

# Frequently Asked Questions Regarding the Genetic Information Nondiscrimination Act



U.S. Department of Labor  
Employee Benefits Security Administration  
August 2010

*Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA) includes provisions that generally prohibit group health plans and health insurance issuers from discriminating based on genetic information. These provisions amend the Employee Retirement Income Security Act (ERISA), administered by the Department of Labor; the Public Health Service Act (PHS Act), administered by the Department of Health and Human Services; and the Internal Revenue Code (the Code), administered by the Department of Treasury (the Treasury) and the Internal Revenue Service (IRS). The Department of Labor has jurisdiction with respect to employment-based group health plans. HHS in conjunction with the States administers these provisions with respect to health insurance issuers. The Treasury and IRS administer these provisions with respect to employers. Title I of GINA also includes individual insurance market provisions under the PHS Act and privacy and confidentiality provisions under the Social Security Act, which are both within the jurisdiction of HHS. Title II of GINA, under the jurisdiction of the Equal Employment Opportunity Commission, addresses discrimination in employment based on genetic information.*

*The subject of these Frequently Asked Questions are the requirements of Title I of GINA under ERISA, prohibiting discrimination in group health plan coverage based on genetic information.*

*GINA expands the genetic information nondiscrimination protections included in Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Under GINA, group health plans and health insurance issuers cannot base premiums for a plan or a group of similarly situated individuals on genetic information. GINA generally prohibits plans and issuers from requesting or requiring an individual to undergo genetic tests, and prohibits a plan from collecting genetic information (including family medical history) prior to or in connection with enrollment, or for underwriting purposes.*

*GINA applies generally to group health plans. Unlike the provisions under Title I of HIPAA, there is no exception for very small health plans with less than two participants who are current employees.*

*The statutory provisions of GINA are effective for plan years beginning on or after May 21, 2009. The regulations implementing the provisions of GINA were published on October 7, 2009 and are applicable for plan years beginning on or after December 7, 2009. Therefore, for calendar year plans the statute and regulations apply as of January 1, 2010. You can access a copy of these regulations at <http://www.dol.gov/federalregister/PdfDisplay.aspx?DocId=23182>.*

## **Q1: How does GINA expand the genetic information nondiscrimination protections in HIPAA?**

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 provides additional underwriting protections, prohibits requesting or requiring genetic testing, and restricts the collection of genetic information. Specifically:

- GINA provides that group health plans and health insurance issuers cannot adjust premiums or contribution amounts for a plan, or any group of similarly situated individuals under the plan, based on genetic information of one or more individuals in the group. (However, premiums may be increased for the group based upon the manifestation of a disease or disorder of an individual enrolled in the plan.)
- GINA generally prohibits plans and issuers from requesting or requiring an individual to undergo a genetic test. However, a health care professional providing health care services to an individual is

permitted to request a genetic test. A plan or issuer may request the results of a genetic test to determine payment of a claim for benefits, but only the minimum amount of information necessary in order to determine payment. There is also a research exception that permits a plan or issuer under certain conditions to request (but not require) that a participant or beneficiary undergo a genetic test.

- GINA prohibits a plan from collecting genetic information (including family medical history) from an individual prior to or in connection with their enrollment in the plan, or at any time for underwriting purposes. Under GINA, underwriting purposes includes rules for determination of eligibility for benefits and the computation of premium and contribution amounts. Thus, under GINA, plans and issuers are generally prohibited 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). GINA includes an exception for incidental collection of genetic information, provided the information is not used for underwriting purposes. However, the regulations make clear that the incidental collection exception is not available if it is reasonable for the plan or issuer to anticipate that health information will be received in response to a collection, unless the collection explicitly states that genetic information should not be provided.

## **Q2: What is genetic information?**

Genetic information means information about an individual's genetic tests, the genetic tests of family members of the individual, the manifestation of a disease or disorder in family members of the individual or any request for or receipt of genetic services, or participation in clinical research that includes genetic services by the individual or a family member of the individual. The term genetic information includes, with respect to a pregnant woman (or a family member of a pregnant woman) genetic information about the fetus and with respect to an individual using assisted reproductive technology, genetic information about the embryo.

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

## **Q3: Genetic information includes information about an individual's genetic services and tests. What do these include?**

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.

Therefore, 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.

## **Q4: Genetic information includes an individual's genetic tests and information about the manifestation of a disease or disorder in an individual's family member. A genetic test does not include an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition. 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.

While plans and issuers are prohibited from adjusting group premiums or contributions based on genetic information, plans and issuers can increase the 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. This is discussed further at Q6.

**Q5: GINA prohibits a plan from collecting genetic information (including family medical history) prior to or in connection with enrollment, or at any time for underwriting purposes. What does “collect” include?**

Collect means to request, require, or purchase genetic information.

