



SENATE REPUBLICAN

POLICY COMMITTEE

Legislative Notice

No. 55

April 23, 2008

S. 358 – Genetic Information Nondiscrimination Act of 2007

Calendar No. 97

Favorably reported by the Health, Education, Labor and Pensions (HELP) Committee on March 29, 2007 by a vote of 19-2; Senate Report 110-48.

Noteworthy

- The Genetic Information Nondiscrimination Act of 2007 (GINA) is designed to prohibit the use of genetic information for discriminatory purposes with respect to employment and health insurance coverage.
- The bill prevents an insurer from basing eligibility or premium determinations on genetic information. Similarly, the bill prohibits employers, labor organizations, employment agencies and joint labor-management committees from using genetic information to discriminate against an individual through hiring, firing, or other employment decisions.
- In order to address concerns expressed by Senator Coburn and other Republicans, the legislation contains a new remedies “firewall” to preclude duplicative claims, gives insurers clearer authority to use manifest disease information for underwriting, and contains revised Health Insurance Portability and Accountability Act (HIPAA) language which mirrors language contained in the companion House legislation.
- Early versions of GINA have passed the Senate unanimously. On October 14, 2003 the Senate approved S. 1053 by a vote of 95-0. The House did not take up the legislation. On February 16, 2005, the full Senate approved S. 306, as amended, by a vote of 98-0. The House again took no action on the bill.
- The House of Representatives passed similar legislation, H.R. 493, by a vote of 420-3 on April 25, 2007.
- The Congressional Budget Office (CBO) estimated that the bill would have minimal budget impact.
- No Statement of Administration Policy on S. 358 was available at press time.

Background

Recent scientific breakthroughs have opened new doors for medical researchers in analyzing DNA, RNA, and chromosomal changes. While the advancements yield promising hope for individuals diagnosed with rare genetic diseases, they also could lead to discriminatory practices in the health insurance market and in the workplace.¹ The Genetic Information Nondiscrimination Act (GINA) is designed to prohibit the use of genetic information for discriminatory purposes with respect to employment and health insurance coverage.

The bill prevents an insurer from basing eligibility or premium determinations on genetic information. Similarly, the bill prohibits employers, labor organizations, employment agencies, and joint labor-management committees from using genetic information to discriminate against an individual through hiring, firing, or other employment decisions.

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The Genetic Information Nondiscrimination Act of 2007, S. 358, was approved by the HELP Committee on January 31, 2007 by a vote of 19-2. The House of Representatives passed similar legislation, H.R. 493, by a vote of 420-3 on April 25, 2007.

Bill Provisions

Note: This notice pertains to the substitute amendment expected to be offered on the floor.

Title I – Health Insurance

The legislation applies to all health insurance markets, including employer-sponsored group health plans, group and individual health insurance issuers, Medigap policies, and state and local non-federal governmental plans, as well as federal plans. While the Employee Retirement and Income Security Act (ERISA) currently prohibits a group health plan or group health insurance issuer from discriminating against an individual by setting eligibility, premium, or contribution amounts based on the individual's genetic information, this legislation clarifies

¹ It should be noted that the Committee Report accompanying S. 358 found that “there is little evidence or documentation of actual discrimination in health insurance.” Report 110-48.

that genetic information includes information about: 1) an individual's genetic tests, 2) the genetic tests of family members of an individual, and 3) the manifestation of a disease or disorder in a family member of the individual. S. 358 extends such restrictions to insurance issuers in the individual and Medicare supplemental markets. It also extends protections against the use of genetic information to a fetus or embryo.

While group, individual, and Medicare supplemental insurance issuers are prohibited from requesting or requiring an individual to take a genetic test, the legislation specifies such prohibitions shall not interfere with the delivery of health care services. For instance, the measure 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.

Current law already protects the use and disclosure of all individually-identifiable health information, including genetic information. These protections are included under the Department of Health and Human Services (HHS) Standards for Privacy of Individually Identifiable Health Information (medical privacy regulations; 45 CFR Parts 160 and 164; final rule). 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, the legislation expressly bans the use, disclosure, or collecting of genetic information for purposes of underwriting. The requesting, requiring, or purchasing of genetic information prior to enrollment also is prohibited.

S. 358 uses enforcement provisions applied in current law. For instance, ERISA allows group health plan participants or the Department of Labor to sue for equitable relief. The bill 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 an unintentional violation of the protections against genetic discrimination.

With regard to the privacy provisions, the same enforcement structure and penalties apply as created by the Social Security Act for the HHS privacy standards. 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. Moreover, the bill incorporates the same penalty and enforcement structures granted under Title I of the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) for nondiscrimination measures.

Title II - Employment

The bill would prohibit employers, labor organizations, employment agencies, and joint labor-management committees from using genetic information to discriminate against an individual through hiring, firing, compensation, or other employment decisions. Employers are also prohibited from requesting, requiring, or purchasing genetic information of employees. The genetic information protected extends to the employee, his or her spouse and all of their blood relatives, as well as adopted children. Employers who obtain genetic information about their employees inadvertently, through compliance with other laws (such as the Family and Medical Leave Act) or through certain efforts to preserve employee health (such as employee wellness programs or monitoring of biological effects of toxic substances in the workplace) would not be penalized unless they used such information to discriminate against the employee. The bill prohibits disclosure of genetic information except to the employee, health researchers, or in compliance with federal and state law.

Penalties for violation of the law are those available under Title VII of the Civil Rights Act, which prohibits employment discrimination based on race, color, religion, sex, or national origin. The procedures and remedies under the bill are the same as under current law. Employees who believe they have a claim must file a charge with the Equal Employment Opportunity Commission (EEOC) or the appropriate state agency. The EEOC will investigate the claim and bring suit on behalf of the employee if evidence of a violation is found. The EEOC also may pursue mediation if the employer and employee agree to that option. In cases in which the EEOC chooses not to bring suit, the employee may bring suit independently. Penalties for Title VII violations include reinstatement, back pay, injunctive relief, equitable relief, and attorney's and expert witness fees. Certain damages are capped based on the size of the employer.

No charges may be filed for "disparate impact" discrimination, which is not an intentional adverse employment action but a discriminatory effect on a protected class caused by an employment practice or policy that appears to be nondiscriminatory. The bill would direct a commission to be formed six years after the bill's enactment to report on the possibility of allowing disparate impact claims.

Cost

The Congressional Budget Office (CBO) estimates that the bill would have minimal budget impact. Specifically, CBO estimates that enacting the bill would increase the number of individuals who obtain health insurance by about 600 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 some of those newly insured individuals would be tax-deductible. CBO estimates that enacting S. 358 would reduce revenues by less than \$500,000 in each year from 2008 through 2017, by \$1 million over the 2008-2012 period, and by \$2 million over the 2008-2017 period. CBO estimates that the bill would have no significant effect on direct spending.

Administration Position

A Statement of Administration Policy (SAP) was issued on the House Bill, H.R. 1424. It can be found at this link <http://www.whitehouse.gov/omb/legislative/sap/110-2/saphr1424-h.pdf>. No Statement of Administration Policy on the Senate bill was available at press time.

Possible Amendments

With the exception of the substitute amendment, no amendments are expected to be in order pursuant to a unanimous consent agreement.