

BENEFITS LAW JOURNAL

Evolving Genetic Science Spurs Legal Protections: A GINA Primer

Christine Watts Johnston and Mark D. Pomfret

Researchers and scientists continue to make amazing advances in modern medicine. Today's genetic tests can identify whether someone is at heightened risk of developing, or is a carrier of, many specific diseases and disorders, such as cystic fibrosis or spinal muscular dystrophy. Scientists anticipate that they will continue to design more effective drugs and prescribe tailored treatment for individuals based on a person's particular genetic makeup. Similarly, doctors and geneticists are now able to avoid adverse drug reactions through an enhanced knowledge of individual genetics. With this proliferation of newly available personal genetic information comes the risk that such genetic data will be used in ways that harm health plan participants and employees. In recognition of the far-reaching advancements in genetics, including decoding the human genome and the increased use of genomic medicine, and in an effort to help stem concerns about the resulting potential misuse of such genetic information, Congress enacted the Genetic Information Nondiscrimination Act of 2008 (GINA), which is divided into two separate Titles.¹

Title I of GINA applies to group health plans sponsored by private employers, unions, state and local government employers, health insurance issuers, and issuers of Medicare insurance. In short, Title I prohibits discrimination in group premiums based on genetic information and prohibits the use of genetic information for purposes

Christine Watts Johnston and Mark D. Pomfret are Partners at K&L Gates, based in its Boston office. They specialize in employment and labor law. The authors gratefully acknowledge the contributions of Patricia C. Shea of K&L Gates LLP to this article.

of determining eligibility or setting premiums in the individual and Medigap insurance markets. Title I also limits collection of genetic information and prohibits group health plans from using or disclosing genetic information for underwriting purposes. Finally, Title I requires a revision to the privacy regulations under the Health Insurance Portability and Accountability Act (HIPAA) to account for genetic information.² On October 7, 2009, the Departments of the Treasury, Labor, and Health and Human Services issued Interim Final Rules governing Title I.³ The requirements of Title I of GINA became effective for all group health plans and for health insurance issuers offering coverage in connection with such plans for plan years beginning one year after the effective date of the statute (*i.e.*, plans with plan years beginning after May 21, 2009).

Title II of GINA prohibits the use of genetic information in the employment context, prevents employers from requesting, requiring, or purchasing genetic information, and strictly limits any disclosure of genetic information. On November 9, 2010, the Equal Employment Opportunity Commission (EEOC) issued its final regulations implementing Title II of GINA. The final regulations became effective January 10, 2011. Title II of GINA applies to private employers and state and local government employers with 15 or more employees, as well as employment agencies, labor unions, and joint labor-management training programs.

GINA AND ITS REGULATIONS BROADLY DEFINE GENETIC PROTECTION-SPECIFIC TERMS

Because of the technical nature of some of the components of GINA, including certain of the applicable definitions, the EEOC obtained assistance from the National Human Genome Research Institute within the National Health Institute in order to properly define the governing terms. In addition, the EEOC attempted to clarify the meaning of some of the scientifically technical terms by including examples in the regulations.

For purposes of GINA, “genetic information” is defined as information concerning the following:

1. An individual or family member’s genetic tests;
2. A family medical history;
3. Request for or receipt of genetic services or participation in genetic research; or
4. Genetic information of a fetus of an individual or family member or genetic information of an embryo held by an

individual or family member using assisted reproductive technology.⁴

Genetic information does not include information concerning sex, age, race, or ethnicity that is not derived from a genetic test.⁵

The statute and regulations define a “genetic test” generally as “an analysis of human DNA, RNA, chromosomes, proteins or metabolites that detects genotypes, mutations, or chromosomal changes.”⁶ The regulations include a number of specific examples, including testing for breast cancer, screening for conditions such as cystic fibrosis or sickle cell anemia, amniocentesis, newborn screening for genotypes, mutations or chromosomal changes, pharmacogenetic tests that show how someone will react to a drug or drug dosage, DNA testing to detect genetic markers, or paternity testing.⁷ Certain tests, such as testing for a virus not composed of DNA, RNA, chromosomes, proteins or metabolites, tests for infectious diseases transmitted through food handling, and complete blood counts, cholesterol tests, and liver-function tests, however, are not genetic tests.⁸ According to the regulations, drug and alcohol testing is likewise not a genetic test if conducted to detect the presence of such substances. Conversely, a drug or alcohol test would constitute a genetic test if the test is designed to determine whether an individual has a genetic predisposition to drug use or alcoholism.⁹

The regulations distinguish between “genetic information” and a “manifested” condition. A disease, disorder, or pathological condition is considered “manifested” when an individual either has been or reasonably could be diagnosed with the disease or condition by a health professional.¹⁰ This distinction is important in various contexts under GINA. In fact, a plan or issuer is permitted to increase premiums or contribution based on the existence of a manifested disease, but is prohibited from doing so strictly on the basis of genetic information. In addition, a finding of a manifested condition cannot be used to impact other group members or similarly situated individuals under a plan.¹¹ However, for purposes of defining “genetic information” above, information about a manifested disease in an individual’s family members would be protected information, but does not include analysis of metabolites or proteins directly related to a manifested disease that is or reasonably could be diagnosed.

