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Genetic Information Nondiscrimination Act (GINA) Guidance

The Genetic Information Nondiscrimination Act (GINA) was passed to prohibit discrimination based on Genetic Information. [Title I](#) prohibits the use of Genetic Information as a basis for determining eligibility or premiums for group health plans and health insurance issuers and places limitations on genetic testing and the collection of Genetic Information by group health plans and health insurers. Title II prohibits the use of Genetic Information in the employment context and limits employers, unions, employment agencies, apprenticeship programs and other entities subject to Title II (Covered Entities) from requesting, requiring or purchasing Genetic Information, and strictly limits those entities from disclosing Genetic Information.

The Departments of the Treasury (IRS), Labor (DOL) and Health and Human Services (DHHS) (collectively, the Agencies) issued interim final regulations under Title I in October of 2009. The Equal Employment Opportunity Commission (EEOC) issued final regulations under Title II in November of 2010. Together, these provide comprehensive guidance on key benefits and employment issues, especially regarding wellness programs. The Agencies had previously addressed wellness program issues, but the EEOC had not.

“Genetic Information” is defined as information about an individual’s genetic tests or the genetic tests of family members, the manifestation of disease or disorder in family members of the individual (i.e., family medical history), or any request for, or receipt by, an individual or a family member of genetic services. Genetic Information does not include information about a person’s age or gender, but with respect to a pregnant woman, does include the Genetic Information of the fetus. An individual’s manifestation of a genetic disease or condition is not Genetic Information, nor is information about the signs or symptoms the individual has, but information about any genetic test or any family medical history used to diagnose the condition is Genetic Information.

Title I Guidance

GINA does not mandate any specific benefits related to genetic tests, disease, conditions or services, but generally prohibits group health plans and health insurers from:

- increasing premiums or contribution amounts based on Genetic Information;
- requesting or requiring an individual or family member to undergo genetic testing;
- requesting, requiring or purchasing Genetic Information prior to or in connection with enrollment; and
- using Genetic Information for underwriting purposes.

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With respect to the administration of group health plans, both insured and self-funded:

- Health care providers may lawfully order genetic tests and elicit other Genetic Information for purposes of treatment.
- Group health plans and health insurers may obtain Genetic Information for purposes of payment. Once group health plans and health insurers are in possession of Genetic Information, they are prohibited from using that information to discriminate against the individual, to underwrite any coverage for the individual, or to establish any premium or required contributions to be paid by the individual.
- When requesting Genetic Information for payment purposes, group health plans and health insurers must request only the minimum necessary to accomplish that purpose.
- With respect to the adjudication of benefit claims, Genetic Information can be obtained for the express purpose of determining medical necessity as this does not come within the scope of an underwriting purpose.
- Collection of Genetic Information about an individual prior to enrollment in a group health plan, or as part of the plan's enrollment process, will not be considered inadvertently acquired (i.e., not a GINA violation, see below) unless in the enrollment process it is explicitly stated that Genetic Information should not be provided.
- When an employer who self-funds its group health plan is acting in its capacity as an insurer of medical benefits, it is subject to Title I of GINA, not Title II. Indeed, these regulations set up a firewall between Title I and II so that health plan or health insurer provisions and actions are addressed in Title I of GINA, ERISA, the Internal Revenue Code or the Public Health Services Act, and not through Title II of GINA, or other employment discrimination laws.

Title II Guidance

As noted above, the EEOC's final regulations prohibit Covered Entities from requesting, requiring or purchasing Genetic Information, and strictly limits those entities from disclosing Genetic Information. The remedies for violations of Title II track those found in Title VII of the Civil Rights Act of 1964 and other statutes designed to protect employees from discrimination. Among other things, these final regulations provide:

- Claims alleging discrimination or harassment based on Genetic Information are cognizable under GINA.
- Definition of employer includes its agents, and, thus, employers are barred from actions that would cause another entity acting as its agent to discriminate based on Genetic Information.
- Passive or inadvertent acquisitions of Genetic Information are not GINA violations. This exception applies not only in the workplace, but also with respect to Genetic Information obtained inadvertently from social media.

