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GENETIC INFORMATION NONDISCRIMINATION ACT OF 2003

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Mr. GREGG, from the Committee on Health, Education, Labor, and Pensions, submitted the following

REPORT

[To accompany S. 1053]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 1053) to prohibit discrimination on the basis of genetic information with respect to health insurance and employment, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill (as amended) do pass.

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I. PURPOSE AND SUMMARY OF THE LEGISLATION

The purpose of this legislation is to protect individuals from discrimination in health insurance and employment on the basis of genetic information. Establishing these protections will allay concerns about the potential for discrimination and encourage individuals to participate in genetic research and to take advantage of genetic testing, new technologies, and new therapies. The legislation will provide substantive protections to those individuals who may suffer from actual genetic discrimination now and in the future. These

steps are essential to fulfilling the promise of the human genome project.

TITLE I—HEALTH INSURANCE

The legislation applies to employer-sponsored group health plans, health insurance issuers in the group and individual markets, Medigap insurance, and State and local non-federal governmental plans.

Nondiscrimination

Group Health Plan Protections: The Employee Retirement and Security Act (ERISA) currently prohibits a group health plan or health insurance issuer offering coverage in connection with a group health plan from discriminating against an individual in the group in setting eligibility or premium or contribution amounts based on the individual's genetic information. This legislation clarifies that genetic information includes "information about a request for or a receipt of genetic services by an individual or family member of such individual." It also prohibits a health insurance issuer offering health coverage in connection with a group health plan from adjusting premium or contribution amounts for a group on the basis of genetic information concerning an individual in the group or a family member of the individual.

Individual Health Insurance Market Protections: This legislation prohibits health insurance issuers in the individual market from using genetic information about enrollees or their family members to adjust premium or contribution amounts, using genetic information as a condition of eligibility for insurance coverage.

Medicare Supplemental Protections: This legislation prohibits an issuer of a Medicare supplemental policy from denying or conditioning the issuance of a policy, or discriminating in the price of the policy, based on genetic information.

Limitation on Genetic Testing

Group health plans, health insurance issuers in the group and individual market, and issuers of Medicare supplemental policies covered under this Title are prohibited from requesting or requiring an individual to take a genetic test. However, the legislation makes it clear that this provision does not interfere with the delivery of health care services. For instance, this provision does not limit the authority of the treating health care professional to request that an individual or family member undergo a genetic test. Nor does it limit the authority of a health care professional who is employed by or affiliated with a health plan or issuer from notifying an individual about genetic tests or providing information about a genetic test if such actions are carried out as part of a bona fide wellness program. However, the legislation does prohibit a health care professional from requiring that an individual undergo a genetic test.

Privacy and Confidentiality of Genetic Information

The HHS Standards for Privacy of Individually Identifiable Health Information (medical privacy regulations) (45 CFR Parts 160 and 164; final rule) already protect the use and disclosure of all individually-identifiable health information, including genetic

information. However, a permitted "use" of health information under the privacy rules (i.e., a specific item under 'health care operations') is underwriting, a practice that is inherently discriminatory. Therefore, this bill expressly bans the use or disclosure of genetic information for purposes of underwriting. In addition, this bill bans health plans and insurance issuers from collecting (i.e., requesting or requiring) genetic information in the first place for purposes of underwriting.

In addition, this bill further protects the privacy of genetic information by prohibiting plans and insurance issuers from collecting (i.e., requesting, requiring, or purchasing) genetic information prior to enrollment under the plan.

Enforcement

By building these protections into existing statutes (e.g., ERISA PHSA, the Social Security Act, and the IRC), this Title generally uses the same mechanisms to enforce the protections established under this legislation as apply to other violations of these underlying statutes. In addition, this legislation ensures that similarly situated individuals are provided the same protection under the law, regardless of whether they are currently sick or disabled, or currently healthy. All individuals (healthy and sick) have genetic information that could be used to discriminate against them.

With respect to the nondiscrimination requirements, this legislation is based on the same penalty and enforcement structure as Title I of HIPAA, which addresses insurance portability and discrimination based on health-status. In general, under ERISA, group health plan participants or the Department of Labor can sue for equitable relief under ERISA. This legislation further clarifies that with respect to a group health plan, a participant or beneficiary has the right to seek injunctive relief before exhausting administrative remedies if taking the time to pursue administrative remedies would cause irreparable harm to the participant's health. Where a participant or beneficiary obtains equitable relief under ERISA for a genetic discrimination violation, the court has the discretion to reinstate coverage, retroactive to the date of violation and can award a penalty to the participant. The penalty amount payable to the individual is the same as the primary penalty that may be assessed by the Secretary under current law enforcement.

For group health plans and health insurance issuers in the individual and group markets, the appropriate Secretary may impose penalties of $100 per day/per person, with a minimum penalty of $2,500—up to $15,000 for multiple violations that are more than de minimis with an outside cap of up to $500,000 for a violation of the protections against genetic discrimination.

With regard to the privacy provisions established by this legislation, the same enforcement structure and penalties created by the Social Security Act for the HHS privacy standards apply with regard to the privacy protections established for genetic information by this legislation. Under this legislation, the genetic privacy provisions are enforced by the HHS Office of Civil Rights. The Secretary of HHS may impose civil monetary penalties of $100 per violation—up to $250,000 and 10 years in prison for violations committed for commercial advantage, personal gain, or malicious harm.

TITLE II—EMPLOYMENT PROVISIONS

Prohibition on Discrimination

The legislation prohibits the use of genetic information in employment decisions, such as hiring, firing, job assignments, and promotions. This prohibition extends to employers, unions, employment agencies, and labor-management training programs.

Limitation on Acquisition

Employers, labor organizations, employment agencies, and joint labor-management committees are prohibited from requesting, requiring, or purchasing genetic information about an employee or family member, except for the following legitimate reasons: (1) for genetic monitoring of biological effects of toxic substances in the workplace, (2) if the employer provides genetic services, such as through a wellness program, with the employee's prior consent, or (3) for compliance with the certification provision of the Family and Medical Leave Act or its state equivalent. The purchase of commercially and publicly available documents or inadvertently requesting or requiring family medical history would not violate this title. Under each of these exceptions, however, the genetic information still could not be used or disclosed.

Confidentiality Protections

The legislation safeguards the confidentiality of genetic information in the employment setting. If an employer (acting as an employer) acquires genetic information, such information shall be treated and maintained as part of the employee's confidential medical records. Moreover, such information shall not be disclosed except in limited situations, such as to the individual or in order to comply with the certification provisions of Federal or State family and medical leave laws, or a court order.

Enforcement

The legislation protects applicants or employees of employers defined under the Civil Rights Act of 1964 (42 U.S.C. 2000e(f), State employees, Federal employees, Congressional employees, and employees as defined in 3 U.S.C. 411(c). Claimants are required to file a charge with the appropriate enforcement agency within a certain time period, prior to filing a suit in court. The bill provides for the same compensatory and punitive damages available to prevailing plaintiffs under 42 U.S.C. 1981a, which are progressive with the size of the employer and limited to cases of disparate treatment.

Disparate Impact

The bill prohibits claims based on disparate impact and empanels a commission in 6 years to review the science and law of genetics. The purpose of the Commission is to review the science of genetics and advise the Congress on the necessity of providing for a disparate impact cause of action in the future.

Definitions—(Generally Apply to Title I and II)

Genetic information is defined to include information about an individual's genetic tests; the genetic tests of family members of the individual; or the occurrence of a disease or disorder in family

members of the individual. Genetic information does not include information about the sex or age of an individual for purposes of this legislation.

A genetic test is defined as an analysis of DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes. A genetic test does not mean an analysis of (1) proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes or; (2) an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved. The second exception to genetic test only applies to Title I of the legislation.

Genetic Services is defined as a genetic test; genetic counseling (such as obtaining, interpreting, or assessing genetic information), or genetic education.

II. Background and Need for Legislation

Sequencing the Human Genome

Only rarely is a scientific discovery so significant that it has the potential to transform both science and society. Humanity's newly acquired ability to map and understand its own genetic traits may well be one such transforming discovery. While recent advances in genetics are the work of thousands of scientists in dozens of countries, the most prominent symbol of our newfound understanding of genetics was the announcement in April 2003 that a vast team of scientists had determined the exact sequence of the human genetic code and placed that information in public databases.

The most immediate use of the data from sequencing the genome will be to increase our understanding of the links between genes and disease. Medicine has already benefitted from the first trickle of what will eventually become a flood of new discoveries about the links between genetic mutations and particular diseases. One well-known example of such a link is the correlation between mutations in two genes, BRCA1 and BRCA2, and an elevated risk of breast and ovarian cancer. If used to guide medical decision-making, a test for a mutation in one of the two BRCA genes could be of considerable benefit to women in evaluating their risk of disease and in taking steps to reduce that risk.

Yet this new understanding of the genetic basis of disease holds dangers as well as opportunities. Although the knowledge that a person carries a mutation in a disease-related gene may be used to inform future medical treatment or as a stimulus to seek preventive care, that same knowledge could also be used for harmful purposes. A health insurance company might wrongly view the presence of the gene mutation to mean that the person would definitely contract the disease with which that gene is associated and improperly deny that person insurance coverage. An employer might use information about an employee's genetic profile to deny employment to an individual who is healthy and able to do the job. In several hearings on this issue, the Committee heard that many non-specialists regard the presence of a genetic mutation as an unalterable prediction that a person will manifest the disorder associated

with that mutation, rather than simply one of many factors affecting health.[1]

With these misconceptions so prevalent, employers may come to rely on genetic testing to "weed out" those employees who carry genes associated with diseases. Similarly, genetic traits may come to be used by health insurance companies to deny coverage to those who are seen as "bad genetic risks." Enabling employers, health insurers and others to base decisions about individuals on the characteristics that are assumed to be their genetic destiny would be an undesirable outcome of our national investment in genetic research, and may significantly diminish the benefits that this research offers.

Concerns about Misuse of Genetic Information

The appropriate use of genetic information offers enormous opportunities to save lives and prevent the onset of disease. However, the medical progress made possible by genetic research is dependent on the willingness of study volunteers and patients to undergo genetic testing. However, such consent may be difficult to obtain today. Fears about the possible misuse or unauthorized disclosure of genetic information appear to adversely impact the desire of individuals to participate in genetic research.[2] Such fears also extend to clinical practice, discouraging both patients and providers from taking full advantage of genetic tests and technologies.

For instance, a national telephone survey of more than 1,000 people found that 63 percent of respondents said they would not take genetic tests if health insurers or employers could get access to the results.[3] In a study of the use of genetic tests in clinical oncology, 68 percent of patients responding to a questionnaire reported that they would not bill health insurance companies for genetic tests for fear of discrimination, while 26 percent would take tests only using an alias.[4] Genetic counselors report that concerns about breaches of privacy and improper use of genetic information are widespread among their patients. Concealment of the results of genetic tests can have sometimes disastrous consequences for individuals' health. For example, a woman whose doctor is unaware that her genetic profile includes an elevated risk for cancer may be less vigilant about possible warning signs of that cancer than a doctor who was fully aware of her genetic risks.

These surveys are substantiated by evidence documenting reluctance among at-risk populations to undergo genetic testing—even when that testing may allow patients to take steps to lower their risks of contracting a disease. For example, only 43 percent of those at risk for hereditary colon cancer participated in a genetic testing program.[5] Later studies found that 39 percent of those who de-

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[1] For example, testimony of Francis Collins (HELP Committee hearing, July 25, 2001) and Kathleen Zietz (HELP Committee hearing, July 25, 2001).

[2] For example, testimony of Ms. Kathleen Zeitz (HELP Committee hearing, July 25, 2001) and Mr. Jindal (HELP Committee hearing, February 13, 2002).

[3] "Genetic Information and the Workplace", a report issued by the Department of Labor, Department of Health and Human Services, Equal Employment Opportunity Commission and Department of Justice. Report date: January 20, 1998. Displayed at http://www.nhgri.nih.gov/HGP/Reports/genetics__workplace.html.

[4] Matloff, E. et al. "What Would You Do? Specialists' Perspectives on Cancer Genetic Testing, Prophylactic Surgery, and Insurance Discrimination." Journal of Clinical Oncology, 18: 2484–2492 (2000).

[5] Lerman et al., "Genetic testing in families with hereditary nonpolyposis colon cancer." JAMA 281: 1618–1622. (1999)

clined testing cited fears about the potential effect of test results on their health insurance coverage as the primary reason for their refusal.[6] Similar results are seen with other disorders. In a study of women who may carry the BRCA mutation, only 57 percent of women decided to undergo a genetic test to determine whether they carried a mutation in this gene.[7] Although other factors contribute to the decision not to get tested, such as the lack of an effective treatment, fear of genetic discrimination appears to be a primary reason that many people forgo getting genetic tests.

In addition to concerns about discrimination, polls indicate that the public at large desires to keep genetic information private. For instance, in a 1995 Harris poll, 85 percent of respondents indicated that they were either "very concerned" or "somewhat concerned" that insurers and employers might gain improper access to their genetic data.[8] Most recently, in December 2002 a poll taken by the Genetics and Public Policy Center at Johns Hopkins University found that 85 percent of those surveyed felt that employers should not have access to genetic test results.[9] Fears about the possible misuse of genetic knowledge appear to influence the public's desire to protect the privacy of genetic information.

Fears that employees may be subjected to unwanted or covert genetic testing by their employers, or may face discriminatory treatment, on the basis of that testing are not hypothetical. In 2000, the American Management Association conducted a "Workplace Testing Survey" and found that a few of its members did use what they understood to be genetic information in hiring and firing decisions. Of the 2,133 employers surveyed, seven (up from three in 1999) indicated that their companies performed what they thought was genetic testing of employees. Of these seven, four reported performing genetic testing of job applicants, and six reported performing genetic testing of employees. In 1989, the United States Congress Office of Technology Assessment (OTA) surveyed Fortune 500 companies. Of the 330 companies responding, twelve companies admitted to currently conducting genetic tests of employees.

Although surveys and polls demonstrate a fairly widespread fear of discrimination, there is little evidence or documentation of actual discrimination in health insurance. For instance, the American Academy of Actuaries notes that private insurers do not require applicants for insurance to undergo genetic testing or use genetic tests to limit coverage for preexisting conditions.[10]

Another study of insurance practices found there are almost no well-documented cases of health insurers either asking for or using presymptomatic genetic test results in their underwriting decisions. The same study found that "some insurers clearly do use family history information for important disease categories such as heart disease, cancer, and diabetes, but they do so only to look for or

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[6] Hadley, D. et al. "Genetic counseling and testing in families with hereditary nonpolyposis colorectal cancer." Archives of Internal Medicine, 163: 573–582 (2003).

[7] Lerman et al. "BRCA1 testing in families with hereditary breast-ovarian cancer. A prospective study of patient decision making and outcomes." JAMA. 275:1885–1892 (1996).

[8] Statement of Francis S. Collins, M.D., Ph.D. to the Congressional Task Force on Health Records and Genetic Privacy Preventing Genetic Discrimination in Health Insurance, July 22, 1997.

[9] "Public Awareness and Attitudes about Reproductive Genetic Technology" Genetics and Public Policy Center, Johns Hopkins University. December 9, 2002, displayed at http://dnapolicy-contenet.;labvelocity.com/pdfs/4/27374.pdf

[10] American Academy of Actuaries, Genetic Information and Medical Expense Insurance, June 2000.

evaluate other signs of existing or prior disease, not to predict the onset of future health problems."[11]

Despite the apparent conflict between actual discrimination versus the fear or perception of discrimination, consumers remain worried that, once acquired by an insurance company or employer, genetic information could be used in a discriminatory manner. Such concerns about the misuse of genetics are already hindering the potential of the human genome project. Health care professionals advise patients to skip tests or pay for them out of pocket because they are uncertain if genetic information is protected from misuse under the law. Under our current patchwork of varying State and Federal laws, many of which were crafted for different purposes than genetic discrimination, few people truly understand the degree to which their genetic information may or may not be protected. Many of the problems outlined in this section stem from the lack of a comprehensive federal law prohibiting the use of genetic information to deny health insurance coverage or affect employment status.

Fear of discrimination, or even potential discrimination, threatens society's ability to use new genetic technologies to improve human health and the scientific community's ability to conduct research needed to understand, treat, and prevent disease. And, although there may not be proof of widespread discrimination, it is difficult to ignore the few, albeit egregious, cases that have been publicly documented.

