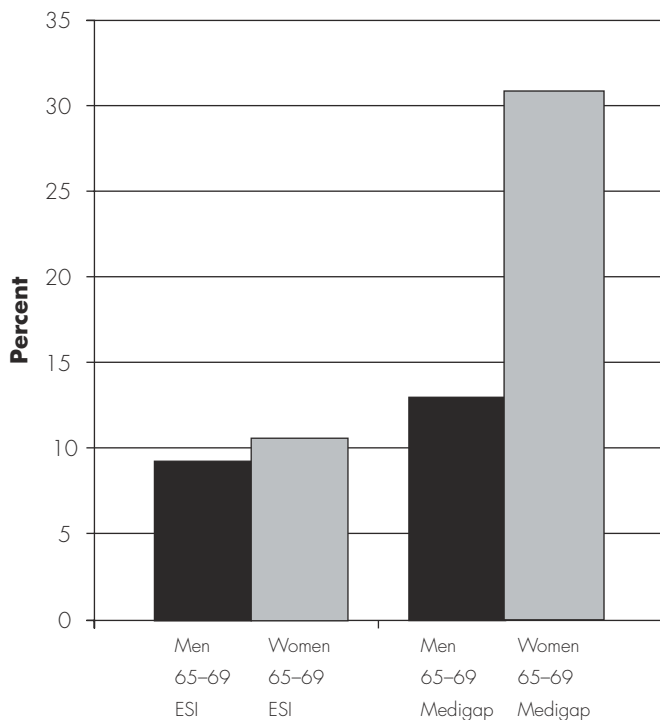
Within the cohort of women age 75 to 84, financial liability is much different for those who are married than for those who are not (Figure B-10). On average, out-of-pocket spending is 20 percent of income among married women age 75 to 84 and 28 percent of income among

those who are not married. Also, the average income net of out-of-pocket spending is \$28,000 among the married women and just under \$15,000 among the unmarried women. The lower liability faced by the married women reflects their substantially higher income, not lower out-of-pocket spending.

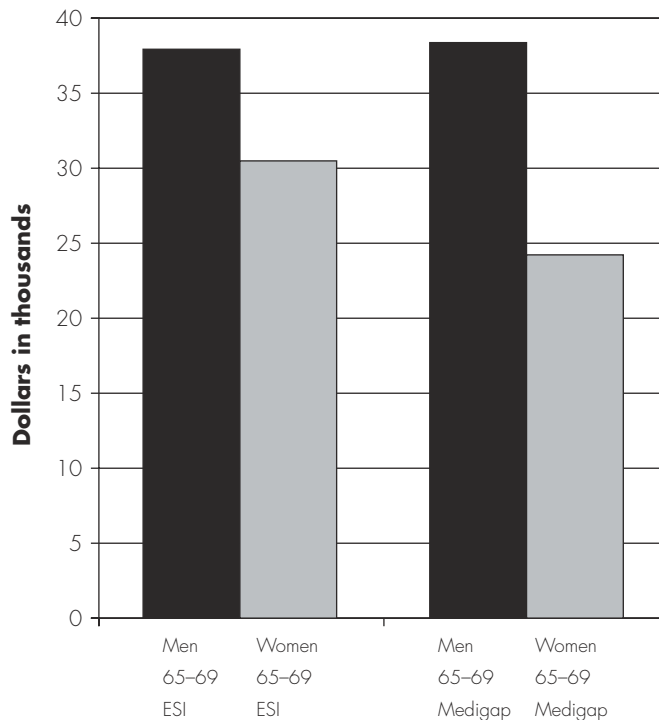
**FIGURE
B-11**

Among beneficiaries, financial liability varies by sex

Men age 65–69 with Medigap pay a lower percent of income out of pocket than women age 65–69 with Medigap



Men age 65–69 with Medigap have higher income net of out-of-pocket spending



Note: ESI (employer-sponsored insurance). Sample size is 365 for men age 65–69 with ESI; 382 for women age 65–69 with ESI; 227 for men age 65–69 with Medigap; 288 for women age 65–69 with Medigap. Analysis is only beneficiaries living in the community who are age 65–69 and enrolled in either ESI or Medigap plans.

Source: MedPAC analysis of Cost and Use file, 2001 Medicare Current Beneficiary Survey.

We examined the effects of gender on financial liability by comparing men and women age 65 to 69. The analysis controls for supplemental insurance status because of its strong effect on financial liability.

