

Genetic Information Nondiscrimination Act of 2008



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Overview

On May 21, 2008, President Bush signed into law the Genetic Information Nondiscrimination Act of 2008 (GINA).¹ The goal of the legislation is to establish a national and uniform basic standard to protect the public from genetic discrimination and allay their concerns about the potential for discrimination in the health insurance and employment settings. These protections will thereby encourage individuals to take advantage of genetic testing, technologies, research and new therapies. Described below is GINA's impact on health insurance policy issuers and health care providers.

Title I of GINA addresses the health insurance industry. GINA prohibits group health plan, individual, and medicare supplemental policy issuers from discriminating in premiums based on genetic information.² These health insurance issuers are barred from requesting or requiring an individual, or family member, from undergoing a genetic test. Additionally, genetic information may neither be collected for underwriting purposes nor prior to enrollment in a plan. However, the results of genetic tests may be obtained without violating GINA if the issuer is making a determination of payment, or if the genetic information is collected incidentally. Finally, genetic tests may be requested—not required—subject to a set of prescribed requirements.

GINA amends portions of broad legislative acts including the Employee Retirement Income Security Act (ERISA),³ the Public Health Security Act (PHSA),⁴ the Internal Revenue Code of 1986,⁵ Title XVIII of the Social Security Act relating to medigap⁶ (SSA), and HIPAA.⁷ The amendments enact protections for genetic information, define key terms, and establish enforcement guidelines, including a safe harbor for inadvertent or *de minimis* violations. The Act charges the Secretaries of the Departments of Labor, Treasury, and Health and Human Services with issuing final regulations by May 21, 2009.⁸

The amendments enacted by GINA are described below, with the ERISA section representing the general changes. However, corresponding changes, with slight variations, were made to the remaining amended acts; these variations are detailed following.

§101: ERISA

Definitions.

- **Family member** – a dependent, and any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative of such individual
- **Genetic information** – information about an individual's genetic tests, the genetic tests of family members, and the manifestation of a disease or disorder in family members of such individual
 - o Genetic information is inclusive of any request for, or receipt of, genetic services or participation in clinical research which includes genetic services by an individual or any family member
 - o Genetic information is exclusive of information about the sex or age of any individual
- **Genetic test** – an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes
 - o An analysis that does not detect genotypes, mutations, or chromosomal changes or is directly related to a manifested disease, disorder, or pathological condition is not a genetic test
- **Genetic services** – a genetic test, genetic counseling (including obtaining, interpreting, or assessing genetic information); or genetic education

1 Pub. L. No. 110-233 (2008).

2 Sections 101-103 of GINA concern group and individual health plan issuers, while § 104 applies to issuers of Medicare supplemental policies. These are the only three types of insurance providers specified in the act, but GINA appears to be inclusive of all health insurance plans. There is no indication that GINA applies to long-term care, life, or disability insurance policy issuers.

3 Employee Retirement Income Security Act of 1974 § 702(b), 29 U.S.C. § 1182(b) (nondiscrimination), § 733(d), 29 U.S.C. § 1191b(d) (definitions), and § 502, 29 U.S.C. § 1132 (enforcement).

4 Public Health Service Act § 2702(b), 42 U.S.C. § 300gg-1(b) (nondiscrimination), § 2791(d), 42 U.S.C. § 300gg-91(d) (definitions), and § 2722(b), 42 U.S.C. § 300gg-22(b) (remedies and enforcement).

5 § 9802(b) (nondiscrimination), § 9832(d) (definitions), and § 4980D (enforcement).

6 § 1182(s)(2), 42 U.S.C. § 1395ss(s)(2).

7 Health Insurance Portability and Accountability Act of 1996 § 1180, Pub. L. No. 104-191.

8 110 Pub. L. No. 233, § 101(f)(1).

