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# New Requirements For Employers, Group Health Plans And Health Insurers Under The Genetic Information Nondiscrimination Act Of 2008

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Employers should be aware of a significant statute that imposes new nondiscrimination requirements on group health plans and employers: the Genetic Information Nondiscrimination Act of 2008, Pub. Law 110-223 ("GINA"), signed into law on May 21, 2008. GINA prohibits discrimination in health coverage and employment that is based on genetic information. The Health Coverage (Title I) provisions are generally effective January 1, 2010, for calendar year plans, and the Employment (Title II) provisions are generally effective November 21, 2009.

## Health Coverage (Title I)

- Group health plans and health insurers may not request or require the provision of genetic information of an individual or the individual's family members and may not use genetic information for decisions regarding coverage, costs of coverage or pre-existing conditions.
- The health coverage provisions of GINA are effective for plan years beginning after May 21, 2009 (January 1, 2010 for calendar year plans). Individual health policies are subject to GINA on and after December 9, 2009.
- The Department of Health and Human Services, the Department of Labor and the Department of the Treasury issued interim final regulations, 74 Fed. Reg. 51664 (October 7, 2009), that are effective for plan years beginning on or after December 7, 2009 (with public comments requested due January 5, 2010). The Department of Health and Human Services also issued proposed regulations, 74 Fed. Reg. 51698 (October 7, 2009), amending the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA") privacy regulations.

## Employment (Title II)

- GINA prohibits the use of genetic information in making employment-related decisions, prohibits the intentional acquisition of genetic information about applicants and employees, imposes strict confidentiality requirements and prohibits retaliation.

- Title II's jurisdiction is similar to that of Title VII of the Civil Rights Act of 1964, as amended, in that it applies to private employers and certain public employers with 15 or more employees, as well as certain other entities.
- The Equal Employment Opportunity Commission ("EEOC") issued proposed regulations, 29 C.F.R. Part 1635 (March 2, 2009), which have yet to be finalized.

This Client Alert provides a summary of some of the significant requirements of GINA that necessitate the immediate attention of employers.

## General

Once GINA takes effect, it will prohibit discrimination based on genetic information, no matter when the information was collected.

What is genetic information?

- An individual's genetic tests, including those done as part of a research study.
- Genetic tests include an analysis of human DNA, RNA, chromosomes, proteins or metabolites that detect genotypes, mutations or chromosomal changes.
- Genetic tests of the individual's family members, defined as dependents and up to and including 4th degree relatives.
- Genetic tests of any fetus of an individual or family member who is pregnant.
- Genetic tests of any embryo legally held by an individual or family member utilizing assisted reproductive technology.
- The manifestation of a disease or disorder in family members (family history). "Manifestation" generally means the actual diagnosis of the disease or disorder, unless it is based only on genetic information (*e.g.,* Huntington's disease).
- Any request for, or receipt of, genetic services or participation in clinical research that includes genetic services (testing, counseling or education) by an individual or family member.

What is not considered genetic information?

- The sex or age of any individual.
- Routine tests that do not measure DNA, RNA or chromosomal changes, such as complete blood counts, cholesterol tests and liver-function tests.
- Analyses of proteins or metabolites that are directly related to a manifested disease, disorder or pathological condition, which could be detected by a health

care professional with appropriate training and expertise in the field of medicine involved.

## Health Coverage Requirements

Title I of GINA prohibits group health plans, health insurance issuers in the group and individual markets, and issuers of Medicare supplemental policies (Medigap) from discriminating based on genetic information and from collecting genetic information.

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| No adjustment to group premiums or contribution amounts | Group health plans and health insurance issuers **may not** adjust premium or contribution amounts based on genetic information.<br>HIPAA prohibits discrimination in individual premiums or contributions based on a health factor but permits increase in the group rate of an employer based on a health factor. Under GINA, health insurance issuers may increase the group rate based on the manifestation of a disease or disorder of an individual enrolled in the plan (*i.e.,* based on the actual claims experience of plan participants). The increased group rate could be based on the claims experience of one individual, provided the adjustment is based on a per-participant rate and no genetic information was used for computing the group rate. |
| Genetic testing and health care provider exception | A group health plan may not request or require an individual or family member to undergo a genetic test. However, GINA does not prohibit a health care professional providing health care services to an individual from requesting that the individual undergo a genetic test. |
| No collection for underwriting purposes | A group health plan or health insurance issuer may not request, require or purchase genetic information for underwriting purposes.<br>“Underwriting purposes” means, for enrollment or continued eligibility purposes for benefits or coverage: (i) computation of premium or contribution amounts for benefits or coverage; (ii) the application of any pre-existing condition exclusions for benefits or coverage; or (iii) activities relating to the creation, renewal or replacement of a contract of health insurance or benefits. |