The data show that for those with ESI, financial liability may be different for women than men (Figure B-11). On the one hand, out-of-pocket spending as a share of income is similar (9 percent for men versus 11 percent for women). On the other hand, income net of out-of-pocket spending appears to be higher among the men (\$37,600 versus \$31,300), even though the difference is not statistically significant.

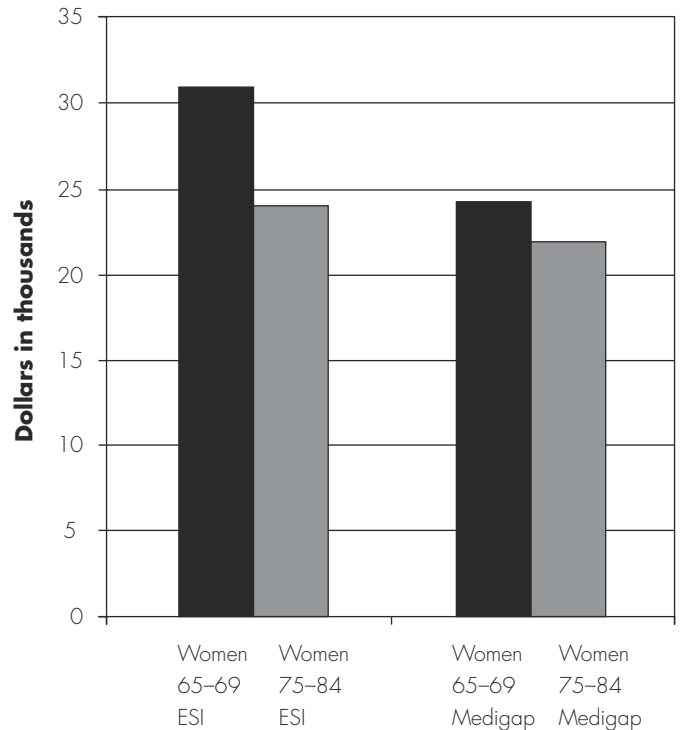
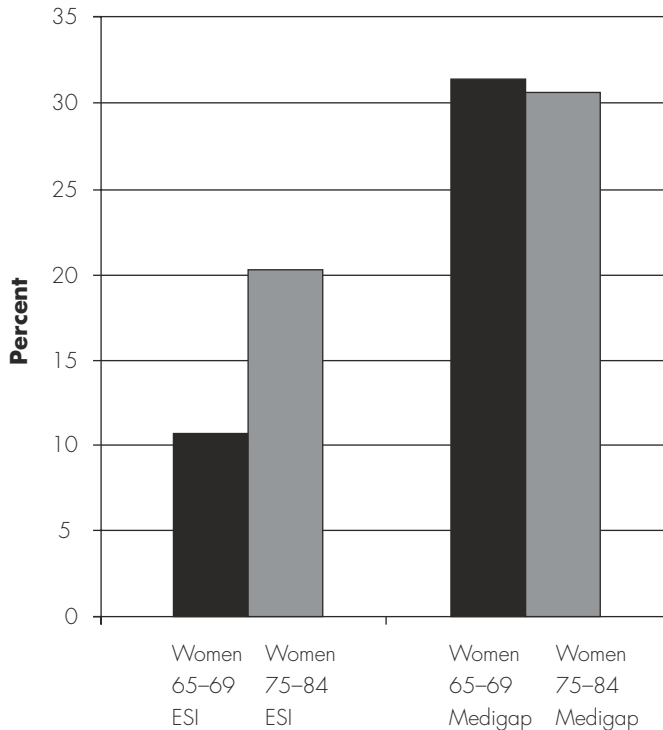
The difference in financial liability between men and women age 65 to 69 is quite large for those with Medigap, where exposure to the cost of noncovered services and premiums is greater. Out-of-pocket spending as a share of income is much higher among the women—31 percent versus 13 percent—and income net of out-of-pocket spending is much lower—\$23,900 versus \$38,200. The greater financial liability faced by the women reflects lower average income relative to the men.

**FIGURE
B-12**

Among female beneficiaries, financial liability varies by age

Women age 65–69 with ESI pay a lower percent of income out of pocket than women age 75–84

Women age 65–69 with ESI have higher income net of out-of-pocket spending than women age 75–84



Note: ESI (employer-sponsored insurance). Sample size is 382 for women age 65–69 with ESI; 607 for women age 75–84 with ESI; 288 for women age 65–69 with Medigap; 829 for women age 75–84 with Medigap. Analysis is only beneficiaries living in the community who are women and enrolled in either ESI or Medigap plans.

