Law and the Public's Health

HEALTH INSURANCE AND THE GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008: IMPLICATIONS FOR PUBLIC HEALTH POLICY AND PRACTICE

PERRY W. PAYNE, JR, MD, JD, MPP
MELISSA M. GOLDSTEIN, JD
HANI JARAWAN, BS, MD CANDIDATE
SARA ROSENBAUM, JD

This installment of *Law and the Public's Health* reports on the Genetic Information Nondiscrimination Act of 2008 (GINA),¹ signed into law by President Bush on May 21, 2008. The goal of GINA is to prevent genetic discrimination in health insurance and employment. Following an overview of the legislation's provisions, this article describes GINA's implications for public health policy and practice in the realm of health insurance.

BACKGROUND

Regulation of insurance and employee health benefit plans, in general

Most Americans derive their health insurance coverage through plans sponsored by employers, either public or private. States have the power to regulate the conduct of state-licensed health insurers. However, under the Employee Retirement Income Security Act of 1974 (ERISA),² state insurance regulations do not apply to self-insured employee health benefit plans. In addition, states vary significantly in the extent to which they regulate insurer practices in both the individual and group markets, with many states providing limited or no protection against genetic discrimination under state-regulated products.

An overview of GINA

GINA, whose health insurance provisions become effective on May 21, 2009 (one year after the date of enactment),³ was enacted following a 13-year debate spanning seven Congresses "to prohibit discrimination on the basis of genetic information with respect to health insurance and employment."¹ To this end, GINA amends numerous existing laws that relate to health insurance and coverage under employee health benefit plans, including ERISA, the Public Health Service Act

(PHSA), the Internal Revenue Code of 1986, the Social Security Act, and the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Like other comprehensive federal insurance reforms, GINA is jointly administered by the U.S. Departments of Health and Human Services, Treasury, and Labor.

Scope of the law. As with regulatory legislation generally, the heart of GINA lies in the definitions that govern its scope. The definition of *genetic information* is central to understanding what GINA protects. Under the law, the term encompasses not only information derived from a plan participant or beneficiary, but also any information about a family member regardless of whether the plan covers the family member. The protections reach an individual's genetic tests, a family member's genetic tests, or any evidence related to the actual manifestation of a disease or disorder in a family member.⁴ The last requirement refers to an individual's family medical history, which is often used as a proxy for understanding (or predicting) the person's own genetic predisposition to certain diseases.

The term *family member* is defined as a dependent, or any first-, second-, third-, or fourth-degree relative of an individual. As a result, the Act's protections extend beyond immediate family members.⁴ In addition, because genetic traits can affect the course of any disease to some extent, the classes of disorders that fall within GINA's protections are not limited to hereditary medical conditions. The definition excludes sex and age as part of the definition of genetic information.⁴

The term *genetic testing* is not limited to deoxyribonucleic acid (DNA) testing but is broadly defined to include "analysis of human DNA, [ribonucleic acid] RNA, chromosomes, proteins, or metabolites that detect genotypes, mutations, or chromosomal changes."⁴ However, despite its apparent inclusion of regularly performed laboratory tests, GINA excludes analysis of proteins or metabolites that "do not detect genotypes, mutations, or chromosomal changes" or analysis that "is directly related to a manifested disease" that could be reasonably detected by a health-care professional.⁴ Finally, *genetic services* are defined as a genetic test, genetic counseling, or genetic education.

GINA's protections. HIPAA provides certain protections against insurance discrimination. GINA essentially extends and broadens these protections, reaching both the group and individual markets as well as the Medicare supplemental (Medigap) market.⁵ GINA

prohibits discrimination with respect to both access to and cost of coverage. At the same time, the law does not reach the content of coverage itself. GINA does not apply to Medicare or Medicaid because both programs bar the use of genetic information as a condition of eligibility.

