

predisposition to breast cancer or associated with certain hereditary diseases, carrier screenings to determine an adult's risk for conditions such as cystic fibrosis or sickle cell anemia, and amniocentesis.¹⁹ Also included in the regulations are examples of tests or procedures that are not genetic tests, among which are complete blood counts, cholesterol tests, liver-function tests, and alcohol and drug tests.²⁰

Genetic monitoring refers to the periodic examination of employees to evaluate acquired modifications to their genetic material, such as chromosomal damage or evidence of increased occurrence of mutations, that may have developed during employment due to exposure to toxic substances in the workplace. The purpose of the monitoring must be to identify and control adverse environmental exposures in the workplace.²¹

3. *Family Members*

A family member of an individual is defined as someone who is a first-degree, second-degree, third-degree, or fourth-degree relative of that individual (including some half-siblings) or someone who is a dependent of that individual. A dependent for this purpose means someone who is a dependent as the result of marriage, birth, adoption, or placement for adoption.²²

Relationship to Definitions Used in Other Employment Nondiscrimination Statutes.

The EEOC has acknowledged that the definitions described are not common to employment nondiscrimination law and are “outside the areas of its expertise” (e.g., terms used in the definition of “genetic test,” including “human DNA, RNA, chromosomes, proteins, or metabolites”).*

* See Preamble to Final Regulations, 75 Fed. Reg. 68911, 68913 (Nov. 9, 2010).

D. Prohibition Against Discrimination Based on Genetic Information

1. *Employers Cannot Discriminate Against Employees Based on Genetic Information*

GINA's employment nondiscrimination requirements prohibit employers from discriminating against any employee with respect to hiring, discharge, compensation, terms, conditions, or privileges of employment on the basis of genetic information with respect to the employee.²³ The preamble to the final regulations recognizes that employers that sponsor group health plans (including self-insured group health plans) must comply with Title II of GINA when operating as employers, while their plans must comply with Title I of GINA, noting that health benefits are within the definition of “compensation, terms, conditions, or privileges of employment.”²⁴

GINA also imposes other nondiscrimination requirements that could affect group health plans, though as a practical matter, these requirements are likely to come into play less often for such plans than the prohibition against discrimination in the “hiring, discharge, compensation, terms, conditions, or privileges of employment” provision discussed earlier. For example, employers cannot fail or refuse to hire, or discharge any employee because of genetic information. They cannot limit, segregate, or classify employees in any way that would deprive or tend to deprive them of employment opportunities or adversely affect their status as employees because of genetic information relating to the employee.²⁵ Nor can employers discriminate or retaliate against individuals who oppose unlawful practices under GINA, or who make a charge, testify, assist, or participate in any investigation, proceeding, or hearing related to the employment nondiscrimination requirements.²⁶ Employers will not violate GINA if they limit or restrict an employee's job duties based on

¹⁹ EEOC Reg. § 1635.3(f)(2).

²⁰ EEOC Reg. § 1635.3(f)(3).

²¹ Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 201(5) (2008), to be codified at 42 U.S.C. § 2000ff; EEOC Reg. § 1635.3(d).

²² Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 201(3) (2008), to be codified at 42 U.S.C. § 2000ff-1; EEOC Reg. § 1635.3(a). The definition of dependent for this purpose is the same as applies for purposes of the HIPAA special enrollment provisions found in ERISA § 701(f)(2).

²³ EEOC Reg. § 1635.4(a). Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 202 (2008), to be codified at 42 U.S.C. § 2000ff-1; Preamble to Final Regulations, 75 Fed. Reg. 68911, 68930 (Nov. 9, 2010).

²⁴ Preamble to Final Regulations, 75 Fed. Reg. 68911, 68930 (Nov. 9, 2010).

²⁵ Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 202(a) (2008), to be codified at 42 U.S.C. § 2000ff-1; EEOC Reg. §§ 1635.4 and 1635.5.

²⁶ Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 207(f) (2008), to be codified at 42 U.S.C. § 2000ff-6; EEOC Reg. § 1635.7.

genetic information because they were required to do so by a law or regulation mandating genetic monitoring (e.g., by regulations administered by the Occupational and Safety Health Administration (OSHA)).

Note that the employment nondiscrimination requirements are part of a statute of much broader application that happens, as a small part of its overall application, to impact employee benefit plans.