Source: MedPAC analysis of Cost and Use file, 2001 Medicare Current Beneficiary Survey.

We examined the effect of age on financial liability by comparing women age 65 to 69 to women age 75 to 84. We again control for supplemental insurance.

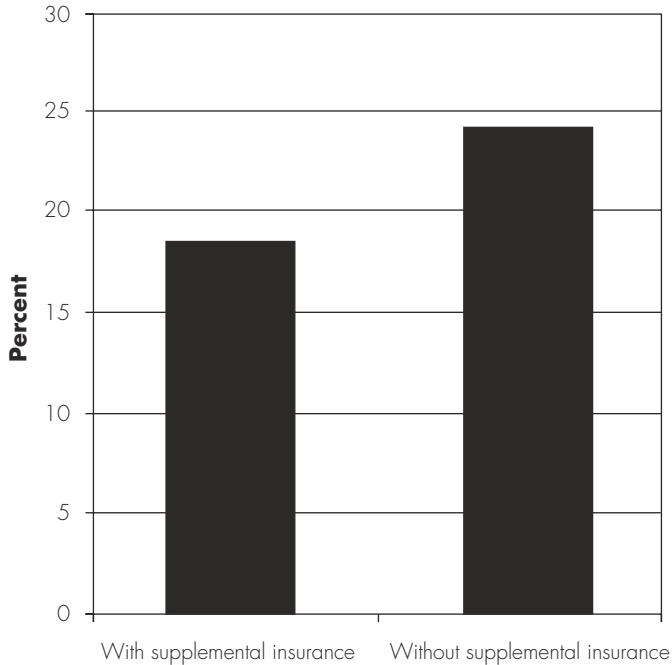
Among beneficiaries with ESI, financial liability increases with age (Figure B-12). Out-of-pocket spending as a share of income is lower among the younger cohort, 11 percent versus 20 percent. In addition, the women age 65 to 69 had higher income net of out-of-pocket spending, \$31,300 versus \$23,800. These results reflect higher income and lower out-of-pocket spending among the younger women.

Among beneficiaries with Medigap, the impact of age is much smaller. The average of out-of-pocket spending as a share of income is about 31 percent for both age groups, and income net of out-of-pocket spending is similar: \$23,900 for the younger women and \$21,400 for the older women. We see similar financial liability for these populations because income is only slightly higher among the younger women.

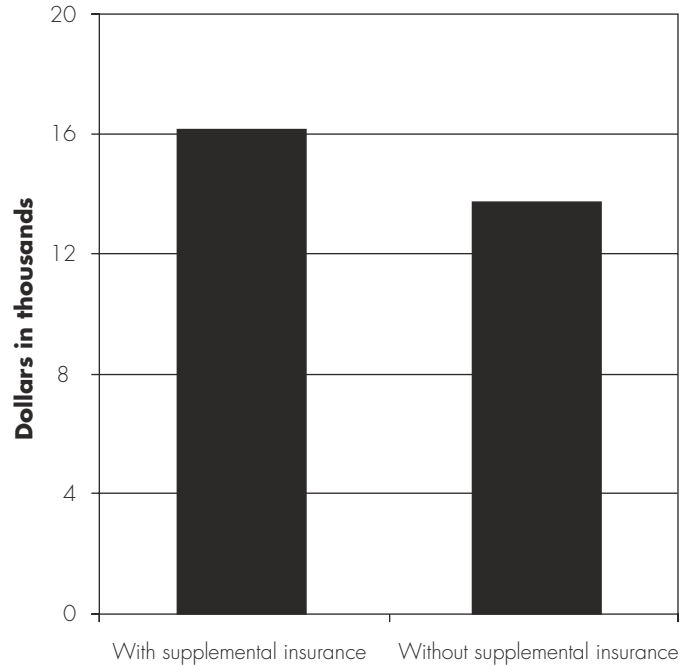
**FIGURE
B-13**

Among disabled beneficiaries, financial liability varies by presence of supplemental insurance

Out-of-pocket spending as percent of income appears to be lower for the disabled with supplemental insurance, but the difference is not statistically significant



Disabled beneficiaries who have supplemental insurance have higher income net of out-of-pocket spending