- Underwriting purposes –
 - o rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage;
 - o the computation of premium or contribution amounts;
 - o the application of any pre-existing condition exclusion under the plan or coverage; and
 - o other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits

No discrimination in group premiums based on genetic information. A Group Health Issuer⁹ may not adjust premium or contribution amounts on the basis of genetic information. The insurance issuer may increase the premium for an employer based on the manifestation of a disease or disorder of an enrolled individual, however, such manifestation cannot be used as genetic information about other group members to further increase the premium for the employer.

Limitations on genetic testing. A Group Health Issuer shall not request or require an individual, or a family member of such individual, to undergo a genetic test, however no limitations are placed on a health care professional's authority to request that such individual undergo a genetic test. A Group Health Issuer may request and obtain the results of a genetic test to make a determination regarding payment, provided the request is limited only to the minimum amount of information necessary to accomplish the intended purpose.

Research exception. A Group Health Issuer may request, but not require, that a participant or beneficiary undergo a genetic test if each of the following conditions is met:

- The request is made in writing;
- The plan or issuer clearly indicates that compliance with the request is voluntary and non-compliance will have no effect on enrollment status or premium or contribution amounts;
- No genetic information collected or acquired shall be used for underwriting purposes;
- The plan or issuer notifies the Secretary in writing that the plan or issuer is conducting activities pursuant to the exception, including a description of the activities; and
- The plan or issuer complies with such other conditions as the Secretary may require.

Prohibition on collection of genetic information. A Group Health Issuer shall not request, require, or purchase genetic information for underwriting purposes or with respect to any individual prior to such individual's enrollment under the plan or coverage. This prohibition shall not be violated if a Group Health Issuer obtains genetic information incidental to the requesting, requiring, or purchasing of other information.

Application. GINA applies to all group health plans and health insurance issuers, as well as to the genetic information of a fetus or embryo.

Enforcement. The Secretary of Labor may impose a penalty against any plan sponsor of a group health plan, or any health insurance issuer offering health insurance coverage in connection with the plan, for any failure by such sponsor or issuer to meet the requirements with respect to genetic information.¹⁰ The amount of the penalty shall be \$100 per day in the noncompliance period with respect to each participant or beneficiary to whom such failure relates. With respect to any failure, the noncompliance period begins on the date such failure first occurs and ends on the date the failure is corrected. If failures are not corrected before the date on which the plan receives a notice from the Secretary and which occurred or continued during the period involved, the amount of the penalty imposed shall not be less than \$2,500. If violations are more than *de minimis*, minimum fines imposed will be \$15,000.¹¹

Penalty limitations and safe harbor provision. No penalty shall be imposed on any failure during any period for which it is established to the satisfaction of the Secretary of Labor that the person otherwise liable for such penalty did not know, and exercising reasonable diligence would not have known, that such failure existed. Further, no penalty shall be applied if such failure was due to reasonable cause and not to willful neglect and such failure is corrected during the

9 A Group Health Issuer refers to a group health plan and a health insurance issuer offering group health insurance coverage in connection with a group health plan.

10 The requirements of subsections (a)(1)(F), (b)(3), (c), or (d) of section 702, or section 701, or 702(b)(1) of ERISA, Pub. L. No. 93-406.

11 GINA has not created a private right of action in the health insurance title. A private right of action for employment discrimination may be available under the employment title, patterned after Title VII of the Civil Rights Act of 1964. This right of action provides for jury trials and compensatory and punitive damage awards. ERISA § 502, 29 U.S.C. § 1132.

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. Penalties for these unintentional failures shall not exceed the lesser of 10 percent of the aggregate amount paid or incurred by the plan sponsor during the preceding taxable year for group health plans or \$500,000. Additionally, in the case of a failure due to reasonable cause and not to willful neglect, the Secretary may waive all or part of the penalty imposed if the penalty would be excessive relative to the failure involved. This safe harbor provision applies to the ERISA and PHSA amendments which include group and individual health insurance policy issuers; it does not apply to issuers of medicare supplemental policies.

Regulations and effective date. The Secretary of Labor shall issue final regulations not later than May 21, 2009, and the amendments made by this section shall apply with respect to group health plans for plan years beginning after the same date.¹²

PHSA

Section 102 of GINA includes the amendments to the PHSA. The substantive changes made to ERISA correspond to the PHSA, however the PHSA amendments contain an additional section that places restrictions on the *individual* insurance market.

