

GINA: Frequently Asked Questions

Dear Reader:

The following document was created from the MTAS website ([mtas.tennessee.edu](https://www.mtas.tennessee.edu)). This website is maintained daily by MTAS staff and seeks to represent the most current information regarding issues relative to Tennessee municipal government.

We hope this information will be useful to you; reference to it will assist you with many of the questions that will arise in your tenure with municipal government. However, the *Tennessee Code Annotated* and other relevant laws or regulations should always be consulted before any action is taken based upon the contents of this document.

Please feel free to contact us if you have questions or comments regarding this information or any other MTAS website material.

Sincerely,

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(Primary source: <http://www.dol.gov> [1])

Q: 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.

Q: 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.

Q: 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.

Q: 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.

Q: 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.

Q: 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.

Q: 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.

Q: 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) 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 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

1. 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
2. More favorable cost-sharing for preventive services, including genetic screening; and
3. 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.

Q: Is there an exception to GINA for small plans?

No. There is no exception for very small health plans or those less than two participants.

Q: How many employees does an employer have to employ to be covered under GINA?

Employers who have 15 or more employees working for at least 20 or more calendar weeks in the current or preceding calendar year.

Q: Who is considered a covered family member under GINA?

Any person who is within a fourth-degree relation of the individual. The EEOC's proposed regulations further define "family member" as a person who is or becomes related through marriage, birth, adoption, or placement for adoption.

Q: When can an employer, employment agency, labor organization or training program have access to genetic information?

When the information is publicly available or when the information is provided inadvertently as part of the person's medical history or the medical history of a family member. Another possibility is when the person's written authorization is obtained as part of an employer-sponsored genetic monitoring program concerning toxic substances in the workplace. In addition, when the employer offers health or genetic services, including services offered as part of a wellness program which includes the person's written authorization. Lastly, where the employer operates as law enforcement and requires the person's DNA for quality control purposes in the forensic lab or human remains identification settings.

For more information on GINA, visit <http://www.eeoc.gov/laws/types/genetic.cfm> [2].

Links:

[1] <http://www.dol.gov>

[2] <http://www.eeoc.gov/laws/types/genetic.cfm>

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