

## ***HEALTH LAW ALERT***

***October 7, 2009***

### **Genetic Information Insurance Rules Published Rules Affect Underwriting Practices, Health Risk Assessments, Disease Management and Wellness Programs**

Today, three Federal agencies published interim final rules implementing the Genetic Information Nondiscrimination Act (GINA), which Congress passed in May 2008 “to prohibit discrimination on the basis of genetic information with respect to health insurance and employment.” The rules, which implement only the insurance-related provisions of GINA Title I, clarify that insurers and group health plans are prohibited from collecting “genetic information” prior to enrollment or for “underwriting purposes” and from using such information in setting premiums.

The rules prohibit common practices such as providing rewards to individuals for filling out Health Risk Assessments that contain questions about the health history of family members. The rules are likely to affect insurers’ underwriting practices (particularly in the individual market), including rating methodologies, enrollment applications, and pre-enrollment collection of information from health care providers. The agencies also indicate that the rules may affect wellness programs, disease management programs, and, in some cases, information collected during (or prior to) mergers and acquisitions.

The Departments of Treasury, Labor, and Health and Human Services jointly published the rules at 74 Federal Register 51664 (Oct. 7, 2009).<sup>1</sup> Interested parties may submit comments on the interim final rules by January 5, 2010. The rules go into effect for group plan years beginning on or after December 7, 2009 and for individual policies “offered, sold, issued, renewed, in effect, or operated” on or after December 7, 2009.

The HHS Office for Civil Rights separately published a proposal to implement changes to the HIPAA Privacy Rule that GINA requires. [Click here](#) for a Health Law Alert on these proposed rules (look under “Health Law Alerts”). [Click here](#) for a compiled version of selected nondiscrimination and wellness rules, published by the Department of Health and Human Services (HHS), including HHS’s new GINA interim final rule.

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<sup>1</sup> When effective, the Departments of Treasury’s and Labor’s rules will be in 26 C.F.R. Part 54, and 29 C.F.R. Part 2590, respectively. The Department of Health and Human Services’ rules, which apply to health insurers and group health plans, will be in 45 C.F.R. Parts 144, 146, and 148. The agencies plan to “address in future regulatory guidance” the additional enforcement authority that GINA confers on them.

## The Genetic Information Nondiscrimination Act

Title I of GINA prohibits health insurers, group health plans, and issuers of Medicare Supplement (Medigap) insurance from (a) using genetic information in determining the amount of premium that groups or individuals pay, (b) requesting (or requiring) individuals to undergo genetic tests, and (c) requesting (or purchasing) genetic information prior to enrollment or for underwriting purposes.

Under the statute and the interim final rules, genetic information includes information about “the manifestation of a disease or disorder in family members of [an] individual,” in addition to information from genetic tests. Thus, information commonly requested in Health Risk Assessments, enrollment applications, and disease management screening programs about the medical history of an individual’s parents (or other family members) qualifies as “genetic information” subject to the GINA rules. This means that any collection of information about family health history, such as family history of high blood pressure, diabetes, or cancer, will need to be scrutinized under the GINA rules.

The rules clarify that an individual’s genetic information does *not* include information about the individual’s own manifestation of a disease or disorder. Accordingly, high blood pressure diagnosed in an individual’s parent qualifies as genetic information about the individual, but high blood pressure diagnosed in the individual him/herself is not genetic information.

### Prohibition on Collecting Genetic Information

**For Underwriting Purposes.** Under GINA, insurers and group health plans are prohibited from collecting genetic information for “underwriting purposes.”<sup>2</sup> The agencies instruct that the “definition of underwriting is broader than merely activities relating to rating and pricing a . . . policy.” The statute broadly defines the “underwriting purposes” for which genetic information cannot be collected to include an insurer’s or group health plan’s (a) rules concerning eligibility for benefits and (b) processes for determining eligibility for benefits. Thus, the agencies explain, “underwriting purposes” include “providing discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment (HRA) or participating in a wellness program.”

The GINA rules therefore prohibit insurers and group health plans from collecting genetic information, for example:

- To establish premium rates (for group or individual coverage) or to determine the appropriateness of imposing a pre-existing condition exclusion on an

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<sup>2</sup> Although these insurance rules do not prohibit the *use* of genetic information for all underwriting purposes, GINA requires and the HHS Office for Civil Rights has proposed changes to the HIPAA Privacy Rule that prohibit health plans from using and disclosing genetic information for all underwriting purposes.

individual policyholder—activities traditionally considered to be “underwriting purposes.”

