

Genetic Information Nondiscrimination Act: A Primer on Title II

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Earlier this month, the Equal Employment Opportunity Commission (EEOC) issued its long-awaited final regulations under Title II of the Genetic Information Nondiscrimination Act of 2008 (GINA). While GINA may not be on every employer's "radar screen," it carries with it important obligations that employers need to understand to mitigate the risk of liability. This is especially important since there is no "intent" requirement under GINA. Thus, employers can be found to violate the law even without intending to do so.

To help employers navigate the new legal landscape, we have prepared a summary of the law and EEOC regulations in a question-and-answer format.

What is GINA?

President George W. Bush signed GINA into law on May 21, 2008. The premise of the law is simple: to allay public fear about anticipated misuse of genetic information in health insurance and employment that may have otherwise stymied continued development in the field of genomic medicine. *See* 42 U.S.C. § 2000ff *et seq.*

There are two major components to the law:

Title I of GINA includes provisions that generally prohibit group health plans and health insurance issuers from discriminating based on genetic information. In short, the law expands the genetic information protections included in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) that prevent a plan or issuer from imposing a preexisting condition exclusion provision based solely on genetic information, and prohibit discrimination in individual eligibility, benefits, or premiums

GINA at a Glance

Synopsis:

Prohibits employers from requesting, requiring, or purchasing genetic information in the workplace

Employers Affected:

Applies to private and state and local government employers with 15 or more employees (except in some states)

Effective Date:

Law in effect since November 21, 2009; regulations in effect January 10, 2011

To Do:

- Ensure policies include references to nondiscrimination on the basis of genetic information, and include prohibitions on the acquisition of genetic material on company systems.
- Include GINA safe harbor language on all requests for medical information.
- Ensure that GINA is included on postings (revised EEO poster is sufficient).

based on any health factor (including genetic information).¹

Title II of GINA prohibits employers from requesting, requiring, or purchasing genetic information and strictly limits the disclosure of genetic information, as described in more detail below. The law itself borrows from other discrimination statutes, such as Title VII of the Civil Rights Act of 1964, in its enforcement mechanism and procedures.

Which employers are covered under the law?

Title II applies to private and state and local government employers with 15 or more employees, employment agencies, labor unions, and joint labor-management training programs.

What is the effective date?

GINA itself has been in effect since November 21, 2009. The recently announced EEOC regulations under Title II are effective January 10, 2011.

What is “genetic information”?

The definition of genetic information for purposes of Title II is broad and includes the following:

- 1) An individual’s genetic tests
- 2) Genetic tests of that individual’s family members
- 3) The manifestation of disease or disorder in family members of the individual (referred to as “family medical history”)
- 4) An individual’s request for, or receipt of, genetic services, or participation in clinical research that includes genetic services
- 5) Genetic information of a fetus carried by a pregnant woman who is a family member of the individual and the genetic information of any embryo legally held by the individual or family member using an assisted reproductive technology

Genetic tests include but are not limited to an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detect genotypes, mutations, or chromosomal changes. Genetic tests specifically include screenings for the BRCA1 or BRCA2 variants linked to a predisposition for breast cancer; tests for genetic variations associated with hereditary colon cancer; tests for genetic variations suggestive of Huntington’s Disease; and genetic analyses related to cystic fibrosis, sickle cell anemia, spinal muscular atrophy, or fragile X syndrome. The definition also includes amniocentesis tests, newborn screenings, and DNA testing for family relationships (for example, paternity tests).

Genetic tests *do not* include tests for viruses and other tests that are not related to human DNA. For example, a test for the presence of alcohol is not a genetic test. A test to determine whether an individual is predisposed to alcoholism is a genetic test.

¹ This primer does not cover this portion of the law; our analysis of the proposed regulations can be found in our October 16, 2009 LawFlash, “New GINA Regulations Severely Hamper Health Risk Assessments,” at http://www.morganlewis.com/pubs/EB_GINARegulations_LF_16oct09.pdf.

