



Genetic Information Nondiscrimination Act (GINA)

The Genetic Information Nondiscrimination Act of 2008 (GINA) provides broad protections in employment and health coverage against the improper collection, use or disclosure of individuals' genetic information.

- Title I of GINA prohibits group health plans and health insurance issuers from discriminating based on genetic information and from collecting genetic information.
- Title II of GINA, which applies to employers with 15 or more employees, protects job applicants and employees from employment discrimination based on their genetic information.

“Genetic information” means information about an individual's genetic tests, the genetic tests of the individual's family members and the manifestation of a disease or disorder in the individual's family members.

GINA's protections also apply to employer-sponsored wellness programs that ask employees to answer questions about their health and family medical histories.

LINKS AND RESOURCES

- [Interim final rules](#) under Title I of GINA addressing genetic nondiscrimination in health coverage (the Title I Regulations)
- [Final rules](#) under Title II of GINA addressing the use of genetic information in the employment context (the Title II Regulations)
- FAQs on [Title I](#) and [Title II](#) of GINA

DEFINITION OF GENETIC INFORMATION

GINA defines “genetic information” to mean information about:

- An individual's genetic tests;
- The genetic tests of family members of the individual; and
- The manifestation of a disease or disorder in family members of the individual.

Genetic information also includes any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by the individual or any family member of the individual. 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 are also considered genetic information protected by GINA.

The term does not include information about the sex or age of any individual.

IMPACT ON HEALTH PLANS (TITLE I OF GINA)

Title I of GINA deals with genetic nondiscrimination in health plan coverage and regulates group health plans (including small group health plans), health insurance issuers offering health insurance coverage in the individual market, non-federal governmental plans and issuers of Medicare supplemental policies.

In general, GINA prohibits group health plans and insurance issuers from:

- Adjusting group premium or contribution amounts on the basis of genetic information;

- Requesting or requiring individuals (or their family members) to undergo a genetic test (with limited exceptions, such as for determinations regarding payment based on medical appropriateness); and
- Requesting, requiring or purchasing genetic information prior to or in connection with enrollment, or at any time for underwriting purposes.

GINA also amended the HIPAA privacy regulations by prohibiting the use or disclosure by a group health plan, health insurance issuer or issuer of a Medicare supplemental policy of genetic information about an individual for underwriting purposes. For purposes of HIPAA, genetic information must be treated as health information.

IMPACT ON EMPLOYERS (TITLE II OF GINA)

Title II of GINA prohibits employment discrimination on the basis of genetic information. In general, employers with **15 or more employees**, employment agencies, labor organizations and joint labor-management committees may not discriminate against an employee, individual or member based on genetic information. Under Title II:

- Employers may not discharge, fail or refuse to hire or otherwise discriminate against any employee with respect to the compensation, terms, conditions or privileges of employment because of genetic information;
- Employment agencies may not fail or refuse to refer for employment, or otherwise discriminate against any individual, because of genetic information;
- A labor organization may not exclude or expel from membership, or otherwise discriminate against, any member because of genetic information; and
- Individuals may not be discriminated against because of genetic information with respect to admission or employment in any program established to provide training or apprenticeship.

Employers, employment agencies, labor organizations and joint labor-management committees are also prohibited from requesting, requiring or purchasing genetic information about an individual or family member, except where the entity:

- Inadvertently requests or requires family medical history of the individual or family member;
- Offers health or genetic services, the individual provides specific authorization and individual information is not released to others;
- Requests or requires family medical history to comply with the federal Family and Medical Leave Act (FMLA) or state family and medical leave laws;
- Purchases documents that are commercially and publicly available that include family medical history;
- Uses the information for genetic monitoring of the biological effects of toxic substances in the workplace, if certain detailed conditions are met; or
- Conducts DNA analysis for law enforcement purposes as a forensic laboratory and requires such analysis for quality control.

Finally, genetic information about an individual must be maintained separately and treated as a **confidential medical record**. Genetic information about an individual may be disclosed to the individual, to an occupational or other health researcher, in response to a court order, to government officials investigating compliance, for FMLA leave purposes, or to a public health agency regarding a contagious disease presenting an imminent hazard (only when certain specifically outlined conditions are met).

IMPACT ON USE OF HEALTH RISK ASSESSMENTS

Title I of GINA

GINA's Title I Regulations clarify that collecting genetic information prior to or in connection with enrollment, or for underwriting purposes, will affect the use of health risk assessments (HRAs). HRAs are tools commonly used by wellness and disease management programs. Title I Regulations place strict limits on wellness and disease management programs offered under group health plans that utilize HRAs requesting genetic information. Pursuant to Title I Regulations, group health plans may not:

- Provide a reward or incentive to an individual for completing an HRA that requests genetic information, such as family medical history; or
- Request genetic information as part of an HRA that must be completed before enrollment in the plan or eligibility for additional benefits under the plan, such as a disease management program.

A reward or incentive can take many forms, including premium discounts or rebates, reduced deductibles or copayments, cash rebates or gift certificates. The regulations suggest that rewards or incentives also include those related to health flexible spending arrangements or health reimbursement arrangements. Rewards or incentives do not have to be based on the outcome of the HRA to be impermissible.

The Title I Regulations indicate, however, that the following uses or types of HRAs will not violate GINA:

- Collecting genetic information after enrollment in the plan, if no reward or incentive is provided;

- Using two separate HRAs—one that requests genetic information and one that does not. The HRA requesting genetic information must not include an incentive, must be voluntary and must not affect the reward given for the other HRA; or
- Asking HRA questions that do not directly request genetic information, if the HRA clearly states that genetic information should not be provided.

Title II of GINA

HRAs that are not used in connection with group health plans are subject to Title II of GINA, which prohibits employment discrimination on the basis of genetic information. As an exception to GINA's general prohibition on requesting employees' genetic information, employers may request genetic information if they offer health or genetic services, including services offered under a voluntary wellness program. For this exception to apply, the following criteria must be met:

- The employee must provide the information voluntarily, meaning that the employee is not required to provide the information and is not penalized if he or she decides not to provide the information;
- The employer must obtain prior knowing, voluntary and written authorization from the employee;
- Individually identifiable genetic information must be provided only to the employee (or family member, if the family member is receiving genetic services) and the licensed health care professionals or board certified genetic counselors involved in providing such services, and must not be accessible to managers, supervisors or others who make employment decisions, or to anyone else in the workplace; and
- The information must be used only for the purposes for which the authorization was obtained and must not be disclosed to the employer except in aggregate terms.

The Title II Regulations provide that an employer does not violate GINA when the employer offers financial incentives to employees for completing HRAs with questions about family medical history, only if the employer makes clear that the incentives are available regardless of whether the employees complete the questions about family medical history.

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