

A Discussion Guide for Clinicians



Introduction

In May 2008, President George W. Bush signed into law the Genetic Information Nondiscrimination Act (GINA). All aspects of the law were in effect as of November 2009. The regulatory process is ongoing, and we will update this document as necessary.

GINA protects individuals from the misuse of genetic information in health insurance and employment.

GINA was created to remove barriers to the appropriate use of genetic services by the public.

This document provides a basic introduction to GINA for clinicians, as well as guidance for talking about GINA with patients.

An Overview of GINA

GINA does not change, and should not impede, medical practice. It affects health insurers and employers, and research* suggests that the law's protections might ease concerns some patients have when considering genetic testing.

*see, for example:

Hudson KL, Holohan MK, Collins FS. 2008. Keeping pace with the times--the Genetic Information Nondiscrimination Act of 2008. *N Engl J Med* 358(25):2661-3.

Oster E, Dorsey ER, Bausch J, Shinaman A, Kayson E, Oakes D, Shoulson I, Quaid K. 2008. Fear of health insurance loss among individuals at risk for Huntington disease. *Am J Med Genet A* 15;146A(16):2070-7.

Hall MA, McEwen JE, Barton JC, Walker AP, Howe EG, Reiss JA, Power TE, Ellis SD, Tucker DC, Harrison BW, McLaren GD, Ruggiero A, Thomson EJ. 2005. Concerns in a primary care population about genetic discrimination by insurers. *Genet Med* 7(5):311-6.

PROTECTIONS GINA PROVIDES

Under GINA, group and individual health insurers cannot

- use a person's genetic information to set eligibility requirements or establish premium or contribution amounts.
- request or require that a person undergo a genetic test.

Under GINA employers cannot

- use a person's genetic information in decisions about hiring, firing, job assignments, or promotions.
- request, require, or purchase genetic information about an employee or family member.

TYPES OF GENETIC INFORMATION PROTECTED BY GINA

- family medical history
- carrier testing: e.g., cystic fibrosis, sickle cell anemia, spinal muscular atrophy, fragile X and other conditions
- prenatal genetic testing: e.g., amniocentesis, chorionic villus sampling, and other techniques);
- susceptibility and predictive testing: e.g., BRCA testing for risk of breast or ovarian cancer, testing for Huntington disease, or HNPCC testing for risk of colon cancer
- analysis of tumors or other assessments of genes, mutations, or chromosomal changes.

NOTE: Information about sex, age, or common blood tests such as CBC or cholesterol testing is not covered.

GINA DOES NOT PROVIDE PROTECTIONS AGAINST OR APPLY TO

- a condition that is already diagnosed and manifest, even if that condition is genetic.
- life, disability, or long-term-care insurers (as of the date listed on this document).
- information about current health status.
- employers with fewer than 15 employees.
- certain groups of individuals.

Member Groups Exempt from GINA

GINA Does NOT Apply To

- members of the United States military,
- veterans obtaining health care through the Veteran's Administration
- individuals using the Indian Health Service, or
- federal employees enrolled in the Federal Employees Health Benefits program (FEHB).

These groups and programs are not covered because the laws GINA amended do not apply to them. However, the military and veterans' health-care systems have their own policies in place that provide protections similar to those in GINA. Federal employees are likewise protected by Executive Order 13145 (2000). For information about these protections, see **Figure 1** at the end of the guide.

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NOTE: Insurers may still base decisions on the current health status of the patient. A positive genetic test result, in the absence of other signs and symptoms, does not constitute a diagnosed condition under GINA.

CLINICAL IMPLICATIONS

GINA regulates health insurers and employers, not health-care professionals. The law does not require that health-care professionals counsel patients about GINA. Doing so, however, might help your patients feel more comfortable about providing family history information, taking a genetic test, or participating in genetic research.

The law should not keep you from taking a comprehensive family history. It protects patients from having that information misused.

Except in limited circumstances (see the note under genetic testing), health insurers and employers cannot request genetic information (including family history) from patients or from providers when obtaining medical records. Therefore, requests by health insurers and employers for a patient's relevant medical history soon will state: "do not provide genetic information...."

GINA does not directly require health professionals to delete genetic information when providing medical records.

GENETIC TESTING

GINA does not compel health-care providers to order genetic tests they would not have ordered otherwise. GINA does not require health insurance to cover the cost of genetic testing or follow-up care.

NOTE: Insurers may still insist on proof of medical necessity for a test or for treatment. In some circumstances, the medical-necessity justification may include conveying family history or other genetic information. For example, a health insurer may request family history information to assess the necessity of BRCA testing for breast and ovarian cancer.

When to Talk about GINA with a Patient

- If the patient asks or expresses concern about privacy or use of genetic information, including family history information
- If you are proposing genetic testing
- If the patient is requesting genetic testing

Remember: If the patient already has manifest disease, GINA's protections do not apply.

GINA AND HEALTH-CARE REFORM

The new health legislation enacted in March 2010 intersects with GINA in certain ways, as follows:

- Whereas GINA already is in effect, some aspects of the new legislation do not take effect for several years.
- The health insurance legislation seeks to improve coverage for Americans and provides health-insurance coverage to the uninsured, whereas GINA seeks to prevent discriminatory treatment.
- The health insurance legislation will provide access to care to some individuals not helped by GINA, such as those with manifest genetic conditions.

Suggestions for Discussions with Your Patients

GENERAL INFORMATION

There is a law – the Genetic Information Nondiscrimination Act, GINA for short – that protects you from misuse of genetic information in health insurance and employment. Genetic information includes family medical history and the results of genetic tests. I can review other types of genetic information with you, if you wish.

