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What Employers Need To Know About the Genetic Information Nondiscrimination Act of 2008

By Denise L. Atwood, Esq. and Elizabeth J. McNamee, Esq.

After thirteen years of debate in Congress, on May 21, 2008, President George W. Bush signed into law the Genetic Information Nondiscrimination Act of 2008 ("GINA"). This new law prohibits genetic discrimination in two general areas – employment and health insurance. GINA amends several statutes, including Title VII of the Civil Rights Act, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the Employee Retirement Income Security Act of 1974 ("ERISA"), the Public Health Service Act ("PHSA"), the Internal Revenue Code of 1986, and Title XVIII ("Medicare") of the Social Security Act.

GINA does not apply to members of the United States Military, to veterans obtaining health care through the Veteran's Administration, or to the Indian Health Service, because the laws amended by GINA do not apply to these groups and programs. Nor does GINA include protection from genetic discrimination in life insurance, disability insurance, or long-term-care insurance.

This summary is intended to highlight some of GINA's key provisions for employers and group health plan sponsors.

Background and Overview of GINA

Surveys and polls cited in GINA's legislative history indicate that the fear of genetic discrimination appears to be the primary reason that individuals forgo having genetic tests performed. Although Congress found little evidence of actual widespread genetic discrimination, the few cases that did exist were egregious. By

prohibiting genetic discrimination with respect to employment and health insurance, Congress sought to encourage individuals to participate in genetic research and to take advantage of genetic testing and therapies with respect to their own health.

Title I of GINA prohibits group health plans and health insurance issuers from discriminating on the basis of genetic information with respect to eligibility, premiums, and contributions. Title II of GINA prohibits employers from discriminating on the basis of genetic information in employment decisions.

Both Titles I and II generally share the same definitions of "genetic information," "genetic test," and "family members."

Genetic Information
Genetic information includes:

(1) Information about an individual's genetic tests;

(2) Information about the genetic tests of the family members of an individual; and

(3) The manifestation of a disease or disorder in the family members of an individual.

Congress included an individual's family medical history within the definition of "genetic information" because it recognized that, just as a genetic trait may be viewed to indicate that an individual has an increased risk for a particular disease, so could the history of a particular disease within an individual's family.

Genetic information concerning an individual or family member includes the genetic information of the fetus of a pregnant woman and an embryo legally held by an individual or family member using assisted reproductive technology. Genetic information does not include information about the sex or age of an individual.

Genetic information includes not only genetic test results, but also any request for, or receipt of, genetic services or participation in clinical research, which includes genetic services by an individual or family member.

Genetic Test
A "genetic test" is generally defined as the analysis of an individual's DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes. It does not include an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes.

For purposes of Title I, a "genetic test" also does not include an analysis of proteins or metabolites that is directly related to a manifested disease. In other words, the definition of a genetic test, for health insurance purposes, is intended to include information about an individual's genetic predisposition to a disease, but not information about an existing disease. In making the distinction, Congress indicated that there were important and necessary uses of information about an existing disease in the health insurance setting that did not apply in the employment context. Congress also recognized that existing state and federal law already regulated the use of health information related to a manifested disease in insurance rating and eligibility practices.

Family Members
"Family members" are broadly defined in GINA to include both: (1) dependents of an individual who are, or may become, eligible under the terms of a group health plan; and (2) anyone who is a relative of the individual or the dependent of the individual (up to the fourth degree). Congress chose to include more than just blood relatives of an individual because of potential discrimination that an individual could face due to: (1) the impact of possible medical costs of such non-blood relatives if they are covered under the health plan or policy; or (2)

lost productivity if the employee needed to take time off to care for such relative.

Title I – Application of GINA to Group Health Plans and Health Insurance

Title I of GINA applies to employer-sponsored group health plans [including plans with less than two participants and retiree-only plans that are otherwise exempt from existing nondiscrimination provisions under HIPAA, health insurance issuers in both the group and individual markets, Medigap insurance, and state and local non-federal governmental group health plans. This summary focuses on the application of GINA to employer-sponsored group health plans, and does not address changes in the individual insurance market or with respect to Medigap insurance.

New Nondiscrimination Rules

HIPAA's existing nondiscrimination rules provide some protection against discrimination based on an individual's genetic information. HIPAA prohibits a group health plan or health insurance carrier from charging one individual within a group higher rates than other similarly situated individuals in the same group based on a health status-related factor. HIPAA already includes genetic information as part of its definition of a "health status related factor."