2. “Firewall” Between GINA’s Employment Nondiscrimination and Health Insurance Rules

In its final regulations under Title II of GINA, the EEOC has attempted to create a “firewall” between the employment nondiscrimination requirements contained in Title II and the group health plan and health coverage provisions contained in Title I, by explicitly identifying certain matters that are not enforceable under GINA Title II.²⁷ The firewall is intended to eliminate double liability—that is, to prevent causes of action based on GINA’s employment nondiscrimination requirements from being asserted with respect to matters that are subject to enforcement under the group health plan and health coverage provisions.²⁸ For example, under the firewall provision, if an employer fires an employee because of anticipated high health claims based on genetic information, that violation is enforceable under Title II even though it involves access to health benefits. If a health plan or health insurer discriminates with respect to health plan eligibility, benefits, or premiums based on genetic information, that is subject to enforcement under Title I exclusively.²⁹

The firewall does not mean that particular circumstances cannot result in violations of both Title I and Title II. For example, if an employer contracts with a health insurer to request genetic information, the employer will violate Title II, and the insurer may have violated Title I. Similarly, if an employer amends its plan to require an individual to undergo a genetic test, then the employer has violated Title II, and the plan may violate Title I when it administers the requirement.³⁰

3. Employers Cannot Request, Require, or Purchase Genetic Information Except Under Limited Circumstances

GINA’s employment nondiscrimination requirements generally prohibit an employer from requesting, requiring, or purchasing genetic information relating to an employee or a family member of an employee.³¹ The EEOC notes, in the preamble to its final regulations, that an employer can violate this requirement without a specific intent to acquire genetic information.³² For this purpose, “request” includes doing any of the following in a way that is likely to result in a covered entity (e.g., an employer) obtaining genetic information:

- conducting an Internet search;
- actively listening to third-party conversations;
- searching an individual’s personal effects; or
- asking for information about an individual’s current health status.³³

Not every acquisition of genetic information violates GINA, however, and the final regulations provide some important exceptions to this requirement. The general prohibition against requesting, requiring, or purchasing genetic information does not apply under the following circumstances:

- the employer offers health or genetic services, including such services offered as part of a voluntary wellness program; the employee provides prior, knowing, voluntary, and written authorization; and additional conditions relating to individually identifiable information are met;³⁴

²⁷ EEOC Reg. § 1635.11(b)(1).

²⁸ EEOC Reg. § 1635.11(b)(2).

²⁹ EEOC Reg. § 1635.11(b)(2).

³⁰ EEOC Reg. § 1635.11(b)(2), Examples (i) and (iii).

³¹ Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 202(b) (2008), to be codified at 42 U.S.C. § 2000ff-1; EEOC Reg. § 1635.8.

³² Preamble to Final Regulations, 75 Fed. Reg. 68911, 68913.

³³ EEOC Reg. § 1635.8(a).

³⁴ The regulations state that this exception will only be available for a wellness program that is voluntary, meaning that the employer “neither requires the individual to provide genetic information nor penalizes those who choose not to provide it.” EEOC Reg. § 1635.8(b)(2). This position is consistent with the EEOC’s prior informal positions relating to the ADA. (For more information about the ADA, see Section XX.) For detailed coverage of wellness programs, see *Consumer-Driven Health Care* (Thomson Reuters/EBIA, 2004-present, updated quarterly).

- the employer requests or requires family medical history from the employee to comply with the certification provisions of FMLA § 103 or similar requirements under state family and medical leave laws;
- the information is in documents purchased by the employer that are commercially and publicly available (but not including medical databases or court records);
- the information is to be used for genetic monitoring of the biological effects of toxic substances in the workplace and certain notice, authorization, disclosure and other requirements are met;
- the employer conducts DNA analysis for law enforcement purposes as a forensic laboratory or for human remains identification, and certain other requirements are met; or
- the employer inadvertently requests or requires an employee's (or family member's) family medical history. With regard to this exception, an employer's receipt of genetic information in response to a lawful request for medical information will be deemed inadvertent if language is included to specifically direct the individual or health care provider not to provide genetic information.³⁵

Model Language for Requesting Medical Information. The final regulations include model language to be used by an employer lawfully requesting medical information so that any genetic information included with the response will be deemed inadvertent. Although use of the model language is not required, it provides a welcome safe harbor for employers making such requests. Employers that fail to give a notice or use similar language when requesting medical information will not be prevented from establishing that a particular receipt of genetic information was inadvertent if its request for medical information was not “likely to result in a covered entity obtaining genetic information” (e.g., where an overly broad response was received in response to a tailored request for medical information).^{*} The model language provided in the regulations is —

The Genetic Information 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.[†]

* EEOC Reg. § 1635.8(b)(1)(i)(C).