PROHIBITION ON PLAN COLLECTION OF GENETIC INFORMATION

As a general rule, Title I of GINA provides that group health plans cannot collect genetic information for “underwriting purposes.” For purposes of the law, underwriting purposes include the following:

- Rules for determining both initial and continued eligibility;
- Calculation of premiums or contributions, including discounts and other premium differentials; or
- Application of a pre-existing condition exclusion.¹²

The definition of underwriting also includes a “catch-all” for “other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.”¹³ A determination of whether a benefit is medically appropriate is not considered underwriting. Thus, if a determination as to the propriety of a benefit requires a determination on the basis of genetic information, the plan may permissibly condition the benefit on that genetic information, so long as the plan requests only the minimum genetic information necessary to make that determination. Moreover, the plan may deny a benefit contingent on genetic information if it is not provided the requisite information and cannot make the appropriate determination as to whether a benefit is medically appropriate.¹⁴

Group health plans are likewise prohibited from collecting genetic information prior to or in connection with enrollment. However, the regulations include an exception for “incidental” collection where the collection occurs in connection with the collection of other information, as long as such a collection is not for underwriting purposes.¹⁵ A collection would not be deemed “incidental” if it would be reasonable to anticipate that genetic information will be received as part of a collection, unless the request explicitly states that genetic information should not be included. The regulations offer eight different examples of collections that would or would not violate the group health plan collection prohibitions, based on varying facts and circumstances. Similarly, the regulations provide six examples illustrating how the rules relating to requests for genetic information for purposes of determining the medical appropriateness of benefits are applied.¹⁶

GROUP HEALTH PLANS CANNOT REQUEST OR REQUIRE GENETIC TESTS

GINA also mandates that group health plans and health insurance issuers refrain from requesting or requiring an individual or family member of an individual to undergo a genetic test. The rules do not affect the authority or ability of a health care professional to request genetic testing. Under the applicable regulations, health plans or insurance issuers may request that an individual undergo a genetic test for the purpose of research if the test complies with applicable laws and regulations governing human testing. The request must be made in writing and clearly provide that compliance is voluntary and

noncompliance will not affect eligibility, premium, or contribution amounts.¹⁷

PROHIBITION ON EMPLOYER ACTIVITIES: DISCRIMINATION, RETALIATION, AND ACQUISITION OF INFORMATION

At its core, Title II of GINA prohibits employers, employment agencies and labor organizations from discriminating on the basis of genetic information against individuals with regard to employment decisions affecting the terms and conditions of employment. The law further prohibits employers from limiting, segregating, or classifying individuals to deprive them of employment opportunities or affect their employment status on the basis of genetic information, unless otherwise required by law, such as safety and health restrictions under the Occupational Health and Safety Act. GINA also provides protection to individuals against retaliation on the basis of opposition to an illegal practice or participation in any proceeding related to GINA.¹⁸

The most restrictive provisions of GINA relate to an employer's (or other covered entity's) acquisition of genetic information. The statute generally provides that employers may not "request, require, or purchase genetic information" relating to an employee or family member, subject to limited exceptions.¹⁹ The regulations make clear that the term "request" includes conducting an Internet search that would result in the acquisition of genetic information or "actively listening" to conversations or searching personal effects for the purpose of obtaining genetic information.²⁰ Despite this broad prohibition, there are significant exceptions.

EXCEPTIONS TO PROHIBITION ON ACQUISITION

Inadvertence

In order to fall within the "inadvertence" exception, an employer must direct (in writing, unless requests for medical information are typically made verbally) the health care provider to whom it made the lawful request for medical information not to provide genetic information. Indeed the regulations provide "safe harbor" language that, if used, will ensure that receipt of genetic information is deemed inadvertent.²¹ That language is as follows:

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.²²

While failure to include the “safe harbor” language would not automatically render the receipt of genetic information intentional, an employer would have the burden to show that the request was not likely to result in the receipt of such information. In other words, the employer would be required to prove that the provider’s response was overbroad.