While HIPAA protects individuals in a group from being charged premiums or contributions that are higher than the premiums or contributions for similarly situated individuals based on genetic information, there was no such protection for the group as a whole. GINA amends ERISA, the Internal Revenue Code, and PHSA to prohibit group health plans and health insurance issuers offering group health insurance from adjusting premiums or contributions for the group based on the genetic information of an individual in the group.

GINA does not prohibit a health insurance issuer from increasing a group's rates based on the manifestation of a disease or disorder of a participant in the group's plan. However, the manifestation of the disease or disorder in the participant cannot also be used as genetic information of other family members to further increase the group premium.

Limitation on Genetic Testing

GINA also prohibits group health plans and health insurance issuers from requesting or requiring an individual to take a genetic test. However, Congress did not want to interfere with certain existing health care practices, so it included the following clarifications.

First, the prohibition should not be construed to limit the ability of a health care provider from requesting (but not requiring) that his or her patient undergo a genetic test.

Second, the prohibition should not be construed to limit the ability of group health plans and health insurance issuers from obtaining and using the results of a genetic test to determine whether or not to pay a claim, provided that only the minimum amount of information necessary to adjudicate the claim is requested, consistent with the Department of Health and Human Services Standards For Privacy of Individually Identifiable Health Information (the "Privacy Rules"). The legislative history provides the following example:

> A health plan may cover colonoscopies every 10 years for participants over age 50, but will also cover annual colonoscopies for participants who have a mutation in one of several genes associated with an elevated risk for colon cancer. If a participant seeks coverage for annual colonoscopies on grounds that he or she has such genetic mutation, the plan can require that the participant provide evidence of the genetic mutation.

GINA also includes an exception that allows group health plans and health insurance issuers to request (but not require) genetic testing for research if certain requirements are met.

Prohibition on Collection of Genetic Information for Underwriting Purposes

GINA generally prohibits group health plans and health insurance issuers from requesting, requiring, or purchasing genetic information: (1) for underwriting purposes; or (2) with respect to any individual prior to such individual's enrollment as part of the application or other pre-enrollment process or interaction. However, a group health plan or health insurance issuer will not violate this provision if it obtains genetic information that is incidental to the collection of other information concerning an individual prior to enrollment if the information is not used for underwriting purposes.

HIPAA Privacy

HIPAA's Privacy Rules currently permit the use of protected health information (which includes genetic information) for underwriting purposes. Congress found this practice inherently discriminatory and inconsistent with the purpose of GINA. Therefore, GINA directs the Secretary of Health and Human Services to revise the Privacy Rules to prohibit the use or disclosure of genetic information for underwriting purposes by group health plans and health insurance issuers.

Enforcement

With respect to the nondiscrimination provisions, the Secretary of the Department of Labor may impose a penalty against a plan sponsor of a group health plan, or any health insurance issuer offering health insurance coverage in connection with the plan, for any violation of the genetic nondiscrimination rules of $100 per day for each individual to whom the failure relates for as long as the failure exists. If the failure is not corrected before the date on which the plan receives a notice of the violation from the Secretary, the minimum penalty that will be imposed is $2,500 (or $15,000 if the violations are more than de minimis). However, the penalty will not apply if:

(1) The person liable for the penalty did not know, and in exercising reasonable diligence would not have known, that such failure existed; or

(2) If the failure was due to reasonable cause and not willful neglect and the failure is corrected within 30 days of the first date the person liable for such penalty knew, or in exercising reasonable diligence would have known, that such failure existed.

The maximum penalty for failures which are due to reasonable cause and not willful neglect will not exceed the lesser of: (1) 10% of the amount paid or incurred by the plan sponsor during the preceding taxable year for all of its group health plans; or (2) $500,000. The Secretary of Labor may waive all or any part of the penalty as long as the failure is due to reasonable cause and not willful neglect to the extent that the payment of the penalty would be excessive relative to the failure.

Identical enforcement authority was provided to the Secretary of Health and Human Services (who has authority to impose penalties for violations of GINA against insurers) and the Secretary of the Treasury Department (who has authority to impose excise tax penalties against group health plans).