As with prior antidiscrimination laws, GINA reaches both state-regulated insurance and self-insured employee health benefit plans, revising both ERISA (which governs all private employee health benefit plans) and the PHSA (which applies to state-regulated insurance products). Under prior law, insurers were prohibited from using genetic information in determining an individual's eligibility or setting premiums for the individual while premiums for the rest of the group stayed the same.⁶ GINA revises ERISA to prohibit group health plans and health insurance issuers "offering group health insurance coverage in connection with a group health plan [from adjusting] premium or contribution amounts for the group covered under such plan on the basis of genetic information," thereby broadening prior protections to encompass the entire coverage group.⁷

GINA prohibits group health plans from requesting or requiring an individual or a family member of that individual to undergo a genetic test as a condition of enrollment.⁸ Further, the law prevents group health plans from requesting, requiring, or purchasing genetic information for underwriting purposes or with respect to any individual prior to such individual's enrollment under the plan or coverage in connection with such enrollment. Indeed, the collection of the information itself is a violation of GINA, without any evidence of discrimination.⁸ These protections extend to genetic information of a fetus carried by a pregnant woman (or pregnant family member) and to that of embryos legally held by an individual or family member utilizing assisted reproductive technology.⁹

The law does contain limitations and exceptions. GINA does not prohibit medical underwriting based on current health status, nor does it mandate coverage for any particular medical tests or treatments. In essence, GINA protects people whose tests show a genetic susceptibility to disease but not those in whom a genetic illness has been diagnosed. Insurers also remain free to create benefit design limits that exclude coverage of certain conditions that have genetic origins or complications.

Nor does the law bar treating health professionals from requesting that patients undergo a genetic test; furthermore, under certain circumstances, health insurers can request, but not require, that an individual have a genetic test performed for the purposes of research.⁸ Although "research" is not well defined in

the Act, several conditions must apply for an insurer to request that a participant or beneficiary undergo a genetic test for the purposes of research, including but not limited to compliance with state/federal laws regulating human subjects research and informing individuals that compliance is voluntary and will not affect their enrollment status or premiums.⁸ Also, health insurers can obtain and use genetic test results when making a determination regarding payment, as long as they use the "minimum amount of information necessary to accomplish the intended purpose."⁸ While "minimum amount of information necessary" is not defined by the Act, GINA specifically references HIPAA when discussing how the definition is to be approached.⁸ The law classifies the "incidental" acquisition of information by an insurer or group health plan as a nonviolation.⁸

Whereas HIPAA's previous restrictions on the use of genetic information did not apply to the individual insurance market, GINA extends its protections to individual coverage as well. The law specifically prohibits individual insurers from using genetic information for eligibility, premium adjustment or contribution, or preexisting condition exclusion purposes.¹⁰ As with group plans, the law does not prohibit medical underwriting based on current health status or mandate coverage for any particular medical tests or treatments. As noted, GINA applies in the same manner to Medicare supplemental policies¹¹ and to nonfederal government employee health benefit plans, which are exempt from ERISA.¹²

GINA also adds privacy protections by requiring amendments to the HIPAA Privacy Rule that would specifically classify genetic information as protected health information and prohibit covered entities from disclosing genetic information for underwriting purposes.¹³

Enforcement. GINA authorizes the Secretary of Labor (in the case of ERISA-governed plans) and the Secretary of Health and Human Services (in the case of other group and individual insurers) to impose modest penalties for failure to meet the requirements of the Act. The law's enforcement mechanisms focus on incentivizing compliance and thus provide for a waiver or limitation of penalties if a violation (1) was not discovered after exercising reasonable diligence, or (2) did not result from willful neglect. In both cases, the Secretary may determine whether waiver or limitation of penalty is appropriate to the extent that the penalty would be excessive relative to the violation involved.^{10,14,15} In the case of non-ERISA plans, the law creates federal fallback authority that provides for federal enforcement in the absence of state action.^{10,15}

IMPLICATIONS FOR PUBLIC HEALTH POLICY AND PRACTICE

GINA has important implications for public health policy and practice. By augmenting the meaning of genetic nondiscrimination to include a significant federal floor of protection for genetic information, the law may encourage greater use of genetic information in health promotion as well as diagnosis and treatment. As with HIPAA's other patient protections, GINA does not preempt more stringent state laws, thereby leaving untouched state laws that may protect other aspects of discrimination, such as prohibitions against discrimination in coverage itself.

