

COMPLIANCE OVERVIEW

Provided by Clarke & Company Benefits, LLC

GINA FAQs 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.

To assist health plans with GINA compliance, the Department of Labor (DOL) issued frequently asked questions (FAQs) regarding GINA. This Compliance Overview includes select FAQs from the DOL.

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 about their family medical histories.
- A wellness program may request family medical history if it is unrelated to enrollment and there is no reward for providing the information.



How does GINA expand the genetic information nondiscrimination protections in HIPAA?

Before the Affordable Care Act (ACA), HIPAA prevented a plan or issuer from imposing a preexisting condition exclusion based solely on genetic information. Under the ACA, plans are prohibited from excluding coverage or benefits due to any preexisting condition. HIPAA continues to prohibit 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.

<p>Premiums or contributions</p>	<p>GINA provides that group health plans 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.</p>
<p>Genetic testing</p>	<p>GINA generally prohibits plans 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.</p>
<p>Genetic information</p>	<p>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).</p> <p>GINA includes an exception for incidental collection of genetic information, provided that the information is not used for underwriting purposes. However, 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.</p>

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.

Genetic information includes information about an individual's genetic services and tests.

What do these include?

“Genetic services” means 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.

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 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 below.

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.

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 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.

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.

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.

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.

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 GINA](#) and provide the notice to the address specified in the instructions.

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 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 an 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 pre-existing condition exclusion under the plan; and
- Other activities related to the creation, renewal or replacement of a contract of health insurance or health benefits.

Can a plan require an individual to complete an 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:

- The genetic information that is obtained is not used for underwriting purposes; and
- 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.

Can a plan require that an individual complete an 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):

- Prior to or in connection with enrollment; or
- 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 the 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:

- The genetic information that is obtained is not used for underwriting purposes; and

- 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.

Source: U.S. Department of Labor