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| | "Underwriting" also includes, regardless of the amounts involved: (i) changing deductibles or other cost-sharing mechanisms; (ii) providing discounts or rebates; or (iii) premium differentials.<br>These restrictions do not apply to "incidental collection" where genetic information incidental to the collection of other information relating to the individual is obtained. This exception does not apply where it is reasonable to anticipate that health information will be received, unless the collection explicitly states that genetic information should not be provided. |
| No collection for purposes of enrollment | A group health plan may not request, require or purchase genetic information with respect to any individual prior to the individual's enrollment in the plan (or in connection with enrollment in the plan). |
| Exception for medical appropriateness and payment determinations | A group health plan may obtain and use the results of a genetic test in determining whether the benefit is "medically appropriate" or in making a determination of whether payment may be made under the plan. This request must be limited to the minimum information necessary to accomplish the intended purpose. |
| Exception for conducting research | Genetic information may be requested for purposes of conducting lawful research. The plan must indicate: (i) the request is voluntary; (ii) non-compliance will have no effect on enrollment or premium or contribution amounts; and (iii) no genetic information will be used for underwriting purposes. The plan must also notify the implementing agencies of its intent to use this exception. The Department of Labor has published a notification form and instructions, OMB Control Number 1210-0136, for a group health plan or health insurer to request the research exception. |

## Special Rules for Wellness Programs

Wellness programs generally offer benefits and reduced costs of coverage for certain medical services and related programs. Wellness programs that provide any kind of reward, regardless of the amount of the reward, for completing health risk assessments ("HRAs") that request genetic information, including family medical history, violate the GINA underwriting restrictions.

This means that wellness programs may not request genetic information prior to enrollment. Further, any HRA requesting genetic information after enrollment must be limited to information not protected under GINA and the HRA request must inform the individual that genetic information is not to be provided. The interim regulations state that a wellness program could provide two HRAs: (i) one that requests genetic information, such as family medical history, provided there is no reward or incentive of any kind or amount; and (ii) one that requests information not protected under GINA for which a reward may be provided (as long as the request makes it clear that genetic information is not to be provided). If, under a wellness program, an on-site health care professional is providing health care services to an individual, the professional may be able to request genetic information for purposes of the provision of health care services under the health care provider exception.

## HIPAA Privacy

GINA requires amendments to the HIPAA privacy regulations to clarify that genetic information includes health information governed by the privacy rules ("protected health information," or PHI) and to prohibit the use or disclosure of genetic information at any time for underwriting purposes. The amendments to the HIPAA privacy rules will be effective 180 days after final regulations are issued. GINA also amends HIPAA statutory provisions to prohibit a group health plan or health insurer from imposing a pre-existing condition exclusion based solely on genetic information. Under the HIPAA proposed regulations, HIPAA-covered entities must revise their Notice of Privacy Practices to include a statement that genetic information may not be used or disclosed for underwriting purposes.

## Employment Discrimination Requirements

Similar to the type of conduct prohibited by Title VII of the Civil Rights Act of 1964, as amended, Title II of GINA prohibits the use of genetic information when making decisions related to any terms, conditions or privileges of employment. It also prohibits covered entities from intentionally requesting, requiring or purchasing genetic information of an employee or an employee's family member, with certain limited exceptions, such as where the employer requests or requires family medical history from the employee to comply with the certification provisions of the Family and Medical Leave Act ("FMLA").

With respect to confidentiality, GINA requires that if a covered entity possesses genetic information about an employee, such information must be maintained separately from other employee files, and be treated as a confidential medical record of the employee, similar to confidential medical records under applicable provisions of the Americans with Disabilities Act. Such confidential information must not be disclosed, except: (i) at the written request of the employee; (ii) to an occupational or other health researcher if the research is conducted in compliance with applicable laws and regulations; (iii) in response to a court order (with certain exceptions); (iv) to government officials investigating compliance with GINA; (v) in compliance with the FMLA; or (vi) to federal, state or local public health agencies, but only with regard to particular information that concerns a contagious disease that presents an imminent hazard of death or life-threatening illness.

GINA's retaliation rules prohibit any person from discriminating against any individual because such individual has opposed any act or practice made unlawful by GINA or because such individual made a charge, testified, assisted or participated in any manner in an investigation, proceeding or hearing under GINA.

Finally, although GINA does not presently provide for a cause of action based on "disparate impact" (*i.e.,* when neutral policies or practices have a disproportionate, adverse impact on any protected class), GINA provides that a Genetic Nondiscrimination Study Commission be established on the six-year anniversary of GINA's enactment in order to review the developing science of genetics and to make recommendations to Congress whether to provide a disparate impact cause of action under GINA.

## Implications for Employers

Steps for employers:

- Update federal employment law postings (including EEOC's "EEO is the Law" poster);
- Update employment policies, such as anti-discrimination handbook policies, to include "genetic information" as one of the protected categories;
- Train managers (i) not to ask about employees' or applicants' genetic information, (ii) not to discriminate against employees or applicants based on genetic information, (iii) how to keep known genetic information confidential, and (iv) not to retaliate against employees or applicants asserting their rights under GINA;
- Review wellness programs and HRAs and revise as necessary to comply with GINA and prevent improper inquiries;
- Update group health plan documents and summary plan descriptions for GINA requirements, including that protected health information under HIPAA covers genetic information;
- Review underwriting procedures and practices, particularly as to information sharing with group health insurers for purposes of underwriting any group health policies; and
- Be prepared to update HIPAA Privacy Notices for GINA.

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