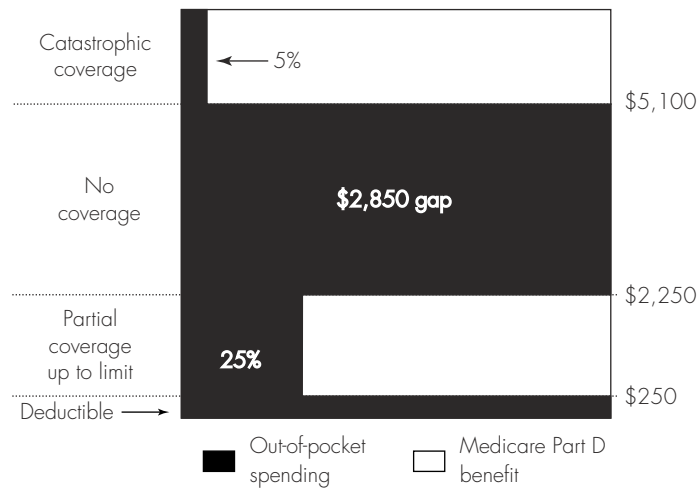
Note: Sample size is 1,461 for disabled with supplemental insurance; 357 for disabled without supplemental insurance. Analysis is only disabled beneficiaries living in the community who are not enrolled in a Medicare managed care plan.

Source: MedPAC analysis of Cost and Use file, 2001 Medicare Current Beneficiary Survey.

A serious issue for beneficiaries eligible for Medicare due to disability (those under age 65) is that a high share, 19 percent, lack supplemental insurance. We compared the disabled beneficiaries with only traditional Medicare coverage to those who have supplemental insurance (Figure B-13).

Those without supplemental coverage appear to have greater financial liability. They have \$13,400 of income

net of out-of-pocket spending, while those with supplemental insurance have \$16,200. About 77 percent of this difference is due to higher income among those with supplemental coverage, and the remaining 23 percent is due to their lower out-of-pocket spending. Out-of-pocket spending as a share of income appears to be higher among the disabled without supplemental insurance, even though the difference is not statistically significant.

**FIGURE
B-14****Standard Medicare drug benefit, 2006**

Note: In 2006, the standard drug benefit will have a deductible of \$250. For drug expenditures above \$250, beneficiaries face a coinsurance rate of 25 percent, until reaching a coverage limit of \$2,250. If the program and the beneficiary have combined drug spending over \$2,250, the beneficiary is solely responsible for the next \$2,850 in drug spending, until reaching the catastrophic limit of \$5,100. At \$5,100 in total drug spending, beneficiaries will have spent \$3,600 out of pocket: \$250 for the deductible, \$500 for the 25 percent coinsurance on \$2,000, and \$2,850 for the "gap."

A prominent feature of the MMA is a prescription drug benefit beginning in 2006. Overall, the drug benefit will reduce beneficiaries' out-of-pocket spending. However, the drug benefit has cost sharing for which the beneficiary is responsible (Figure B-14).

The Congressional Budget Office estimates that in 2006 the standard drug benefit for an enrollee with no other form of drug coverage will have an annual premium of \$420. The drug benefit also will have a deductible of \$250. For drug expenditures above \$250, the drug benefit will pay 75 percent of expenditures, and the beneficiary will face a coinsurance of 25 percent until drug expenditures reach a coverage limit of \$2,250. If combined drug spending by a beneficiary and the program exceeds \$2,250, the beneficiary will be solely responsible for the next \$2,850 in drug spending, until reaching a

catastrophic limit of \$5,100. For drug expenditures beyond the catastrophic limit, the program will pay 95 percent of costs and the beneficiary will pay the remainder.

The cost-sharing parameters will increase each year. Beginning in 2007, the deductible, the coverage limit, and the catastrophic limit will increase by the per capita increase in total spending on covered prescription drugs in the previous year.

The MMA has other provisions that will increase beneficiaries' out-of-pocket spending. These include increasing the Part B deductible from \$100 to \$110 in 2005, increasing the Part B deductible at the same rate as the Part B premium each year starting after 2005, and linking beneficiaries' share of the Part B premium to their income beginning in 2007.