Examples of Genetic Discrimination

Although genes are facially neutral markers, many genetic conditions and disorders are associated with particular racial and ethnic groups, and gender. Members of those groups may be stigmatized or discriminated against as a result of that genetic information. This principle was evident in the 1970s, which saw the advent of programs to screen and identify carriers of sickle cell anemia, a disease which afflicts African-Americans. The screening programs were designed to identify both healthy carriers and carriers with the manifested disease, even though neither prenatal diagnosis nor treatment was available at the time. Scientists suggested that even healthy carriers might be hyper-susceptible to certain workplace toxins such as benzene, lead, cadmium, carbon monoxide, and cyanide. Based on these opinions, employers began testing workers for the gene even though available evidence and studies did not support this theory. See Genetic Discrimination in the Workplace: An Overview of Existing Protections, 30 Loyola University of Chicago Law Journal 393, 402–03 (Spring 1999), citing Katherine Brokaw, Comment, Genetic Screening in the Workplace and Employer's Liability, Columbia Journal of Law & Social Problems 317, 324, n. 33 (1990).

State legislatures began to take steps in the area, and in the early 1970s began mandating genetic screening of all African Americans for sickle cell anemia, leading to further fear and discrimination. Inadequate measures to keep the test results confidential led to stigmatization and discrimination against sickle cell car-

[11] Mark A. Hall and Stephen S. Rich, "Laws Restricting Health Insurers' Use of Genetic Information: Impact on Genetic Discrimination." American Journal of Human Genetics, January 2000.

riers in employment. Further, lack of knowledge and understanding of the disease led to discrimination against many carriers of the trait even though they would never develop sickle cell disease. To alleviate some of this stigma, Congress in 1972 passed the National Sickle Cell Anemia Control Act, which withholds federal funding from states unless sickle cell testing is voluntary. See 42 U.S.C. § 300b.

Between 1968 and 1993, Lawrence Berkeley Laboratory, a research institution operated jointly by state and federal agencies, gave employees pre-placement medical examinations that included, without the employees' knowledge or consent, blood and urine tests for syphilis, sickle cell trait, and/or pregnancy. In Norman-Bloodsaw v. Lawrence Berkeley Laboratory, 135 F.3d 1260, 1269 (9th Cir. 1998), the court held that "it goes without saying that the most basic violation possible involves the performance of unauthorized tests—that is, the non-consensual retrieval of previously unrevealed medical information that may be unknown even to plaintiffs. These tests may also be viewed as searches in violation of Fourth Amendment rights that require Fourth Amendment scrutiny. The tests at issue in this case thus implicate rights protected under both the Fourth Amendment and the Due Process Clause of the Fifth or Fourteenth Amendments."

In 2001, railroad workers at Burlington Northern Santa Fe Railroad (BNSF) were subjected to genetic testing without their knowledge or informed consent. BNSF conducted genetic tests on samples drawn under false pretenses to try to determine whether employee's symptoms resembling carpal tunnel syndrome were caused by a genetic mutation. Employees of BNSF testified before Congress about how they were denied employment benefits and were otherwise deprived of equal protection under the law due to the misuse of their genetic information. On April 6, 2001, BNSF settled the suit filed by the Brotherhood of Locomotive Engineers with the Equal Employment Opportunity Commission under the ADA.[12]

Federal Law on Genetic Discrimination in Health Insurance

The Health Insurance Portability and Accountability Act (HIPAA) affords some protection against discriminatory practices in health insurance based on an individual's genetic information. In general, HIPAA ensures that individuals who change health insurance carriers (usually after switching jobs or losing employment) do not have their coverage denied or unduly restricted because of preexisting medical conditions. HIPAA also prohibits a health insurance carrier from charging one individual within a group higher rates than other "similarly situated" individuals in the same group or determining eligibility to enroll in health insurance coverage, based on a health status-related factor. HIPAA includes genetic information as part of its definition of a "health status-related factor" which cannot be used to deny coverage, and excludes genetic information (in the absence of a diagnosis) from its definition of a preexisting medical condition.

Nonetheless, the Act has several important limitations in protecting Americans against genetic discrimination in health insurance. First, its protections against denying coverage on the basis of

[12] Testimony of David Escher, HELP Committee Hearing, July 25, 2001.

factors related to health status apply only to the group insurance market. HIPAA does not address discrimination in the individual market, and state laws vary considerably with regard to restrictions on using genetic information to set premiums or determine eligibility. In addition, HIPAA does not prohibit an insurance company from raising the premiums for the group health plan as a whole, based on the genetic information of an individual in that group.

Based on the evidence described above and on testimony received at several hearings on genetic discrimination, the Committee determined that new Federal legislation is required to ensure that individuals are not denied health insurance coverage or do not have their premium rates raised due to genetic information that is not an analysis of metabolites or proteins directly related to a manifested disease, disorder, or pathological condition.

HIPAA and Privacy

In addition to its provisions on health insurance coverage, HIPAA also deals with the privacy of medical records. HIPAA stated that if Congress failed to enact a comprehensive law on medical privacy by August 21, 1999, then the Secretary of HHS would be required to issue privacy regulations. Since Congress was unable to enact a privacy law by the required deadline, HHS issued regulations on medical records privacy in December 2000 that went into effect for large businesses in April 2003 and will take effect for small businesses one year later.

The HHS medical privacy regulations are of obvious relevance to the debate on genetic discrimination. While people fear discriminatory action based on their genes, they also fear the unauthorized disclosure or collection of genetic information. The need to protect the privacy of genetic information is important. Knowledge that a person has a particular medical condition or genetic trait may be embarrassing or damaging to that individual, or his or her family members.

Although the HHS privacy regulations are extensive in many respects, they are limited by the underlying statutory framework of HIPAA, which authorized them to apply only to three named categories of businesses: providers, payers and information clearinghouses. However, medical information may be widely dispersed beyond these "covered entities".

Due to the underlying statutory constraints of HIPAA, the new HHS privacy regulations cannot directly affect employers or other non-covered entities. Instead, the regulations require any non-covered entity (a "business associate") to enter into a contract with a covered entity promising that it will respect the privacy of information transmitted from the covered entity to the non-covered entity. Witnesses at several Committee hearings testified that a statutory framework to protect genetic information directly—even when held by a non-covered entity such as an employer—would be a clearer and more effective system of regulation than relying solely on the indirect system of "business associate" contracts established under the HIPAA regulations.[13] Based on this and other evidence, the committee determined that further statutory provisions were need-

[13] Testimony of Joanne L. Hustead (HELP Committee hearing, February 13, 2002).

ed to regulate directly the collection and disclosure of genetic information by employers and other workforce organizations not covered directly within the framework of the HIPAA regulations.

Within the sphere of health insurance, the regulations promulgated under HIPAA provide extensive regulatory direction on the permitted and impermissible uses of protected health information, including genetic information. In its deliberations, the Committee took note of these recently promulgated regulations and determined that it would be advisable to enact genetic protections that were consistent with this existing framework.

Federal Protections Against Genetic Discrimination in Employment

Federal employees have considerable protection against genetic discrimination under the terms of Executive Order 13145 issued on February 10, 2000, 65 CFR 6877. Under this order, Federal employees may not be discharged or otherwise subjected to restrictions in their employment or their employment-related benefits on the basis of protected genetic information. The Executive Order also provides protections against improper collection of employees' genetic information and against unauthorized disclosure of that information. Despite these protections, the Executive Order has no enforcement provisions.

Most employees in the private sector, however, enjoy no similar protections. In several hearings, the committee heard testimony that existing Federal employment laws, the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964 (Title VII) provide limited or uncertain protections against the discriminatory use of genetic information in the workplace.[14]

Title VII of the Civil Rights Act of 1964

Title VII of the Civil Rights Act of 1964 makes it illegal for an employer, labor organization, employment agency, or training program to "discriminate against any individual * * * because of such individual's race, color, religion, sex, or national origin." While this law provides robust guarantees against discrimination on the basis of these characteristics just described, its applicability to genetic discrimination is limited. The plain language of the statute provides no obvious protection against genetic discrimination. However, Title VII may indirectly offer some protections against discrimination on the basis of a person's genetic makeup when that discrimination disproportionately affects individuals on the basis of one of the characteristics named in the Act.

For example, the genetic mutation associated with Tay-Sachs Disease is found most commonly in persons with an Eastern European Jewish ethnic background. If an employer were to selectively refuse to hire carriers of the Tay-Sachs mutation, this action would have a disproportionate effect on people with a specific national or ethnic origin. In this limited circumstance, the individuals experiencing such discrimination might have a claim under Title VII.[15]

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[14] For example, testimony of Sen. Tom Daschle, Dr. Francis Collins, and EEOC Commissioner Paul Steven Miller (HELP Committee hearing, July 20, 2000).

[15] See *Norman-Bloodsaw* v. *Lawrence Berkeley Lab.,* 135 F.3d 1260, 1272–72 (9th Cir. 1988). In this case, the Lawrence Berkeley Labs had subjected the plaintiffs to testing the disorders that included sickle cell disease, a condition that is especially prevalent among African-Ameri-

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However, for acts of genetic discrimination that do not have a discriminatory effect on members of class of individuals named in the Civil Rights Act, Title VII would provide no apparent protection against genetic discrimination.

State Law on Genetic Discrimination

To fill the void created by the absence of clear protections at the Federal level, many states have enacted laws that seek to prohibit genetic discrimination in health insurance and/or employment. To date, 31 states have passed laws on genetic discrimination in employment and 34 have passed laws on genetic discrimination in health insurance.[16] Among the states that prohibit discrimination in the issuing of health insurance, many cover only the group health insurance market and exclude individual health insurance policies, while others do the reverse. Many states exclude family medical histories from their definition of genetic information or include only the results of tests that are performed with announced intention of detecting genetic mutations.

Regardless of the technical aspects of any particular state law, there is necessarily a significant gap in any state's ability to deter genetic discrimination in health insurance. Congress delegated to the States the authority to regulate most aspects of insurance through enacting the McCarran-Ferguson Act of 1945. However, employer-purchased plans were exempted from state regulation by the Employee Retirement Income Security Act of 1974. Under this Act, no state may regulate the type of health insurance plans typically provided to employees as part of their employment benefits. Only the Congress can therefore enact a truly comprehensive law prohibiting genetic discrimination in all areas of health insurance.

In view of the need for national comprehensive protections against genetic discrimination, the committee has considered and unanimously approved the Genetic Information Nondiscrimination Act to provide the American people with the assurances they deserve that their genetic profiles will not be used to deny them health insurance or to discriminate against them in the workplace.

III. Legislative History and Votes in Committee

Upon becoming Chairman of the HELP Committee at the beginning of the 108th Congress, Senator Gregg made passage of genetic nondiscrimination legislation a top priority for the committee and placed the issue on the committee calendar for consideration in Spring 2003. Senator Gregg regularly convened discussions for the purpose of merging the two most prominent pieces of legislation addressing genetic discrimination and producing a new bill for consideration by the committee. On May 20, 2003, an agreement was reached on such a unified, bipartisan bill. On May 21, 2003, the Committee considered this legislation, as a manager's amendment to the "Genetic Information Nondiscrimination Act of 2003" (S. 1053), sponsored by Senator Snowe, and approved it without objection.

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cans. The Court found that in subjecting African-American employees to testing for this disorder, Lawrence Berkeley Labs violated their protections under title VII.

[16] Genetic Technologies Project, National Conference of State Legislatures; displayed at http://www.ncsl.org/programs/health/genetics/ndishlth.htm and http://www.ncs1.org/programs/health/genetics/ndiscrim.htm; displayed as of July 31, 2003.

Background

Legislation addressing genetic discrimination first appeared in the 103rd Congress as part of the national health reform debate. In the 104th Congress, as government and private-sector scientists were getting closer to sequencing the human genome, a handful of bills addressing genetic discrimination exclusively were introduced. Sponsors of these bills included an almost equal number of Republicans and Democrats. The various bills focused on different concerns about genetic discrimination and privacy. Most of these bills addressed discrimination in health insurance, while others also addressed genetic privacy and employment discrimination.

During the 104th, the HELP Committee began to hold hearings on the topic. The first hearing examined the public policy implications of advances in genetics research. In 1996, the Senate passed the first genetic nondiscrimination legislation as part of the Health Insurance Portability and Accountability Act (HIPAA). HIPAA was signed into law in 1996 (P.L. 104–191; August 21, 1996). It prohibits discrimination against an individual in a group based on health status, including genetic information, and it primarily applies to group health plans and health insurance issuers in the group market.

HIPAA did not directly address medical privacy; however, HIPAA required HHS to promulgate comprehensive medical privacy regulations if Congress did not pass legislation addressing the same by August 21, 1999. Several bills addressing comprehensive medical privacy were introduced in the 105th and 106th Congress, but the Senate did not act, and HHS proceeded to promulgate regulations.

From 1996 through 2002, the committee explored thoroughly issues related to genetic discrimination in health insurance and employment. The committee held a total of five hearings on genetic discrimination. In addition, the committee has also held hearings on medical privacy, which is relevant to genetics.

Committee Hearings on Genetic Discrimination

July 25, 1996: Advances in Genetics Research and Technologies: Challenges for Public Policy.—Examining recent developments in genetics research, public policy issues with regard to access to and use of genetic information, and the impact of genetic technologies on certain sectors of industry, health care delivery systems, and the public.

May 21, 1998: Genetic Information and Health Care.—Examining proposals to prohibit health care discrimination based on genetic information, including related measures on S. 89 and S. 422.

July 20, 2000: Genetic Information in the Workplace.—Examining issues relating to the development of Federal policy governing the treatment of an individual's genetic information in the workplace in light of the recent Human Genome Project break-throughs.

July 25, 2001: Fulfilling the Promise of Genetic Research: Ensuring Nondiscrimination in Health Insurance and Employment.—Examining S. 318, to prohibit discrimination on the basis of genetic information with respect to health insurance, and related genetics research issues regarding employment discrimination and prevention of disclosure of genetic information to third parties.

Feb. 13, 2002: Protecting Against Genetic Discrimination: The Limits of Existing Laws.—Examining the existing laws and proposed legislation necessary to protect genetic information in order to prevent genetic discrimination that may lead to loss of health insurance or employment discrimination, including S. 318 and S. 382, to prohibit discrimination on the basis of genetic information with respect to health insurance.

Committee, Floor Consideration

Subsequent to HIPAA, both the HELP Committee and the full Senate have considered broader genetic discrimination legislation. In the 106th Congress, Senator Jeffords introduced the Patient's Bill of Rights Act (S. 326), which included genetics nondiscrimination and privacy provisions applying to health insurance. The genetics provision in this legislation was a modified version of the "Genetic Information Nondiscrimination in Health Insurance Act of 1997" (S. 89), introduced by Senator Snowe in the 105th Congress.

During the Committee's consideration of S. 326, Senator Dodd offered an amendment that would have limited the disclosure of predictive genetic information and prohibited employers from discrimination on the basis of genetic information. The amendment was not accepted. Senator Jeffords agreed to hold a hearing on genetic discrimination in the workplace, which he did on July 20, 2000. The Patient's Bill of Rights legislation (S. 326), with the modified genetic nondiscrimination provision from S. 89, was approved by the HELP Committee on March 18, 1999 by a vote of 10 yeas to 8 nays.

The full text of S. 326 was incorporated into Senate Amendment 1232, to the Patient's Bill of Rights (S. 1344), which was approved by the Senate on July 15, 1999. This bill was considered during a House/Senate conference, with House bill H.R. 2990, which did not produce a Conference Report for reasons other than genetic nondiscrimination.

Also in the 106th Congress, on June 29, 2000, Senator Daschle offered Senate Amendment 3688, genetic nondiscrimination he had previously introduced (S. 1322), the Labor/HHS appropriations legislation (H.R. 4577). The Amendment was not accepted. To the same legislation, Senator Jeffords offered Senate Amendment 3691, genetic nondiscrimination legislation (S. 543) introduced by Senator Snowe on March 4, 1999, and that Amendment was approved. The provision was not included in the final Labor/HHS report.

In the 107th Congress, Senator Daschle reintroduced the "Genetic Nondiscrimination in Health Insurance and Employment Act" (S. 318) on February 13, 2001. Senator Snowe reintroduced the "Genetic Information Nondiscrimination in Health Insurance Act of 2001" (S. 382).

On June 28, 2001, Senator Ensign offered Senate Amendment 849, to the Patient's Bill of Rights legislation (S. 1052) under consideration by the full Senate. The amendment was approved without objection. The amendment contained provisions relating to discrimination and privacy in health insurance and employment. The Senate did not appoint conferees on S. 1052, and there was no further action on this Amendment.

