

"In broad terms, the provisions of GINA are aimed at preventing health insurance and workplace discrimination based upon an individual's genetic information."

The Genetic Information Nondiscrimination Act of 2008

by

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INTRODUCTION

On May 21st, President Bush signed into law the "Genetic Information Nondiscrimination Act of 2008" (also known as "GINA"). In broad terms, the provisions of GINA are aimed at preventing health insurance and workplace discrimination based upon an individual's genetic information. Although Federal regulations have previously provided some limited protections in the genetics area – in the context of HIPAA's nondiscrimination rules and HIPAA's restrictions on pre-existing condition exclusions – GINA represents the Federal government's first full-scale entry into the arena of attempting to prevent discrimination based on genetic information.

What is the "genetic information" to which the provisions of GINA apply? According to GINA, genetic information means, with respect to any particular individual, information about (i) the individual's genetic tests, (ii) the genetic tests of the individual's family members, and (iii) the manifestation of a disease or disorder in the individual's family members. Genetic information includes a request for (or receipt of) genetic services by an individual, and also includes participation by an individual in clinical research which includes genetic services. For this purpose, the term "genetic services" includes a genetic test, genetic counseling (including obtaining, interpreting or assessing genetic information) or genetic education.

Genetic information does not include any information about the sex or age of an individual. For any individual, however, it does include (i) any genetic information of any fetus carried by the individual, and (ii) any genetic information of any embryo legally held by the individual.

DISCUSSION

GINA sets forth two basic types of nondiscrimination rules relating to an individual's genetic information. First, GINA sets forth rules relating to genetic nondiscrimination in health insurance (and, in so doing, GINA amends the provisions of ERISA, the Public Health Service Act, and the Tax Code). Second, GINA also sets forth rules relating to genetic nondiscrimination in an employer's employment practices. Below, we'll summarize some of the important provisions of both aspects of this new law.

I. Genetic Nondiscrimination in Health Insurance.

Title I of GINA applies to group health plans and health insurance issuers offering group health insurance coverage in connection with a group health plan. For this purpose, the terms "group health plan" and "health insurance issuer" generally

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have the same meaning as they do in the context of HIPAA's portability rules, except that (i) there is no exception from the provisions of GINA for small group health plans that cover fewer than two participants who are current employees, and (ii) self-funded nonfederal governmental plans cannot elect out of GINA's provisions.

1. GINA's Prohibitions.

- Prohibition Against Premium or Contribution Discrimination. Under the provisions of GINA, group health plans and health insurance issuers may not adjust the premiums or contribution amounts required for the group covered under a group health plan on the basis of genetic information. This new rule is similar to the rule contained in the HIPAA nondiscrimination rules that prevents a group health plan or health insurance issuer from charging a particular individual a higher premium based on genetic information. But, this new rule applies to the entire group covered under the group health plan (instead of simply on a participant-by-participant basis).

Note that this new rule does not prevent a health insurance issuer from increasing the premiums it charges to an employer based on the manifestation of a particular disease or disorder in an individual enrolled in the employer's group health plan. In such a case, though, the manifestation of that disease or disorder cannot be used by the health insurance issuer as genetic information about other group members (for example, family members of the individual in whom the disease or disorder manifested itself) in order to further increase the employer's premiums.

- Prohibition on Genetic Testing. GINA also sets forth a broad general rule under which group health plans and health insurance issuers cannot request or require an individual (or his or her family members) to undergo a genetic test. Note, though, that the provisions of GINA indicate that this general rule does not limit the authority of a health care professional who is providing health care services to an individual to request that the individual undergo a genetic test. Also, notwithstanding this general rule, the provisions of GINA specifically allow group health plans and health insurance issuers to use the results of a genetic test in making payment determinations (presumably in situations where, for example, the results may help determine whether a particular expense is a covered expense under the particular group health plan). In so doing, however, the group health plans and health insurance issuers may only request the minimum amount of information necessary in order to make the payment determination. Finally, the provisions of GINA also specifically allow group health plans and health insurance issuers to request (but not require) that an individual undergo a genetic test in connection with research activities, if certain prescribed requirements are met.
- Prohibition on Collecting Genetic Information. The provisions of GINA also state that group health plans and health insurance issuers cannot (i) request, require or purchase any genetic information for certain underwriting purposes, or (ii) request, require or purchase any genetic information with respect to any individual prior to such individual's enrollment under the plan or coverage in connection with such enrollment. There is an exception to this rule for genetic information that is obtained incidental to other information that is requested, required or purchased about an individual.