With respect to the genetic privacy provisions, the same enforcement structure and penalties created under HIPAA's Privacy Rules apply. The Department of Health and Human Services Office of Civil Rights enforces the Privacy Rules and may impose civil monetary penalties of $100 per violation up to a maximum of $25,000 per calendar year for violations of an identical

requirement. The U.S. Department of Justice enforces HIPAA's criminal penalties and may impose fines up to $250,000 and/or 10 years in prison for knowing violations.

Effective Date
The genetic nondiscrimination rules apply to group health plans for plan years beginning after May 21, 2009. For calendar year plans, this means that plan sponsors must comply by January 1, 2010. The Departments of Labor, Health and Human Services, and Treasury were directed to issue final regulations no later than May 21, 2009.

The changes to the Privacy Rules are effective one year after the date of GINA's enactment (i.e., May 21, 2009). The Department of Health and Human Services was directed to issue a notice of revisions to the Privacy Rules within 60 days of GINA's enactment and to issue final regulations no later than May 21, 2009.

Title II – Application of GINA to Employment Practices

Title II of GINA applies to employers, labor organizations, and joint labor-management committees and generally prohibits employment discrimination based on the genetic information of an employee or the employee's family members. This summary focuses on the obligations imposed upon employers.

Genetic Discrimination Prohibited
GINA expands Title VII of the Civil Rights Act of 1964 by imposing pervasive restrictions on an employer's collection, use, and disclosure of genetic information. GINA applies to all employers who are subject to Title VII[1], as well as to employment agencies and labor organizations as defined in Title VII.

Generally, under GINA, employers cannot discriminate in the terms and conditions of employment based on an individual's genetic information; employers are prohibited from retaliating against an employee or employees who oppose genetic discrimination; and employers are prohibited from collecting genetic information about an employee (or an employee's family member), whether by request, mandate or purchase, from a third party.

Thus, GINA makes it unlawful for an employer to fail or refuse to hire an individual, or to discharge an employee, or otherwise discriminate against an employee with respect to compensation, terms, conditions, or privileges of employment because of the employee's genetic information. For example, under GINA it is unlawful for an employer to refuse to hire an individual based on a fear that the individual may develop a disease such as Parkinson's because of a family history of such disease.

Under GINA, it is also unlawful for an employer to limit, segregate, or classify its employees in any way that could deprive an employee of employment opportunities because of his/her genetic information.

Limitation on an Employers Acquisition of Genetic Information
GINA's restrictions on an employer's ability to collect an employee's genetic information (including the information of his/her family member) are the area where employers may face hurdles in understanding permissible versus impermissible inquiries. There are six limited exceptions where an employer will not be deemed to violate this acquisition prohibition:

(1) Where an employer inadvertently requests or requires family medical history of the employee or of the family member of the employee. Congress included this exception to address the so-called "water cooler problem," in which an employer may unintentionally receive genetic information

1 Those employing 15 or more employees.

through casual conversations with an employee.

(2) Where an employer provides health or genetic services through a wellness program offered as an employee benefit, provided certain conditions are met. To qualify for this exception, the employee must provide prior, knowing, voluntary, and written authorization; only the employee (or the employee's family member if the family member is receiving genetic services) and the licensed health care professional, or board certified genetic counselor providing the services, may receive the individually identifiable genetic information; and the results of the genetic services may only be disclosed to the employer in the aggregate and individually identifiable information may not be included. Employers that have implemented wellness programs need to reassess their programs to ensure that they comply with these conditions – namely, limiting their involvement to configuration of the wellness program.

(3) Where an employer requests or requires family medical history from an employee about him/her or with respect to a family member, including manifested diseases or disorders, to comply with the certification provision of the Family Medical Leave Act of 1993 ("FMLA") or state equivalent; such as when an employee seeks time off to care for a sick family member.

(4) Where an employer purchases commercially and publicly available documents, such as periodicals or news publications that include family medical histories (except medical databases or court records). The legislative history indicates that this exception was designed, similar to the first exception noted above, to address an employer's inadvertent acquisition of family medical history, such as when an employer purchases a local newspaper that contains the obituary of an employee's parent.

(5) In narrowly defined circumstances, where the genetic information is to be used by the employer for genetic monitoring of the biological effects of toxic substances in the workplace, provided certain conditions are met. The employer must give written notice of the monitoring to the employee. Unless the genetic monitoring is required by federal or state law, the employee must provide prior, knowing, voluntary, and written authorization. The employer must provide the employee with the results of the monitoring. The monitoring must be conducted in compliance with any federal or state genetic monitoring regulations. Finally, the monitoring results may only be disclosed to the employer in the aggregate and individually identifiable information may not be included.