The final GINA regulations also exclude inadvertent acquisition based on an overheard conversation or a response to an ordinary expression of concern about someone’s well-being.²³ Similarly, if an employer learns of protected genetic information from an individual or a third party as a result of an unsolicited communication, or through a social media platform, such an acquisition will not be deemed to violate the law.²⁴

ADA and FMLA Compliance Issues

Employers may lawfully request medical information in connection with employee requests for accommodations under the Americans with Disabilities Act (ADA) and with requests for medical leave for an employee’s own serious health condition under the Family and Medical Leave Act (FMLA), provided the employer complies with the requirements of the ADA and FMLA respectively concerning permissible medical inquiries. For example, under the ADA, employers may only ask for documentation concerning the need for an accommodation when the need is not obvious and must not request information beyond that necessary to substantiate the need for the requested accommodation. Employers who do utilize permissible medical examinations related to employment must ensure that “reasonable measures within its control” are taken to ensure that genetic information is not compromised.²⁵ The reasonableness of measures will vary based on facts.

Wellness Programs

Employers also may legally obtain genetic information in conjunction with a wellness program. In order to remain compliant, employer wellness programs cannot require the provision of genetic information of participants and cannot penalize employees who do

not provide it.²⁶ Likewise, an employer cannot lawfully offer financial incentives for employees to provide genetic information as part of a health risk assessment. In order to fall within the wellness program exclusion, an employer must provide a clear, written authorization describing the type of information that will be obtained, the purposes for which it will be obtained, and a description of the restrictions on the use of the information.²⁷ In particular, individually identifiable genetic information may only be provided to the genetic counselors or professionals administering the tests. It cannot be shared with managers or other employees. In addition, such information may only be disclosed to the employer in aggregate terms, not as it relates to a specific individual.²⁸

Employers may offer financial incentives for those employees who have provided genetic information indicating a risk of a health condition as an inducement to participate in health promoting programs, so long as the programs are offered to those employees who currently have health issues or are at higher risk due to lifestyle choices. If an employer provides such incentives, however, it remains bound to do so in accordance with the applicable provisions of the ADA, HIPAA, and other laws. For example, an employer may be required to provide a reasonable accommodation to allow a disabled employee to enjoy the benefits of employment, including the benefit of a wellness program incentive, under appropriate circumstances. Likewise, should a wellness program constitute a group health plan under HIPAA (as amended by GINA), it would be subject to HIPAA requirements.

Publicly Available Information

Employers and other covered entities are permitted to obtain genetic information from commercially and publicly available sources, such as newspapers, magazines, books, television, or the Internet. However, such sources must not be restricted, and the entity cannot have sought access to such public sources “with the intent of obtaining genetic information.”²⁹ An entity’s ability to permissibly obtain publicly available information is limited by the fact that it cannot access sources that focus on issues such as genetic testing and genetic discrimination where it would be “likely” to acquire protected information.³⁰

Monitoring Effects of Toxic Substances and Law Enforcement

An employer may also obtain genetic information for use in the genetic monitoring of the biological effects of toxic substances in the workplace.³¹ However, the employer must either be required to conduct such testing, or obtain knowing, voluntary, and written authorization that is easily understandable and describes the information that will be obtained and the restrictions on its use. Such a monitoring

program must provide for the reporting of results in aggregate terms. Similarly, an employer who regularly handles genetic information, including for forensic purposes, may acquire genetic information for quality control type purposes.³²

CONFIDENTIALITY

A covered entity that does lawfully possess protected genetic information must keep it confidential and use or disclose it only as permitted by law. For example, employer-sponsored health plans that maintain genetic information will need to safeguard genetic information in accordance with the protections generally afforded by HIPAA's Privacy Rule with respect to protected health information. These health plans will also need to add a new statement to their HIPAA Notices of Privacy Practices explaining that they may not use the genetic information for underwriting purposes so that individuals who are the subject of the information are aware of this additional restriction.

Given the heightened confidential status of genetic information and similar to other medical information, genetic information must not be included in an employee personnel file. Even if genetic information is obtained through publicly available information as described above, employers must not discriminate, and accordingly should maintain the confidentiality of such information in the same manner as any non-public genetic information. Likewise, while the law does not require that employers remove genetic information that predated the statute from personnel files, in light of the protections against discrimination and retaliation, employers are well advised to consider removing any genetic information from personnel files. Disclosures of genetic information are permitted:

1. Upon written request of the individual about whom the information pertains;
2. To an occupational or health researcher in compliance with applicable regulations;
3. In response to a court order;
4. To government officials in conjunction with a GINA compliance investigation;
5. In conjunction with an FMLA certification; and
6. To a public health agency where an imminent risk exists, provided that the individual at issue is notified.³³

Additional safeguards also apply to ensure that health plans that maintain genetic information use it only as permitted by HIPAA's Privacy Rule.

GINA VIOLATIONS

GINA provides for penalties of \$100 per day per beneficiary for plans that are noncompliant with Title I of GINA, and imposes minimum penalties of \$2,500, or \$15,000 for more severe or prolonged violations, or in cases of willful neglect. A limit to the total penalty for unintentional failures is set at \$500,000 or 10 percent of the aggregate amount paid or incurred by the plan sponsor during the preceding year for group health plans.