In the 107th Congress, Senator Daschle introduced the "Genetic Nondiscrimination in Health Insurance and Employment Act" (S. 381) on February 13, 2001 (along with HELP Committee members

Kennedy, Dodd, Harkin, Mikulski, Murray, Reed, Clinton, Edwards, and Wellstone). Later in the 107th Congress, Senator Snowe (along with HELP Committee members Frist, Jeffords, Enzi, Collins, DeWine, and Gregg) modified her legislation from the prior Congress to reflect the release of the HHS medical privacy regulations and to include a new Tittle II addressing employment discrimination. She introduced this new legislation (S. 1995) on March 6, 2002. Working from these two bills, HELP Committee began to explore whether and how these bills could be merged into a singe bipartisan bill.

In the 108th Congress, Senator Daschle reintroduced his bill as part of a broader civil rights bill "a Bill to Protect the Civil Rights of All Americans" (S. 16) on January 7, 2003. At the beginning of the 108th, Chairman Gregg announced that the committee would consider genetic nondiscrimination legislation in the Spring. HELP Committee members and the sponsors of the two bills redoubled their efforts to merge the Snowe and Daschle legislation for the purposes of creating a single bipartisan bill that could be considered by the committee. These efforts continued from January 2003 until through May 20, 2003, when an agreement was reached.

On May 13, 2003, Senator Snowe reintroduced her legislation from the 107th Congress (S. 1995) without modification. This legislation (S. 1053), was the bill that the committee moved to consider. During the May 21, 2003 executive session, Chairman Gregg offered a manager's substitute to S. 1053, the compromise language based on the Snowe and Daschle legislation, which was agreed to without objection. Senate bill S. 1053, as modified by the manager's substitute, was approved without objection by the committee on May 21, 2003.

IV. Explanation of Bill and Committee Views

TITLE I—GENETIC NONDISCRIMINATION IN HEALTH INSURANCE

Definitions

The definitions of "family member," "genetic information," "genetic test," and "genetic services" provide the foundation for this legislation. These terms are used in every section of Title I and have the same definition in each instance. The committee wishes to emphasize that Title I only applies to health insurance underwriting and eligibility practices and is not in any manner intended to regulate the delivery of medical care and treatment.

The legislation includes "the occurrence of a disease or disorder in family members of the individual," herein after referred to as "family medical history," in the definition of genetic information. The committee intends for "family medical history" to be understood as it is used by medical professionals when treating or examining patients. For example, the American Medical Association (AMA) has developed an adult family history form as a tool to aid the physician and patient to rule out a condition that may have developed later in life, which may or may not have been inherited. This form requests information about the patient's brothers, sisters, children, biological mother, the mother's brothers, sisters, and their children, maternal grandfather, maternal grandmother, biological father, the father's brothers, sisters, and their children, and paternal grandfather. The committee expects that the use of "fam-

ily history" in this bill will evolve with the medical profession and the tools they develop in this area.

The committee realizes that a family medical history could be used as a surrogate for a genetic trait by a health plan or health insurance issuer. A consistent history of a heritable disease in a patient's family may be viewed to indicate that the patient himself or herself is at increased risk for that disease. For this reason, the committee believes it is important to include family medical history in the definition of "genetic information." In so doing, the committee followed the recommendations of numerous leading experts in genetic science.

A key element in the definition of genetic information is the term "genetic test. "Genetic test" is defined in the legislation to mean "an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, chromosomal changes." This definition excludes "an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved." The committee is aware that many laboratory tests analyzed to determine existing diseases, disorders, and conditions are metabolite or protein-based tests and does not intend to include in the definition of genetic information such tests when they indicate the presence of a manifested disease, disorder, or pathological condition.

The committee recognizes that, as part of the underwriting process, an individual may be asked to be examined by a physician or take certain lab tests. The committee also recognizes that medical underwriting may not involve such an exam or new tests and may instead be based on a medical records review or a review of previously-taken lab tests. For instance, a person applying for health insurance who has had a full physical six months prior, may simply supply the results of such prior tests to the insurance company rather than submit to retaking the same battery of tests. In this case, the committee intends that any analysis of proteins and metabolites that indicates a manifested disease, disorder, or pathological condition would still fall within the exception to "genetic test" in this section, regardless of the fact that the test had been conducted preceding the application for coverage.

By including the exception to genetic test for a manifested disease, disorder, or pathological condition, the committee sought to draw a bright line between genetic information and information about a manifested disease, disorder, or pathological condition. In addition to genetic traits, there are other factors that may contribute to the manifestation of a disease or disorder. The committee believes there is great danger, especially in these early stages of scientific discovery, of genetic information being misapplied in the context of health insurance underwriting and thus believes it should be prohibited. While this distinction is important for purposes of this legislation, the committee recognizes that it may not be possible or even desirable in health care delivery or scientific research to isolate genetic information as it pervades health information.

This legislation intentionally does not include in its definition of "genetic information" the results of analyses of proteins or metabo-

lites that indicate a manifested disease, disorder, or pathological condition. The committee recognizes that, while it may have been easier to craft a single set of federal rules governing discrimination based on all health information, rather than trying to isolate and define genetic information, State and Federal law already regulates the use of health information in rating and eligibility practices. With respect to group health plans, ERISA, the Public Health Service Act (PHSA), and the Internal Revenue Code (IRC) currently ban discrimination in eligibility or premiums based on the health-status of an individual in the group. This prohibition was enacted as part of the Health Insurance Portability and Accountability Act in 1996. In addition, states regulate rating and eligibility practices of insurance issuers in the individual market, a highly sensitive market with characteristics unique to each state. As the primary regulators of this market, states can reassess and change their regulations of this market to ensure that carriers will continue to offer products. The committee saw no rationale for supplanting the group market rules or preempting state rating requirements. Instead, the committee invested substantial time and effort circumscribing genetic information.

The terms "genetic information" and "genetic test" address the substantive results of tests, and the legislation prohibits discrimination on the basis of these factors. The legislation also protects, in the same manner, against discrimination on the basis of an individual having taken a test. In addition, the legislation protects the activities associated with genetic information, including genetic counseling (such as obtaining, interpreting, or assessing genetic information) and genetic education. All these functions are protected under the definition of "genetic services."

Sec. 101. Amendments to Employee Retirement Income Security Act of 1974

The committee recognizes that ERISA Section 702(a)(1)(F) and 702(b) currently prohibits a group health plan and a health insurance issuer offering group health insurance coverage in connection with a group health plan from discriminating—in eligibility for enrollment or premium contributions—against an individual in the group based on the individual's health status-related factors, including genetic information. With this section, the committee intends to clarify and expand these protections, and the remedies and enforcement provided for these protections, for group health plan participants and beneficiaries governed by ERISA.

Genetic Services: The committee believes that, in addition to discrimination based on actual genetic information, there is potential for discrimination based on the mere action of requesting or receiving a genetic service. For example, a health plan could potentially assume that a participant has a genetic disorder, such as Huntington's disease, because the participant, or his or her family member, requested or received a genetic test for the disease. This provision clarifies, within the existing prohibition banning discrimination in enrollment against an individual in the group, that the term genetic information includes "information about a request for or receipt of genetics services by an individual or family member of such individual."

The committee's interpretation regarding the inclusion of "information about a request for or receipt of genetics services by an individual or family member of such individual" applies in each section in which this provision appears, including Sec. 102(a)(1)(B) with respect to health insurance issuers offering coverage in connection with a group health plan, Sec. 2753(a) with respect to a health insurance issuer in the individual market, Section 103(a)(2) with respect to group health plans governed by the Internal Revenue Code, and Section 104 with respect to an issuer of a Medicare supplemental policy.

Discrimination in Premiums Against the Group as a Whole: While current law protects individuals in a group from being charged premiums or contributions that are higher than the premiums or contributions for similarly situated individuals, there is no such protection in current law for the group as a whole. Thus, this section prohibits a health insurance issuer offering health coverage in connection with a group health plan from adjusting premium or contribution amounts for a group on the basis of genetic information concerning an individual in the group or a family member of the individual.

The committee is aware that health plans and insurers use actual claims experience to set initial and renewal premiums for groups. And, among the claims experience that a health plan may use to set or renew premium rates are the costs, as opposed to the results, of genetic tests and services. The committee believes that the costs of medical items and services used by an individual do not meet the definition of "genetic information" or "genetic services" under this bill, and therefore are not banned for use by health plans to set or renew premiums rates for the group as a whole.

The committee also recognizes that claims data used to set or renew premiums for the group as a whole are likely to include a range of information such as utilization, payment, and cost data for family members of individuals enrolled in the group. While genetic information is defined broadly in this bill to include "family history," the committee does not believe, nor does it intend for this provision to prohibit a health plan from setting or renewing rates for the group as a whole based on the claims data concerning health status of members of the group who may also happen to be family members of other individuals in the group. The committee believes that the inclusion of family history in the definition of genetic information should not pose this problem because nothing in this legislation prohibits a health plan from taking into consideration when setting or renewing premiums the health information of each person enrolled in the group.

The interpretation of this section 101(a)(2) applies in each section in which this provision appears in the bill, including Sec. 102(a)(1)(B) with respect to health insurance issuers offering coverage in connection with a group health plan and Section 103(a)(2), with respect to group health plans governed by the Internal Revenue Code.

Limitation on Genetic Testing: Sec. 101(b) places limits on a group health plan's ability to request or require an individual, or the family member of the individual, to take a genetic test. As the decision to take a genetic test is a personal one and could be influenced by many factors, including whether or not any treatment ex-

ists for a particular disease, the committee included this prohibition to ensure that individuals would not feel compelled to take a genetic test. However, the committee also wishes to ensure that this provision does not interfere with health care practices that could be beneficial to the individual, so several clarifications of this provision are included in the legislation. For instance this provision does not limit in any manner the authority of the treating health care professional to request that an individual or family member undergo a genetic test. However, the treating health care professional may not require the individual or family member to undergo a genetic test.

The committee believes that, given different motivations by and perceptions of health plans versus treating health care professionals, this distinction is warranted. However, the committee is also aware that some health plans go beyond the insurance function and engage in wellness and disease management programs; and the committee does not wish to discourage such efforts. Thus, this Section 101(b) makes it clear that this legislation does not limit the authority of a health care professional who is employed by or affiliated with the group health plan or health insurance issuer who is providing health care services to the enrolled individual as part of a bona fide wellness program from notifying such individual about the availability of a genetic test or providing information about the genetic test.

The term "bona fide wellness program" is defined by interim final regulations promulgating ERISA's non-discrimination provisions under Section 702. In summary, these regulations define a "bona fide wellness program" as one that does more than simply charging differential premiums based on health risk factors. For instance, a bona fide wellness program might include a rebate for not smoking, but it would also have to offer a smoking cessation program. The committee believes that the concept of a bona fide wellness program is important in the context of genetic discrimination to ensure that a health plan does not use a wellness program as a subterfuge to discriminate in insurance premiums based on genetic information.

The provision prohibiting a health plan from requesting or requiring an individual to undergo a genetic test was included to protect health plan participants from actions that would allow a health plan to obtain genetic information to be used for the purposes of insurance discrimination. It only addresses the act of requesting or requiring an individual to undergo a test. The committee recognizes that this provision does not address the use, disclosure, or collection of existing test results and intends for the flow of genetic information to be governed by the HHS medical privacy rules and Section 105 of of Title I of this legislation.

The interpretation of this section 101(b) applies in each section in which this provision appears in the bill, including Section 102 with respect to health insurance issuers, Section 103 with respect to group health plans governed by the Internal Revenue Code, and Section 104 with respect to an issuer of a Medicare supplemental policy.

Application: This section applies to all non-governmental ERISA group health plans, including plans with less than two participants that are exempt from ERISA's existing nondiscrimination provi-

sions. The committee believes that since the requirements of this section do not impose an administrative burden and since they are applied to individual insurance, there is no rationale for excluding these groups from this section. This section also applies to retiree-only plans. The interpretation of this section also applies in each section in which this provision appears in the bill, including Section 102 with respect to health insurance issuers offering coverage in connection with a group health plan and Section 103 with respect to group health plans governed by the Internal Revenue Code.

Enforcement and Remedies: The legislation clarifies and strengthens remedies and enforcement available to all group health plan participants and beneficiaries governed by ERISA for violations of genetic discrimination under this section. Specifically, enforcement of this section is built on existing remedies under Section 502(a)(1) of ERISA, which provides ERISA plan participants with a private right of action, as well as the Secretarial enforcement mechanisms from Title I of HIPAA, which address insurance portability and discrimination based on health-status.

The committee believes that building on the existing statutory framework is the preferred way to ensure effective enforcement and equity among ERISA plan participants and beneficiaries, particularly since Section 702 of ERISA already prohibits discrimination in eligibility or premiums based on health-status, including genetic information. For violations of this provision, group health plan participants or DOL can sue for equitable relief under ERISA. In addition, the Secretary of Treasury may assess an excise tax for a plan's failure to comply with the existing non-discrimination requirements.

This legislation maintains these existing enforcement mechanisms, but also clarifies that, with respect to a group health plan's violation of this section, a participant or beneficiary has the right to seek injunctive relief before exhausting administrative remedies if taking the time to pursue administrative remedies would cause irreparable harm to the participant's health. The committee also recognizes that while access to health coverage for a genetic predisposition itself would not likely threaten a participant's current health status, a health plan's denial of eligibility under the plan based on genetic information, could potentially threaten other aspects of an individual's, or his or her beneficiary's, health.

In addition to injunctive relief, this legislation also clarifies the nature of equitable relief available under section 502(a) with respect to a genetic discrimination violation under this Act. Where a participant or beneficiary obtains equitable relief under ERISA for a genetic discrimination violation, the court has the discretion to reinstate coverage, retroactive to the date of the violation. The committee recognizes that most disputes over plan eligibility or premiums are resolved quickly and do not typically require legal action. The committee intends to clarify in statute that the court has the discretion to reinstate coverage retroactively with regard to violations of genetic disrimination.

Should a participant or beneficiary recover benefits under Section 502(a)(1)(B) for a violation of the amendments made by section 101 of this act, this legislation gives the court discretion to levy a penalty against the administrator for failure to comply with the re-

quirements of this title. The amount of the penalty is not more than $100 for each day in the non-compliance period, and it is payable to the participant or beneficiary involved. The committee recognizes that, while the process is a departure from current law remedies, the level of remedy available under this provision for violations of genetic discrimination parallels what exists under current law for other HIPAA violations. In designing this provision, the committee was aware of similar provisions under ERISA where the court has the discretion to award penalties for a failure to provide plan documents or COBRA violations. The committee believes that this approach gives victims of genetic discrimination an effective remedy while simultaneously preserving equity in remedies for ERISA plan participants and beneficiaries.

The committee acknowledges that a private remedy is designed to primarily help the individual pursuing the remedy. Therefore the legislation applies the existing Secretarial enforcement mechanism and penalty structure created by HIPAA to the enforcement of genetic discrimination violations. The only changes this legislation makes to this model are to give enforcement authority to the Secretary of Labor rather than the Secretary of Treasury, and to convert the excise taxes to civil monetary penalties. Since DOL currently oversees HIPAA compliance and enforcement, and conducts plan audits, the committee believes that this model will encourage more efficient and timely enforcement of the requirements of genetic nondiscrimination.

This legislation does not alter or modify existing remedies or enforcement, or any interpretation thereof, for any provision of current law other than violations of genetic discrimination as defined under this legislation. For example, this legislation does not modify the remedies available for violations of other health-status related discrimination under Section 702.

Sec. 102. Amendments to the Public Health Service Act

Group Insurance Market: The genetic nondiscrimination provisions that apply to insurance issuers offering coverage in connection with a group health plan are identical to the provisions created by section 101 of this act as amendments to ERISA. With one exception, there are duplicate provisions in the PHSA for each of the requirements in ERISA. Since ERISA provides the exclusive remedy for all ERISA group health plan participants, including those enrolled by a health insurance issuer offering coverage in connection with a group health plan, the legislation does not duplicate the remedies and enforcement provisions in the PHSA. However, the committee emphasizes that all group health plan participants and beneficiaries are entitled to the remedies and enforcement mechanisms under ERISA.

Individual Insurance Market: This provision prohibits a health insurance issuer in the individual market from establishing rules of eligibility (including continued eligibility) or setting premium rates for an individual based upon genetic information (including information about a request for or receipt of genetic services by an individual or family member of such individual). The committee recognizes that currently there are no nondiscrimination protections in federal law for the individual market and that states have the ability to extend genetic nondiscrimination protections to the

individual insurance. However, the committee has chosen to create this federal floor for several reasons.