Family medical history—or the manifestation of a disease or disorder—includes diseases, disorders, or pathological conditions that an individual has been or could reasonably be diagnosed with by a healthcare professional.

What does GINA prohibit?

Employers have three main obligations under GINA: (1) to refrain from discriminating against individuals on the basis on genetic information; (2) to refrain from acquiring genetic information; and (3) to avoid disclosure of genetic information once it is acquired (advertently or inadvertently).

1. Discrimination

GINA prohibits discrimination and/or retaliation against individuals on the basis of genetic information, no matter how that information is acquired. This includes limiting, segregating, or classifying employees because of genetic information (for example, reassigning an individual from a stressful position after learning that she has a family medical history of heart disease).

Neither the statute nor the regulations create a cause of action for disparate impact (for example, when a facially neutral policy has a discriminatory impact on individuals because of genetic information).

2. Acquisition of Genetic Information

Employers may not request, require, or purchase the genetic information of an individual or of his or her family member. Requests under GINA specifically include conducting an Internet search on an individual in a way that is likely to result in obtaining genetic information, “actively” listening to third-party conversations, or searching through an individual’s belongings for the purpose of obtaining genetic information, as well as making requests for information about an individual’s current health status in a way that is likely to result in obtaining genetic information.

There are a number of significant exceptions, including (but not limited to) the following:

- **Inadvertent Discovery.** “Inadvertent” disclosures are not actionable under GINA. That carve-out, however, is deceptive, and is not as broad as its language would lead employers to believe.

The EEOC regulations recognize that employers may inadvertently receive genetic information in response to lawful requests for medical information (for example, when an employer receives genetic information as a result of a Family and Medical Leave Act certification). However, disclosures will *only* be considered inadvertent if (1) the employer directs the individual and/or healthcare provider not to provide genetic information or (2) the employer can establish that its request was sufficiently limited to make inadvertent disclosure unlikely.

To that end, the EEOC suggests that the following “safe harbor” language be included on medical certification requests to ensure that the inadvertent disclosure exception applies:

The Genetic Nondiscrimination Act of 2008 (GINA) prohibits employers and other entities covered by GINA Title II from requesting, or requiring genetic information of an

individual or family member of the individual, except as specifically allowed by this law. To comply with this law, we are asking that you not provide any genetic information when responding to this request for medical information. “Genetic information,” as defined by GINA, includes an individual’s family medical history, the results of an individual’s or family member’s genetic tests, the fact that an individual or an individual’s family member sought or received genetic services, and genetic information of a fetus carried by an individual or an individual’s family member or an embryo lawfully held by an individual or family member receiving assistive reproductive services.

The EEOC will deem any receipt of genetic information that follows the receipt of this language as “inadvertent.” (Because the EEOC has specifically exempted from GINA requests for family medical information to substantiate the need for leave to care for a family member, as described below, employers should consider modifying and/or adding to the disclaimer to clarify that such requests are proper.)

The regulations also list other situations where the “inadvertent” disclosure doctrine may apply. For example, a manager who overhears a conversation between two employees, or receives unsolicited information in response to a casual “How are you?” will fall under the exception.

- **Voluntary Disclosure.** The GINA Title II regulations also exempt disclosures made as part of a voluntary wellness program that offers health or genetic services. This exception only applies where the following conditions are met:
 - The provision of genetic information by the individual is voluntary, meaning that the employer neither requires the individual to provide genetic information nor penalizes those who choose not to provide it.
 - The individual provides prior knowing, voluntary, and written authorization (including electronic authorization) using a form provided by the employer. The form should be written so that the individual from whom information is sought is reasonably likely to understand it, and should clearly describe the type of genetic information that will be obtained and the purpose for which it is being obtained, as well as the limitations on disclosure of genetic information.
 - Individually identifiable genetic information is provided only to the individual (or family member, if the family member is receiving services) and to the healthcare professionals involved, and is not accessible to managers, supervisors, or others who make employment decisions, or anyone else in the workplace.
 - Individually identified genetic information is not provided or disclosed to the employer, except in aggregate terms that do not disclose the identity of specific individuals.

