Your Genetic Information and Your Health Plan

Know The Protections Against Discrimination

The Genetic Information Nondiscrimination Act **(GINA)**

This publication has been developed by the U.S. Department of Labor, Employee Benefits Security Administration, and is available on the web at www.dol.gov/ebsa

For a complete list of the agency's publications, call our toll free number at 1-866-444-3272

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Introduction

Whether you know it or not, you may be one of the millions of Americans affected by a genetic disorder.

While no one has perfect genes, tests exist today that can identify a predisposition to a wide array of genetic disorders including diabetes, breast cancer, colon cancer, Alzheimer's disease, and many others. These tests do not guarantee that an individual will get a particular disease, but they can help in making informed decisions about health care and provide the opportunity for early identification, treatment, or even prevention of disease.

However, many people don't take these tests. Studies indicate that one major reason is that many Americans fear that the results of genetic testing could be used against them, particularly by their health insurer or employer.

The Genetic Information Nondiscrimination Act of 2008 (GINA) addresses this concern by prohibiting discrimination in group health plan coverage based on genetic information. GINA expands on the provisions in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) which protect against discrimination based on genetic information. HIPAA prevents a plan or issuer from imposing a preexisting condition exclusion based solely on genetic information, and prohibits discrimination in individual eligibility, benefits, or premiums based on any health factor (including genetic information).

GINA expands these protections in a number of ways:
Group health plans and health insurers cannot base health care premiums for plans or a group of similarly situated individuals on genetic information.
Plans and insurers are prohibited from requesting or requiring an individual to undergo a genetic test, and
Plans and insurers are prohibited from collecting genetic information (including family medical history) prior to or in connection with enrollment, or for underwriting purposes.

The Department of Labor, the Department of the Treasury, and the Department of Health and Human Services are responsible for the administration of the provisions of GINA prohibiting discrimination by group health plans and health insurance issuers based on genetic information. The GINA protections for the individual insurance market and privacy and confidentiality under the Social Security Act are within the jurisdiction of the Department of Health and Human Services. The provisions of GINA addressing discrimination in employment based on genetic information is under the jurisdiction of the Equal Employment Opportunity Commission.

This publication addresses the GINA provisions applicable to employment-based group health plans.

What is Genetic Information?

Genetic information includes:

- Information about an individual's or family members' genetic tests;
- The manifestation of a disease or disorder in family members;
- Any request for or receipt of genetic services; or
- Participation in clinical research that includes genetic services by an individual or family member.

For pregnant women (or a family member of a pregnant woman), this includes genetic information about the fetus or embryo (when assisted reproductive technology is used).

Genetic information does not include information about the sex or age of any individual.

What is a Manifested Disease?

A manifested disease is a disease, disorder, or pathological condition for which an individual has been or could reasonably be diagnosed by a health care professional (with appropriate training and expertise in the field of medicine involved).

A disease is not manifested if a diagnosis is based principally on genetic information. For example, an individual whose genetic tests indicate a genetic variant associated with colorectal cancer and another that indicates an increased risk of developing cancer, but who has no signs or symptoms of disease and has not and could not reasonably be diagnosed with a disease does not have a manifested disease.

What are Genetic Services and Tests?

Genetic services mean genetic tests, genetic counseling, or genetic education. Genetic test means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes. A genetic test does not include an analysis of proteins or metabolites directly related to a manifested disease, disorder, or pathological condition.

Some examples of genetic tests are tests to determine whether an individual has a BRCA1, BRCA2, or colorectal cancer genetic variant. In contrast, an HIV test, complete blood count, cholesterol test, liver function test, or test for the presence of alcohol or drugs is not a genetic test.

Health Plan Premiums

GINA prohibits a group health plan from adjusting group premium or contribution amounts for a group of similarly situated individuals based on the genetic information of members of the group. This is a change from HIPAA's prior nondiscrimination requirements, which allowed plans to adjust premiums or contributions for the group health plan or group of similarly situated individuals (but not for specific individuals within the group) based on genetic information. Therefore, even if a plan obtained individual genetic information about group members before GINA's effective date (January 1, 2010 for calendar year plans), it cannot be used to adjust the group premium.

Plans can charge a higher group premium or contribution based on the manifested disease or disorder of an individual enrolled in the plan. This is because information about an individual's manifested disease or disorder is not genetic information with respect to that individual. However, a plan cannot use the manifestation of a disease or disorder in one individual as genetic information about other group members to further increase the group premium.

A plan can take into account the costs associated with providing benefits for covered genetic tests or genetic services in determining overall premium or contribution amounts.

Note that under HIPAA, a plan cannot charge an individual more for coverage than other similarly situated individuals in the group based on any health factor, including a manifested disease or disorder.