Endnotes

- 1 Another database—the Survey of Income and Program Participation (SIPP)—includes data on households’ income, assets, and out-of-pocket spending. However, the data on out-of-pocket spending are not reliable, so we did not use the SIPP in our analysis.
- 2 Our estimate of the poverty rate among Medicare beneficiaries overstates the official poverty rate for this population. Two factors contribute to the overstatement. First, our data reflect income for individuals and married couples, but official poverty measures are based on household income. If an unmarried beneficiary with very low income lives with an adult child with a very high income, the beneficiary is considered low income under our measure but high income under official poverty measures. Second, although we adjusted our income data for underreporting, the database we benchmarked to (Current Population Survey) probably underreports as well, but to a lesser extent than the MCBS.
- 3 This measure assumes that beneficiaries use the same services under Medicare-only coverage as they use under ESI coverage. In addition, it assumes that beneficiaries pay the same price for each service. In practice, the price for a service often differs by type of insurance coverage. For example, people who have group health coverage often pay lower prices for prescription drugs than people who are uninsured.
- 4 The lower income among 65- to 69-year-old men with ESI may reflect, in part, employers offering lower cash wages and salaries if they provide health benefits for their retirees.

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A P P E N D I X

C

**Commissioners' voting
on recommendations**

Commissioners' voting on recommendations

In the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, the Congress required MedPAC to call for individual Commissioner votes on each recommendation, and to document the voting record in its report. The information below satisfies that mandate.

Chapter 1: Implementing the Medicare drug benefit: Formulary and plan transition issues

No recommendations

Chapter 2: The Medicare Modernization Act and chronic care improvement

No recommendations

Chapter 3: Dual eligible beneficiaries: An overview

No recommendations

Chapter 4: Purchasing strategies

No recommendations

Chapter 5: Defining long-term care hospitals

5A The Congress and the Secretary should define long-term care hospitals by facility and patient criteria that ensure that patients admitted to these facilities are medically complex and have a good chance of improvement.

- Facility-level criteria should characterize this level of care by features such as staffing, patient evaluation and review processes, and mix of patients.
- Patient-level criteria should identify specific clinical characteristics and treatment modalities.

Yes: Burke, DeBusk, DeParle, Durenberger, Feezor, Hackbarth, Muller, Nelson, Newhouse, Raphael, Reischauer, Rowe, Smith, Stowers, Wakefield, Wolter

Absent: Rosenblatt

5B The Secretary should require the Quality Improvement Organizations to review long-term care hospital admissions for medical necessity and monitor that these facilities are in compliance with defining criteria.

Yes: Burke, DeBusk, DeParle, Durenberger, Feezor, Hackbarth, Muller, Nelson, Newhouse, Raphael, Reischauer, Rowe, Smith, Stowers, Wakefield, Wolter

Absent: Rosenblatt

Chapter 6: Hospice care in Medicare: Recent trends and a review of the issues

No recommendations

Chapter 7: Information technology in health care

No recommendations

Acronyms

Acronyms

AAFP	American Academy of Family Physicians	DUR	drug utilization review
ACE	angiotensin-converting enzyme	EHR	electronic health record
ACR	American College of Radiology	EMM	electronic materials management
ADL	activity of daily living	EPO	exclusive provider organization
ADM	automated dispensing machine	ESI	employer-sponsored insurance
AHRQ	Agency for Healthcare Research and Quality	ESRD	end-stage renal disease
AIDS	acquired immunodeficiency syndrome	FDA	Food and Drug Administration
ALJ	administrative law judge	FFS	fee-for-service
AMCP	Academy of Managed Care Pharmacy	FPL	federal poverty level
APR-DRG	all patient refined diagnosis related group	GAO	General Accounting Office
ARB	angiotensin-receptor blocker	GDP	gross domestic product
AV	arteriovenous	GFR	glomerular filtration rate
BBA	Balanced Budget Act of 1997	HCC	hierarchical condition category
BBRA	Balanced Budget Refinement Act of 1999	HCN	Healthcare Collaborative Network
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000	HHS	Department of Health and Human Services
CAD	coronary artery disease	HIMSS	Healthcare Information and Management Systems Society
CAHPS	Consumer Assessment of Health Plans Survey	HIPAA	Health Insurance Portability and Accountability Act of 1996
CBO	Congressional Budget Office	HL7	Health Level 7
CCI	Correct Coding Initiative	HMO	health maintenance organization
CCIP	Chronic Care Improvement Program	HRA	health reimbursement account
CCU	critical care unit	HRR	hospital referral region
CDC	Centers for Disease Control and Prevention	HSA	hospital service area
CDSS	clinical decision support systems	HSC	Center for Studying Health System Change
CES	Consumer Expenditure Survey	ICD-9-CM	International Classification of Diseases, 9th revision, Clinical Modification
CHF	congestive heart failure	ICD-10-CM	International Classification of Diseases, 10th revision, Clinical Modification
CHI	Consolidated Health Informatics	ICU	intensive care unit
CKD	chronic kidney disease	IDS	integrated delivery system
CMS	Centers for Medicare & Medicaid Services	IDTF	independent diagnostic testing facility
COPD	chronic obstructive pulmonary disease	IEEE	Institute of Electrical and Electronics Engineers
COX-2	cyclo-oxygenase-2	IOM	Institute of Medicine
CPOE	computerized provider order entry	IRF	inpatient rehabilitation facility
CPS	Current Population Survey	IT	information technology
CT	computed tomography	K/DOQI	Kidney Disease Outcome Quality Initiative
DEFRA	Deficit Reduction Act	LOINC	Logical Observation Identifiers Names and Codes
DESI	Drug Efficacy Study Implementation	LOS	length of stay
DICOM	Digital Imaging and Communications in Medicine	LTCH	long-term care hospital
DMERC	durable medical equipment regional contractor	MA	Medicare Advantage
DMO	disease management organization	MAC	Medicare Administrative Contractor
DoD	Department of Defense		
DRG	diagnosis related group		