First, the committee had access to the nation's leading experts and scientists in the field of genetics, including those from the National Human Genome Research Institute of the NIH, to assist in crafting delicate public policy in a field that is fairly new and rapidly advancing. Second, due to the rapid advancement of the science of genetics, protections vary widely from state to state, providing some consumers with better protection than others. Third, the committee believes that there is a timely need for a national standard to prevent genetic discrimination, and consumers across the nation should not have to wait for the actions of dozens of individual state legislatures.

This legislation applies the same enforcement model that Title I of HIPAA created for the enforcement of group-to-individual portability and other requirements for genetic discrimination violations, by an issuer in the individual market. Under that model, states are free to adopt the federal standard or create a more protective standard. If a state fails to substantially enforce the federal standard, the Secretary of HHS shall enforce the requirements against the insurance issuers in that state. To enforce their rights under this legislation, individuals may use whatever means, such as grievances and appeals, assistance from the State insurance commissioner's office, or any other remedies that may be available under state law, such as taking legal action, if the State's law provides such a remedy.

Sec. 103. Amendments to the Internal Revenue Code

The genetic nondiscrimination provisions that apply group health plans governed by the Internal Revenue Code (i.e., church plans) are identical to the provisions created by section 101 of this act as amendments to ERISA, with the exception of the enforcement and remedies provision of this legislation. Church plan participants and beneficiaries are not covered under ERISA Section 502 and thus do not have the rights provided under Section. However, since Church plans are generally not subject to ERISA, any state law claims that a participant or beneficiary may have is not preempted. The legislation does not alter the enforcement mechanisms otherwise available under the IRC with respect to group health plans. Thus, the Secretary of Treasury would have the authority to enforce the nondiscrimination provisions against group health plans governed by the IRC. The committee included this section in order to extend the genetic nondiscrimination group health plans not covered by ERISA.

The committee believes that employees and dependents covered under state and local governmental group health plans should also be covered by the protections of this legislation. Under HIPAA, state and local governmental plans may opt out of the protections that would otherwise apply to group health plans, and some have exercised that option. The committee believes that this legislation provides important protections without imposing a regulatory or cost burden on the plan, and thus believes that an opt-out is both inappropriate and unnecessary. This legislation thus ensures its protections are applicable and enforceable on state and local governmental group health plans.

Sec. 105. Privacy and Confidentiality

Sec. 105(b). Compliance with certain confidentiality standards with respect to genetic information

At a February 13, 2002 hearing before the HELP Committee, the HHS Assistant Secretary of Planning and Evaluation testified about the interaction between genetic nondiscrimination legislation and the medical privacy rules. The Assistant Secretary testified that the HHS medical privacy rules cover all health information, including genetic information, in the same manner, and urged the committee not to craft legislation that creates a different set of privacy rules for genetic information.

In general, the committee believes that treating all health information in a consistent or similar matter will encourage third-party payers to cover genetics tests, technologies, and services. After hearing much testimony and working with a wide range of stakeholders and consumer organizations, the committee was convinced that consistent treatment of all medical information is important in enabling genetics to become part of main stream medicine. Finally, the committee concluded, especially with respect to the "use and disclosure" of information, that it is inherently difficult to separate genetic information from other medical information in the delivery of health care and medical research, and therefore inconsistent rules for the "use and disclosure" of different categories of health information would likely be burdensome and potentially harmful to patient care.

In general, the legislation recognizes that the HHS medical privacy regulations apply to the "use and disclosure" of genetic information, provided that such regulations are not in conflict with this Title.

However, a provision in the medical privacy regulations pertaining to underwriting and insurance rating is inherently discriminatory, and thus inconsistent with the purpose of this legislation. Specifically, there is a provision in the privacy regulations, under the heading of "health care operations," that allows, without prior consent, a covered entity to "use or disclose" genetic information for purposes of premium rating, underwriting, or establishing or renewing a contract for coverage or insurance. Since one of the purposes of this legislation is to prevent discrimination in premium rates, this provision prohibits a plan or issuer from using or disclosing genetic information for purposes of underwriting, determining eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or benefits.

In addition, the legislation states that a covered entity shall not request, require, or purchase genetic information concerning a participant, beneficiary, or enrollee prior to the enrollment and in connection with such enrollment under the plan, coverage, or policy. This language was included because the HHS medical privacy regulations presume that covered health care entities possess health care information and thus the regulations focus on the "use and disclosure" of protected health information. Since health insurance issuers typically treat underwriting as a separate business function and process from coverage decisions and medical management, the committee believes that this important layer of protection will not

adversely impact the delivery of patient care and health care improvement activities.

The committee believes that if a covered entity is barred from using or disclosing genetic information for purposes of underwriting, they should not be able to collect such information in the first place as part of the underwriting, application, or some other pre-enrollment process or interaction. However, the Committee also recognizes that there may be situations in which a health plan or insurance issuer obtains genetic information prior to enrollment, but not in connection with that particular enrollment. For instance, an individual seeking coverage under a plan currently may have been enrolled in the plan previously, and therefore the plan has likely, in making coverage determinations or conducting disease management activities, collected genetic information prior to the individual's current enrollment. Or, if a family member of an individual enrolling for coverage under a plan is already a member of the plan, such plan would likely have collected genetic information "prior to enrollment." The committee did not intend to prohibit this type of collection and thus includes in the legislation the phrase "and in connection with such enrollment" to clarify. However, the committee emphasizes that, regardless of the means by which genetic information is collected, whether in connection with enrollment or not, Sections 101–104 of the legislation prohibits health plans and health insurance issuers from using genetic information to adjust premiums or determine eligibility.

The committee understands that genetic information permeates health information and that covered entities may inadvertently or unintentionally acquire genetic information. For instance, a health insurance issuer may purchase another health plan and all of its medical records, or request medical records or previously taken lab tests for purposes of underwriting. Or, in filling out an application for insurance that includes a medical questionnaire, an individual may voluntarily offer additional health information, such as family medical information which is considered genetic information under this bill. Thus, a provision addressing "incidental collection" is included in the legislation that makes it clear that if a plan, or an issuer obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning an individual, such request, requirement, or purchase shall not be considered a violation if it is not obtained for purposes of underwriting and any genetic information obtained incidentally is not used or disclosed in violation of the HHS medical privacy regulations.

The legislation applies to all group health plans and issuers that are otherwise covered by the HHS medical privacy rules. Therefore, there are a very limited number of plans and issuers, such as a group health plan with less than 50 participants that self-administers, that are covered by the nondiscrimination provisions of this bill but not under this section. The committee believes that since the privacy provisions contained in this legislation are inextricably linked to and coordinated with the HHS privacy regulations, it would be difficult for an entity to comply with the requirements of this section without also complying with all of the medical privacy regulations. The committee did not wish to introduce for the first time such a substantial burden on very small plans.

Covered entities under the genetic privacy and confidentiality standards of this legislation are subject to the same penalties and enforcement structure that exist for the HHS privacy regulations under sections 1176 and 1177 of the Social Security Act.

The Secretary of HHS has the exclusive authority to enforce the privacy requirements of this section. As a result, enforcement of this legislation, with respect to a specific entity, may be split. For instance, for a group health plan, the Department of Labor will enforce the insurance discrimination provision under Section 101 of this bill, but HHS will enforce the requirements of this section. The committee believes that, given that this provision is inextricably linked to the medical privacy rules, HHS is ideally situated to enforce these provisions against all covered entities. Moreover, HHS's ability to enforce this section is further bolstered by its expertise in the medical privacy regulations, the fact that the agency is already enforcing in this area, and the fact that the agency has assigned the HHS Office of Civil Rights to focus on privacy enforcement.

TITLE II—EMPLOYMENT

Sec. 201. Definitions

As a guiding principle, the Genetic Information Nondiscrimination Act of 2003 is designed to extend to individuals in the area of genetic discrimination the same procedures and remedies as are provided under Title VII of the Civil Rights Act of 1964, as amended. These individuals include employees and applicants working in the private sector, in federal and state governments (including presidential and gubernatorial appointees), as well as congressional employees. The corresponding employers of these individuals, as well as employment agencies, labor organizations, and joint labor-management committees are covered by the legislation in the same manner as current law.

As in Title I of the legislation, "genetic information" is defined as information about an individual's or family member's genetic tests, or information about the occurrence of a disease or disorder in family members of the individual. Likewise, "genetic test" is defined in the same way under Titles I and II, except that the Employment title does not include an exception for an analysis that is directly related to a manifested disease, disorder, or pathological condition. In making this distinction, the committee recognizes there are important and necessary uses for non-genetic health information in the health insurance setting that are not applicable in the employment context.

Section 210 specifically provides that the parties "shall not be considered to be in violation of this title based on the use, acquisition, or disclosure of medical information that is not genetic information about a manifested disease, disorder, or pathological condition of an employee or member, including a manifested disease, disorder, or pathological condition that has or may have a genetic basis."

As stated in the discussion of Title I, the committee realizes that a family medical history could be used as a surrogate for genetic traits by a health plan or health insurance issuer. A consistent history of a heritable disease in a patient's family may be viewed to

indicate that the patient himself or herself is at increased risk for that disease. For this reason, the committee believes it is important to include family medical history in the definition of "genetic information." In so doing, the committee followed the recommendations of numerous leading experts in genetic science. Further, the bill applies to spouses and adopted children of an individual because of the potential discrimination an employee or member could face because of an employer's or other entities' concern over potential medical or other costs and their effect on insurance rates.

Secs. 202–205. Prohibited practices

Generally, employers, labor organizations, employment agencies, and joint labor-management committees are prohibited from using, acquiring or disclosing the genetic information of an individual or his/her family members.

Use of Genetic Information: "Use" of genetic information, as drafted in the legislation, utilizes the language of Section 703 of the Civil Rights Act of 1964, as amended, and the same forms of discriminatory acts are outlawed. These acts include refusing to hire or discharging a person based on the genetic information including family history of disease. For example, it would be unlawful for an employer to refuse to hire an otherwise healthy applicant because of a fear that he may develop Parkinson's disease because of a family history of such disease. The prohibition also extends to limiting, segregating, or classifying an individual in a way that would deprive him or her of employment opportunities.

Acquisition of Genetic Information: Banning the use of genetic information alone would not reach the full range of serious concerns that the Genetic Information Nondiscrimination Act is seeking to address. The committee recognizes that the fear of misuse of genetic information and privacy concerns deter individuals from being tested for genetic disorders, seeking genetic services, or participating in important genetic research. Scientific advances in the field of genetics hold great promise for medical prevention and new treatments and therapies. As a matter of sound public policy, the committee is concerned that this promise will go unfulfilled if individuals are afraid to get genetic tests or seek genetic counseling out of fear that they will face discrimination in their employment.

To this end, the legislation makes it unlawful for an employer, labor organization, employment agency, or joint labor-management committee to request, require, or purchase genetic information, except under limited circumstances. Most notably, this prohibition addresses the concerns raised in the case against Burlington Northern Sante Fe Railroad. The company, allegedly without employees' consent or knowledge, conducted genetic tests on blood samples it had previously received from some workers. The U.S. Equal Employment Opportunity Commission filed suit against the company under the Americans with Disabilities Act, relying on the third prong of the definition of "disability" as "being regarded as having such an impairment." The case was ultimately settled so the courts have not had the opportunity to interpret the full application of the "regarded as" prong to genetics discrimination.

The committee's decision to include a prohibition against acquiring genetic information was informed by witnesses who appeared before us, and existing law and regulations. Witnesses at the com-

mittee hearing on February 13, 2002, stressed the need to avoid unintended consequences and to anticipate the requirements of existing employment statutes in order to avoid conflicts. The committee has carefully considered the existing laws and regulations that touch on the flow of information in the workplace and incorporated five exceptions.

The first exception addresses the so-called "water cooler problem," in which an employer unwittingly receives otherwise protected genetic information in the form of family medical history through casual conversations with a worker. The committee recognizes that conversations among co-workers about the health of a family member are common and intends to prevent such normal interaction from becoming the basis of litigation under this Act. Without the exception, the committee is concerned that discussion in the workplace of a family member's health condition that is genetically based could be interpreted as an employer requesting or requiring genetic information from an individual. Under the legislation, an employer, labor organization, employment agency, or joint labor-management committee will not violate the ban on acquiring genetic information where it "inadvertently requests or requires family medical history" of the individual or family member of the individual.

The second exception—which preserves employer-sponsored wellness programs—is necessary to achieve the bill's stated goal of encouraging employees to take advantage of genetic technologies and opportunities to improve human health without fear of discrimination by their employer. To qualify for the exception, this program must be a bona fide wellness program as defined under Section 702 of ERISA. Participation in the program must be voluntary and confidential, and safeguards must be in place to ensure that the sponsoring employer, labor organization, employment agency, or joint labor-management committee does not have access to individually identifiable health information, as defined under the HHS medical privacy regulations.

The committee is concerned that restrictions on information about the health condition of a family member would conflict with the certification procedures under federal and state family and medical leave laws. For example, an employee seeking time off to care for a sick family member may be required to certify the request with a note from the treating physician. The doctor's note may contain genetic information, which is defined for the purposes of this legislation to include family medical history. The third exception eliminates the potential for conflict with existing laws by exempting requests or requirements for family medical history when sought "to comply with the certification provisions of section 103 of the Family and Medical Leave Act of 1993 (29 U.S.C. 2613) or such requirements under State family and medical leave laws."

The committee recognizes that family medical history can easily and inadvertently be obtained. The fourth exception, like the first, relates to the inadvertent acquisition of family medical history. The committee is concerned that the proscriptions of the legislation would be violated, for example, through the purchase of a local newspaper containing the obituary of an employee's parent who died of breast cancer. This exception was included to satisfy the principle in the bill that the rules be clear and that the bill not pro-

vide a basis for frivolous claims. Specifically, the fourth exception provides an exemption where an employer, labor organization, employment agency, or joint labor-management committee "purchases documents that are commercially and publicly available (including newspapers, magazines, periodicals, and books, but not including medical databases or court records) that include family medical history." In referring to "documents," the committee is mindful of Rule 34 of the Federal Rules of Civil Procedure that includes the same materials that are electronically available.

The final exception to the rule against requesting, requiring, or purchasing genetic information protects genetic monitoring of biological effects of toxic substances in the workplace, but only in limited circumstances. The employer, labor organization, employment agency, or joint labor-management committee must give written notice. Unless the monitoring is required by federal or state law, the individual must provide prior, knowing, voluntary and written authorization. The individual must be provided the results of the monitoring. The monitoring must be conducted in compliance with any genetic monitoring regulations, whether promulgated under the Occupational Safety and Health Act (or its state equivalent), the Federal Mine Safety and Health Act, or the Atomic Energy Act. Finally, the monitoring results may only be disclosed to the employer, labor organization, employment agency, or joint labor-management committee in the aggregate and where no individually identifiable information is included.

Regardless of whether an exception applies, the bill makes clear that genetic information, once acquired, may not be used or disclosed in violation of the legislation.

Sec. 206. Confidentiality of genetic information

Faced with concerns about the disclosure of confidential genetic information, individuals may not take advantage of genetic tests, services or counseling, or participate in genetic research. The committee believes that there are very few instances when an employer, labor organization, employment agency, or joint labor-management committee would have a legitimate need to divulge the genetic information that may be in its possession. The legislation adopts the general rule that such information shall be maintained on separate forms and in separate medical files and be treated as a confidential medical record. This is consistent with the ADA's requirements regarding the maintenance and treatment of medical information.

Also as a general rule, an employer, labor organization, employment agency, or joint labor-management committee is prohibited under this legislation from disclosing genetic information. Both for practical reasons and in order not to subject these entities to conflicting legal obligations, five exceptions have been included in the legislation. The genetic information may be provided directly to an individual who receives genetic services. The information may also be disclosed to an occupational or health researcher for research in compliance with 45 CFR Part 46, in response to a court order (with certain limitations), to government officials investigating compliance with this title, and in connection with federal or state family and medical leave certification provisions.

Sec. 207. Remedies and enforcement

The committee recognizes that an effective remedial scheme and proper enforcement are a necessary element in ensuring that the protections in this legislation are realized in the workplace.[17] To this end, the committee has taken advantage of the expertise and process of the EEOC. The legislation protects applicants or employees of employers defined under the Civil Rights Act of 1964, 42 U.S.C. 2000e(f), state employees, federal employees, Congressional employees, and employees as defined in 3 U.S.C. 411(c). Claimants are required to file a charge with the appropriate enforcement agency, within a certain time period, prior to filing a suit in court. The bill provides for the same compensatory and punitive damages available to prevailing plaintiffs under 42 U.S.C. 1981a.