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- Genetic Information is not, however, deemed to have been obtained “inadvertently,” where there is intentional eavesdropping, a deliberate follow-up question designed to elicit such information is asked, or a request is made of a source and/or in a context where Genetic Information is likely to be elicited.
- Where a Covered Entity requests health-related information, it can come within this inadvertently-acquired exception, if it includes an express warning as part of the request, either orally or in writing, not to provide Genetic Information in response to the request. The warning is not required for a Covered Entity to prove that the disclosure of Genetic Information was inadvertent; the warning only serves as a safe harbor. Sample language for this safe harbor is included in the final regulations.
- Employers must provide this warning to health care providers it engages to conduct employment-related medical examinations.
- Employers who have not requested it, but who receive Genetic Information as part of a request for a reasonable accommodation under the ADA, or as part of a medical certification for an FMLA leave or any other leave or disability law, will not have violated GINA.
- Covered entities that obtain Genetic Information through publicly available sources do not violate GINA, though information sources with limited access (e.g., permission or a pass code is needed) are not deemed public sources for this purpose.
- Covered Entities may also engage in genetic monitoring of the biological effects of toxic substances in the work place, provided that they provide written notice of the monitoring, and, if the monitoring is not required by law, they obtain a knowing, written and voluntary authorization from the employees to be monitored that meets regulatory requirements. In any event, the monitoring must be done in compliance with all applicable law.
- Covered Entities in possession of Genetic Information must keep it in the same manner and with the same protections that they must keep PHI in their possession under HIPAA and medical information under the ADA. Genetic Information obtained prior to the passage of GINA that remains in an employee’s file is not a violation of GINA, but disclosing it to a third party is.

Wellness Program Guidance

Wellness programs that provide rewards for completing health risk assessments (HRAs) violate the prohibition against requesting Genetic Information for underwriting purposes.

Group health plans and insurers can collect Genetic Information through an HRA, however, if: (i) no rewards are provided, and (ii) the information is not solicited prior to enrollment. They may also offer HRAs that do not collect Genetic Information.

Notwithstanding the preceding, Covered Entities may offer certain kinds of financial inducements to encourage participation in health plans or to obtain genetic services, but they may not offer an

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inducement to provide Genetic Information. Thus, if a reward is offered for taking an HRA, and the HRA does request Genetic Information, GINA will not be violated if: (i) participants are clearly told that responding to the questions that elicit Genetic Information is wholly voluntary, and (ii) the reward is not dependent on answering those questions.

Covered Entities can also offer financial rewards for participating in disease management or other programs that encourage healthy lifestyles, but to avoid a GINA violation (i) individuals must voluntarily provide Genetic Information to obtain such rewards, and (ii) these same programs and inducements must also be offered to individuals (a) who are not genetically pre-disposed, but who have those same health conditions, or (b) whose lifestyle choices put them at risk of acquiring those conditions.

Wellness programs that constitute group health plans must comply with both Titles I and II of GINA.

Covered Entities may contract with third parties to operate a wellness program, or they may do it in-house, so long as individually identifiable Genetic Information is accessible only by (i) the individual, (ii) a health care provider involved in the wellness program, or (iii) a wellness program administrator. In no case may individually identifiable Genetic Information be shared with managers, supervisors, others who make employment decisions or anyone else in the workplace.

Action Steps

Employers or other Covered Entities should review their employment practices with respect to employment-related medical testing, supervisor training, workplace monitoring, employee handbooks with regards to accessing, storing, and disseminating Genetic Information, and make whatever changes are necessary to comply with GINA.

Those Covered Entities that sponsor or administer group health plans should conduct a similar review with respect to Genetic Information available to the plan with respect to claim adjudication, provider communications, insurance or TPA reports, etc. Covered Entities should also ensure that their plan documents and HIPAA policies and procedures are revised, if necessary, to comport with GINA.

If you have any questions about these GINA requirements, and how they apply to your group health plan, wellness program, or general employment practices, please contact any of the Honigman attorneys listed in this Alert.

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