MAOI	monoamine oxidase inhibitors	PCP	primary care physician
M+C	Medicare+Choice	PhRMA	Pharmaceutical Research and Manufacturers of America
MCBS	Medicare Current Beneficiary Survey	PMPM	per member per month
MedPAC	Medicare Payment Advisory Commission	POV	power operated vehicle
MEI	Medicare Economic Index	PPS	prospective payment system
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003	P&T	pharmacy and therapeutics
MRI	magnetic resonance imaging	QI	qualifying individual
MSA	metropolitan statistical area	QIO	quality improvement organization
NCVHS	National Committee on Vital and Health Statistics	QMB	qualified Medicare beneficiary
NEMA	National Electrical Manufacturers Association	REBUS/	
NHII	National Health Information Infrastructure	PMMIS	Renal Beneficiary Utilization System/Program Management and Medical Information System
NHPCO	National Hospice and Palliative Care Organization	RFID	radio frequency identification
NHS	National Health Service (England)	SCHIP	State Children’s Health Insurance Program
NIH	National Institutes of Health	SGR	sustainable growth rate
NKF	National Kidney Foundation	S/HMO	Social Health Maintenance Organization
NPfIT	National Programme for Information Technology (England)	SIPP	Survey of Income and Program Participation
NSAID	nonsteroidal anti-inflammatory drug	SLMB	specified low-income Medicare beneficiary
OASIS	Outcome and Assessment Information Set	SNF	skilled nursing facility
OBRA	Omnibus Budget Reconciliation Act	SNOMED	Systemized Nomenclature of Medicine
OIG	Office of Inspector General	SSA	Social Security Administration
OOP	out-of-pocket	SSRI	selective serotonin reuptake inhibitor
PACE	Program of All-Inclusive Care for the Elderly	USP	United States Pharmacopeia
PACS	picture archiving and communications system	VA	Department of Veterans Affairs
PBM	pharmacy benefit manager	VHA	Veterans Health Administration
PCCM	primary care case manager	WPP	Wisconsin Partnership Program

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Autry O.V. "Pete" DeBusk is chairman, chief executive officer and founder of DeRoyal, a global supplier of medical products and services in the acute care, patient care, wound care, and original equipment manufacturing markets. Mr. DeBusk formed his first company in 1970 with a patent he received on an orthopedic product. In 1976 he consolidated his many product lines into one company, DeRoyal Industries. A member of several community organizations, Mr. DeBusk is also chairman of the Board of Trustees at Lincoln Memorial University in Harrogate, TN, as well as a founder of the Autry O.V. DeBusk facility, Boys and Girls Club, Powell, TN. As an innovative leader in the medical industry, he received a prestigious award from Duke University in 2000 recognizing his original contributions to orthopedic surgery. He received his B.S. degree from Lincoln Memorial University and attended graduate school at the University of Georgia.