Because the legislation expressly covers state employees, the committee wishes to review the record of state discrimination in genetics. Based on early genetic science, States enacted laws that provided for the sterilization of "undesirable" persons having presumed genetic "defects" such as mental retardation, mental disease, epilepsy, blindness, and hearing loss, among other conditions. The first sterilization law was enacted in the State of Indiana in 1907. In the years following, many States enacted legislation that either incorporated provisions or drew inspiration from the first sterilization law. A majority of States adopted sterilization laws to "correct" apparent genetic traits or tendencies. Many of these State laws have since been repealed, and many have been modified to include essential constitutional requirements of due process and equal protection.

The Supreme Court's earliest decision on the constitutionality of state sterilization statutes certainly does not reflect contemporary norms, but the case has never been officially overruled by the Court. *Skinner* v. *Oklahoma,* 316 U.S. 535 (1942). The current explosion in the science of genetics, and the history of sterilization laws by the States based on early genetic science, compels Congressional action in this area.

Sec. 208. Disparate impact

Due to the unique nature of genetic information and our current understanding of this developing area of science, the Committee has determined that only disparate treatment cases should be permitted under this legislation at this time. The bill contemplates that the science could change in the future and has called for the creation of a study commission six years after the date of enactment to review this issue. The Commission's purpose is to advise

[17] The advisability of applying existing administrative procedures to genetic discrimination claims was best described by Cari M. Dominguez, Chair of the U.S. Equal Employment Opportunity Commission in testimony before the Committee: "We at the EEOC feel that the EEOC has an established and familiar administrative procedure, including a well-received mediation program, which has proven successful in resolving discrimination charges swiftly, to the satisfaction of all parties, and without litigation. * * * Where the EEOC finds cause to believe that discrimination has occurred, we have a conciliation procedure through which many charges are also resolved. Because it provides incentives and opportunities for settlement, the administrative process is much less costly and burdensome, both to those involved and to the judicial system, than a process that would permit immediate access to the courts. Moreover, during the past several years, the Commission has made changes to charge processing, enabling us to keep up with our current caseload as well as reduce our charge backlog. EEOC also has expertise in the development of employment nondiscrimination enforcement policies that shield workers from unlawful discrimination and ensure that legitimate needs are met."

Congress on the advisability of providing for a disparate impact cause of action in the future.

Sec. 209. Construction

As stated previously, it is the Committee's intent to provide clear rules of conduct to all parties in order to promote compliance and avoid needless or frivolous lawsuits. In most instances, the legislation is designed to work in conjunction with existing laws and not to override current protections, rights, or defenses. Several rules of construction have been included in the legislation to assist courts in interpreting Congressional intent.

The Committee recognizes that both the ADA and the Rehabilitation Act of 1973 regulate the use of genetic information in some manner. The first rule of construction expressly states that nothing in Title II shall be construed to limit the rights or protections of an individual under those two laws. Individuals remain free to seek redress for violations of the ADA, the Rehabilitation Act, and the Genetic Information Nondiscrimination Act. The Committee emphasizes, however, that this legislation in no way alters the current law prohibiting double recovery of damages based on the same facts or a common occurrence. See, e.g., *Anderson* v. *Group Hospitalization,* 820 F.2d 465 (D.C. Cir. 1987); *Skinner* v. *Total Petroleum,* 859 F.2d 1439 (10th Cir. 1988); *Kim* v. *Nash,* 123 F.3d 1046 (8th Cir. 1997); *Atkinson* v. *Anadarko Bank and Trust Company,* 808 F.2d 438, 441 (5th Cir.) cert. denied 483 US 1032 (1987); *Squires* v. *Bonser,* 54 F.3d 168 (3d Cir. 1995); and *Mason* v. *Oklahoma Turnpike Authority,* 115 F. 3d 1442 (10th Cir. 1997).

The second rule of construction is included to ensure that claims against parties are brought in the capacity in which they act. The committee recognizes that an employer, labor organization, employment agency, or joint labor-management committee can act in its capacity as an employer, or in its capacity under ERISA as a plan sponsor, fiduciary, or plan administrator. The actions of an employer, labor organization, employment agency, or joint labor-management committee when taken in its capacity as a plan sponsor, fiduciary, or plan administrator, would be governed by Title I of this legislation. Currently, courts must decide whether conduct of an employer violates ERISA or Title VII of the Civil Rights Act of 1964, depending on whether the employer was acting in its capacity as a group health plan or as an employer, respectively. The committee does not intend to extend liability under Title II, where broader remedies may be more attractive than the remedies under Title I, for violations of Title I. The legislation should not be interpreted to change current law and courts will continue to evaluate the facts in light of existing precedent.

The third rule of construction reiterates that the Genetic Information Nondiscrimination Act serves as a Federal floor for genetics rights and does not preempt Federal and State laws that provide equal or greater protections to individuals. This follows the long line of Federal employment, wage & hour, and other laws. The remaining rules of construction make clear that this legislation shall not be construed to interfere with the normal operation of several existing statutes and programs; specifically, these are the Armed Forces Repository of Specimen Samples for the Identification of Remains, applicable workers' compensation laws, occupational and

other health research pursuant to 45 C.F.R. Part 46, and regulatory actions by the Occupational Safety and Health Administration and the Mine Safety and Health Administration.

V. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 19, 2003.

Hon. JUDD GREGG,
Chairman, Committee on Health, Education, Labor, and Pensions, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 1053, the Genetic Nondiscrimination Act of 2003, as ordered reported by the Committee on Health, Education, Labor, and Pensions on May 21, 2003.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Alexis Ahlstrom (for the federal budget impact), Leo Lex (for the state and local impact), and David Auerbach (for the private-sector impact).

Sincerely,

DOUGLAS HOLTZ-EAKIN,
Director.

Enclosure.

S. 1053—The Genetic Information Nondiscrimination Act of 2003

S. 1053 would prohibit the use of genetic information (including results of genetic tests and family history of disease) by employers in employment decisions and by health insurers and health plans in making enrollment determinations and setting insurance premiums.

CBO estimates that enacting the bill would increase the number of individuals who obtain insurance by fewer than 500 people per year, nearly all of whom would obtain insurance in the individual market. The bill would affect federal revenues because the premiums paid by those newly insured individuals would be tax-deductible. CBO estimates that enacting S. 1053 would decrease revenues by less than $500,000 in each year from 2004 through 2013.

The bill would require the Secretaries of Health and Human Services (HHS), Labor, and the Treasury to issue regulations to carry out the provisions of this bill, and would require the Secretaries of HHS and Labor to enforce those provisions. In addition, the bill would establish a commission to review the science of genetics and to make recommendations to the Congress on the need to establish a disparate impact standard for genetic discrimination. The bill would authorize the appropriation of such sums as necessary to establish the commission and to carry out the other provisions of the bill. Assuming the appropriation of the necessary amounts, CBO estimates that implementing S. 1053 would increase discretionary spending by less than $500,000 in 2004 and by $2 million over the 2004–2013 period. We estimate that the bill would have no significant effect on direct spending.

S. 1053 would preempt some state laws that establish confidentiality standards for genetic information, and it would restrict how state and local governments use such information in employment

practices and in the provision of health care to employees. The preemption and the limitations on state and local actions would be intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA), but there is little indication that state, local, or tribal governments currently engage or are likely to engage in the activities prohibited by the bill. Consequently, CBO estimates that the costs of the mandates would not be significant and would not exceed the threshold established in UMRA ($59 million in 2003, adjusted annually for inflation).

The bill contains a number of private-sector mandates on health insurers, health plans, employers, labor unions, and other organizations. CBO estimates that the direct cost of those requirements would not exceed the annual threshold specified in UMRA ($117 million in 2003, adjusted annually for inflation) in any of the first five years the mandates would be effective.

The CBO staff contacts for this estimate are Alexis Ahlstrom, (for federal budget impact), Leo Lex (for the state and local impact), and David Auerbach (for the private-sector impact). This estimate was approved by Robert A. Sunshine, Assistant Director for Budget Analysis.

VI. Application of Law to the Legislative Branch

Section 102(b)(3) of Public Law 104–1, the Congressional Accountability Act (CAA), requires a description of the application of this bill to the legislative branch. S. 1053 prohibits discrimination on the basis of genetic information with respect to health insurance and employment. With respect to health insurance, the provisions of S. 1053 would indirectly apply to the Federal Employees Health Benefits Program (FEHBP) which contracts with insurance issuers and provides coverage to Members and employees of the legislative branch. The impact of this legislation on the FEHBP may not be relevant, however, given that the FEHBP already has broad nondiscrimination rules in place, and given the fact that, pursuant to existing laws and regulations, eligibility for enrollment in the FEHBP is based solely on employment with the Federal Government, not medical conditions. With respect to employment, Executive Order 13145, issued February 10, 2000, prohibits discrimination in Federal employment based on genetic information, and current laws and regulations ensure that disqualification for Federal employment can only be based on job-related criteria. Through the CAA, these laws, and S. 1053, would be applicable to the legislative branch.

VII. Regulatory Impact Statement

The committee has determined that there will be minimal increases in the regulatory burden imposes by this bill.

Title I of the bill generally builds on existing regulatory structures and industry practices. It is composed of several sections and applies to group health plans, group health insurance, insurers in the individual market, and issuers of Medicare supplemental policies. All non-governmental and many non-Federal State and local governmental group health plans are subject to existing protections under ERISA, PHSA, and IRC that pertain to discrimination based on health-status. These plans are also currently subject to the HHS

medical privacy rules. While the legislation adds to the substance of these existing requirements, it does not add any major new concepts or requirements, such as a notice requirement. Based on these factors, the committee has determined that there will be negligible regulatory impact with respect to group health plans.

Although insurance issuers of Medicare supplemental policies and individual policies are not subject to Federal law banning genetic discrimination, many States have already passed laws in this area. In addition, the majority of these issuers are currently subject to the HHS medical privacy rules. Thus, the committee has determined that there will be minimal regulatory burden imposed with respect to insurance issuers Medicare supplemental policies and individual policies.

VIII. SECTION-BY-SECTION ANALYSIS

TITLE I—GENETIC NON-DISCRIMINATION IN HEALTH INSURANCE

Sec. 101. Amendments to Employee Retirement Income Security Act of 1974

Subsection (a). Prohibition of Health Discrimination on the Basis of Genetic Information or Genetic Services

Sec. 101(a)(1)—No Enrollment Restriction for Genetic Services. This provision amends ERISA 702(a)(1)(F) to include "information about a request for or receipt of genetics services by an individual or family member of such individual."

Sec. 101(a)(2)—No Discrimination in Group Premiums Based on Genetic Information. This provision amends ERISA 702(b) to prohibit a health insurance issuer offering group health coverage in connection with a group health plan from adjusting premium or contribution amounts for a group on the basis of genetic information concerning an individual in the group or a family member of the individual.

Sec. 101(b)—Limitations on Genetic Testing. This section amends Section 702 of ERISA to include a prohibition on genetic testing. Specifically, this provision prohibits a group health plan or a health insurance issuer offering group health insurance coverage in connection with a group health plan from requesting or requiring an individual or a family member of such individual to undergo a genetic test. This section does not limit the authority of the treating health care professional to request that such individual or family member undergo a genetic test. Nor does it limit the authority of a health care professional who is employed by or affiliated with the group health plan or health insurance issuer and who is providing health care services to the enrolled individual as part of a bona fide wellness program (as defined under regulations promulgating ERISA Section 702 at 29 CFR 2590.702(f)) from notifying such individual about the availability of a genetic test or providing information about the genetic test. Finally, this section does not authorize or permit a health care professional to require that an individual undergo a genetic test.

Application to All Plans. This provision applies the requirements of the amendments made by section 101 of the Genetic Information Nondiscrimination Act to small group health plans (and group health insurance coverage offered in connection with a group

health plan) that are otherwise exempt, under Section 732(a) of ERISA, from the other non-discrimination prohibitions under Section 702 of ERISA. Therefore, the requirements of such amendments apply to a group health plan (and group health insurance coverage offered in connection with a group health plan) that, on the first day of the plan year, has less than two participants who are current employees for any plan year. Such amendments also apply to retiree only group health plans (and group health insurance coverage offered in connection with a group health plan).

Section 101(c)—Remedies and Enforcement. This section amends Section 502 of ERISA to clarify and strengthen remedies available to group health plan participants for violations of the genetic nondiscrimination provisions added by Title I.

(1) Injunctive Relief for Irreparable Harm.—This provision clarifies that an ERISA plan participant or beneficiary can seek relief in court under Section 502(a)(1)(B) of ERISA for a violation of the amendments made by section 101 of this Act, prior to the exhaustion of the plan's administrative remedies under Section 503 of ERISA. To qualify for such relief, a participant or beneficiary must demonstrate to the court, by a preponderance of evidence, that the exhaustion of administrative remedies would cause irreparable harm to the health of such participant or beneficiary. Any determinations made, either previously or while an action under this provision is pending, under the plan's administrative remedies shall be given due consideration by the court.

(2) Equitable Relief for Genetic Discrimination.—This provision clarifies and expands the type of equitable relief and penalties available under Section 502 of ERISA for a violation of this Section.

(A) Reinstatement of Benefits Where Equitable Relief Has Been Awarded.—If a participant or beneficiary recovers benefits under Section 502(a)(1)(B) of ERISA for a violation of the amendments made by section 101 of this Act, this provision allows the court, in its discretion, to reinstate coverage retroactively. Specifically, where a participant or beneficiary has been wrongfully denied eligibility under the plan due to a violation of such section, the court can award reinstatement of a participant's or beneficiary's coverage, retroactive to the date of the denial of such eligibility.

(B) Administrative Penalty Where Equitable Relief Has Been Awarded.—If a participant or beneficiary recovers benefits under Section 502(a)(1)(B) for a violation of the amendments made by section 101 of this Act, this provision allows the court, in its discretion, to levy a penalty on the administrator who fails to comply with the requirements of this title. Such administrator can be held personally liable for a penalty in the amount of not more than $100 for each day in the non-compliance period. Such penalty shall be payable to the participant or beneficiary involved. The non-compliance period is defined as the period beginning on the date that the failure, a violation of any of the provision of this Section, occurs and ending on the date that such failure is corrected.

(3) Secretarial Enforcement Authority.—Under current law, HIPAA's existing non-discrimination provisions are enforced by the personal remedies available under ERISA 502(a)(1) or (3). In addition, the Department of the Treasury and Internal Revenue Service may levy an excise tax against a group health plan for its failure

to comply with HIPAA's requirements. The Department of Labor is not currently authorized to impose penalties for HIPAA violations. This provision maintains the size and framework of the HIPAA excise tax, but transfers the enforcement authority to the Department of Labor solely for the purposes of enforcing this section.

Amount of Penalty.—Specifically, the Secretary of Labor may impose a civil penalty against a group health plan for any violation of this Section in the amount of $100 for each day in the non-compliance with respect to each individual to whom such failure relates. A higher penalty of $2,500 for each day of non-compliance shall be applied where there is one or more failure with respect to an individual involved and where the plan did not correct the failure within the specified time. A penalty of $15,000 shall be applied if the violation under this Title in any year is more than di minimis.

Limitations.—No penalty applies under this paragraph if the Secretary determines that the person did not know, or through reasonable diligence would not have known, that such failure existed. A penalty shall be imposed on any failures due to reasonable cause and not willful neglect; and if such failure is corrected within 30 days of discovery. The overall limitation for unintentional failures due to reasonable cause shall not exceed the lesser of 10 percent of the amount paid or incurred by the employer during the preceding taxable year for group health plans or $500,000. The Secretary may waive all or part of any penalty imposed by this section if the penalty would be excessive relative to the failure involved.

Sec. 101(d)—Definitions. This section adds new definitions to Section 733(d) of ERISA with respect to genetic non-discrimination.

Family Member.—Means the spouse of the individual, a dependent child of the individual, including a child who is born to or placed for adoption with the individual, and all other individuals related by blood to the individual or the spouse or child.

Genetic Information.—Means information about an individual's genetic tests, the genetic tests of family members of the individual, or the occurrence of a disease or disorder in family members of the individual. It does not include information about the sex or age of an individual.

Genetic Test.—Means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes. It does not mean an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes or an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

Genetic Services.—Means a genetic test; genetic counseling (such as obtaining, interpreting, or assessing genetic information); or genetic education.