- In a Health Risk Assessment, if an individual receives a reward or benefit in return for completing the assessment, “regardless of the amount of the reward.” The requirement that the individual complete the assessment in return for the reward is a rule concerning eligibility for benefits that the GINA rules deem to be conducted for an “underwriting purpose.” Accordingly, genetic information—including family health history—cannot be collected under the circumstances.
- To proactively screen enrollees for disease management or wellness program eligibility. Health plan enrollees who participate in disease management or wellness programs receive benefits that other enrollees do not. Determining whether enrollees qualify for those benefits is an “underwriting purpose” for which collection of genetic information is prohibited.

The rules provide an exception to this prohibition on collection of genetic information that allows an insurer or group health plan to collect the genetic information necessary to demonstrate that a benefit is medically appropriate. Hence, an insurer that conditions a benefit on medical appropriateness is allowed to require an enrollee to provide the genetic information necessary<sup>3</sup> to demonstrate the benefit is appropriate under the circumstances. For example, the agencies suggest that an insurer could require genetic information as a condition for covering a cancer drug that (according to scientific research) is not effective for individuals with a particular genetic make-up.

This exception only applies when an enrollee “seeks a benefit.” Accordingly, while an insurer or group health plan cannot collect genetic information to “target” enrollees for participation in disease management or wellness programs, once an enrollee seeks—requests—to participate in a program, the insurer or group health plan may use genetic information as necessary to determine whether the enrollee is eligible.

**Prior to or in Connection with Enrollment.** Insurers and group health plans “must not collect genetic information with respect to any individual prior to that individual’s effective date of coverage . . . nor in connection with the rules for eligibility [including eligibility for benefits] that apply to that individual.” This broad prohibition applies even to genetic information that an insurer or group health plan might receive, despite not requesting it—such as family history embedded in medical records provided by a doctor. The GINA rules do permit this type of “incidental” collection of genetic information, however, provided that an insurer or group health plan “explicitly states that genetic information should not be provided” in response to its request for health (or other) information. Thus, to ensure compliance with the GINA rules, an insurer or group health

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<sup>3</sup> The insurer must comply with the HIPAA Privacy Rule’s minimum necessary limitation when requesting the genetic information under this medical appropriateness exception.

plan must specify that genetic information should *not* be included in response to any request for information. An insurer therefore violates the GINA rules even by inadvertently collecting genetic information:

- On an application for enrollment, unless the application specifically instructs the applicant to avoid providing genetic information;
- From a health care provider prior to an individual's enrollment, unless the insurer's request for information from the health care provider explicitly asks the provider not to provide genetic information;
- In the acquisition of another company, if any of the genetic information is to be used in connection with eligibility for coverage or benefits and the information is requested without explicitly excluding genetic information.

Although the GINA rules prohibit collection of genetic information prior to enrollment, there are circumstances in which an insurer or group health plan may collect genetic information about an individual after enrollment. For example, an insurer may collect a Health Risk Assessment containing genetic information from a current enrollee, provided that no reward, benefit, or program enrollment is contingent upon completing the assessment. The agencies clarify that this type of legal genetic information collection does not violate the GINA prohibition on collection of genetic information prior to enrollment when the enrollee later re-enrolls for coverage (*e.g.*, at an annual open-enrollment period). The insurer must, however, refrain from using the genetic information it legally collected in considering the re-enrollment.

### **Use of Genetic Information for Premium Rating**

Group health plans and insurers are prohibited from using genetic information as a factor in determining group premiums or contributions. Insurers in the individual market are likewise prohibited from using genetic information in determining individual rates. Although HIPAA Title I has long prohibited the use of genetic information to discriminate against individuals within a group, this provision of GINA “is a change from prior law” that specifically prohibits the use of genetic information in establishing rates, “even when a [group health] plan or [health insurance] issuer has lawfully obtained genetic test results or other genetic information.” Hence, genetic information, including health history of family members not covered by a policy, cannot affect premium paid for a group or individual policy.

### **Impact on Health Insurers**

HHS explains that the GINA rules will require insurers, especially those in the individual market, “to review their applications and underwriting policies and procedures to ensure that genetic information is not collected or used for underwriting purposes [and] to train underwriters to avoid using genetic information in underwriting.” This review needs to

include an evaluation of applications for coverage, the process by which the insurer collects information from health care providers during the underwriting process, and any other pre-enrollment data collection processes. Insurers and group health plans that offer Health Risk Assessments, wellness programs, and disease management programs will also need to review applicable policies and procedures to ensure that genetic information is only collected and used as permitted by the GINA rules. Moreover, entities involved in insurer or group health plan mergers or acquisitions need to consider how the GINA rules affect data requests that might yield genetic information.

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