Health Plans Subject to New Regulations under GINA

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In 2008, the Genetic Information Nondiscrimination Act (GINA) was enacted. The purpose of the legislation was to prevent both employers and health plans from discriminating against individuals with regard to health coverage and terms of employment based on genetic information. There are two titles to the legislation:

1. Title I, which applies to group health plans and health insurance issuers, amended the Employee Retirement Income Security Act (ERISA), Public Health Service Act, Internal Revenue Code, and Social Security Act to prohibit any discrimination in health coverage based on genetic information.
2. Title II, which applies to employers, prohibits discrimination against employees or applicants based on genetic information in hiring or any other terms, conditions, or privileges of employment.

The regulations under Title I were published in the *Federal Register* October 7, 2009,[1] to take effect in the group market the first day of the plan year beginning on or after December 7, 2009. Title II of GINA, applicable to employers, took effect November 21, 2009, but regulations have not yet been issued by the Equal Employment Opportunity Commission, so employers must comply as best they can in good faith. The remainder of this article will focus on the regulations that have been issued under Title I.

As a general matter, Title I of GINA prohibits health plans and insurers from basing premiums on genetic information, requiring that a plan participant take a genetic test, or asking for any "genetic information" as part of enrollment under the plan or at any time for purposes of "underwriting."

The definition of "genetic information" is important to understand in analyzing these regulations. Genetic information is defined in the regulations as "information about the individual's genetic tests or the genetic tests of family members, the manifestation of a disease or disorder in family members of such individual (that is, family medical history), or any request of or receipt by the individual or family members of genetic services." While it is likely that many if not most participants have not undergone genetic tests, the inclusion of family medical history as genetic information will have a significant impact on plan operations since underwriting as well as wellness programs have often relied on such information.

The meaning of "genetic test" is actually quite narrow. It includes a test only if it detects genotypes, mutations, or chromosomal changes. On the other hand, it excludes tests such as HIV test, complete blood count, cholesterol test, liver function test, or test for the presence of alcohol or drugs.

While generally a healthcare plan or issuer cannot require that individuals undergo genetic tests, there are three exceptions that are applicable to healthcare professionals, when payment is sought, or when research is involved. Under the first exception, a healthcare professional who is providing healthcare services to an individual can request that an individual undergo a genetic test. The second exception permits a plan or issuer to obtain and use the result of a genetic test for purposes of payment. As stated in the regulations:

> *In some cases, the appropriateness of certain courses of treatment for a patient depends on the patient's genetic makeup. A plan or issuer is permitted to condition payment for an item or service based on medical appropriateness that depends on an individual's genetic makeup. Under these narrow circumstances, a plan or issuer may condition payment on the outcome of a genetic test, and may refuse payment for the item or service if the individual does not undergo the genetic test.*

Under the third exception, a group health plan or issuer is permitted to request but not require a genetic test for purposes of research that complies with 45 CFR Part 46 (protection of human subjects in research).

As mentioned above, genetic information cannot be used for purposes of underwriting. While traditionally underwriting has meant the process under which an insurer decides how much of a premium to charge for the risk it

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is undertaking, the GINA regulations provide for a much broader definition:

> *Underwriting purposes means, with respect to any group health plan, or health insurance coverage offered in connection with a group health plan—(A) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage as described in § 54.9802–1(b)(1)(ii) (including changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program); (B) The computation of premium or contribution amounts under the plan or coverage (including discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program).*

These regulations, especially with this expansive definition of "underwriting," have a profound impact on wellness programs. Very frequently, wellness programs provide an incentive for a plan participant to complete a health risk assessment, which asks for family health history so wellness activities can be focused on known risks of the participant. The regulations make it clear such incentives can no longer be offered as before.

The regulations do provide two alternative approaches as far as wellness programs are concerned. A wellness program can request family health information as long as it is not prior to enrollment and as long as there is no incentive to provide it. In the other alternative, a health risk assessment program can be broken down into two portions: one of which does not request family health history, which can utilize an incentive; and the second part requests family health history, which is totally voluntary with no incentive to participate. However, in determining what constitutes an incentive, not only are financial rewards such as premium reductions included but so are additional medical services even if such additional services are geared to conditions disclosed by the family health information. Here are three examples from the regulations:

> *Example 1. (i) Facts. A group health plan provides a premium reduction to enrollees who complete a health risk assessment. The health risk assessment is requested to be completed after enrollment. Whether or not it is completed or what responses are given on it has no effect on an individual's enrollment status, or on the enrollment status of members of the individual's family. The health risk assessment includes questions about the individual's family medical history.*
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> *(ii) Conclusion. In this Example 1, the health risk assessment includes a request for genetic information (that is, the individual's family medical history). Because completing the health risk assessment results in a premium reduction, the request for genetic information is for underwriting purposes. Consequently, the request violates the prohibition on the collection of genetic information in paragraph (d)(1) of this section.*
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> *Example 2. (i) Facts. The same facts as Example 1, except there is no premium reduction or any other reward for completing the health risk assessment.*
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> *(ii) Conclusion. In this Example 2, the request is not for underwriting purposes, nor is it prior to or in connection with enrollment. Therefore, it does not violate the prohibition on the collection of genetic information in this paragraph (d).*
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> *Example 4. (i) Facts. The facts are the same as in Example 1, except there is no premium reduction or any other reward given for completion of the health risk assessment. However, certain people completing the health risk assessment may become eligible for additional benefits under the plan by being enrolled in a disease management program based on their answers to questions about family medical history. Other people may become eligible for the disease management program based solely on their answers to questions about their individual medical history.*
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> *(ii) Conclusion. In this Example 4, the request for information about an individual's family medical history could result in the individual being eligible for benefits for which the individual would not otherwise be eligible. Therefore, the questions about family medical history on the health risk assessment are a request for genetic information for underwriting purposes and are prohibited under this paragraph (d). Although the plan conditions eligibility for the disease management program based on determinations of medical appropriateness, the exception for determinations of medical appropriateness does not apply because the individual is not seeking benefits.*

What is of particular concern in these regulations is the fact that they make it much more difficult to obtain family health information since there can be no reward for providing such information as part of a health risk assessment. Even more worrisome is the fact that the regulations view as a prohibited incentive the provision of additional services under a wellness program related to conditions disclosed by family health information. Interestingly enough, another example of a disease management program in the regulations appears to indicate it is acceptable to announce that a disease management program exists (the example involving a diabetes management program) and require that the participant show that he or she is at genetic risk of suffering from the disease if he or she is not currently diagnosed with it.

Since these regulations were issued as interim final regulations (meaning they must be complied with but are subject to revision), it is hoped that incentives relating to health risk assessments and disease management programs will be reexamined so that plan benefits can be provided at the earliest appropriate time for those participants for whom the services will be of the greatest benefit. Wellness programs need to be encouraged and broadened, and it is hoped the GINA regulations will be modified to reflect that objective. ■

The above discussion is intended to briefly summarize certain recent legal developments in employee benefits, but is not intended to be legal advice and must not be relied upon as such. All readers are urged to raise any concerns they may have based on matters discussed in this column with experienced benefits legal counsel.

REFERENCE

1. Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance Coverage and Group Health Plans. *Federal Register.* October 7, 2009; 74(193): 51664-51697.