Sec. 101(e).—Regulations and Effective Date. The Secretary of Labor shall issue final regulations not later than one year after enactment. The amendments made by this act shall apply to group health plans for plan years beginning 18 months after enactment.

Sec. 102. Amendments to the Public Health Service Act

Subsection (a).—Amendments Relating to the Group Market

(1) Prohibition of Health Discrimination on the Basis of Genetic Information or Genetic Services.—Section 2702(a)(1)(F) and 2702(b) of the Public Health Service Act currently prohibits a group health plan and a health insurance issuer offering group health insurance coverage in connection with a group health plan from discriminating—in eligibility for enrollment or premium contributions—against an individual in the group based on the individual's health status-related factors, including genetic information. In general, this section clarifies and expands this provision by prohibiting discrimination based on genetic information.

(A) No Enrollment Restriction for Genetic Services.—This provision clarifies within the existing prohibition banning discrimination in enrollment against an individual in the group that the term genetic information includes "information about a request for or receipt of genetics services by an individual or family member of such individual."

(B) No Discrimination in Group Premiums Based on Genetic Information.—This provision prohibits a health insurance issuer offering group health coverage in connection with a group health plan from adjusting premium or contribution amounts for a group on the basis of genetic information concerning an individual in the group or a family member of the individual.

(2) Limitations on Genetic Testing.—This section amends section 2702 of the Public Health Service Act to include a prohibition on genetic testing. Specifically, this provision prohibits a group health plan or a health insurance issuer offering group health insurance coverage in connection with a group health plan from requesting or requiring an individual or a family member of such individual to undergo a genetic test. Section 102 does not limit the authority of the treating health care professional to request that such individual or family member undergo a genetic test. Nor does it limit the authority of a health care professional who is employed by or affiliated with the group health plan or health insurance issuer and who is providing health care services to the enrolled individual as part of a bona fide wellness program (as defined under regulations promulgating PHSA section 2702 at 45 CFR 146.121(f)) from notifying such individual about the availability of a genetic test or providing information about the genetic test. Finally, this section does not authorize or permit a health care professional to require that an individual undergo a genetic test.

Application to All Plans.—This provision applies the requirements of the amendments made by section 102(a) of the Genetic Information Nondiscrimination Act to small group health plans (and group health insurance coverage offered in connection with a group health plan) that are otherwise exempt, under section 2721(a) of the Public Health Service Act, from the non-discrimination prohibitions under section 2702. Therefore, the requirements of such amendments apply to a group health plan (and group health insurance coverage offered in connection with a group health plan) that, on the first day of the plan year, has less than two participants who are current employees for any plan year. Such amendments

also applies to retiree only group health plans (and group health insurance coverage offered in connection with a group health plan).

(3) Remedies and Enforcement.—This section amends section 2722(b) of the Public Health Service Act to allow for enforcement of the requirements the amendments made by section 102(a) against health insurance issuers offering group health insurance coverage in connection with a group health plan. The enforcement mechanism is the same as that created by HIPAA to enforce existing non-discrimination provisions against health insurance issuers offering group health insurance coverage in connection with a group health plan Under Section 2702 of the PHSA. In general, a State may require health insurance issuers to meet the requirements of HIPAA. If a State fails to substantially enforce a provision with respect to health insurance issuers, the Secretary of HHS shall enforce.

Secretarial Enforcement Authority Relating to Genetic Discrimination.—In cases where the Secretary of HHS determines that a State has failed to substantially enforce the requirements of the amendments made by section 102(a) against a health insurance issuer offering group health insurance coverage, the Secretary has the authority to impose a civil monetary penalty on the issuer.

Amount of Penalty.—Specifically, the Secretary of HHS may impose a civil penalty against a group health plan for any violation of the amendments made by section 102(a) in the amount of $100 for each day in the noncompliance with respect to each individual to whom such failure relates. A higher penalty of $2,500 for each day of non-compliance shall be applied where there is one or more failure with respect to an individual involved and where the plan did not correct the failure within the specified time. A penalty of $15,000 shall be applied where the violation under the amendments made by section 102(a) in any year is more than de minimis.

Limitations.—No penalty applies under this paragraph if the Secretary determines that the person did not know, or through reasonable diligence would not have know, that such failure existed. No penalty shall be imposed on any failures due to reasonable cause and not willful neglect; and if such failure is corrected within 30 days of discovery. The overall limitation for unintentional failures due to reasonable cause shall not exceed the lesser of 10 percent of the amount paid or incurred by the employer during the preceding taxable year for group health plans or $500,000. The Secretary may waive all or part of any penalty imposed by this section if the penalty would be excessive relative to the failure involved.

(4) Definitions.—This section adds new definitions to section 2791(d) of the PHSA with respect to genetic non-discrimination. The definitions are identical to the definitions applying to group health plans under section 101.

Subsection (b). Amendments Relating to the Individual Market

(b)(1). Adds a new section 2753 to subpart 2 to title XXVII of PHSA relating to genetic nondiscrmination.

Sec. 2753(a)—Prohibition on Genetic Information as a Condition of Eligibility. A health insurance issuer in the individual market may not establish rules for eligibility (including continued eligibility) for an individual to enroll for coverage based on genetic in-

formation (including information about a request for or receipt of genetic services by an individual or family member of such individual).

Sec. 2753(b)—Prohibition on Genetic Information in Setting Premium Rates. A health insurance issuer in the individual market shall not adjust the premium or contribution amounts for an individual on the basis of such individual's genetic information (including information about a request for or receipt of genetic services).

Sec. 2753(c)—Limitation on Genetic Testing. This provision prohibits a health insurance issuer in the individual market from requesting or requiring an individual or a family member of such individual to undergo a genetic test. This provision does not limit the authority of the treating health care professional to request that such individual or family member undergo a genetic test. Nor does it limit the authority of a health care professional who is employed by or affiliated with the group health plan or health insurance issuer and who is providing health care services to the enrolled individual as part of a bona fide wellness program (as defined under regulations promulgating PHSA section 2702 at 45 CFR 146.121(f)) from notifying such individual about the availability of a genetic test or providing information about the genetic test. Finally, this provision does not authorize or permit a health care professional to require that an individual undergo a genetic test.

(2) Remedies and Enforcement.—This section amends section 2761 of PHSA to establish the same enforcement mechanism and Secretarial authority against health insurance issuers in the individual market as is provided for enforcing the genetic non-discrimination provisions against health insurance issuers in the group market.

Subsection (c). Elimination of Option of Non-Federal Governmental Plans to be Excepted From Requirements Concerning Genetic Information

This subtitle creates an exception to the existing opt-out provision under section 2721(a)(1)(2) of the PHSA that provides non-federal governmental plans the ability to opt out of certain requirements created by HIPAA. Therefore, all non-federal governmental health plans must comply with the genetic non-discrimination requirements created by this Act in the same manner as other non-governmental group health plans.

Subsection (d)—Regulations and Effective Date

Not later than one year after the date of enactment of this title, the Secretary of Labor and the Secretary of HHS (as the case may be) shall issue final regulations to carry out the amendments made by this section. The amendments made by this section shall apply to group health plans and insurance for plan years beginning after the date that is 18 months after the date of enactment of this title. The amendments made by this section shall apply to insurance in the individual market 18 months after date of enactment.

Sec. 103.—Amendments to the Internal Revenue Code of 1986

Subsection (a)(1). Nondiscrimination on the Basis of Genetic Information or Genetic Services

Sections 9802(a)(1)(F) and 9802(b) currently prohibit a group health plan from discriminating—in eligibility for enrollment or premium contributions—against an individual in the group based on the individual's health status-related factors, including genetic information. In general, this section clarifies and expands this provision by prohibiting discrimination based on genetic information.

Sec. 103(a)(1)—No Enrollment Restriction for Genetic Services. This provision clarifies within the existing prohibition banning discrimination in enrollment against an individual in the group that the term genetic information includes "information about a request for or receipt of genetics services by an individual or family member of such individual."

Sec. 103(a)(2)—No Discrimination in Group Premiums Based on Genetic Information. Section 9802(b) of IRC is amended to prohibit a group health plan from adjusting premium or contribution amounts for a group on the basis of genetic information concerning an individual in the group or a family member of the individual.

Sec. 103(b)—Limitations on Genetic Testing. This section amends Section 9802 of the IRC to include a prohibition on genetic testing. Specifically, this provision prohibits a group health plan from requesting or requiring an individual or a family member of such individual to undergo a genetic test. Section 103 does not limit the authority of the treating health care professional to request that such individual or family member undergo a genetic test. Nor does it limit the authority of a health care professional who is employed by or affiliated with the group health plan or health insurance issuer and who is providing health care services to the enrolled individual as part of a bona fide wellness program (as defined under regulations promulgating Code Section 9802 at 26 CFR 54.9802–1T(f)) from notifying such individual about the availability of a genetic test or providing information about the genetic test. Finally, this section does not authorize or permit a health care professional to require that an individual undergo a genetic test.

Application to All Plans.—This provision applies the requirements of the amendments made by section 103 of the Genetic Information Nondiscrimination Act to small group health plans that are otherwise exempt, under Section 9831(a)(2) of the IRC, from the non-discrimination prohibitions under Section 9802 of the IRC. Therefore, the requirements of the amendments made by section 103 apply to a group health plan that, on the first day of the plan year, has less than two participants who are current employees for any plan year. The requirements of the amendments made by section 103 also applies to retiree only group health plans (and group health insurance coverage offered in connection with a group health plan).

Sec. 103(c)—Definitions. This section adds new definitions to Section 9832(d) of the IRC with respect to genetic non-discrimination. The definitions are identical to the definitions applying to group health plans under Section 101.

Sec. 103(d)—Regulations and Effective Date. The Secretary of the Treasury shall issue final regulations not later than one year after

enactment. The amendments made by this act shall apply to group health plans for plan years beginning 18 months after enactment.

Sec. 104. Amendments to Title XVIII of the Social Security Act Relating to Medigap

Subsection (a). Nondiscrimination

Sec. 104(a)(1)—Amends Section 1882(s)(2) of the Social Security Act by adding the following: An issuer of a Medicare supplemental policy shall not deny or condition the issuance or effectiveness of the policy, and shall not discriminate in the pricing of the policy (including premium rate adjustments) of an individual on the basis of genetic information (or information about a request for, or receipt of, genetic services by such individual or family member of such individual).

Sec. 104(a)(2)—Effective Date. Prohibition in (a)(1) applies for policy years beginning after the date that is 18 months after the date of enactment

Sec. 104(b)(1)—Limitation on Genetic Testing. This provision amends 1882 of the Social Security Act to prohibit an issuer of a Medicare supplemental policy from requesting or requiring an individual or a family member of such individual to undergo a genetic test. This provision does not limit the authority of the treating health care professional to request that such individual or family member undergo a genetic test. Nor does it limit the authority of a health care professional who is employed by or affiliated with the issuer of the Medicare supplemental policy and who is providing health care services to the enrolled individual as part of a bona fide wellness program (as defined under regulations promulgating ERISA Section 702) from notifying such individual about the availability of a genetic test or providing information about the genetic test. Finally, this provision does not authorize or permit a health care professional to require that an individual undergo a genetic test.

Definitions.—The definitions of "family member," "genetic information," and "genetic test," and "genetic services" are identical to the definitions applying to group health plans under Section 101. This subsection includes the following additional definition:

Issuer of a Medicare Supplemental Policy.—includes a third-party administrator or other person acting for or on behalf of such issuer.

Sec. 104(b)(2)—Conforming Amendment. The legislation requires an issuer to conform to and abide by the protections against genetic discrimination described in this Section in order to be certified by the Secretary as an issuer of a Medigap policy.

Sec. 104(c)—Transition Provisions. The Secretary of HHS identifies whether a State needs to change its statute or regulations to comply with this section. A State has until the earlier of the date the State changes its statute or regulations to conform to this section, or October 1, 2004 to make the necessary changes and will not be considered out of compliance until such date. The National Association of Insurance Commissioners (NAIC) regulations shall be considered to be the applicable NAIC model regulation if such regulations are updated in a timely manner to be consistent with the Genetic Information Nondiscrimination Act. If the NAIC does not

modify its model regulations in the time frame established, the Secretary of HHS shall, not later than October 1, 2004, promulgate the regulation. If a State requires conforming legislation but its legislature is not scheduled to meet in 2004, the date of required compliance specified by this paragraph is the first day of the first calendar quarter beginning after the close of the first legislative session of the State legislature that begins on or after July 1, 2004. For a State that has a 2-year legislative session, each year of such sessions shall be deemed to be a separate regular session of the State legislature.

Sec. 105. Privacy and Confidentiality

Sec. 105(a)—Applicability. The provisions in this section apply to all group health plans, health insurance issuers (including issuers offering coverage in connection with group health plans or individual health coverage), and issuers of Medicare supplemental policies as defined in previous sections of this Act and without any exception for small groups or a non-federal governmental opt-out.

Sec. 105(b). Compliance with Certain Confidentiality Standards with Respect to Genetic Information.

(1) In General.—The medical privacy rules promulgated by HHS (45 CFR Parts 160 and 164; final rule) shall apply to the use and disclosure of genetic information.

(2) Prohibition on Underwriting and Premium Rating.—As an exception to (1), a group health plan, health insurance issuer, or issuer of a Medicare supplemental policy shall not use or disclose genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determining eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or benefits.

Sec. 105(c). Prohibition on Collection of Genetic Information.

(1) In General.—A group health plan, health insurance issuer, or issuer of a Medicare supplemental policy shall not request, require, or purchase genetic information for purposes of underwriting, determining eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage under the plan or for health insurance or benefits.

(2) Limitation Relating to the Collection of Genetic Information Prior to Enrollment.—A group health plan, health insurance issuer, or issuer of Medicare supplemental policy shall not request, require, or purchase genetic information concerning a participant, beneficiary, or enrollee prior to the enrollment, and in connection with such enrollment, of such individual under the plan, coverage, or policy.

(3) Incidental Collection.—Where a group health plan, health insurance issuer, or issuer of a Medicare supplemental policy obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning an individual, such request, requirement, or purchase shall not be considered a violation if it is not obtained for purposes of underwriting as defined under paragraph (1) and any genetic information obtained incidentally is not used or disclosed in violation of the HHS medical privacy regulations.

Sec. 105(d)—Application of Confidentiality Standards. The requirements of this Section apply only to group health plans, health insurance issuers, and issuers of a Medicare supplemental policies that are otherwise covered under the HHS medical privacy regulations. Therefore, the health plan exceptions contained in the medical privacy regulations also apply with respect to the requirements under this Section. The requirements of this section do not apply to genetic information that is not considered to be individually-identifiable under HHS medical privacy regulations.

Sec. 105(e)—Enforcement. Covered entities under this section are subject to the same penalties that exist for medical privacy regulations under sections 1176 and 1177 of the Social Security Act for privacy and confidentiality violations of genetic information under Section 105.

Sec. 105(f)—Preemption. The preemption provision for this section is the same standard that exists for the medical privacy regulations. Specifically, a requirement under this section shall supersede any contrary provision of State law unless such provision of State law imposes requirements, standards, or implementation specifications that are more stringent than those imposed under this section. No penalty, remedy, or cause of action to enforce such as State law that is more stringent shall be preempted by this section. This provision shall not be construed to establish a penalty, remedy, or cause of action under State law if it is not otherwise available under State law.

Sec. 105(g)—Coordination with Privacy Regulations. The Secretary of HHS shall implement and administer this section in a manner that is consistent with the medical privacy regulations.

Sec. 105(h)(1)—Definitions. The definitions of "family member," "genetic information," "genetic services," and "genetic test" are identical to the definitions in Section 101 of this bill. However, a new definition of group health plan is included.

(2) Group Health Plan/Health Insurance Issuer.—These terms include only those plans and issuers that are otherwise covered under the HHS medical privacy regulations and under (d)(1) of this section.

(3) Issuer of a Medicare Supplemental Policy.—Means an issuer described in section 1882 of the Social Security Act.

(4) Secretary.—Means the Secretary of Health and Human Services.

Sec. 106. Assuring Coordination

(a) The Secretary of Treasury, the Secretary of Health and Human Services, and the Secretary of Labor shall ensure, through the execution of an interagency memorandum of understanding, that regulations, rulings, and interpretations are administered to have the same effect when there is two or more agencies of jurisdiction. Such Secretaries shall pursue coordinated enforcement strategies and assign priorities in enforcement.

(b) The Secretary of Health and Human Services shall have sole authority over Section 105, the privacy and confidentiality standards pertaining to genetic information.