† EEOC Reg. § 1635.8(b)(1)(i)(B).

The exception for inadvertent receipt of genetic information has been referred to as the “water cooler exception.” In the preamble to its final regulations, the EEOC notes that Congress did not want casual conversation among co-workers regarding a person’s health to trigger federal litigation whenever someone mentioned something that might constitute protected family medical history. For example, an employer might inadvertently acquire family medical history if a manager or supervisor overhears a conversation among co-workers that includes family medical history, such as a conversation in which one employee tells another that her father has Alzheimer’s disease. Similarly, a casual question between colleagues, or between a supervisor and supervisee, concerning the health of a child, such as “How’s your son feeling today?” would not violate GINA. But comments to the final regulations raised concern with the breadth of this exception, and the final regulations consequently include some additional examples to limit the scope. For example, probing follow-up questions in response to an inadvertent acquisition of genetic information about an employee’s family member, such as asking whether other family members have the condition or whether the employee has been tested for it, do not fall within the “inadvertent” exception.³⁶

³⁵ Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 202(b) (2008), to be codified at 42 U.S.C. § 2000ff-1; EEOC Reg. § 1635.8(b)(1).

³⁶ EEOC Reg. § 1635.8(b)(1). See Preamble to Final Regulations, 75 Fed. Reg. 68911, 68919-20 (Nov. 9, 2010).

4. **Employers Must Maintain Confidentiality of Genetic Information, Subject to Limited Disclosures**

If an employer possesses genetic information about an employee, the employment nondiscrimination requirements of GINA require such information to be maintained “on separate forms and in separate medical files” and to be treated as a confidential medical record of the employee. Compliance with the confidential medical record requirements under ADA § 102(d)(3)(B) is considered to satisfy this employment nondiscrimination requirement under GINA.³⁷ The EEOC has noted that the application of GINA’s confidentiality provisions is not limited to paper records, so an employer in possession of electronic genetic information must similarly ensure that the information is kept confidential and disclosed only to the extent permitted under GINA.³⁸

As a general rule, such genetic information may not be disclosed. However, it may be disclosed under the following limited circumstances (and subject to additional conditions):

- to the employee (or family member if the family member is receiving the genetic services) at the written request of the employee or family member;
- to an occupational or other health researcher if research is conducted in compliance with 45 CFR Part 46 (regarding the protection of human research subjects);
- in response to a court order, except that (a) the employer may disclose only the genetic information expressly authorized by the order, and (b) if the order was secured without the employee’s knowledge, the employer must inform the employee of the court order and any genetic information that was disclosed under the order;
- to government officials who are investigating compliance with GINA;
- to the extent that disclosure is made in connection with the employee’s compliance with the certification provisions of FMLA § 103 or similar state family and medical leave laws; or
- to federal, state, or local public health agencies regarding the manifestation of a disease or disorder in family members of an individual concerning a contagious disease that presents an imminent hazard of death or life-threatening illness. The employee whose family member is the subject of disclosure must also be notified of the disclosure.³⁹

Disparate Impact Not a Cause of Action Under GINA’s Employment Nondiscrimination Requirements. Claims under Title VII of the Civil Rights Act may be based on a disparate impact theory—that is, on an allegation that the challenged practice has a disparate impact on the basis of race, color, religion, sex, or national origin, and the respondent fails to demonstrate that the challenged practice is job-related for the position in question and consistent with business necessity. (See Section XXI for details.) However, the employment nondiscrimination requirements of GINA provide that disparate impact on the basis of genetic information will not establish a cause of action under GINA.*

* Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 208(a) (2008), to be codified at 42 U.S.C. § 2000ff-7 (referring to the definition of disparate impact found in 42 U.S.C. § 2000e-2(k)); EEOC Reg. § 1635.5(b).