Application to the individual insurance market. A health insurance issuer offering health insurance coverage in the individual market is prohibited from establishing rules for eligibility (including continued eligibility) on the basis of genetic information. Further, health insurance issuers in the individual market are prohibited from setting premium rates or creating preexisting condition exclusions on the basis of genetic information unless the rates or preexisting condition exclusions are made on the basis of a manifestation of a disease or disorder.

Enforcement. The Secretary of Health and Human Services shall have the same authority with regard to enforcement in the individual market as set forth above.¹³

Internal Revenue Code of 1986

In addition to the above, § 103 of GINA adds an enforcement section authorizing an additional tax on group health plans that fail to meet the requirements of GINA.

Title XVIII of the Social Security Act Relating to medigap

Section 104 of GINA applies the same substantive amendments from ERISA to issuers of medicare supplemental policies, including third-party administrators or other persons acting for or on behalf of such issuer. This section also includes certain transition provisions that allow States until July 1, 2009 to conform their regulatory program to the GINA amendments.

NAIC standards. The National Association of Insurance Commissioners (NAIC) may modify its regulations to conform to GINA until October 31, 2008. Should NAIC fail to make the appropriate modifications, the Secretary of Health and Human Services will be required to make the changes necessary to conform with GINA by July 1, 2009.

Privacy and Confidentiality

Section 105 of GINA revises the HIPAA privacy regulation to include genetic information as health information described in HIPAA. Additionally, the use or disclosure by a covered entity that is a group health plan, health insurance issuer that issues health insurance coverage, or issuer of a medicare supplemental policy of protected health information that is genetic information about an individual shall not be a permitted use or disclosure.

¹² In practice, because GINA will primarily impact group health insurance issuers with policies with closed enrollments and a fiscal year calendar, the changes will be effective for policies renewed on January 1, 2010.

¹³ The "safe harbor" provision detailed in the ERISA section also applies to the PHSA.

Procedure and enforcement. The revisions indicated above shall be made by notice in the Federal Register published not later than July 21, 2008. A covered entity that is a group health plan, health insurance issuer, or issuer of a medicare supplemental policy that violates the HIPAA privacy regulation with respect to the use or disclosure of genetic information shall be subject to the penalties described in sections 1176 and 1177 of HIPAA, in addition to any other sanctions or remedies that may be available under law.

Implications to Health Care Providers

Broadly defined terms. The definitions of “family member,” “genetic information,” and “underwriting purposes” give GINA a broad application. For example, GINA applies even to requests for genetic testing and to the manifestation of diseases or disorders in family members. This broad reach of the Act will require health insurers and health care providers to limit access to information, particularly in the pre-enrollment or renewal periods, relating to family members.

Forthcoming regulations. The true scope of GINA, like the laws GINA modifies, will be largely determined by these forthcoming regulations.

Protection of information. It remains an open question whether health insurers or health care providers need to segregate genetic information. Certainly, the legislation suggests health insurers should limit the amount of family information that is commingled, as well as the information passed on to underwriters. Based on forthcoming regulations, yet another layer of information protection may be required, potentially placing genetic information in a special class along with patient psychiatric and substance abuse records. Special authorizations may be required to disclose genetic information, and limitations may be placed on the ability of providers to produce a patient’s genetic information in response to a subpoena or other request.

Safe harbor. Provided failures are unintentional and remedied within the 30-day notice period, the Secretary may waive penalties, or insurers may avoid penalties entirely. Diligent attention to notices of violations will afford health insurers or health care providers the opportunity to remedy failures and minimize the imposition of monetary fines.

Excluded insurance. By including group and individual health insurance plans, as well as issuers of medicare supplemental policies, GINA covers the vast majority of health insurance policies. It is unclear whether there is a class or category of insurance which GINA does not reach. It is clear, however, that GINA does not affect issuers of other common types of insurance, including disability, life, and long-term care insurance policy issuers.