Sec. 107. Regulations and Effective Date

No later than one year after the date of enactment, the Secretaries of Labor, HHS, and Treasury shall issue final regulations. Except as provided in Section 104 with respect to an issuer of a Medicare supplemental policy, the requirements of this Act shall take effect 18 months after enactment.

TITLE II—EMPLOYMENT

Sec. 201. Definitions. The section defines the parties covered by the act—employer, employment agency, labor organization—and ensures that state, federal and congressional employees receive the same protections. Family members are defined as the spouse or dependent child of an individual, including adopted children, and all other individuals related by blood to the individual or his/her spouse. Genetic information is defined as information about genetic tests of an individual or his/her family member. Genetic information also means information about the occurrence of disease or disorder in family members of the individual. It does not, however, include information about the sex or age of an individual. The section defines genetic monitoring, services and tests consistent with Title I.

Sec. 202. Employer Practices. An employer is prohibited from using genetic information to discriminate against an individual in employment. The section also makes it unlawful for an employer to request, require or purchase genetic information. Several specific exceptions are included: where an employer inadvertently requests or requires family medical history information; pursuant to an employer-sponsored wellness program; where the information relating to a family member is requested or required to comply with the certification provisions of federal or state family and medical leave laws; where an employer purchases family medical history information that is publicly available through such items as newspapers, periodicals and books; or where the information is used for genetic monitoring of the biological effects of toxic substances in the workplace. Despite lawful acquisition of the information through these exceptions, the section makes clear that the employer still may not use or disclose the information in violation of the Title.

Sec. 203. Employment Agency Practices. This section extends parallel obligations and exceptions to employment agencies as apply to employers under Sec. 202.

Sec. 204. Labor Organization Practices. This section extends parallel obligations and exceptions to labor organizations as apply to employers under Sec. 202.

Sec. 205. Training Programs. This section extends parallel obligations and exceptions to joint labor-management committees as apply to employers under Sec. 202.

Sec. 206. Confidentiality of Genetic Information. The section provides that an individual's genetic information shall be treated and maintained as part of the individual's confidential medical records. Disclosure is prohibited, except to: the individual; an occupational or health researcher; in response to an order of a court; to government officials investigating compliance with this Title; or to the extent that disclosure is made in connection with the employee's compliance with the certification provisions of Section 103 of the Fam-

ily and Medical Leave Act, or such requirements under state family and medical leave laws.

Sec. 207. Remedies and Enforcement. The bill incorporates by reference the powers, remedies, and procedures set forth in Title VII the Civil Rights Act of 1964, as amended. Similar powers, remedies and procedures are specified for state, federal and congressional employees.

Sec. 208. Disparate Impact. The bill prohibits claims based on disparate impact, and empanels a commission in six years to review the science of genetics and make recommendations to Congress regarding whether to provide a disparate impact cause of action under this Act.

Sec. 209. Construction. This section provides several rules of construction to clarify the intent of the Committee and to assist courts in interpreting the Title. The section makes clear that this Title shall not be construed to limit the rights or protections of individuals under the Americans with Disabilities Act or the Rehabilitation Act of 1973. Similarly, the section clarifies that Title II does not create violations for employers, employment agencies, labor organizations, or joint labor-management committees of provisions under Title I. The section clarifies that the Act sets the floor for individual rights and protections and does not limit the rights and protections under other federal or state laws. Workers compensation laws are neither expanded nor restricted by the bill. Finally, the section provides rules of construction to ensure the proper operation of federal programs and laws, including the Armed Services Repository of Specimen Samples, occupational health and safety research, and workplace safety and health laws and regulations.

Section 210. Medical Information That Is Not Genetic Information. The section clarifies that an employer, employment agency, labor organization or joint labor-management committee shall not be considered to be in violation of this Title based on the use, acquisition, or disclosure of medical information of an employee or member that is not genetic information, about a manifested disease, disorder or pathological condition that has or may have a genetic basis.

Sec. 211. Regulations. The EEOC is charged with issuing final regulations under this Title within one year of enactment.

Sec. 212. Authorization of Appropriations. Such sums as may be necessary.

Sec. 213. Effective Date. Eighteen months after enactment.

TITLE III—MISCELLANEOUS PROVISION

Sec. 301. Severability. If any provision of this Act, or an amendment made by this Act, or the application of such provision or amendment is held to be unconstitutional, the remainder of this Act shall not be affected.

IX. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new mat-

ter is printed in italic, existing law in which no change is proposed is shown in roman):

* * * * * * *

Employee Retirement Income Security Act of 1974

* * * * * * *

SEC. 502. (a) A civil action may be brought—

(1) by a participant or beneficiary—* * *

* * * * * * *

(m) In the case of a distribution to a pension plan participant or beneficiary in violation of section 206(e) by a plan fiduciary, the Secretary shall assess a penalty against such fiduciary in an amount equal to the value of the distribution. Such penalty shall not exceed $10,000 for each such distribution.

(n) ENFORCEMENT OF GENETIC NONDISCRIMINATION REQUIREMENTS.—

(1) INJUNCTIVE RELIEF FOR IRREPARABLE HARM.—With respect to any violation of subsection (a)(1)(F), (b)(3), or (c) of section 702, a participant or beneficiary may seek relief under subsection 502(a)(1)(B) prior to the exhaustion of available administrative remedies under section 503 if it is demonstrated to the court, by preponderance of the evidence, that the exhaustion of such remedies would cause irreparable harm to the health of the participant or beneficiary. Any determinations that already have been made under section 503 in such case, or that are made in such case while an action under this paragraph is pending, shall be given due consideration by the court in any action under this subsection in such case.

(2) EQUITABLE RELIEF FOR GENETIC NON-DISCRIMINATION.—

(A) REINSTATEMENT OF BENEFITS WHERE EQUITABLE RELIEF HAS BEEN AWARDED.—The recovery of benefits by a participant or beneficiary under a civil action under this section may include an administrative penalty under subparagraph (B) and the retroactive reinstatement of coverage under the plan involved to the date on which the participant or beneficiary was denied eligibility for coverage if—

(i) the civil action was commenced under subsection (a)(1)(B); and

(ii) the denial of coverage on which such civil action was based constitutes a violation of subsection (a)(1)(F), (b)(3), or (c) of section 702.

(B) ADMINISTRATIVE PENALTY.—

(i) IN GENERAL.—An administrator who fails to comply with the requirements of subsection (a)(1)(F), (b)(3), or (c) of section 702 with respect to a participant or beneficiary may, in an action commenced under subsection (a)(1)(B), be personally liable in the discretion of the court, for a penalty in the amount not more than $100 for each day in the noncompliance period.

(ii) NONCOMPLIANCE PERIOD.—For purposes of clause (i), the term "noncompliance period" means the period—

(I) beginning on the date that a failure described in clause (i) occurs; and

(II) ending on the date that such failure is corrected.

(iii) PAYMENT TO PARTICIPANT OR BENEFICIARY.—A penalty collected under this subparagraph shall be paid to the participant or beneficiary involved.

(3) SECRETARIAL ENFORCEMENT AUTHORITY.—

(A) GENERAL RULE.—The Secretary has the authority to impose a penalty on any failure of a group health plan to meet the requirements of subsection (a)(1)(F), (b)(3), or (c) of section 702.

(B) AMOUNT.—

(i) IN GENERAL.—The amount of the penalty imposed by subparagraph (A) shall be $100 for each day in the noncompliance period with respect to each individual to whom such failure relates.

(ii) NONCOMPLIANCE PERIOD.—For purposes of this paragraph, the term "noncompliance period" means, with respect to any failure, the period—

(I) beginning on the date such failure first occurs; and

(II) ending on the date such failure is corrected.

(C) MINIMUM PENALTIES WHERE FAILURE DISCOVERED.—Notwithstanding clauses (i) and (ii) of subparagraph (D):

(i) IN GENERAL.—In the case of 1 or more failures with respect to an individual—

(I) which are not corrected before the date on which the plan receives a notice from the Secretary of such violation; and

(II) which occurred or continued during the period involved;

the amount of penalty imposed by subparagraph (A) by reason of such failures with respect to such individual shall not be less than $2,500.

(ii) HIGHER MINIMUM PENALTY WHERE VIOLATIONS ARE MORE THAN DE MINIMIS.—To the extent violations for which any person is liable under this paragraph for any year are more than de minimis, clause (i) shall be applied by substituting "$15,000" for "$2,500" with respect to such person.

(D) LIMITATIONS.—

(i) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—No penalty shall be imposed by subparagraph (A) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such penalty did not know, and exercising reasonable diligence would not have known, that such failure existed.

(ii) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN CERTAIN PERIODS.—No penalty shall be imposed by subparagraph (A) on any failure if—

(I) such failure was due to reasonable cause and not to willful neglect; and

(II) such failure is corrected during the 30-day period beginning on the first date the person other-

wise liable for such penalty knew, or exercising reasonable diligence would have known, that such failure existed.

(iii) OVERALL LIMITATION FOR UNINTENTIONAL FAILURES.—In the case of failures which are due to reasonable cause and not to willful neglect, the penalty imposed by subparagraph (A) for failures shall not exceed the amount equal to the lesser of—

(I) 10 percent of the aggregate amount paid or incurred by the employer (or predecessor employer) during the preceding taxable year for group health plans; or

(II) $500,000.

(E) WAIVER BY SECRETARY.—In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the penalty imposed by subparagraph (A) to the extent that the payment of such penalty would be excessive relative to the failure involved.

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PART 7—GROUP HEALTH PLAN REQUIREMENTS

Subpart A—Requirements Relating to Portability, Access, and Renewability

SEC. 701. INCREASED PORTABILITY THROUGH LIMITATION ON PREEXISTING CONDITION EXCLUSIONS.

(a) LIMITATION ON PREEXISTING CONDITION EXCLUSION PERIOD; CREDITING FOR PERIODS OF PREVIOUS COVERAGE.—* * *

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SEC. 702. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.

(a) IN ELIGIBILITY TO ENROLL.—

(1) IN GENERAL.—Subject to paragraph (2), a group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any of the following health status-related factors in relation to the individual or a dependent of the individual:

(A) Health status.

(B) Medical condition (including both physical and mental illnesses).

(C) Claims experience.

(D) Receipt of health care.

(E) Medical history.

(F) Genetic information *(including information about a request for or receipt of genetic services by an individual or family member of such individual)*.

(G) Evidence of insurability (including conditions arising out of acts of domestic violence).

(H) Disability.

* * * * * * *

(b) IN PREMIUM CONTRIBUTIONS.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not require any individual (as a condition of enrollment or continued enrollment under the plan) to pay a premium or contribution which is greater than such premium or contribution for a similarly situated individual enrolled in the plan on the basis of any health status-related factor in relation to the individual or to an individual enrolled under the plan as a dependent of the individual.

(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

(A) to restrict the amount that an employer may be charged for coverage under a group health plan, *except as provided in paragraph (3)*; or

(B) to prevent a group health plan, and a health insurance issuer offering group health insurance coverage, from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.

(3) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON GENETIC INFORMATION.—For purposes of this section, a group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not adjust premium or contribution amounts for a group on the basis of genetic information concerning an individual in the group or a family member of the individual (including information about a request for or receipt of genetic services by an individual or family member of such individual).

(c) GENETIC TESTING.—

(1) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require an individual or a family member of such individual to undergo a genetic test.

(2) RULE OF CONSTRUCTION.—Nothing in this part shall be construed to—

(A) limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or a family member of such individual undergo a genetic test;

(B) limit the authority of a health care professional who is employed by or affiliated with a group health plan or a health insurance issuer and who is providing health care services to an individual as part of a bona fide wellness program to notify such individual of the availability of a genetic test or to provide information to such individual regarding such genetic test; or

(C) authorize or permit a health care professional to require that an individual undergo a genetic test.

(d) APPLICATION TO ALL PLANS.—The provisions of subsections (a)(1)(F), (b)(3), and (c) shall apply to group health plans and health insurance issuers without regard to section 732(a).

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SEC. 733. DEFINITIONS.

(a) GROUP HEALTH PLAN.—For purposes of this part—

(1) IN GENERAL.—* * *

* * * * * * *

(b) * * *

(c) * * *

(d) OTHER DEFINITIONS.—For purposes of this part—

(1) COBRA CONTINUATION PROVISION.— * * *

* * * * * * *

(4) * * *

(5) FAMILY MEMBER.—The term "family member" means with respect to an individual—

(A) the spouse of the individual;

(B) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and

(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

(6) GENETIC INFORMATION.—

(A) IN GENERAL.—Except as provided in subparagraph, (B) the term genetic information means information about—

(i) an individual's genetic tests;

(ii) the genetic tests of family members of the individual; or

(iii) the occurrence of a disease or disorder in family members of the individual.

(B) EXCLUSIONS.—The term "genetic information" shall not include information about the sex or age of an individual.

(7) GENETIC TEST.—

(A) IN GENERAL.—The term "genetic test" means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

(B) EXCEPTIONS.—The term "genetic test" does not mean—

(i) an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or

(ii) an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

(8) GENETIC SERVICES.—The term "genetic services" means—

(A) a genetic test;

(B) genetic counseling (such as obtaining, interpreting, or assessing genetic information); or

(C) genetic education.

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Public Health Service Act

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SEC. 2702. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.

(a) IN ELIGIBILITY TO ENROLL.—

(1) IN GENERAL.—Subject to paragraph (2), a group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not establish rules for eligibility (including continued eligibility) of any of the following health status-related factors in relation to the individual or a dependent of the individual:

(A) Health status.

(B) Medical condition (including both physical and mental illnesses).

(C) Claims experience.

(D) Receipt of health care.

(E) Medical history.

(F) Genetic information *(including information about a request for a receipt of genetic services by an individual or family member of such individual).*

(G) Evidence of insurability (including conditions arising out of acts of domestic violence).

(H) Disability.

* * * * * * *

(b) IN PREMIUM CONTRIBUTIONS.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not require any individual (as a condition of enrollment or continued enrollment under the plan) to pay a premium or contribution which is greater than such premium or contribution for a similarly situated individual enrolled in the plan on the basis of any health status-related factor in relation to the individual or to an individual enrolled under the plan as a dependent of the individual.

(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

(A) to restrict the amount that an employer may be charged for coverage under a group health plan*, except as provided in paragraph (3)*; or

(B) to prevent a group health plan, and a health insurance issuer offering group health insurance coverage, from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.

(3) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON GENETIC INFORMATION.—For purposes of this section, a group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not adjust premium or contribution amounts for a group on the basis of genetic information concerning an individual in the group or a family member of the individual (including in-

formation about a request for or receipt of genetic services by an individual or family member of such individual).

(c) GENETIC TESTING.—

(1) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require an individual or a family member of such individual to undergo a genetic test.

(2) RULE OF CONSTRUCTION.—Nothing in this part shall be construed to—

(A) limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or a family member of such individual undergo a genetic test;

(B) limit the authority of a health care professional who is employed by or affiliated with a group health plan or a health insurance issuer and who is providing health care services to an individual as part of a bona fide wellness program to notify such individual of the availability of a genetic test or to provide information to such individual regarding such genetic test; or

(C) authorize or permit a health care professional to require that an individual undergo a genetic test.

(d) APPLICATION TO ALL PLANS.—The provisions of subsections (a)(1)(F), (b)(3), and (c) shall apply to group health plans and health insurance issuers without regard to section 2721(a).

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SEC. 2722. ENFORCEMENT.

(a) STATE ENFORCEMENT.—

(1) STATE AUTHORITY.—* * *

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(b) SECRETARIAL ENFORCEMENT AUTHORITY.—

(1) LIMITATION.—* * *

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(2) * * *

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(3) ENFORCEMENT AUTHORITY RELATING TO GENETIC DISCRIMINATION.—

(A) GENERAL RULE.—In the cases described in paragraph (1), notwithstanding the provisions of paragraph (2)(C), the following provisions shall apply with respect to an action under this subsection by Secretary with respect to any failure of a health insurance issuer in connection with a group health plan, to meet the requirements of subsection (a)(1)(F), (b)(3), or (c) of section 2702.

(B) AMOUNT.—

(i) IN GENERAL.—The amount of the penalty imposed under this paragraph shall be $100 for each day in the noncompliance period with respect to each individual to whom such failure relates.

(ii) NONCOMPLIANCE PERIOD.—For purposes of this paragraph, the term "noncompliance period" means, with respect to any failure, the period—

(I) beginning on the date such failure first occurs; and

(II) ending on the date such failure is corrected.

