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The Genetic Information Nondiscrimination Act of 2008 (GINA)

The Genetic Information Nondiscrimination Act of 2008 (GINA), signed into law on May 21, 2008, prohibits group health plans, health insurers and employers from discriminating against individuals on the basis of their genetic information. The Internal Revenue Service, Department of Labor, and Centers for Medicare and Medicaid Services published interim final regulations implementing GINA. For group health plans, these regulations are effective for plan years beginning on or after December 7, 2009.

General Rule

GINA prohibits group health plans and health insurers from:

- Modifying premium or contribution rates for a group based on genetic information of individuals in the group;
- Requiring or requesting that an individual or a family undergo a genetic test;
- Using or disclosing genetic information, including information that an individual or family requested or obtained genetic services for underwriting purposes; or
- Requesting, requiring or purchasing genetic information about individuals prior to their enrollment in the group health plan or for underwriting purposes.

There is a research exception that allows group health plans and health insurers to request, but not require, individuals to undergo genetic testing if certain conditions are met.

Practices Still Permitted By GINA

The following practices are still permitted by GINA:

- Modifying premiums or contributions based on an individual's manifestation of a disease, even one with a genetic basis;
- Group health plans and insurers may still obtain and use the results of a genetic test when making claim payment determinations; and
- GINA does not prevent health care professionals from asking patients to undergo genetic tests or from learning of the results.

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Enforcement

ERISA's existing enforcement scheme generally applies to GINA violations for group health plans, as follows:

- Individuals may sue to restore coverage without exhausting their administrative remedies upon a showing that exhaustion would cause irreparable harm to their health
- The DOL may sue to enforce GINA and seek to impose a \$100/day penalty for GINA violations, with a \$2,500 minimum if the failure is not corrected before the group health plan receives notice of the violation from the DOL
- No penalty if the Plan Administrator did not know and exercising reasonable diligence would not have known of the failure
- No penalty if the failure is due to reasonable cause, not willful neglect, and is corrected within 30 days

Impact On Wellness Programs

Employers may acquire genetic information for wellness programs only if:

- The individual provides prior, knowing and voluntary written authorization;
- If the individual (or family member) and the licensed health care provider or board-certified genetic counselor receive the information; and
- Any individual identifiable genetic information is only available for the purposes of these services being offered and is not disclosed to the employer except in aggregate terms that do not disclose the identity of specific employees.

Health risk assessments (HRAs) cannot include questions regarding the manifestations of a genetic disease or disorder of family members. The EEOC has indicated that HRA disability-related questions are not job-related and consistent with business necessity and likely violate the ADA. An HRA that seeks genetic information but does not involve any reward or penalty will be permitted.

Predictive modeling, whereby third parties analyze a group health plan's health data to predict the chances of various individuals contracting a disease or disorder may be prohibited to the extent such health data contains Genetic Information.

Definitions

GINA has some important defined terms, the most significant are:

Genetic Information: Genetic Information includes the following:

- Information about the individuals' genetic test
- The genetic test of the individuals' family members
- Manifestation of disease or disorder in the individual or his family member, including the genetic information of a fetus of a pregnant female or an embryo created with the assistance of reproductive technology legally held by the individual
- The request for or receipt of genetic services
- Participation in clinical research that includes genetic services by the individual or any family member of the individual

Genetic Test: An analysis of human DNA, RNA, chromosome proteins or metabolites that detects genotypes, mutations or chromosomal changes, with certain exceptions

Genetic Services: A genetic test, genetic counseling or genetic education

Family Member: Means an employees' covered dependant or anyone so eligible and who may be within the fourth degree of consanguinity to any of them

Underwriting Purposes: Underwriting purposes for which genetic information is prohibited includes:

- Rules for determining eligibility for benefits (includes continuing eligibility);
- Setting premium or contribution amounts;
- Applying pre-existing condition exclusions; and
- Other activities related to the creation, renewal or replacement of health insurance or health benefits.

If you have any questions or need assistance in this matter, please contact any of the attorneys listed on this Employee Benefits Alert.

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