5. **Use of Medical Information That Is Not Genetic Information**

An employer may acquire, use, and disclose medical information that is not genetic information about a manifested disease, disorder, or pathological condition of an employee without violating GINA’s employment nondiscrimination requirements, even if that manifested disease, disorder, or pathological condition has or may have a genetic basis.⁴⁰

³⁷ Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 206(a) (2008), to be codified at 42 U.S.C. § 2000ff-5; EEOC Reg. § 1635.9. The final regulations clarify that an employer will not be liable for leaving genetic information in personnel files that was there prior to November 21, 2009 (GINA’s effective date), but such genetic information will be subject to the same use and disclosure restrictions as would apply if it were obtained since GINA became effective.

³⁸ EEOC Informal Discussion Letter (May 31, 2011), available at http://www.eeoc.gov/eeoc/foia/letters/2011/ada_gina_confidentrequire.html (as visited Sept. 12, 2011). Note that informal discussion letters do not constitute the official opinion of the EEOC.

³⁹ Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 206(b) (2008), to be codified at 42 U.S.C. § 2000ff-5; EEOC Reg. § 1635.9.

⁴⁰ Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 210 (2008), to be codified at 42 U.S.C. § 2000ff-9; EEOC Reg. § 1635.12.

Caution: Other Federal and State Laws May Still Apply. Employers should be careful in relying on the “use of medical information” provision of the employment nondiscrimination requirements. Although such use and disclosure may be permitted under GINA, the statute does not preempt other federal or state laws that might provide equal or greater protection to an individual, such as the ADA and the Rehabilitation Act. For example, although information that an employee currently has a disease, such as cancer, is not subject to GINA’s confidentiality provisions, such information would be protected under the ADA, and an employer would be liable under that law for disclosing the information, unless a specific ADA exception applied. The preamble to the final regulations indicates, for example, that although the ADA currently permits employers to obtain medical information, including genetic information, from post-offer job applicants, GINA prohibits acquisition of genetic information from post-offer applicants.* For more information about the ADA, see Section XX.

* Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 209(a)(1) (2008), to be codified at 42 U.S.C. § 2000ff-8; EEOC Reg. §§ 1635.11 and 1635.12. See also Preamble to Final Regulations, 75 Fed. Reg. 68911, 68929-68931 (Nov. 9, 2010).

E. Enforcement

1. Overview of Enforcement

The EEOC has responsibility to enforce GINA’s employment nondiscrimination requirements against private employers. These requirements may generally be enforced in the same manner as Title VII of the Civil Rights Act of 1964 with respect to those employers that are subject to Title VII. Employers that are subject to the employment nondiscrimination requirements of GINA on some other basis are subject to other enforcement provisions set forth in Title II. Certain exceptions apply.⁴¹ Remedies available for violations of GINA’s Title II provisions include certain compensatory and punitive damages, reasonable attorney’s fees, and injunctive relief.⁴²

Violations of the health insurance provisions of Title I are subject to enforcement under ERISA, the PHSA, and the Code.⁴³ The final regulations under GINA Title II attempt to create a firewall to eliminate double liability between the employment nondiscrimination requirements contained in Title II and the group health plan and health coverage provisions contained in Title I.⁴⁴ But the firewall does not mean that particular circumstances cannot result in violations of both Title I and Title II. See subsection D for further discussion of the firewall, and see Section XXI for more information about the enforcement provisions of Title VII of the Civil Rights Act of 1964 in general.

2. Posting Requirement

Employers are required to post a notice that explains the provisions of GINA’s employment nondiscrimination requirements, including information about how to file a complaint. The notice must be prepared or approved by the EEOC and must be posted in “conspicuous places” where notices to employees are customarily posted.⁴⁵ A revised copy of the “Equal Employment Opportunity is the Law” poster is available on the DOL’s website.⁴⁶

There are three ways for employers to comply with the requirement that they post updated information. They can (a) print the new “EEO is the Law” poster supplement and post it alongside the September 2002 or August 2008 version they currently have posted; (b) print and post the November 2009 poster; or (c) order a new poster from the EEOC. As a practical matter, we recommend using the November 2009 poster, which contains a full description of the current rules and would be less confusing for employees.

⁴¹ Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 207 (2008), to be codified at 42 U.S.C. § 2000ff-6.

⁴² EEOC Reg. § 1635.10.

⁴³ For detailed coverage of GINA’s Title I requirements, see *HIPAA Portability, Privacy & Security* (Thomson Reuters/EBIA, 1997-present, updated quarterly).

⁴⁴ EEOC Reg. § 1635.12.

⁴⁵ EEOC Reg. § 1635.10(c).

