



Federal Legislative Brief

Federal Genetic Information Nondiscrimination Act 2008-11

Move Over HIPAA, Make Room for GINA!

On May 21, 2008, President Bush signed the Genetic Information Nondiscrimination Act (GINA) into law, which establishes a national, uniform, basic standard to protect individuals from discrimination in health care and employment practices based on genetic information. GINA amends the Employee Retirement Income Security Act (ERISA), the Health Insurance Portability and Accountability Act (HIPAA), the Internal Revenue Code (IRC), and the Public Health Service Act (PHSA). It also expands the Civil Rights Act of 1964 giving the EEOC jurisdiction under Title VII of the 1964 Civil Rights Act to provide remedies for employment related violations.

Effective Dates

The rules governing health plans and insurers go into effect for plan years beginning on or after May 8, 2009 (one year following date of the law's enactment). Employment related rules go into effect November 8, 2009 (eighteen months following the date of the law's enactment).

Overview

GINA establishes federal protection against the misuse of Genetic Information in the workplace. It limits its scope to genetic discrimination in health insurance and employment practices. Although it establishes some basic rules, the expanse of this law will become clearer once the DOL and EEOC publish regulations.

Definition of Genetic Information

For purposes of GINA, "Genetic Information" means "information about (i) such individual's genetic tests, (ii) the genetic tests of family members of such individual, and (iii) the manifestation of a disease or disorder in family members of such individual." It also includes "any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual." Additionally, genetic information related to an individual or family member of an individual includes the genetic information of any fetus carried by a pregnant woman and the genetic information of any embryo legally held by an individual or family member using assisted reproductive technology. Genetic information does not include information about the gender 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. "Genetic Services" include genetic counseling or genetic education.

Federal Genetic Information Nondiscrimination Act 2008-11

Details: Health Plans

GINA provides new guidance effecting health insurers, health plans (insured and self-funded) and health plan sponsors, including small group health plans (15 lives and up), individual health plan policies, Medicare supplemental policies, and state and local governmental plans. GINA does not apply to federal governmental plans.

1. **Prohibitions.** GINA prohibits group health plans and health insurers from using Genetic Information for purposes of setting premium rates or minimum contribution requirements. It prohibits all group health plans from requesting or requiring genetic testing of plan participants or their family members as a condition of enrollment in a health plan. No health insurer nor health plan can request or require or purchase genetic information for underwriting purposes or in connection with enrollment. Neither Medicare policy issuers nor individual policy issuers can establish eligibility rules or impose pre-existing condition limitations or engage in discriminatory pricing of their policies based on Genetic Information.
2. **Permissible Uses.** Insurers and health plans may obtain and use the results of genetic tests to make determinations regarding claims payments. They may only request the minimum necessary data to adjudicate claims. Insurers may request, but may not require, an individual to undergo a genetic test for research purposes if (a) the research complies with the Common Rule (Part 46 of Title 45, Code of Federal Regulations); (b) it is clearly specified that compliance with the request to submit to genetic testing is voluntary and that refusal to undergo the test will not impact enrollment status or premium or contribution amounts; (c) they notify the Secretary of the Department of Health and Human Services that such activities are being conducted; (d) they provide the Secretary with a description of the activities; and (e) they comply with other requirements set forth by the Secretary.
3. **GINA and State Laws.** Many states, including California, have passed similar genetic antidiscrimination laws related to health plans, none of which will apply to self-funded health plans. By amending ERISA, GINA covers almost all health plans. By amending the PHS Act, it will apply to governmental plans other than federal plans.
4. **HIPAA Compliance.** GINA also amends HIPAA with respect to privacy and security of protected health information to require inclusion of Genetic Information. As such use and disclosure of Genetic Information must meet HIPAA's privacy standards including the protection of patients' rights with regard to it.
5. **Penalties for Violation of GINA in the Health Care Setting.** For purposes of ERISA, violations of GINA are subject to a \$100 per day penalty for each participant harmed, assessed against a Plan Sponsor or insurer for any failure to meet GINA's requirements.

Additionally, the Department of Labor will assess penalties not exceeding the lesser of 10% of the aggregate plan premium/expenses for a plan year or \$500,000 for failures due to a reasonable cause and not as a result of willful misconduct. In that case, the penalties can range from \$15,000 per failure or higher. There also may be additional penalties under the IRC and HIPAA.

Details: Employment Practices

1. **Prohibitions.** Employers, employment agencies, labor organizations, joint labor-management committees, and other employment organizations including state and local governments, must not discriminate against an employee based on genetic information. They may not refuse to hire or discharge an employee or otherwise discriminate as to compensation or other privileges of employment on the basis of Genetic Information. Employment agencies may not refuse to refer a candidate and labor organizations cannot deny admission of an individual to apprenticeship or training programs, or cause an employer to discriminate against an employee/union member on the basis of genetic information.
2. **Permissible Uses.** These organizations may obtain genetic information when the organization:
 - Inadvertently requests or requires family history of the employee or family member of the employee;
 - Offers health or genetic services and certain conditions are met, such as obtaining an individual's voluntary, written authorization, and disclosure to the entity is limited to aggregate terms that do not disclose the identity of an individual;
 - Requests or requires family medical history to comply with certifications required by the Family and Medical Leave Act;
 - Purchases commercial and publicly available documents that include medical history;

Federal Genetic Information Nondiscrimination Act 2008-11

- Uses the information for genetic monitoring of the biological impact of toxic substances in the workplace, and certain conditions are met; or,
 - In certain circumstances, conducts DNA analysis for law enforcement purposes as a forensic laboratory and requires such analysis for quality control purposes.
3. **Maintenance of Records.** Just as under the HIPAA privacy rules applicable to protected health information in the health plan environment, state and federal privacy rules applicable under employment law will require that Genetic Information be contained in medical files separate from employment files and be treated as a confidential medical record. Organizations can disclose Genetic Information only under limited circumstances such as:
- At the request of the individual;
 - To an occupational researcher meeting federal regulations;
 - As certification of FMLA leave;
 - To public health agencies in the event of an eminent threat of a life-threatening contagion.

It is worth noting that GINA does not make an exception for discovery requests or subpoenas in a litigation setting.

4. **Remedies.** Individuals who believe they have been aggrieved may rely on Title VII of the Civil Rights Act of 1964 by filing a complaint with the Equal Employment Opportunity Commission (EEOC) or similar agency on the state level. We expect the EEOC to produce regulations on genetic discrimination in the near future. They may also avail themselves of state privacy statutes and obtain relief through civil actions for both compensatory and possibly punitive damages.

What Must Employers Do

1. Review personnel policies and procedures to assure confidentiality of any Genetic Information currently on hand;
2. Establish procedures for separating Genetic Information from other personnel records;
3. Follow up with insurers on its response to GINA prior to your next open enrollment; and,
4. Instruct privacy officers and key personnel to establish training modules as needed.

GINA touches many aspects of our business. I recommend that employers be diligent in determining the extent Genetic Information is collected or maintained whether it be for employment or health plan purposes. This law contains and allows for stiff penalties for its violations. As technology and science advance in the field of genetics, Genetic Information will clearly be a part of the employment process and health plan management.

We will keep you informed of developments.

You may view H.R. 493 at http://www.abferisa.com/documents/GINA_HR493.pdf

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