The national standard created by GINA may decrease fears associated with genetic testing and encourage the proliferation of genetic testing that is beneficial to the public health. A central purpose of GINA that emerged over the 13-year debate that preceded enactment has been the need to allay consumers' fears about genetic testing.¹⁶⁻¹⁸ Consumers considering participation in genetic research or seeking genetic tests for personal health concerns have expressed fear about insurer misuse of information;^{16,19,20} passage of GINA hopefully may begin to allay these fears. In effect, GINA represents a clear statement of policy regarding the importance of balancing the benefits of a technology that is of great social value but nonetheless deserving of national standards to guard against discrimination.¹⁷

Reconciling GINA with more stringent state laws will prove to be challenging in its own right. One recent study that examined more than 500 HIPAA preemption cases involving the meaning of more stringent state health information privacy laws found widespread litigation and confusion over how such a standard should be applied.²¹ While GINA sets a baseline standard of protection, the law does not preempt state or federal laws that offer more protection than GINA. (Notably, while the law makes an explicit statement regarding preemption with regard to employment, it does not do so with regard to health insurance.) Numerous states have passed genetic nondiscrimination laws, some of which may offer more protection for genetic information than GINA. But as with HIPAA, the extent to which laws in fact offer greater safeguards may not be known definitively in the absence of a judicial challenge. Furthermore, a preemption statute that creates a floor does not address industry's objection to the lack of national uniformity in insurance standards.²² As a result, group health plans and multistate health insurers will need to continue a careful focus on underlying state laws.

In addition, GINA does not apply to benefits not defined as health insurance, such as long-term care,

disability, and life insurance. As scholars have noted, lawmakers eliminated these products early in the legislative process to find areas of consensus.¹⁶ These important limitations may leave individuals without essential antidiscrimination protections; even if they reside in states that apply nondiscrimination rules to all state-licensed insurance products, state protections do not apply to benefits offered by self-insured employer plans governed by ERISA.²³ Thus, even in GINA's wake, insurers will be able to use genetic testing information related to chronic diseases such as Alzheimer's disease^{24,25} to determine eligibility for life, long-term care, or disability insurance.

An additional concern focuses on GINA's potential to actually decrease utilization of genetic tests, as a result of coverage rollbacks by health insurers (in the form of exclusions or higher cost sharing), who both fear the legal liability created by possessing such information (through claims payment) and simultaneously see less business utility of coverage because of new limits on their use of such information. While such a concern is highly speculative, changes in coverage and payment policies in GINA's wake merit careful monitoring. This concern is reflected in a recent online statement by industry lawyers, who suggested that group health plans and insurers should "consider updating their practices to limit their collection of genetic information and thereby decrease potential exposure to genetic discrimination claims."²⁶

The law also creates specific challenges for the public health community, the first of which is simply informing the public of the rights it secures. GINA was passed at a time when Americans are focused on other issues and, like so many other insurance laws, is complex and difficult to interpret into consumer-friendly information. The law concerns a testing market that remains quite limited other than perhaps pregnancy and newborn-related genetic testing. However, as the use of genetic testing grows, it is expected that the importance of GINA will grow, along with the need for translational public health communication activities.

A final challenge will be determining how to judge the success of GINA. Successful outcomes may include an increase in the use of genetic tests deemed important to health and health care, as well as sustained coverage standards and low levels of noncompliance. A confounding fact, however, is the continuing debate over the social and medical utility value of more genetic testing without concomitant treatment programs to accompany diagnoses and an unwillingness to expand coverage without greater evidence of efficacy.

Unlike genetic screenings of the human body, no tests exist to predict the potential results of new laws.

However, with ongoing monitoring by the public health community and appropriate responses from state governments, group health plans, and health insurers, GINA may offer an important initial step in protecting Americans from genetic discrimination. While the law is not an end in and of itself, it should be viewed as an entry point into an era in which genetic information is an integral aspect of a highly functional, patient-centered health-care system.

Perry W. Payne, Jr., is an Assistant Research Professor, Melissa M Goldstein is an Associate Research Professor, and Sara Rosenbaum is the Hirsh Professor and Chair, all in the Department of Health Policy at The George Washington University Medical Center, School of Public Health and Health Services in Washington, D.C. Hani Jarawan is an MD candidate at The George Washington University. Dr. Payne has received research support from the National Heart Lung and Blood Institute, National Institutes of Health, Grant No. K12 HL090020-01.

Address correspondence to: Perry W. Payne, Jr., MD, JD, MPP, Department of Health Policy, The George Washington University Medical Center, School of Public Health and Health Services, 2021 K St. NW, Ste. 800, Washington, DC 20006; tel. 202-467-2251; fax 202-296-0025; e-mail <Perry.Payne@gwumc.edu>.

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