(C) MINIMUM PENALTIES WHERE FAILURE DISCOVERED.—Notwithstanding clauses (i) and (ii) of subparagraph (D):

(i) IN GENERAL.—In the case of 1 or more failures with respect to an individual—

(I) which are not corrected before the date on which the plan receives a notice from the Secretary of such violation; and

(II) which occurred or continued during the period involved;

the amount of penalty imposed by subparagraph (A) by reason of such failures with respect to such individual shall not be less than $2,500.

(ii) HIGHER MINIMUM PENALTY WHERE VIOLATIONS ARE MORE THAN DE MINIMIS.—To the extent violations for which any person is liable under this paragraph for any year are more than de minimis, clause (i) shall be applied by substituting "$15,000" for "$2,500" with respect to such person.

(D) LIMITATIONS.—

(i) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—No penalty shall be imposed by subparagraph (A) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such penalty did not know, and exercising reasonable diligence would not have known, that such failure existed.

(ii) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN CERTAIN PERIODS.—No penalty shall be imposed by subparagraph (A) on any failure if—

(I) such failure was due to reasonable cause and not to willful neglect; and

(II) such failure is corrected during the 30-day period beginning on the first date the person otherwise liable for such penalty knew, or exercising reasonable diligence would have known, that such failure existed.

(iii) OVERALL LIMITATION FOR UNINTENTIONAL FAILURES.—In the case of failures which are due to reasonable cause and not to willful neglect, the penalty imposed by subparagraph (A) for failures shall not exceed the amount equal to the lesser of—

(I) 10 percent of the aggregate amount paid or incurred by the employer (or predecessor employer) during the preceding taxable year for group health plans; or

(II) $500,000.

(E) WAIVER BY SECRETARY.—In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part of all of the penalty imposed

by subparagraph (A) to the extent that the payment of such penalty would be excessive relative to the failure involved.

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PART C—DEFINITIONS; MISCELLANEOUS PROVISIONS

SEC. 2791. DEFINITIONS.

(a) GROUP HEALTH PLAN.—

(1) DEFINITION.—* * *

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(b) * * *

(c) * * *

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(d) OTHER DEFINITIONS.—

(1) APPLICABLE STATE AUTHORITY.—* * *

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(15) FAMILY MEMBER.—The term "family member" means with respect to an individual—

(A) the spouse of the individual;

(B) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and

(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

(16) GENETIC INFORMATION.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the term "genetic information" means information about—

(i) an individual's genetic tests;

(ii) the genetic tests of family members of the individual; or

(iii) the occurrence of a disease or disorder in family members of the individual.

(B) EXCLUSIONS.—The term "genetic information" shall not include information about the sex or age of an individual.

(17) GENETIC TEST.—

(A) IN GENERAL.—The term "genetic test" means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

(B) EXCEPTIONS.—The term "genetic test" does not mean—

(i) an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or

(ii) an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

(18) GENETIC SERVICES.—The term "genetic services" means—

(A) a genetic test;

(B) genetic counseling (such as obtaining, interpreting, or assessing genetic information); or

(C) genetic education.

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PART B—INDIVIDUAL MARKET RULES

Subpart 1—Portability, Access, and Renewability Requirements

SEC. 2741. GUARANTEED AVAILABILITY OF INDIVIDUAL HEALTH INSURANCE COVERAGE TO CERTAIN INDIVIDUALS WITH PRIOR GROUP COVERAGE.

(a) GUARANTEED AVAILABILITY.—

(1) IN GENERAL.—* * *

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Subpart [3]2—Other Requirements

SEC. 2751. STANDARDS RELATING TO BENEFITS FOR MOTHERS AND NEWBORNS.

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SEC. 2752. REQUIRED COVERAGE FOR RECONSTRUCTIVE SURGERY FOLLOWING MASTECTOMIES.

The provisions of section 2706 shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as they apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market.

SEC. 2753. PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION.

(a) PROHIBITION ON GENETIC INFORMATION AS A CONDITION OF ELIGIBILITY.—A health insurance issuer offering health insurance coverage in the individual market may not establish rules for the eligibility (including continued eligibility) of any individual to enroll in individual health insurance coverage based on genetic information (including information about a request for or receipt of genetic services by an individual or family member of such individual).

(b) PROHIBITION ON GENETIC INFORMATION IN SETTING PREMIUM RATES.—A health insurance issuer offering health insurance coverage in the individual market shall not adjust premium or contribution amounts for an individual on the basis of genetic information concerning the individual or a family member of the individual (including information about a request for or receipt of genetic services by an individual or family member of such individual).

(c) GENETIC TESTING.—

(1) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—A health insurance issuer offering health insurance coverage in the individual market shall not request or require an individual or a family member of such individual to undergo a genetic test.

(2) RULE OF CONSTRUCTION.—Nothing in this part shall be construed to—

(A) limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or a family member of such individual undergo a genetic test;

(B) limit the authority of a health care professional who is employed by or affiliated with a health insurance issuer and who is providing health care services to an individual as part of a bona fide wellness program to notify such individual of the availability of a genetic test or to provide information to such individual regarding such genetic test; or

(C) authorize or permit a health care professional to require that an individual undergo a genetic test.

Subpart 3—General Provisions

SEC. 2761. ENFORCEMENT.

(a) STATE ENFORCEMENT.—

(1) STATE AUTHORITY.—* * *

(2) * * *

[(b) SECRETARIAL ENFORCEMENT AUTHORITY.—The Secretary shall have the same authority in relation to enforcement of the provisions of this part with respect to issuers of health insurance coverage in the individual market in a State as the Secretary has under section 2722(b)(2) in relation to the enforcement of the provisions of part A with respect to issuers of health insurance coverage in the small group market in the State.**]**

(b) SECRETARIAL ENFORCEMENT AUTHORITY.—The Secretary shall have the same authority in relation to enforcement of the provisions of this part with respect to issuers of health insurance coverage in the individual market in a State as the Secretary has under section 2722(b)(2), and section 2722(b)(3) with respect to violations of genetic nondiscrimination provisions, in relation to the enforcement of the provisions of part A with respect to issuers of health insurance coverage in the small group market in the State.

SEC 2721. EXCLUSION OF CERTAIN PLANS.

(a) EXCEPTION FOR CERTAIN SMALL GROUP HEALTH PLANS.—The requirements of subparts 1 and 3 [1] shall not apply to any group health plan (and health insurance coverage offered in connection with a group health plan) for any plan year if, on the first day of such plan year, such plan has less than 2 participants who are current employees.

(b) LIMITATION ON APPLICATION OF PROVISIONS RELATING TO GROUP HEALTH PLANS.—

(1) IN GENERAL.—The requirements of subparts 1 through 3 shall apply with respect to group health plans only—

(A) subject to paragraph (2), in the case of a plan that is a nonfederal governmental plan, and

(B) with respect to health insurance coverage offered in connection with a group health plan (including such a plan that is a church plan or a governmental plan).

(2) TREATMENT OF NONFEDERAL GOVERNMENTAL PLANS.—

(A) ELECTION TO BE EXCLUDED.—**[**If the plan sponsor**]** *Except as provided in subparagraph (D), if the plan sponsor* of a nonfederal governmental plan which is a group health plan to which the provisions of subparts 1 through

3 otherwise apply makes an election under this subparagraph (in such form and manner as the Secretary may by regulations prescribe), then the requirements of such subparts insofar as they apply directly to group health plans (and not merely to group health insurance coverage) shall not apply to such governmental plans for such period except as provided in this paragraph.

(B) * * *

(C) * * *

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(D) ELECTION NOT APPLICABLE TO REQUIREMENTS CONCERNING GENETIC INFORMATION.—The election described in subparagraph (A) shall not be available with respect to the provisions of subsections (a)(1)(F) and (c) of section 2702 and the provisions of section 2702(b) to the extent that such provisions apply to genetic information (or information about a request for or the receipt of genetic services by an individual or a family member of such individual).

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INTERNAL REVENUE CODE OF 1986

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Subtitle K—Group Health Plan Requirements

Chapter 100. Group health plan requirements.

CHAPTER 100—GROUP HEALTH PLAN REQUIREMENTS

Subchapter A. Requirements relating to portability, access, and renewability.
Subchapter B. Other requirements.
Subchapter C. General provisions.

Subchapter A—Requirements Relating to Portability, Access, and Renewability

Sec. 9801. Increased portability through limitation on preexisting condition exclusions.
Sec. 9802. Prohibiting discrimination against individual participants and beneficiaries based on health status.
Sec. 9803. Guaranteed renewability in multiemployer plans and certain multiple employer welfare arrangements.

SEC. 9801. INCREASED PORTABILITY THROUGH LIMITATION ON PREEXISTING CONDITION EXCLUSIONS.

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SEC. 9802. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.

(a) IN ELIGIBILITY TO ENROLL.—

(1) IN GENERAL.—Subject to paragraph (2), a group health plan may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any of the following factors in relation to the individual or a dependent of the individual:

(A) Health status.

(B) Medical condition (including both physical and mental illness).

(C) Claims experience.

(D) Receipt of health care.

(E) Medical history.

(F) Genetic information *(including information about a request for or receipt of genetic services by an individual or family member of such individual).*

(G) Evidence of insurability (including conditions arising out of acts of domestic violence).

(H) Disability.

* * * * * * *

(b) IN PREMIUM CONTRIBUTIONS.—

(1) IN GENERAL.—A group health plan may not require any individual (as a condition of enrollment or continued enrollment under the plan) to pay a premium or contribution which is greater than such premium or contribution for a similarly situated individual in the plan on the basis of any factor described in subsection (a)(1) in relation to the individual or to an individual enrolled under the plan as a dependent of the individual.

(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

(A) to restrict the amount that an employer may be charged for coverage under a group health plan*, except as provided in paragraph (3)*; or

(B) to prevent a group health plan from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.

(3) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON GENETIC INFORMATION.—For purposes of this section, a group health plan shall not adjust premium or contribution amounts for a group on the basis of genetic information concerning an individual in the group or a family member of the individual (including information about a request for a receipt of genetic services by an individual or family member of such individual).

* * * * * * *

(c) SPECIAL RULES FOR CHURCH PLANS.—A church plan (as defined in section 414(e)) shall not be treated as failing to meet the requirements of this section solely because such plan requires evidence of good health for coverage of—

(1) both any employee of an employer with 10 or less employees (determined without regard to section 414(e)(3)(C)) and any self-employed individual, or

(2) any individual who enrolls after the first 90 days of initial eligibility under the plan.

(d) GENETIC TESTING AND GENETIC SERVICES.—

(1) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—A group health plan shall not request or require an individual or a family member of such individual to undergo a genetic test.

(2) RULE OF CONSTRUCTION.—Nothing in this part shall be construed to—

(A) limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or a family member of such individual undergo a genetic test;

(B) limit the authority of a health care professional who is employed by or affiliated with a group health plan and who is providing health care services to an individual as part of a bona fide wellness program to notify such individual of the availability of a genetic test or to provide information to such individual regarding such genetic test; or

(C) authorize or permit a health care professional to require that an individual undergo a genetic test.

(e) APPLICATION TO ALL PLANS.—The provisions of subsections (a)(1)(F), (b)(3), and (d) shall apply to group health plans and health insurance issuers without regard to section 9831(a)(2).

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SEC. 9832. DEFINITIONS.

(a) GROUP HEALTH PLAN.—For purposes of this chapter, the term "group health plan" has the meaning given to such term by section 5000(b)(1).

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(d) OTHER DEFINITIONS.—For purposes of this chapter—

(1) COBRA CONTINUATION PROVISION.— * * *

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(6) FAMILY MEMBER.—The term "family member" means with respect to an individual—

(A) the spouse of the individual;

(B) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and

(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

(7) GENETIC SERVICES.—The term "genetic services" means—

(A) a genetic test;

(B) genetic counseling (such as obtaining, interpreting, or assessing genetic information); or

(C) genetic education.

(8) GENETIC INFORMATION.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the term "genetic information" means information about—

(i) an individual's genetic tests;

(ii) the genetic tests of family members of the individual; or

(iii) the occurrence of a disease or disorder in family members of the individual.

(B) EXCLUSIONS.—The term "genetic information" shall not include information about the sex or age of an individual.

(9) GENETIC TEST.—

(A) IN GENERAL.—The term "genetic test" means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

(B) EXCEPTIONS.—The term "genetic test" does not mean—

(i) an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or

(ii) an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

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TITLE XVIII OF THE SOCIAL SECURITY ACT

CERTIFICATION OF MEDICARE SUPPLEMENTAL HEALTH INSURANCE POLICIES

SEC. 1882. (a)(1) * * *

* * * * * * *

(o) The requirements of this subsection are as follows:

(1) Each medicare supplemental policy shall provide for coverage of a group of benefits consistent with subsection (p).

(2) If the medicare supplemental policy provides for coverage of a group of benefits other than the core group of basic benefits described in subsection (p)(2)(B), the issuer of the policy must make available to the individual a medicare supplemental policy with only such core group of basic benefits.

(3) The issuer of the policy has provided, before the sale of the policy, an outline of coverage that uses uniform language and format (including layout and print size) that facilitates comparison among medicare supplemental policies and comparison with medicare benefits.

(4) The issuer of the medicare supplemental policy complies with subsection (s)(2(E) and subsection (v).

* * * * * * *

(s)(1) If a medicare supplemental policy replaces another medicare supplemental policy, the issuer of the replacing policy shall waive any time periods applicable to preexisting conditions, waiting period, elimination periods and probationary periods in the new medicare supplemental policy for similar benefits to the extent such time was spent under the original policy.

(2)(A) The issuer of a medicare supplemental policy may not deny or condition the issuance or effectiveness of a medicare supplemental policy, or discriminate in the pricing of the policy, because of health status, claims experience, receipt of health care, or medical condition in the case of an individual for whom an application is submitted prior to or during the 6 month period beginning with the first month as of the first day on which the individual is 65 years of age or older and is enrolled for benefits under part B.

(B) * * *

(C) * * *

(D) * * *

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(E)(i) An issuer of a medicare supplemental policy shall not deny or condition the issuance or effectiveness of the policy, and shall not

discriminate in the pricing of the policy (including the adjustment of premium rates) of an eligible individual on the basis of genetic information concerning the individual (or information about a request for, or the receipt of, genetic services by such individual or family member of such individual).

(ii) For purposes of clause (i), the terms "family member", "genetic services", and "genetic information" shall have the meanings given such terms in subsection (v).

* * * * * * *

(u)(1) It is unlawful for a person to sell or issue a policy described in paragraph (2) to an individual with knowledge that the individual has in effect under section 1851 an election of an MSA plan or a Medicare+Choice private fee-for-service plan.

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(v) LIMITATIONS ON GENETIC TESTING.—

(1) GENETIC TESTING.—

(A) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—An issuer of a medicare supplemental policy shall not request or require an individual or a family member of such individual to undergo a genetic test.

(B) RULE OF CONSTRUCTION.—Nothing in this title shall be construed to—

(i) limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or a family member of such individual undergo a genetic test;

(ii) limit the authority of a health care professional who is employed by or affiliated with an issuer of a medicare supplemental policy and who is providing health care services to an individual as part of a bona fide wellness program to notify such individual of the availability of a genetic test or to provide information to such individual regarding such genetic test; or

(iii) authorize or permit a health care professional to require that an individual undergo a genetic test.

(2) DEFINITIONS.—In this subsection:

(A) FAMILY MEMBER.—The term "family member" means with respect to an individual—

(i) the spouse of the individual;

(ii) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; or

(iii) any other individuals related by blood to the individual or to the spouse or child described in clause (i) or (ii).

(B) GENETIC INFORMATION.—

(i) IN GENERAL.—Except as provided in clause (ii), the term "genetic information" means information about—

(I) an individual's genetic tests;

(II) the genetic tests of family members of the individual; or

(III) the occurrence of a disease or disorder in family members of the individual.

(ii) EXCLUSIONS.—The term "genetic information" shall not include information about the sex or age of an individual.

(C) GENETIC TEST.—

(i) IN GENERAL.—The term "genetic test" means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

(ii) EXCEPTIONS.—The term "genetic test" does not mean—

(I) an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or

(II) an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

(D) GENETIC SERVICES.—The term "genetic services" means—

(i) a genetic test;

(ii) genetic counseling (such as obtaining, interpreting, or assessing genetic information); or

(iii) genetic education.

(E) ISSUER OF A MEDICARE SUPPLEMENTAL POLICY.—The term "issuer of a medicare supplemental policy" includes a third-party administrator or other person acting for or on behalf of such issuer.

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