(6) Where the employer conducts DNA analysis for law enforcement purposes as a forensic laboratory or for purposes of identifying human remains, and requests or requires genetic information from its employees for analysis of DNA identification markers for quality control to detect sample contamination.

However, employers should be advised that regardless of whether an exception applies, GINA makes clear that genetic information, once acquired, may not be used to discriminate against an individual with respect to employment or benefits, nor may genetic information be disclosed in violation of GINA's confidentiality requirements.

Confidentiality Protections

Under GINA, employers must safeguard the confidentiality of any genetic information it acquires similarly to the manner in which it safeguards other medical information under

the American with Disabilities Act ("ADA"). Accordingly, an employer must maintain genetic information on separate forms and in separate medical files, and above all, the data must be treated as a confidential medical record. Likewise, employers must restrict internal access to only those *who need to know*.

Despite its prohibition on the disclosure of confidential genetic information to third parties, GINA does set forth a few narrowly defined instances where employers may release this confidential data without running afoul of its provisions. Under GINA, genetic information may be disclosed in the following limited circumstances:

(1) Directly to the individual who received genetic services at the individual's written request;

(2) To an occupational or health researcher for certain limited research and under certain enumerated conditions;

(3) Pursuant to a court Order, provided the employer only discloses the genetic information expressly authorized by the Order and informs the individual of the court Order and the genetic information disclosed pursuant to the Order;

(4) To government officials investigating compliance with Title II of GINA;

(5) To the extent the disclosure is made in connection with the employee's compliance with the certification provisions of FMLA or other state equivalent statute; and

(6) To federal, state, or local public health agencies concerning a contagious disease that presents an imminent hazard of death or life-threatening illness, if the genetic information is limited to the manifestation of a disease or disorder in family members of an employee, and the employee is notified of the disclosure.

Enforcement

An individual's rights and remedies under GINA track those available under Title VII. Accordingly, employees must exhaust administrative remedies before they may initiate a lawsuit in a court of law. Under GINA, a damages award is subject to the same restrictions applicable to Title VII. One distinction of GINA to Title VII, however, is the fact that, at this time, GINA does not establish a cause of action based on disparate impact. However, GINA's enactment comes with a mandate that a commission be established through the EEOC no later than six years post enactment to investigate the science and law of genetics, and to in turn recommend to Congress whether disparate impact claims should be allowed under GINA.

It is important to note that GINA does not pre-empt other federal or state laws that provide equal or greater protections to individuals with respect to their genetic information, including the ADA.

GINA also includes a rule of construction that is designed to address the overlap of causes of action concerning genetic discrimination in the context of group health plans. Violations of the genetic discrimination rules in Title I could also be construed as genetic discrimination with respect to an employee's terms and conditions of employment under Title II. To prevent employees from bringing claims for more substantial damages under Title II, GINA appears to prevent an employee from bringing a cause of action against an employer for genetic discrimination with respect to a group health plan under Title II to the extent a cause of action can be brought under Title I. The language in the statute itself is unclear and will likely be subject to future litigation.

Also worthy of noting for employers, and while not specifically related to its prohibition on discrimination, GINA also amended the Fair Labor Standards Act of 1938 ("FLSA"). GINA's amendments to the FLSA increased the penalty for violations of its anti-oppressive child labor and safety provisions. Employers may now face a civil penalty from the US Department of Labor of up to $50,000 where the violation causes the death or serious injury of a minor (under the age of 18); that penalty may be doubled where the violation is found to be willful or is a repeat violation. GINA raises the maximum penalty for other child labor violations from $10,000 per worker to $11,000 per worker, and increases the maximum civil penalty for willful violation of the FLSA overtime and minimum wage provisions from $1,000 to $1,100 per violation. GINA's amendments specific to the FLSA are effective May 21, 2008.

Effective Date

GINA's prohibition against genetic discrimination in employment is effective November 21, 2009. The Equal Employment Opportunity Commission was directed to issue final regulations no later than May 21, 2009.

If you have any questions regarding these new requirements, please call Elizabeth McNamee at 303.634.2092 or Denise Atwood at 602.382.6297.

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