



GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008

On May 21, 2008 the Genetic Information Nondiscrimination Act of 2008 (GINA, Public Law 110-233) was signed into law. The law prohibits employers from using an individual's genetic information when making hiring, firing, job placement or promotion decisions and makes it illegal for group health plans and health insurers to deny coverage to healthy individuals or charge them higher premiums based solely on a genetic predisposition to a disease.

This topic addresses the Title I section of the law concerning health insurance. Title I provisions of GINA apply to group health plans for plan years beginning one year after the law's enactment date of May 21, 2008. The effective date for calendar year plans is January 1, 2010. Failure to comply with Title I of GINA can result in penalties under ERISA, the Public Health Service Act, and/or the Internal Revenue Code.

Three federal agencies (Internal Revenue Service, Department of Labor and the Centers for Medicare and Medicaid Services) jointly issued interim final regulations to provide guidance on the implementation of the GINA law. The regulations were published in the October 7, 2009 Federal Register. The regulations are applicable for group plans on the first day of the plan year beginning on or after December 7, 2009. The regulations for individual plans become applicable with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated on or after December 7, 2009.

This topic has been updated throughout with the impact of the interim final regulations indicated in bold.

Definitions

Family Member - a dependent covered by the group health plan or any other individual who is a first, second, third, or fourth degree relative. GINA does not apply to just family members covered by the plan, but also to other family members that may or may not be covered by the plan. Any reference in GINA to the genetic information of an individual or family member also includes the fetus or embryo of the individual or family member.

The interim final regulations clarify that relatives by affinity (such as by marriage or adoption) are treated in the same way as relatives by consanguinity (relatives who share a common biological ancestor or blood relatives). The definition also treats relatives who are not full blood relatives (e.g., half siblings) in the same way as full blood relatives. Examples are given of individuals who meet the definition of first, second, third or fourth degree relatives.

Genetic Information - information about an individual's genetic tests or the genetic tests of



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the individual's family members, and the manifestation of a disease or disorder in the individual's family members. Genetic information also includes the request or receipt of genetic services or participation in clinical research that includes genetic services, for both the individual and the individual's family members. Information regarding an individual's sex or age is not protected genetic information under GINA.

The interim final regulations contain a definition of genetic information that restates and reorganizes the statutory provisions. Genetic information is defined, with respect to an individual, as information about the individual's genetic tests or the genetic tests of family members, the manifestation of disease or disorder in family members of such individual (that is, family medical history), or any request of or receipt by the individual or family members of genetic services. The definition further clarifies that genetic information does not include information about the sex or age of any individual and clarifies how GINA applies to genetic information about a fetus or embryo.

Genetic Monitoring - the periodic examination of employees to evaluate acquired modifications to their genetic materials, such as chromosomal damage or evidence of increased occurrence of mutations, that may have developed in the course of employment due to exposure to toxic substances in the workplace, in order to identify, evaluate, and respond to the effects or control adverse environmental exposures in the workplace.

Genetic Services - a genetic test, genetic counseling, genetic education, or participation in a research study.

Genetic Test - the analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes. Under GINA, a genetic test does not include the analysis of proteins or metabolites directly related to the manifestation of a disease that could reasonably be detected by a healthcare professional with appropriate training and expertise in the field of medicine involved. Examples of tests covered by GINA include tests for BRCA1/BRCA2 (breast cancer) or HNPCC (colon cancer) mutations, tests for Huntington's disease mutations, carrier screening for disorders such as cystic fibrosis and fragile X syndrome, and classifications of genetic properties of an existing tumor to help determine therapy. Examples of tests not covered by GINA are routine tests such as routine blood counts, cholesterol tests, and liver-function tests.

Manifestation - the interim final regulations added a new definition for manifestation or manifested. A disease, disorder, or pathological condition is manifested when an individual has been or could reasonably be diagnosed by a health care professional with appropriate training and expertise in the field of medicine involved. However, the definition further provides that a disease, disorder, or pathological condition is not manifested if a diagnosis is based principally on genetic information.



Types of Plans Affected

GINA applies to both ERISA and non-ERISA plans regardless of size. It generally does not apply to benefits that are otherwise excepted from HIPAA (e.g., life, accident, disability, long-term-care, or workers compensation coverages). The health insurance provisions of GINA do not apply to members of the US military, to veterans obtaining healthcare through the Veterans Administration, or to the Indian Health Service.

GINA Prohibitions

Title I of the Genetic Information Nondiscrimination Act (GINA) outlines unlawful practices for health insurers and self funded plans relating to the use of genetic information. GINA prohibits the following:

- Health insurers and plans may not require individuals to provide their genetic information or the genetic information of a family member to the insurer or plan for eligibility, coverage, underwriting, or premium-setting decisions;
- Health insurers and plans may not use genetic information either collected with intent, or incidentally, to make enrollment or coverage decisions;
- Health insurers and plans may not request or require that an individual or an individual's family member undergo a genetic test; and
- In the Medicare supplemental policy and individual health insurance markets, genetic information cannot be used as a pre-existing condition.