The regulations also specifically address the common practice of giving financial inducement for individuals to complete health risk assessments (HRAs), which often include questions about family medical history. The EEOC makes clear that these inducements are still allowed—provided that the employer makes it clear, in language reasonably likely to be understood, that the incentive will be made available to the participant whether or not the

participant answers questions regarding genetic information.

- **FMLA Requests for Leave Related to Family Members.** An employer may request family medical information to substantiate the need for leave under the FMLA or an equivalent state or local leave law or pursuant to a policy (even in the absence of applicable federal, state, or local law) that permits the use of leave to care for a sick family member. As mentioned above, employers should consider whether to amend the “safe harbor” disclaimer to make it clear to medical providers that it is acceptable to provide family medical history in connection with a request for leave to care for a family member.
- **Publicly Available Information.** Generally, an employer does not violate GINA by passive acquisition of genetic information from commercially and publicly available sources like newspapers, television, or Internet. With that said, the exception does not apply where, for example, the information is acquired through a limited access site (e.g., Facebook or other social networking sites) which requires specific permission to access certain information, or where there is some specific intent to obtain genetic information through commercially available means.

3. Confidentiality and Nondisclosure

Employers that possess genetic information in writing about an employee must maintain such information on forms and in files that are separate from personnel files and must treat such information as confidential medical records. The information may be maintained in the same file as confidential medical information subject to the Americans with Disabilities Act.

An employer that possesses genetic information—including information acquired inadvertently (except via public sources)—may not disclose it except under the following circumstances:

- To the employee (or family member, if the family member is receiving genetic services) about whom the information pertains upon receipt of the employee’s written request
- In response to a court order, except that the employer may disclose only the genetic information authorized by such an order.² If the employee has no knowledge of the order, the employer shall inform the employee of the order and any genetic information that was disclosed pursuant to such order. *This exception does not allow disclosure in other circumstances in litigation, such as in response to discovery requests or subpoenas, absent court order that specifies genetic information must be disclosed*
- To government officials investigating compliance with GINA
- To the extent the disclosure is made in support of any employee’s compliance with the certification requirements under the FMLA or a state or local leave law

² While the regulations do not specifically address an employer’s disclosure of genetic information to its attorneys, the EEOC’s comments make clear that “a covered entity’s attorney or a business with whom it has contracted to store medical information on its behalf is an agent of the covered entity and would therefore be permitted access to relevant genetic information.”

- To a federal, state, or local public health agency, but only in limited circumstances

Genetic information placed in a file prior to November 21, 2009 (the effective date of GINA) need not be removed. Employers will not be liable under GINA for the existence of this information in the file. These pre-existing documents, however, are subject to the nondisclosure provisions of GINA moving forward.

How would an employee make a complaint?

GINA's enforcement mechanism works just like Title VII. That is, an allegedly aggrieved employee has 180 days from the date of the alleged violation to file a claim of genetic discrimination with the EEOC, or within 300 days if a state or local agency enforces a law that prohibits employment discrimination on the basis of use or acquisition of genetic information or genetic testing. The EEOC (or, if applicable, a state deferral agency) will then investigate the claim.

What is the practical impact on employers?

Employers need to make important adjustments before the January 10, 2011 effective date of the EEOC regulations to avoid liability under GINA. These steps include the following:

- **Review policies.** Employers should ensure that their employment policies include references to nondiscrimination on the basis of genetic information. Policies should also include a prohibition against the use of company systems in any manner likely to obtain genetic material, and include general references to the company's policy not to require genetic information in response to certifications and other requests for medical information.
- **Revise medical forms.** Employers should include the GINA safe harbor language in all requests for medical information moving forward. Companies should also consider including language in certifications for leave to care for family members that make it clear that the disclosure of relevant family medical history is appropriate.
- **Check postings.** Employers should ensure that GINA is referenced on EEO postings (required as of November 21, 2009). The November 2009 revised EEO poster is available at <http://www1.eeoc.gov/employers/poster.cfm>.

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