



# Part IV of IV: Precision Medicine and Pharmacogenomics

Ethical considerations, issues of privacy and  
the Genetic Information Nondiscrimination Act

March 2018

Author



**Mark Holloway**

Senior Vice President  
Director of Compliance Services  
Lockton Benefit Group  
913.960.9567  
mholloway@lockton.com

Access to new information, especially as it relates to medical treatment and healthcare, ushers in new questions about patient privacy, the ethics of having such information and legal considerations that must be addressed.

It's becoming more common for employers to want to offer genetic testing to employees, and some employers may desire to use that access or information for other purposes. Because genetic testing may result in an employee having to confront sensitive issues or even concerns about discrimination, employers need to carefully navigate the legal issues that arise when genetic information might be available.



# Understanding GINA

---

A federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA)<sup>1</sup>, prohibits employers, health insurers and health plans from discriminating based on an individual's genetic makeup. Many states have passed laws protecting an individual's genetic information. GINA does not supersede existing state laws that provide even greater protections.

Among other prohibitions, GINA prevents employers, health plans and health insurers from requiring an individual or family member to undergo a genetic test. Genetic information, in relation to employer health plans, is also considered health information protected by the Health Insurance Portability and Accountability Act (HIPAA) privacy and data security regulations.

GINA's regulations apply to health insurers and health plans under Title I as well as regulations that apply to employers under Title II. GINA's Title I prohibitions are enforced by the IRS, the Department of Labor and the Department of Health and Human Services. Under Title I regulations, there are three things health plans and health insurers generally may not do<sup>4</sup>:

- Adjust premiums or contributions based on genetic information.
- Collect genetic information for underwriting prior to or in connection with enrollment.
- Require an individual or family member to undergo a genetic test.

## What is genetic information?

Under GINA, genetic information includes family medical history and information about an individual's "genetic tests." Genetic tests include any analysis of human DNA, RNA, chromosomes, proteins or metabolites when that analysis detects genotypes, mutations or chromosomal changes.<sup>2</sup>

## What is not considered genetic information?

Information about the manifested disease or disorder of the enrollee himself or information related to the age or sex of an individual is not considered genetic information.<sup>3</sup> Similarly, and of significance for typical biometric screenings offered by a health plan, the regulations exempt tests directly related to a manifested disease or condition.

Thus, tests for HIV, complete blood count, tests for liver function or for the presence of alcohol or drugs are not genetic tests and, therefore, are not genetic information. Presumably, tests to detect an existing disease or condition would fall in this same category. For example, a prostate-specific antigen (PSA) test and similar tests serve such a function.

## Considerations for employers offering genetic testing

To comply with GINA's Title I provisions, if an employer desires to offer its employees the opportunity for voluntary genetic testing, it is prudent to offer testing outside the plan's annual open enrollment period or, with respect to new hires, after initial enrollment. Notwithstanding, employers are permitted to offer incentives to employees on a voluntary basis to engage in medical testing.

What if the employer conducts a health risk assessment unrelated to a health plan and, in the process, requests and collects genetic information?

Title II of GINA prohibits use of genetic information in the employment context, including in the context of job applicants. The law also restricts the deliberate acquisition of genetic information by employers and strictly limits employers from disclosing genetic information.<sup>5</sup> Title II is enforced by the Equal Employment Opportunity Commission (EEOC).



Importantly, Title II includes a broad exception, allowing employers to collect genetic information where “health or genetic services are offered by the employer, including such services offered as part of a wellness program,” provided the employer satisfies other conditions noted below.<sup>6</sup>

How does this broad exception gel with the broad prohibitions in Title I? Additional guidance from the EEOC will be welcome. Until then, Lockton Compliance Services believes the safe play is to treat the program as subject to Title I's prohibitions if the wellness program is:

- A health plan because it supplies medical benefits such as a doctor's care, medical testing or prescription drugs, or
- Part of a health plan (many employers consider their wellness programs to be part of a health plan), or
- Offered in conjunction with a health plan, so the reward for participation in the program is health-plan related, such as a premium discount or deductible waiver, etc.