GINA does not affect how we practice medicine. It affects health-insurance practice and it affects employers.

GINA prevents health insurers and employers from using your genetic test results or family history information against you. For example, they cannot use this information to

- set prices or decide whether you get health insurance, or
- make decisions about hiring, firing, job assignments, or promotions.

The law does not mean that health insurers have to pay for genetic services or genetic tests. It protects the information acquired through the use of those services and tests.

GINA tries to keep your information private. There are only limited circumstances where an employer or health insurer can lawfully request or obtain genetic information from me or from this office. But even if they do obtain the information, it is illegal for them to use it against you.

The law is relatively new, and federal regulations about its application are still being developed.

The protections are strong, but we won't know how the law will work in practice for awhile yet.

IF YOUR PATIENT ALREADY HAS A DIAGNOSED GENETIC DISORDER

Under our current health insurance system, health insurers often base their decisions on your current symptoms and diagnoses. GINA does not prohibit insurers from using information about your condition to make decisions about coverage – even if that condition has a genetic basis.

If you share this information with undiagnosed family members, GINA does protect them because your health is part of their family medical history, which is protected under GINA.

GINA AND FAMILY HISTORY

It is important for me to know about any diseases that have occurred in your family members, and it is important to share with me genetic information about your family members.

It is important that you provide complete family history information because that will help me provide the best care I can.

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Your family history information is protected under the new law and cannot be used by health insurers or employers to discriminate against you. [Stop here if genetic testing is not an issue.]

IF GENETIC TESTING IS POSSIBLE OR RECOMMENDED

Some genetic tests can help predict whether a person will develop certain types of conditions.

Sometimes people are worried that information about their risk of developing a disease, or the risk that other family members could develop that disease, will be used against them in some way.

GINA makes it illegal for health insurers to use the results of genetic tests against you. For example, they can't use that genetic information in setting rates or eligibility for health insurance policies. GINA also makes it illegal for employers to use that information against you in hiring, firing, promotion, or other job decisions.

Under our current system, health insurers can base their decisions about eligibility and rates on your actual health status. So, if a person already has a diagnosed disease or condition, a health insurer can use that health information to make decisions about coverage and rates – even if the disease has a genetic basis.

Visit NCHPEG.org for Case Studies of GINA in Clinical Settings

[GINA and family history](#)

[GINA and genetic testing](#)

[GINA, manifest disease, and predisposition](#)

[GINA and Prenatal Issues](#)

Figure 1: Some Health Systems Not Covered by GINA: Federal Employees, U.S. Military, Veterans, and the Indian Health Service

The Genetic Information Nondiscrimination Act does not apply to Federal Employees participating in the Federal Employee Health Benefits program, participants in the United States Military's Tricare program and the Veterans Health Administration, and the Indian Health Service. As a technical matter, this exception exists because GINA amended existing health insurance and employment laws that do not apply to these groups.

Although GINA does not cover these programs, several have their own internal policies that provide protections similar to those in GINA. Of these, FEHB is probably the strongest: this health insurance plan takes all comers, with no underwriting on the basis of genetic information or any information about health status. There is also an executive order that protects federal employees from genetic discrimination on the job. The U.S. Military and Veterans' health systems have internal policies that also work to prohibit denial of medical or other benefits because of genetic information. As a final note, although the Indian Health Service does not appear to permit discriminatory policies related to genetics, the system has limited funding and other issues that may limit access to care regardless of GINA.

Federal Employees

The Office of Personnel Management, which administers the FEHB program, requires all participating insurers and plans to accept all enrollees regardless of health status. More information is available at www.opm.gov/INSURE/HEALTH/INDEX.ASP

Executive Order 13145 prohibits discrimination in federal employment based on genetic information: <http://www.genome.gov/10002084>

US Military and Veterans Health Administration

Both the U.S. Military and the Veterans Health Administration have internal policies providing protections similar to those in GINA. These policies come from three sources:

1. The National Defense Authorization Act of 2008 (NDAA) Public Law 110-181. Title XVI "Wounded Warrior Matters."

[stating that service members may be medically retired with benefits if they have been in the military for more than six months, and if "the disability was not noted at the time of the member's entrance on active duty (unless compelling evidence or medical judgment is such to warrant a finding that the disability existed before the member's entrance on active duty)],

2. Directive-Type Memorandum (DIM) on Implementing Disability-Related Provisions of the National Defense Authorization Act of 2008 (Pub L. 110-181). Available at <http://prhome.defense.gov/> (stating that hereditary or genetic disease shall be evaluated to determine whether compelling evidence or medical judgment establishes that the disability was incurred prior to entry on active duty. However, even if the conclusion is that the disability was incurred prior to entry on active duty, any aggravation of that disease, incurred while the member is entitled to basic pay, beyond that determined to be due to natural progression shall be determined to be service aggravated.); and

3. Veteran's Health Service: US Department of Veterans Affairs, Office of the General Counsel (1990) Vet Aff Op Gen Couns Prec 67-90.

For a discussion of these policies, see Baruch S, Hudson K. 2008. [Civilian and Military Genetics: Nondiscrimination Policy in a Post-GINA World](#). *The American Journal of Human Genetics* 83: 435-444.

Indian Health Service

Although the Indian Health Service is tasked with fulfilling the treaty obligation for health care for American Indians and Native Alaskans, and does so regardless of health status, funding shortfalls often result in significant limitations on care, meaning that services are technically available but impossible to access in practice. Information about the Indian Health Service may be found at <http://www.ihs.gov/>