"The provisions of Title I of GINA apply with respect to group health plans for plan years beginning after May 21, 2009."

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2. Other Important Rules.

- Individual Market Rules. The provisions of GINA also contain genetic nondiscrimination rules that apply to health insurance issuers offering insurance coverage in the individual market. The prohibitions that apply to health insurance issuers in the individual market are similar to those outlined above. In addition, though, GINA also sets forth additional prohibitions in the individual market context relating to genetic nondiscrimination in terms of eligibility for enrollment and the imposition of pre-existing condition exclusions. These latter prohibitions are already covered in the group context through HIPAA's nondiscrimination rules and HIPAA's restrictions on pre-existing condition exclusions, and were presumably included in the individual market rules in order to place the individual market genetic nondiscrimination rules on equal footing with the group market genetic nondiscrimination rules.
- Required Revisions to the HIPAA Privacy Rules. The provisions of GINA also require the Secretary of Health and Human Services to revise the HIPAA privacy rules to indicate that (i) genetic information is "health information" for purposes of the privacy rules, and (ii) the use or disclosure of genetic information for certain underwriting purposes is not a permitted use or disclosure under the privacy rules.

3. Effective Date. The provisions of Title I of GINA apply with respect to group health plans for plan years beginning after May 21, 2009. Thus, for calendar year group health plans, the provisions of Title I will apply beginning on January 1, 2010. The new individual market rules apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after May 21, 2009. Likewise, the required revisions to the HIPAA privacy rules take effect on May 21, 2009.

II. Genetic Nondiscrimination in Employment.

Title II of GINA applies directly to employers. For this purpose, the term "employer" means an employer subject to the provisions of Title VII of the Civil Rights Act of 1964 (which generally includes an employer that has 15 or more employees for each working day in each of twenty or more calendar weeks in the current or preceding calendar year), and also includes certain other government employers.

1. GINA's Prohibitions.

- Prohibition Against Discrimination Based on Genetic Information. GINA provides a broad general rule under which it is unlawful for an employer, because of an employee's genetic information, to: (i) fail or refuse to hire, or to discharge, the employee; (ii) otherwise discriminate against the employee with respect to the compensation, terms, conditions, or privileges of the employment of the employee; or (iii) limit, segregate, or classify the employee in any way that would deprive (or tend to deprive) the employee of employment opportunities or adversely affect the status of the employee.
- Prohibition on Acquisition of Genetic Information. GINA also provides that it is unlawful for an employer to request, require or purchase genetic information with respect to an employee (or a family member of the employee). There are a number of exceptions to this general rule, including in the situation where an employer requests or requires family medical history from an employee in order to comply with the certification requirements of the FMLA.

"The provisions of Title II of GINA apply beginning on November 21, 2009."

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2. Other Important Rules.

- Confidentiality of Genetic Information. If an employer possesses any genetic information about an employee, GINA requires such genetic information to be maintained on separate forms and in separate medical files by the employer. In addition, GINA requires such genetic information to be treated by the employer as a confidential medical record of the employee.
- Limitation on Disclosures. If an employer possess any genetic information about an employee, GINA provides that an employer cannot disclose that genetic information, except (i) to the employee at his or her written request, (ii) in connection with certain research activities, (iii) in response to a court order, (iv) to government officials who are investigating compliance with Title II of GINA, if the genetic information is relevant to the investigation, (v) to the extent necessary in connection with the employee's certification requirements under the FMLA, or (vi) to a Federal, State or local public health agency that concerns a contagious disease that presents an imminent hazard of death or life-threatening illness.

3. Effective Date. The provisions of Title II of GINA apply beginning on November 21, 2009.

CONCLUSION

Although the provisions of GINA do not take effect immediately, employers would do well to familiarize themselves with the health insurance and employment-related requirements of this new law. Employers should also be on the lookout for the issuance of regulations interpreting and implementing the provisions of GINA. These regulations are required to be issued by various Federal governmental agencies no later than one year after the date of GINA's enactment.

In connection with GINA's enactment, employers will want to consider whether any changes need to be made to (i) the plan document(s) for the employer's group health plan(s), (ii) the employer's HIPAA privacy policies and procedures, and (iii) the employer's written employment policies and procedures (such as the employer's employee handbook). We'll know more about the need for making any such changes once the regulations interpreting and implementing the provisions of GINA are issued.