An employer violating Title II of GINA may be liable for compensatory and punitive damages, reasonable attorney fees, including expert fees and injunctive relief.

PRACTICAL APPLICATIONS

Consistent with the scope and speed with which genetic technology is expanding, the full extent of GINA's applicability and impact is somewhat unclear. However, there are certain fundamental steps employers and insurers can take immediately, if they have not yet done so, to protect their interests. Employers should be certain that the "safe harbor" language is included in any forms that request medical information. Health plans and insurance issuers that are not already compliant with GINA must modify their protocols by, among other things, recognizing the limited occasions on which genetic information may be collected. Likewise, affected businesses should confirm that policies addressing underwriting, claims payment, enrollment, and premium and collections adjustment address prohibitions regarding the use and disclosure of genetic information. Employers should evaluate their employment policies and documents, as well as update waiver and release agreements, to include "genetic information" as a protected category and/or GINA as a relevant law. Finally, businesses and employers might consider reviewing their insurance policies and seeking modification to include coverage for claims based on any GINA violations.

NOTES

1. Pub. L. No. 110-233 (GINA) was enacted on May 21, 2008.
2. Title I of GINA is far reaching. GINA amended the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Services Act (PHS Act), the Internal Revenue Code of 1986 (the Code) and the Social Security Act (SSA) and builds on existing provisions of HIPAA to include the relevant prohibitions against discrimination on the basis of genetic information.

3. The applicable regulations include Department of the Treasury Internal Revenue Service, 26 C.F.R. Part 54, Department of Labor Employee Benefits Security Administration, 29 C.F.R. Part 2590, and the Department of Health and Human Services, Centers for Medicare and Medicaid Services, 45 C.F.R. Parts 144, 146, and 148, 45 C.F.R. Parts 160 and 164.
4. The statute broadly defines “family member” to include any dependent or any first through fourth degree relative of an individual or their dependent. *See* § 54.9802-3T(2). A definition of “dependent” is not included in the statute or regulations, but rather must be determined on the basis of applicable insurance plan documents. *See* 26 C.F.R. § 54.9801-2 (“Dependent means any individual who is or may become eligible for coverage under the terms of a group health plan because of a relationship to a participant.”).
5. GINA § 201(4); 29 C.F.R. § 1635.3(c). The EEOC regulations include both general definitions (§ 1635.2) and definitions specific to GINA (§ 1635.3).
6. 29 C.F.R. § 1635.3(f).
7. *Id.*
8. 29 C.F.R. § 1635(f)(3)(i)-(iv).
9. 29 C.F.R. § 1635(f)(4).
10. 26 C.F.R. § 54.9802-3T(a)(6)(i).
11. 26 C.F.R. § 54.9802-3T(b)(2).
12. 26 C.F.R. § 54.9802-3T(d)(2)(A)-(C).
13. 26 C.F.R. § 54.9802-3T(d)(1)(ii)(D).
14. 26 C.F.R. § 54.9802-3T(d)(1)(iii).
15. 26 C.F.R. § 54.9802-3T(d)(2)(ii).
16. 26 C.F.R. § 54.9802-3T(d)(3).
17. 29 C.F.R. § 2590.702-1(c)(5).
18. 26 C.F.R. § 1635.7.
19. 26 C.F.R. § 1635.8(a).
20. 29 C.F.R. § 1635.8(a).
21. 29 C.F.R. § 1635.8(b)(1)(i)(A).
22. 29 C.F.R. § 1635.8(b)(1)(i)(B).
23. 29 C.F.R. § 1635.8(b)(ii)(A)-(B).
24. 29 C.F.R. § 1635.8(b)(ii)(C)-(D).
25. 29 C.F.R. § 1635.8(d).
26. 29 C.F.R. § 1635.8(b)(2)(i)(A).
27. 29 C.F.R. § 1635.8(b)(2)(i)(B).
28. 29 C.F.R. § 1635.8(b)(2)(i)(D).
29. 29 C.F.R. § 1635.8(b)(4).
30. 29 C.F.R. § 1635.8(b)(4)(iv).

31. 29 C.F.R. § 1635.8(b)(5).
32. 29 C.F.R. § 1635.8(b)(6).
33. 29 C.F.R. § 1635.9(b)(1)-(6).

Copyright © CCH incorporated. All Rights Reserved.
Reprinted from *Benefits Law Journal* Summer 2011, Volume 24,
Number 2, pages 59-68, with permission from Aspen Publishers,
Wolters Kluwer Law & Business, New York, NY, 1-800-638-8437,
www.aspenpublishers.com