**Q6: Can a group health plan adjust the premium that an employer or group of similarly situated individuals must pay under the plan based on genetic information of an individual or individuals covered under the group?**

No. 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, as well as other health factors. Therefore, even if a plan obtained individual genetic information about group members before GINA's effective date, it cannot be used to adjust the group premium.

Under GINA and HIPAA, a plan can charge a higher overall, blended per-participant amount based on the manifestation of a disease or a disorder of an individual enrolled in the plan. 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, 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.

For further discussion of what “manifested disease” means, see Q4.

**Q7: Can an individual's doctor or other health care provider request that the individual undergo a genetic test?**

Generally, yes. GINA prohibits a group health plan from requesting or requiring an individual or a family member of an individual undergo genetic tests. Nonetheless, under GINA, a health care professional who is providing health care services to an individual can request that an individual undergo a genetic test. 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.

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.

**Q8: Can a health plan obtain the results of a genetic test to make a determination regarding payment of a claim for benefits under the plan?**

Generally, yes. 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 is permitted to 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.

**Q9: If a plan normally covers mammograms for participants and beneficiaries starting at age 40, but covers them at age 30 for individuals with a high risk of breast cancer, may the plan require that an individual under 40 submit genetic test results or family medical history as evidence of high risk of breast cancer, in order to have a claim for a mammogram paid?**

Generally, yes. Under GINA, a plan may request and use the results of a genetic test to make a determination regarding payment, as long as the plan requests only the minimum amount of information necessary.

Plans may also request genetic information for the purpose of determining the medical appropriateness of a treatment or service. Because the medical appropriateness of the 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.

**Q10: Can a plan request that a participant or beneficiary undergo a genetic test for research purposes?**

Under GINA, a plan is permitted to request, but not to require, that a participant or beneficiary undergo a genetic test for research purposes if the following four requirements are met:

- The plan makes the request pursuant to research. (Research is defined in 45 CFR 46.102(d)). The research must comply with 45 CFR Part 46 or equivalent Federal regulations and any applicable State or local law or regulation for the protection of human subjects in research.
- The plan must make the request for the genetic test in writing and clearly indicate to each participant and beneficiary that the request is voluntary and will have no effect on eligibility.
- No genetic information collected pursuant to this research exception can be used for underwriting purposes.
- The plan must complete a copy of the "Notice of Research Exception under the Genetic Information Nondiscrimination Act" and provide the notice to the address specified in the instructions. You can access this notice at <http://www.dol.gov/ebsa/GINAexceptioninstructions.html>.

**Q11: GINA prohibits a group health plan from collecting genetic information for underwriting purposes. What does underwriting purposes mean?**

Under GINA, the definition of underwriting purposes is broader than merely activities relating to rating and pricing a group policy. Under GINA, underwriting purposes means, with respect to a group health plan:

- Rules for or determination of eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage (including changes in deductibles or other cost-sharing mechanisms 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 differential mechanisms in return for activities such as completing an HRA or participating in a wellness program);
- The application of any preexisting condition exclusion under the plan; and
- Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

**Q12: Can a plan require an individual to complete a health risk assessment (HRA) prior to or as part of the enrollment process for the plan?**

GINA prohibits a plan from collecting genetic information (including family medical history) prior to or in connection with enrollment. Thus, under GINA, plans and issuers must ensure that any HRA conducted prior to or in connection with enrollment does not collect genetic information, including family medical history.

Under GINA, there is an exception for genetic information that is obtained incidental to the collection of other information, if 1) the genetic information that is obtained is not used for underwriting purposes and 2) if it is reasonable to anticipate that the collection will result in the plan receiving health information, the plan explicitly notifies the person providing the information that genetic information should not be provided.

Therefore, a plan conducting an HRA prior to or in connection with enrollment, should ensure that the HRA explicitly states that genetic information should not be provided.

**Q13: Can a plan require that an individual complete a health risk assessment (HRA) that requests family medical history in order to receive a wellness program reward, such as a financial incentive, in return for the completion of the HRA?**

GINA prohibits a plan from collecting genetic information (including family medical history):

1. prior to or in connection with enrollment; or
2. at any time for underwriting purposes.

Because completing the HRA results in a reward, the request is for underwriting purposes and is 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.

A plan may offer a premium discount or other reward for completion of an HRA that does not request family medical history or other genetic information, such as information about any genetic tests the individual has undergone. The plan should ensure that the HRA explicitly states that genetic information should not be provided. This is because GINA provides an exception for genetic information that is obtained incidental to the collection of other information, if 1) the genetic information that is obtained is not used for underwriting purposes and 2) if in connection with any collection it is reasonable to anticipate that health information will be received, the collection explicitly states that genetic information should not be provided.

Plans may use two separate HRAs; one that collects genetic information, such as family medical history, which is conducted after and unrelated to enrollment and is not tied to a reward, and another HRA that does not request genetic information, which can be tied to a reward. In addition, 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 volunteered family medical history information through an HRA.