For joint research activities conducted by health insurers or plans in collaboration with external research entities, a health insurer or plan in either the group or individual market may request, but not require, in writing that an individual undergo a genetic test. The individual may voluntarily choose to undergo such genetic testing, but non-compliance will not have a negative effect on the premium or enrollment status of the individual. Genetic information may only be used for research and not for underwriting purposes.

The interim final regulations clarify that even when a plan has lawfully obtained genetic test results or other genetic information (e.g., information obtained prior to GINA's effective date), the plan or issuer is still prohibited from using that information to discriminate. Plans and issuers also cannot adjust premium or contribution rates at the group level based on genetic information of one or more individuals in the group.



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GINA Permissible Actions

- GINA does not restrict genetic services, the practice of medicine, or the authority of healthcare professionals, whether or not they are affiliated with a health plan or issuer or an employer. Clinicians and healthcare providers can request that an individual or an individual's family member undergo a genetic test for the purpose of that individual's medical benefit.
- The health insurance provisions of GINA do not cover an individual's manifested disease or condition (e.g., a disease that has already appeared). GINA protects an individual's predictive genetic information. GINA also protects information about manifested disease in an individual's family members (e.g., their family history of disease).
- GINA does not preempt state law; therefore if a states genetic discrimination law provides more extensive protections than GINA, GINA does not change it. State laws apply to insured plans.

GINA & Wellness Programs

GINA permits genetic information to be acquired in conjunction with a wellness program if certain conditions are met. A wellness program that is offered separate from the group health plan cannot require employees to provide genetic information, but is allowed to request employees to voluntarily provide genetic information.

GINA wellness program conditions relating to the acquisition of genetic information include:

- the individual must provide prior, knowing, voluntary and written authorization;
- only the individual (or family member) and the licensed health care professional or genetic counselor who provides genetic services can receive the resulting individually identifiable information; and
- any individually identifiable genetic information cannot be disclosed to the employer except in the aggregate without disclosing the identity of the participant.

The interim final regulations clarify that employers are prohibited from collecting genetic information (including family medical history) prior to enrollment, in health risk assessments (HRAs) if that information will be used for underwriting purposes, which includes offering employees discounts on their monthly premium contributions or lowering the deductible for completion of the HRA. It is permissible for an employer to request enrollees to complete two distinct HRAs after and unrelated to enrollment , one



that doesn't include questions about family medical history, but offers a reward and one that includes family medical history questions, but offers no reward.

Claim Processing Implications

- Health insurers and plans may not adjust premium and contribution amounts for a group on the basis of genetic information. However, the premium or contribution amount for a group can take into consideration the manifestation of a disease of an individual who is enrolled in the plan if the information is not used as genetic information about other group members and to increase employer premium.
- With regard to making coverage decisions for a claim determination, a claims administrator can require genetic information. For example, an administrator can request information about an individual's BRCA status to determine coverage for a prophylactic mastectomy. The administrator should request only the minimum amount of information necessary for decision-making.

The interim final regulations provide that, if an individual seeks a benefit under a plan or coverage, the plan or coverage may limit or exclude the benefit based on whether the benefit is medically appropriate, and the determination of whether the benefit is medically appropriate is not within the meaning of underwriting purposes. However, the plan or issuer is permitted to request only the minimum amount of information necessary to determine medical appropriateness.

GINA & Privacy

The Health Insurance Portability and Accountability Act (HIPAA) privacy rules apply to the use and disclosure of all protected health information which includes genetic information.

GINA expands the HIPAA privacy rules to clarify that the use or disclosure of protected health information that is genetic information for underwriting purposes in group health plans, health insurance coverage, or Medigap policies is not a permitted use or disclosure. A plan would need to redact any genetic information before disclosing protected health information to a third party for purposes of underwriting.

GINA privacy restrictions may also apply to plans that are HIPAA exempt and to an entity (e.g., employer) that is not covered directly by the HIPAA privacy rules. In addition, employers, labor organizations and related entities must keep genetic information confidential and separate from employment records.



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Cross Reference:

[Section 4.15, Privacy and Confidentiality](#)

Additional Information

A guide to GINA including the history of the legislation and examples of what would constitute genetic discrimination is available on the Coalition for Genetic Fairness Web site:

<http://www.geneticfairness.org/ginaresource.html>

The text of the GINA law can be viewed by searching for Public Law 110-233 at:

<http://www.gpoaccess.gov/plaws/index.html>

The GINA interim final regulations are available at:

<http://edocket.access.gpo.gov/2009/pdf/E9-22504.pdf>