On the other hand, if the employer offers a wellness program that is not a health plan, part of a health plan or related to a health plan, which may be difficult to accomplish if medical testing is involved, then an employer may offer voluntary genetic testing, provided the employer meets other specific requirements. The following are required under GINA<sup>7</sup>:

- The employee must provide prior, knowing, voluntary and written authorization for the employer's collection of genetic information.
- Only the employee (or family member if the family member is receiving genetic services) and the licensed healthcare professional or board-certified genetic counselor involved in providing such services may receive individually identifiable information concerning the results of such genetic services.
- Any individually identifiable genetic information provided in connection with the genetic services must be available only for purposes of such services and cannot be disclosed to the employer except in aggregate terms that do not disclose the identity of specific employees.

It would be wise for an employer to review any additional state law requirements in those states where it has employees. Other requirements relating to genetic testing could be imposed under some state laws.

### Best practices for employers who offer voluntary genetic testing

- Ensure the employer does not have any access to the results of genetic tests. The vendor agreement should stipulate its "firewall" is in place.
- Choose only a best-in-class vendor who is well versed in privacy laws at both federal and state levels. Ask for evidence the vendor conducts periodic HIPAA training and has protocols in place for protecting the confidentiality of the information.
- Negotiate indemnification from the vendor in the event of a security breach.



## Ethical issues with genetic testing

---

Huntington's disease is a hereditary neurological disorder. While there is still no cure for Huntington's disease, there is a genetic test that will confirm a diagnosis, identifying that the person will eventually show symptoms of the disease. A person at risk for Huntington's faces a difficult decision whether to be tested for the disease.

This is one of the many ethical issues with genetic testing. Individuals considering genetic testing need to be aware of possible ethical concerns, which may include:

- Whether to terminate a pregnancy: Would the possibility that an unborn child has a genetic disease, such as cystic fibrosis, be reason to terminate a pregnancy? Some individuals say no for religious reasons. For others, the answer may depend on the certainty of the medical test. What if the test can accurately predict the outcome only 50 percent of the time? Or what if the test could not predict the severity of the disease? And for still other individuals, the decision may be a matter of personal ethics.
- Difficult issues related to paternity and adoption: Genetic tests will reveal who is or is not a child's natural parent(s). Consequently, individuals who are blissfully ignorant of their birth parent(s) may face distressing issues with family members who purport to be blood relatives.
- Possibility for early interventions: Women who carry the BRCA mutation are at risk for breast and ovarian cancer. Does the elevated risk of breast cancer (roughly 25 to 85 percent chance of getting the disease) warrant a mastectomy as a preventive measure?<sup>8</sup>

## Conclusion

---

In addition to complying with disclosures under GINA and any applicable state laws, it might also be prudent for employers to encourage employees to engage in genetic counseling prior to undergoing any such testing. Genetic testing could raise difficult ethical issues or other concerns for employees that counseling could help address.<sup>9</sup>

---

<sup>1</sup>Pub. L. No. 110-233 at <https://www.gpo.gov/fdsys/pkg/STATUTE-122/pdf/STATUTE-122-Pg881.pdf>

<sup>2</sup>ERISA Section 733(d)(7)

<sup>3</sup>DOL Reg. §2590.702-1(a)(3)(ii)

<sup>4</sup>ERISA Section 702

<sup>5</sup>42 USC 2000ff-1

<sup>6</sup>42 USC 2000ff-2

<sup>7</sup>42 USC 2000ff-1(b)(2)

<sup>8</sup><https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2996153>

<sup>9</sup><https://www.marchofdimes.org/pregnancy/genetic-counseling.aspx>



**LOCKTON®**

- 
- RISK MANAGEMENT
  - EMPLOYEE BENEFITS
  - RETIREMENT SERVICES



[LOCKTON.COM](http://LOCKTON.COM)