⁴⁶ DOL poster: “Equal Employment Opportunity is the Law,” available at <http://www.dol.gov/ofccp/regs/compliance/posters/pdf/eeopost.pdf> (as visited Sept. 12, 2011).

Copies of the poster and the poster supplement are currently available in English, Spanish, Chinese, and Arabic on the EEOC website.⁴⁷

2010 Form M-1. The DOL has announced the availability of the 2010 Form M-1 Report for Multiple Employer Welfare Arrangements (MEWAs) and Certain Entities Claiming Exceptions (ECEs), which includes several changes. The Form M-1 is an annual report that must be filed with the DOL by most MEWAs providing health benefits, whether or not the MEWA is a group health plan. In addition, many entities claiming not to be MEWAs due to the exception for collectively bargained plans (so-called ECEs) are also required to file Form M-1 for the first three years after they last “originated” (as last explained in the instructions to the form). The administrator of a MEWA or ECE that is required to file must complete Form M-1 using the previous calendar year’s information. The filing deadline for the 2010 Form M-1 is March 1, 2011, with an automatic extension until May 2, 2011, available upon timely request.

Form M-1 requires the administrator to provide information about a MEWA’s or ECE’s compliance with the group health plan mandates contained in Part 7 of ERISA, including (new to the 2010 Form M-1) GINA’s genetic information nondiscrimination requirements. The form’s instructions include a “self-compliance tool” that is not part of the form but may be helpful to the administrator in understanding and answering the compliance questions on the form. The 2010 Form M-1 may be filed electronically (an option encouraged by the DOL) or by mailing the paper form. The online filing system is available at <https://www.askebsa.dol.gov/mewa/default.aspx> (as visited Sept. 12, 2011). The website includes a user guide, FAQs, and a link to submit questions electronically. Form M-1 filings should be completed on a timely basis; substantial penalties apply for failure to comply with the reporting requirements.

For more information, see the 2010 Form M-1 and Instructions.*

* Form M-1 and Instructions, available at <http://www.dol.gov/ebsa/pdf/2010M1Package.pdf> (as visited Sept. 12, 2011).

F. Employer/Plan Administrator Roadmap

As discussed previously, employers that sponsor health plans should consider taking various actions as a result of GINA’s employment nondiscrimination requirements, including the following:

- Review group health plan design, provisions, and administrative procedures. In general, the employment nondiscrimination requirements may be satisfied if they prohibit use of genetic information in employment decisionmaking, restrict the acquisition of genetic information, require that genetic information be maintained as a confidential medical record, and place strict limits on the disclosure of genetic information.
- Become familiar with the final regulations regarding employment nondiscrimination requirements, which became effective January 10, 2011.
- Do not discriminate against employees on the basis of genetic information. For example, avoid making employment decisions involving group health plans based on genetic information, and ensure that eligibility to enroll in a plan and the benefits provided under a plan are not dependent on genetic testing or genetic information.
- Do not request, require, or purchase genetic information except under limited circumstances permitted by the statute and regulations.
- Maintain confidentiality of genetic information, subject to permissible disclosures. Such information should be maintained on forms and in medical files that are separate from personnel files and treated as a confidential medical record.
- Note that other laws need to be taken into account: GINA does not preempt other federal or state laws that might provide equal or greater protection to an individual.

⁴⁷ The DOL’s “EEOC Poster Request Form,” available at <http://www1.eeoc.gov/employers/poster.cfm> (as visited Sept. 12, 2011).

- Review plans' provisions and procedures (in consultation with advisors and insurers, including stop-loss carriers) to determine whether any changes are necessary or advisable. Also review plans and procedures for requirements that are not covered in this Section (such as GINA's health insurance provisions, which are covered in *HIPAA Portability, Privacy & Security* (Thomson Reuters/EBIA, 1997-present, updated quarterly)).
- Review wellness programs to ensure that they meet the requirements specified in the statute and regulations as applicable, including the provisions requiring that the program be voluntary as described by the EEOC.
- Post a notice explaining GINA's employment nondiscrimination requirements that meets the requirements described in the regulations (see subsection E).

Caution. This Section only addresses the application of GINA's employment nondiscrimination requirements to group health plans. Although we have summarized certain provisions, this Section does not attempt to provide the detailed guidance that employers will need to comply with many other aspects of GINA (such as the health insurance provisions and certain aspects of the employment nondiscrimination requirements).

**[Pages 861-920 Are Reserved.
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