Nancy-Ann DeParle, J.D., is a senior advisor to JPMorgan Partners, LLC, and adjunct professor of health care systems at the Wharton School of the University of Pennsylvania. From 1997 to 2000, she served as administrator of the Health Care Financing Administration (HCFA), which is now the Centers for Medicare & Medicaid Services. Before joining HCFA, Ms. DeParle was associate director for health and personnel at the White House Office of Management and Budget. From 1987 to 1989 she served as the Tennessee Commissioner of Human Services. She has also worked as a lawyer in private practice in Nashville, TN, and Washington, DC. She currently serves as a trustee of the Robert Wood Johnson Foundation and a board member of Accredo Health, Cerner Corporation, DaVita, Guidant Corporation, Specialty Laboratories, and Triad Hospitals. She is also a member of the Strategic Advisory Council of the National Quality Forum. Ms. DeParle received a B.A. degree from the

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Allen D. Feezor, M.A., is vice president and chief planning officer for University Health Systems of Eastern Carolina. Previously, he was assistant executive officer, Health Benefit Services, California Public Employees' Retirement System (CalPERS) and CalPERS long-term care program. Before CalPERS, Mr. Feezor was vice president for planning, marketing, and managed care for University Health Systems of Eastern Carolina. From 1985 to 1995, he was chief deputy commissioner for the North Carolina Department of Insurance, where he chaired two national task forces that pioneered state health insurance and small group reform. He has headed the North Carolina Teachers', State Employees' and Retirees' Health Plan and has served as senior Washington representative for the Blue Cross/Blue Shield Association. He was a founding faculty member of the National Academy for State Health Policy and a contributor to two Institute of Medicine studies. He currently serves on the boards of the North Carolina Center for Public Policy Research and the North Carolina Institute of Medicine. Mr. Feezor earned his B.A. and M.A. degrees in political science from Duke University.

Glenn M. Hackbarth, J.D., is chairman of the Commission and an independent consultant living in Bend, OR. He has experience as a health care executive, government official, and policy analyst. He was chief executive officer and one of the founders of Harvard Vanguard Medical Associates, a multispecialty group practice in Boston that serves as a major teaching affiliate of Harvard Medical School. Harvard Vanguard was created from the staff-model delivery system that was the original core of Harvard Community Health Plan. Mr. Hackbarth previously served as senior vice president of Harvard Community Health Plan. From 1981 to 1988, he held positions at the U.S.

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Ralph W. Muller is chief executive officer of the University of Pennsylvania Health System, one of the largest academic health systems in the country. Most recently he served as managing director of Stockamp & Associates, a hospital consulting firm, and as a visiting fellow at the King's Fund in London. From 1985 to 2001, he was president and chief executive officer of the University of Chicago Hospitals and Health Systems (UCHHS). Before joining the hospital, he held senior positions with the Commonwealth of Massachusetts, including deputy commissioner of the Department of Public Welfare. Mr. Muller is past chairman of the Association of American Medical Colleges, past chairman of the Council of Teaching Hospitals and Health Systems, and past vice-chairman of the University Health System Consortium. He is past chairman of the National Opinion Research Center, a social service research organization. Mr. Muller received his B.A. in economics from Syracuse University and his M.A. in government from Harvard University.

Alan R. Nelson, M.D., is an internist-endocrinologist who was in private practice in Salt Lake City until becoming chief executive officer of the American Society of Internal Medicine (ASIM) in 1992. Following the merger of ASIM with the American College of Physicians (ACP) in 1998, Dr. Nelson headed the Washington office of ACP-ASIM until his semi-retirement in January 2000 and now serves as special advisor to the executive vice president and chief executive officer of ACP. He was president of the American Medical Association from 1989 to 1990. Dr. Nelson also serves on the Board of Trustees of Intermountain HealthCare, a large integrated health system headquartered in Salt Lake City. A member of the Institute of Medicine of the National Academy of Sciences (IOM), he serves on the IOM Roundtable on Environmental Health Sciences Research and Medicine and was chair of the study committee on Racial and Ethnic Disparities in Health Care. Dr. Nelson received his M.D. from Northwestern University.

