



Regulations on Genetic Information Nondiscrimination Affect Use of Health Risk Assessments, Other Programs

The Genetic Information Nondiscrimination Act of 2008 (GINA) protects individuals from discrimination based on their genetic information. Title I of GINA governs the collection and use of genetic information by health plans and insurers. Regulations recently issued under Title I will have an immediate impact on many plan sponsors who use health risk assessments or offer disease management programs.

Background

The Genetic Information Nondiscrimination Act of 2008 was enacted on May 21, 2008. (See our May 27, 2008 [For Your Information](#).) GINA consists of two parts. Title I, which governs the collection and use of genetic information by health plans and insurers, is effective for plan years beginning after May 21, 2009. Title II, which governs the acquisition and use of genetic information by employers and labor organizations, becomes effective on November 21, 2009. Earlier this year, the EEOC issued proposed regulations under Title II of GINA. (See our March 17, 2009 [For Your Information](#).)

Although GINA directed that regulations governing Title I be issued by May 21, 2009, the deadline was not met. On October 7, 2009, the U.S. Departments of Health and Human Services (HHS), Labor and the Treasury issued [interim final regulations](#) under Title I, which will become effective for plan years beginning on or after December 7, 2009. At the same time, HHS issued proposed regulations modifying the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule to incorporate the requirements of Title I.

BUCK COMMENT. *Interim final regulations have the weight of final regulations but are subject to future modification. Unfortunately for plan sponsors, the interim regulations leave little time for coming into compliance.*

Overview of Title I

Title I of GINA limits the collection and use of genetic information by group health plans and health insurers. “Genetic information” for purposes of GINA means information about –

- an individual’s genetic tests or the genetic tests of a family member
- any request for, or receipt of, genetic services by an individual or family member
- the manifestation of a disease or disorder in an individual’s family members (i.e., family history).

Family members are broadly defined to include individuals who may qualify as a dependent under HIPAA special enrollment rules (i.e., anyone eligible for enrollment under the plan as a dependent of an employee), any other first, second, third or fourth degree relative, and a fetus or embryo.

The restrictions of Title I of GINA fall into three broad categories –

Prohibition of Group-Based Discrimination. Group health plans and health insurers are prohibited from adjusting premiums or contributions for the group on the basis of the genetic information of individuals within the group. The law does permit insurers to increase premiums based on claims data, but prohibits them from using the manifestation of the disease in one individual as genetic information for other family members.

Limitations on Genetic Tests. Group health plans and health insurers are prohibited from requiring that an individual or family member undergo a genetic test, and can request that they take a genetic test only in connection with research programs that meet certain requirements. The law does permit plans and insurers to request and obtain the results of a genetic test if needed regarding a determination of payment. However, in that case the plan can only request the minimum amount of information necessary for the determination.

Limitations on Collection of Genetic Information. Group health plans and insurers are prohibited from collecting genetic information related to an individual prior to the individual's enrollment in the plan or in connection with the individual's enrollment. It also prohibits the collection of genetic information at any time for underwriting purposes.

The Interim Final Regulations

For the most part, the interim final regulations simply restate the language of the statute or provide some illustrative examples. However, they also contain the following clarifications –

- *Definition of family member.* Family member includes individuals related by affinity (e.g., adoption or marriage) or by blood (i.e., a common ancestor), and includes half-siblings.
- *Payment exception for genetic tests.* The regulations clarify that when a plan's coverage of an expense depends on whether the service was medically appropriate, the plan can request the results of an individual's genetic test if that information is necessary to determine whether the medically appropriate standard is met. For example, if a plan limits coverage for mammograms before age 40 to individuals at risk for breast cancer, it could request the results of a genetic test in order to determine whether to pay a claim involving a mammogram for someone under age 40.
- *Incidental collection of genetic information.* The law provides that a plan or insurer that acquires genetic information incidental to the collection of other information prior to enrollment will not violate GINA as long as it does not use the information for underwriting purposes. A collection of genetic information will not be considered "incidental" if it is reasonable to anticipate that genetic information will be received unless the collection specifically states that such information should not be provided.

The interim final regulations also contain some significant (and unexpected) rules regarding the collection of genetic information that will have a significant impact on the administration of health risk assessments and disease management programs. These are described below.

Impact on Health Risk Assessments and Disease Management Programs

Health risk assessments (HRAs) and disease management programs often request family medical history. This information is used to help assess the individual's future risk for specific health conditions and also to design appropriate wellness activities. Because family medical history is considered genetic information, the collection and use of that information is governed by GINA.

Prohibition on Collecting Genetic Information for Underwriting Purposes

As discussed above, GINA prohibits group health plans and insurers from collecting genetic information for underwriting purposes. The interim final regulations state that "underwriting purposes" include the rules for determining eligibility for benefits or the computation of contribution amounts in return for activities such as completing a health risk assessment (HRA) or participating in a wellness program, including –

- changing deductibles or other cost sharing mechanisms
- providing discounts, rebates, and payments in kind, or
- other premium differential mechanisms.

As a result, an individual cannot be required to complete a health risk assessment that asks for family history as a condition for receiving an incentive under a health plan. This prohibition applies regardless of the amount of the incentive and is separate from the limitation on incentives based on health status. Similarly, a plan generally is prohibited from requesting family history or other genetic information to identify individuals who may be eligible for a disease management program.

BUCK COMMENT. *The Title I regulations do not apply to rewards offered outside the group health plan, such as gift cards and taxable cash for completing an HRA. However, those programs may need to satisfy the requirements for voluntary wellness programs under GINA Title II.*

Determination of Medical Appropriateness. The regulations provide that if an individual seeks a benefit under a group health plan and coverage will be based on whether the benefit is medically appropriate, the determination of medical appropriateness is not within the meaning of underwriting purposes. In those instances, the plan can collect the relevant genetic information and condition the benefit on that information.

