

COMPLIANCE OVERVIEW

Provided by Clarke & Company Benefits, LLC

Genetic Nondiscrimination Rules for Health Plans

The Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits the improper collection, use or disclosure of genetic information by employers and health plans. In general, GINA prohibits group health plans and insurance issuers from:

- ✓ Adjusting group premium or contribution amounts on the basis of genetic information;
- ✓ Requesting or requiring individuals (or their family members) to undergo a genetic test (with limited exceptions, such as for determinations regarding payment based on medical appropriateness); and
- ✓ Collecting genetic information prior to or in connection with enrollment, or at any time for underwriting purposes.

This Compliance Overview provides a summary of GINA's nondiscrimination rules for health plans.

LINKS AND RESOURCES

- [Interim final regulations](#) under GINA addressing genetic nondiscrimination in health coverage (the Title I Regulations)
- The DOL's [FAQs on GINA Title I](#) (relating to health plan coverage)

HIGHLIGHTS

GENETIC INFORMATION

- Information about an individual's genetic tests or the genetic tests of the individual's family members;
- The manifestation of a disease or disorder in family members of the individual (that is, family medical history); or
- An individual's request for or receipt of genetic services.

WELLNESS PROGRAMS

- GINA's protections also apply to employer-sponsored wellness programs that ask employees to answer questions about their health and family medical histories.
- A plan may use an HRA that requests family medical history if it is requested to be completed after, and unrelated to, enrollment, and if there is no premium reduction or any other reward for completing the HRA.



CLARKE & COMPANY
BENEFITS LLC

This Compliance Overview is not intended to be exhaustive nor should any discussion or opinions be construed as legal advice. Readers should contact legal counsel for legal advice.

BACKGROUND

GINA prohibits employers and health plans from improperly collecting, using and disclosing individuals' genetic information.

- GINA's health plan provisions (Title I) are designed to protect individuals from genetic discrimination with respect to their health coverage.
- The employment provisions of GINA (Title II) are designed to protect job applicants, current and former employees, labor union members, apprentices and trainees from genetic discrimination in employment.

The Departments of Labor (DOL), Health and Human Services (HHS) and the Treasury issued [interim final regulations](#) in October 2009, providing guidance on how GINA affects health plan coverage. The regulations apply to plan years beginning on or after Dec. 7, 2009 (Jan. 1, 2010, for calendar year plans). The DOL has also provided [frequently asked questions](#) (FAQs) regarding GINA.

OVERVIEW OF GINA TITLE I

GINA contains requirements related to genetic nondiscrimination in health plan coverage, which regulate:

- Group health plans (including small group health plans);
- Health insurance issuers offering health insurance coverage in the group and individual markets;
- Non-federal governmental plans; and
- Issuers of Medicare supplemental policies.

In general, GINA prohibits group health plans and insurance issuers from:

- ✓ Adjusting group premium or contribution amounts on the basis of genetic information;
- ✓ Requesting or requiring individuals (or their family members) to undergo a genetic test (with limited exceptions such as for determinations regarding payment based on medical appropriateness); and
- ✓ Collecting genetic information prior to or in connection with enrollment, or at any time for underwriting purposes.

IMPORTANT DEFINITIONS

Genetic Information

Genetic information means information about:

- The genetic tests of an individual or the individual's family members;
- The manifestation of a disease or disorder in an individual's family members (family medical history);
- An individual's request for, or receipt of, genetic services, or the participation in clinical research involving genetic services by the individual or a family member; or
- The genetic information of a fetus carried by an individual or a family member or legally held by an individual or family member using assisted reproductive technology.

However, genetic information does **not** include information about the sex or age of the individual or any family members. It also does not include information about the race or ethnicity of the individual or family members that is not derived from a genetic test.

Genetic Tests

In general, a genetic test is an analysis of human DNA, RNA, chromosomes, proteins or metabolites that detects genotypes, mutations or chromosomal changes. Genetic tests include, but are not limited to, the following:

- Tests to determine whether someone has a predisposition to breast cancer, hereditary nonpolyposis colon cancer or Huntington's disease;
- Carrier screening for adults to determine the risk of conditions like cystic fibrosis, sickle cell anemia, spinal muscular atrophy or fragile X syndrome in future offspring;
- Amniocentesis and other evaluations used to determine whether a fetus has a genetic abnormality;
- Newborn screening tests to detect or indicate genotypes, mutations or chromosomal changes;
- Preimplantation genetic diagnosis performed on embryos created using in vitro fertilization;
- Pharmacogenetic tests that detect genotypes, mutations or chromosomal changes that indicate how an individual will react to a drug or a particular dosage of a drug;
- DNA testing to detect genetic markers that are associated with information about ancestry; and
- DNA testing that reveals family relationships, such as paternity.

The following tests and procedures are **not** considered genetic tests:

- Analysis of proteins or metabolites that does not detect genotypes, mutations or chromosomal changes;
- A medical examination that tests for the presence of a virus that is not composed of human DNA, RNA, chromosomes, proteins or metabolites;
- A test for infectious and communicable diseases that may be transmitted through food handling; and
- Complete blood counts, cholesterol tests and liver function tests.

A test for the presence of alcohol and illegal drugs is not a genetic test. However, a test to determine whether a person has a genetic predisposition to alcoholism or drug use is a genetic test.

Genetic Services

Genetic services include genetic tests, genetic counseling (including obtaining, interpreting or assessing genetic information) or genetic education.

Family Members

Family members include an individual's dependents (as a result of marriage, birth, adoption or placement for adoption) and relatives through the fourth degree. The rule specifies the degrees of relation as follows:

- First degree—Parents, siblings and children
- Second degree—Grandparents, grandchildren, uncles, aunts, nephews, nieces and half-siblings
- Third degree—Great-grandparents, great-grandchildren, great uncles/aunts and first cousins
- Fourth degree—Great-great-grandparents, great-great-grandchildren and first cousins once-removed (children of the individual's first cousins)

IMPACT ON USE OF HEALTH RISK ASSESSMENTS

GINA's prohibition on collecting genetic information prior to or in connection with enrollment, or for underwriting purposes, affects the use of health risk assessments (HRAs). HRAs are tools commonly used in connection with wellness and disease management programs.

Under GINA, group health plans may not:

- ✓ Provide a reward or incentive to an individual for completing an HRA that requests genetic information, such as family medical history; or
- ✓ Request genetic information as part of an HRA that must be completed before enrollment in the plan or eligibility for additional benefits under the plan, such as a disease management program.

A reward or incentive can take many forms, including premium discounts or rebates, reduced deductibles or copayments, cash rebates or gift certificates. The regulations suggest that rewards or incentives also include those related to health flexible spending arrangements or health reimbursement arrangements. Rewards or incentives do not have to be based on the outcome of the HRA to be impermissible.

The following uses or types of HRAs are permissible under GINA:

- Collecting genetic information after enrollment in the plan if no reward or incentive is provided;
- Using two separate HRAs—one that requests genetic information and one that does not. The HRA requesting genetic information must not include an incentive, must be voluntary and must not affect the reward given for the other HRA; or
- Asking HRA questions that do not directly request genetic information, if the HRA clearly states that genetic information should not be provided.

COMPLIANCE STEPS

Plan sponsors should review their health plans, including any wellness and disease management programs, to be sure that they do not inappropriately request or receive genetic information, and evaluate whether any changes are necessary regarding the administration of benefits. Plan sponsors that decide to implement a wellness and disease management program should work with their advisors to structure an HRA that does not offer incentives or rewards for providing genetic information.