Joseph P. Newhouse, Ph.D., is the John D. MacArthur Professor of Health Policy and Management at Harvard University and director of Harvard's Division of Health Policy Research and Education. At Harvard since 1988, Dr. Newhouse was previously a senior corporate fellow and head of the economics department at RAND. He has conducted research in health care financing, economics, and policy, and was the principal investigator for the RAND Health Insurance Experiment. Recipient of several professional awards, he is a member of the Institute of Medicine, a former chair of the Prospective Payment Assessment Commission, and a former member of the Physician Payment Review Commission. He is the inaugural president of the American Society of Health Economics, a past president of the Association for Health Services Research and the International Health Economics

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John W. Rowe, M.D., is chairman and chief executive officer of Aetna Inc., one of the nation's largest health care insurers. Prior to joining Aetna, Dr. Rowe served as president and chief executive officer of Mount Sinai NYU Health. Previously, Dr. Rowe was president of The Mount Sinai Hospital and the Mount Sinai School of Medicine in New York City, where he currently is a professor of medicine. Before joining Mount Sinai in 1988, Dr. Rowe was a professor of medicine and the founding director of the Division on Aging at Harvard Medical School and chief of gerontology at Boston's Beth Israel Hospital. He is a specialist in geriatric medicine and nephrology and has authored over 200 scientific publications, mostly on the physiology of the aging process, as well as a leading textbook of geriatric medicine. Dr. Rowe was director of the MacArthur Foundation Research Network on Successful Aging and is co-author, with Robert Kahn, Ph.D., of *Successful Aging* (Pantheon, 1998). He served on the Board of Governors of the American Board of Internal Medicine and as president of the Gerontological Society of America. He is a member of the Institute of Medicine of the National Academy of Sciences and chairman of the Board of Trustees of the University of Connecticut. He earned his B.A. degree from Canisius College and his M.D. from the University of Rochester.

David A. Smith is a senior fellow at Demos, a New York based public policy research center. He previously served as director of the Public Policy Department of the AFL-CIO. Prior to joining the AFL-CIO, he served as senior deputy budget director and as Commissioner of Economic Development for the City of New York. Mr. Smith spent most of the 1980s in Washington as an aide to Senator Edward M. Kennedy and as a senior economist at the Joint Economic Committee. Mr. Smith has taught economics and public policy at the University of Massachusetts and the New School for Social Research, and is a senior fellow at the Century Foundation. He is a member of the Board of Directors of Public Campaign and of the National Bureau of Economic Research, and a fellow of the National Academy of Social Insurance. Mr. Smith attended Tufts University and received an M.Ed. from Harvard University.

Ray E. Stowers, D.O., is director of the Oklahoma Rural Health Policy and Research Center as well as director of rural health in the Department of Family Medicine at Oklahoma State University College of Osteopathic Medicine. He was in private rural practice for 25 years at Family Medicine Clinics, Inc. in Medford, OK, and serves on the Policy Board of the National Rural Health Association. Dr. Stowers is a member of the Board of Trustees of the American Osteopathic Association and has served that organization in many capacities, including several related to physician coding and reimbursement issues. He has been on the Physician Payment Review Commission and was a founding member of the American Medical Association's Relative Value Update Committee. Dr. Stowers received his B.S. and B.A. degrees from Phillips University in Oklahoma and his D.O. degree from the University of Health Sciences College of Osteopathic Medicine in Kansas City, MO.

Mary K. Wakefield, Ph.D., R.N., F.A.A.N., is director and professor, Center for Rural Health at the University of North Dakota. Dr. Wakefield has held administrative and legislative staff positions in the U.S. Senate and served on many public and private health-related advisory boards. From 1997 through 1998, she was on President Clinton's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. Dr. Wakefield was a member of the Institute of Medicine's Committee on Quality Health Care in America and is a fellow of the American Academy of Nursing. In 2000, she was appointed to the National Advisory Committee on Rural Health, Office of Rural Health Policy, Health Resources and Services Administration. Dr. Wakefield received her B.S. in nursing from the University of Mary, Bismarck, ND, and her M.S. and Ph.D. from the University of Texas at Austin.

Nicholas J. Wolter, M.D., is a pulmonary and critical care physician who serves as chief executive officer for Deaconess Billings Clinic (DBC), Billings, Montana. DBC is a regional, not-for-profit medical foundation consisting of a multispecialty group practice, hospital, health maintenance organization, research division, and long-term care facility serving a vast rural area in the northern Rockies. Dr. Wolter began his Billings Clinic practice in 1982 and served as medical director of the hospital's intensive care unit from 1987 to 1993. He began his leadership role with the successful merger of the clinic and hospital in 1993. Dr. Wolter is a diplomate of the American Board of Internal Medicine and serves on the boards of many regional and national health care organizations. He has a B.A. degree from Carleton College, an M.A. degree from the University of Michigan and an M.D. degree from the University of Michigan Medical School.

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