Genetic Testing

Group health plans and health insurers generally cannot request or require an individual or family member to undergo a genetic test. However, there are three exceptions to this general rule:

Provision of Health Care Services

A health care professional who is providing health care services to an individual can request that an individual undergo a genetic test. For example, if during the course of a routine physical exam, a physician learns that an individual has family medical history indicating a potential risk for Huntington's disease, the physician can recommend that the individual undergo a related genetic test. This would not violate GINA. This would be true even if the doctor were employed by an HMO, so long as the physician was providing health care services to the individual for whom the genetic test was recommended.

A health care professional includes but is not limited to a physician, nurse, physician's assistant, or technicians that provide health care services to patients.

Payment of Claims

If a plan conditions payment for an item or service based on medical appropriateness and the medical appropriateness depends on the genetic makeup of the patient, then the plan can condition payment for the item or service on the outcome of a genetic test. The plan may also refuse payment in that situation if the patient does not undergo the genetic test. The plan may request only the minimum amount of information necessary to make a determination regarding payment.

For example, if a plan normally covers mammograms starting at age 40, but covers them at age 30 for individuals with a high risk of breast cancer, the plan generally may require that an individual under 40 submit genetic test results or family medical history as evidence of a high risk of breast cancer in order to have the claim for the mammogram paid. Because the medical appropriateness of a mammogram depends on the patient's genetic makeup, the minimum amount of information necessary for determining payment of the claim may include the results of a genetic test or the individual's family medical history.

Research

There is also a research exception that allows a plan to request (but not require) a genetic test if four requirements are met:

- The plan's request for the genetic test is made in writing and clearly indicates to each participant and beneficiary that the request is voluntary and will have no effect on plan eligibility;
- The plan makes the request pursuant to research which complies with Federal, State or local laws that protect human subjects in research;
- None of the genetic information collected is used for underwriting purposes; and
- The plan files a notice concerning the research exception with the Department of Labor.

Collection of Genetic Information

Under GINA, collecting genetic information includes requesting, requiring or purchasing the information.
Plans cannot collect your genetic information, including your family medical history, either before you enroll or in connection with your enrollment in the group health plan.

Group health plans and health insurers generally cannot request or require an individual or family member to undergo a genetic test. However, there are three exceptions to this general rule:

- Rules for or determination of eligibility for benefits under the plan or coverage at or after enrollment (including changes in deductibles or other cost-sharing in return for activities such as completing a Health Risk Assessment (HRA) or participating in a wellness program);
- Computation of premium or contribution amounts under the plan (including discounts, rebates, payments in kind or other premium differences in return for activities such as completing an HRA or participating in a wellness program);
- The application of any preexisting condition exclusions allowed by the plan; and
  Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

GINA generally prohibits plans from offering rewards in return for the provision of genetic information, including family medical history information collected as part of a Health Risk Assessment (HRA).

However, genetic information that is obtained incidental to the collection of other information is permitted if:
1.) The genetic information is not used for underwriting purposes; and

2.) if in instances where it is reasonable to anticipate that a collection will include health information, the collection explicitly states that genetic information should not be provided.

Health Risk Assessments
Some group health plans ask individuals to complete health risk assessments (HRAs) prior to or as part of the enrollment process for the plan. If the HRAs request genetic information, including family medical history, they are prohibited.

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 (it is not used for underwriting purposes).

If an HRA does not request family medical history or other genetic information, such as information about any genetic tests the individual has undergone, a plan may offer a premium discount or other reward for completing the HRA. The HRA must explicitly state that genetic information should not be provided. This ensures that any genetic information collected is within the incidental collection exception. However, the plan may not use any genetic information it obtains incidentally for underwriting purposes.

Under GINA group health plans may also reward:
- Participation in an annual physical examination with a physician (or other health care professional) who is providing health care services to the individual, even if the physician may ask for family medical history as part of the examination;
- more favorable cost-sharing for preventive services, including genetic screening; and
- participation in certain disease management or prevention programs. The incentives to participate in such programs must also be available to individuals who qualify for the program but have not provided family medical history information through an HRA.

Resources

If you have questions regarding your GINA rights under an employer-sponsored group health plan, call the Department of Labor's Employee Benefits Security Administration toll free at 1-866-444-3272 or contact EBSA electronically. You can also visit the EBSA Web site for more information including a list of all of the publications available from EBSA. For more information on HIPAA, you can request a copy of *Your Health Plan and HIPAA…Making the Law Work for You.*

The individual market provisions under GINA are administered by the Department of Health and Human Services' Centers for Medicare & Medicaid Services.

The privacy and confidentiality provisions are administered by the Department of Health and Human Services' Office for Civil Rights.

The employment-related provisions are administered by the Equal Employment Opportunity Commission (EEOC).

Note: The Affordable Care Act provides additional protections for your benefits under your health plan. This publication does not reflect the passage of the Affordable Care Act. For further information, visit the EBSA Web site. Also visit the Department of Health and Human Services Web site.

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This booklet constitutes a small entity compliance guide for purposes of the Small Business Regulatory Enforcement Act of 1996.