BUCK COMMENT. *Disease management programs may be able to be redesigned to fall within this exception.*

Prohibition on Collecting Genetic Information Prior to or in Connection with Enrollment

The GINA prohibition on collecting genetic information prior to or in connection with enrollment will apply to HRAs that request family medical history, even when there is no incentive provided to complete them. The preamble to the regulations clarifies that “prior to enrollment” means prior to the effective date of the individual’s coverage under the plan. The preamble also states that genetic information collected for a proper purpose while an individual is a plan participant will not be treated as collected prior to enrollment if the individual subsequently reenrolls after dropping coverage.

The preamble discusses how this applies to plans that provide for annual enrollment, stating that a collection of genetic information made after a current enrollment will not be considered made prior to a subsequent enrollment unless the collection will be used to affect that subsequent enrollment. However, it does not indicate when a collection will be deemed to affect subsequent reenrollment.

BUCK COMMENT. *The language suggests that plans will not be able to administer HRAs that request family medical history during annual enrollment, but it is unclear when the collection of genetic information will be deemed to affect subsequent enrollment. Additional guidance is needed.*

Examples

The regulations provide several examples that are helpful in understanding the GINA rules –

- A group health plan provides a premium reduction to enrollees who complete an HRA after enrollment. The HRA includes questions about family medical history. Since completing the HRA results in a premium reduction, the request is for underwriting purposes and violates the prohibition on collecting genetic information under GINA.
- Same facts as the above example, except that no premium reduction or reward is provided for completing the HRA. Since the HRA is completed after enrollment and is not used for underwriting purposes, it does not violate GINA.
- A group health plan requests that enrollees complete an HRA before enrollment and includes questions on family medical history. There is no penalty or reward for completing the HRA. Since the HRA requests genetic information prior to enrollment, and is not an incidental request, this request violates GINA.
- A group health plan requests that enrollees complete an HRA after enrollment and does not provide a premium reduction or reward. The HRA includes questions about family medical history. Based on their answers to the questions about family medical history, enrollees may become eligible for additional benefits under the plan by enrolling in a disease management program. Since completing the HRA results in additional benefits, the request is for underwriting purposes and violates the prohibition on collecting genetic information under GINA.

- A group health plan offers a diabetes management program that provides enhanced benefits related only to diabetes for individuals who qualify for the program. The plan sends out a notice to all participants describing the program and asks individuals interested in enrolling to demonstrate that they have diabetes or are at risk for developing the disease. Individuals who do not currently have diabetes may submit genetic information to demonstrate that they are at risk. Since the plan is only requesting genetic information to determine whether the disease management program is medically appropriate for the individual, and only requests the minimum necessary for that purpose, the collection is not for underwriting purposes and does not violate GINA.
- A group health plan requests that enrollees complete two distinct HRAs after enrollment. The first HRA does not include a request for any genetic information. The plan offers a reward for completing the first HRA. The second HRA asks about family medical history and genetic tests. The plan offers no reward for completing the second HRA, and makes it clear that completion is completely voluntary and does not affect the reward for completing the first HRA. Since the first HRA does not request genetic information and the second HRA does not provide a reward or incentive and is completed after enrollment, the combination of the two HRAs does not violate GINA.

BUCK COMMENT. *Some administrators modified their HRAs in response to GINA to state that completion of questions requesting genetic information, including family medical history, was voluntary and that an individual would not have to answer them to receive the incentive for completing the HRA. However, if the HRA is completed before an individual is enrolled in the plan, including questions that request genetic information would violate GINA's prohibition on collecting genetic information prior to enrollment. While not specifically addressed in the regulations, it appears that even if the HRA explicitly states that answering questions related to genetic information is voluntary, including those questions in an HRA that provides an incentive for completion violates the prohibition on collecting genetic information under GINA.*

Coordination with HIPAA Privacy Rule

HHS also issued proposed regulations under the HIPAA Privacy Rule to coordinate them with the GINA Title I regulations. In addition to explicitly stating that genetic information is protected health information and modifying some terms to make their meaning consistent with their meaning under GINA, the proposed regulations would modify the HIPAA Privacy Rule to prohibit health plans from using or disclosing genetic information for underwriting purposes. They would also require plans that use protected health information for underwriting purposes to include a statement in their notice of privacy practices that they are prohibited from using an individual's genetic information for that purpose. HHS has requested comments regarding the timing of any required changes to the notice of privacy practices.

Penalties for Noncompliance

The plan sponsor of a health plan that fails to comply with Title I of GINA may be subject to a penalty of up to \$100 per day for each individual to whom the failure relates. Even unintentional failures may result in penalties of up to \$500,000.

Effective Date

GINA Title I and the interim final regulations are effective January 1, 2010 for calendar year plans. Thus it appears that genetic information collected through HRAs prior to January 1, 2010 will not violate GINA as long as the information is not used for an incentive or reward in the group health plan in 2010.

BUCK COMMENT. *Since many employers have already completed their planning for 2010 benefit programs and open enrollment, they will need to quickly review their use of health risk assessments and incentives for compliance with these requirements during this current open enrollment period.*

For non-calendar year plans, the interim final regulations are effective for plan years beginning on or after December 7, 2009.

Conclusion

Employers that offer premium reductions and other incentives to employees for completing HRAs during open enrollment will need to immediately review and, if necessary, revise these programs to make certain they will not violate GINA. Disease management programs also will need to be reassessed. Buck's consultants are available to discuss these new requirements with you and assist in your compliance efforts.

This FYI is intended to provide general information. It does not offer legal advice or purport to treat all the issues surrounding any one topic.