



Employee Benefits Law Alert

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GINA Interim Final Regulations: The Effect on Group Health Plans

On October 7, 2009, the Department of Labor, the Department of Treasury, and the Department of Health and Human Services issued interim final regulations implementing Sections 101 to 103 of the Genetic Information Nondiscrimination Act of 2008 (GINA). These regulations become effective December 7, 2009 and apply to group health plans for plan years beginning on or after that date. With the effective date looming, plan sponsors and those responsible for administering group health plans must take action to ensure compliance with GINA and the new implementing regulations. Special attention must be paid to ensure that group health plan enrollment procedures and wellness or disease management programs that make use of health risk assessments comply with the new regulations.

Background

Enacted on May 21, 2008, GINA prohibits discrimination in health coverage based on genetic information as well as the collection of such information in certain circumstances. Specifically, GINA prohibits group health plans from:

- Increasing group premium or contribution amounts based on genetic information;
- Requesting or requiring an individual or family member to undergo genetic testing; or
- Requesting, requiring, or purchasing genetic information prior to or in connection with enrollment, or at any time for underwriting purposes.

The Regulations

Selected Definitions

The regulations define "genetic information" as information about (1) an individual's genetic tests; (2) the genetic tests of an individual's family members; (3) the manifestation of a disease or disorder in an individual's family members; or (4) any request or receipt by the individual or his or her family members of genetic services. A disease or disorder is manifested when an individual has been, or could reasonably be, diagnosed by a health care professional with appropriate training and expertise in the field of medicine involved.

A "family member" is "a dependent of an individual and any other individual that is a first-, second-, third-, or fourth-degree relative of the individual or of the dependent of the individual." Relatives by marriage or adoption are treated the same as blood or ancestral relatives. In addition, relatives that are not full blood relatives are treated the same as full blood relatives.

"Collecting" information means to request, require, or purchase such information.

“Underwriting purposes” include rules for, or determination of, eligibility for plan benefits. Notably, this term includes changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment (HRA) or participating in a wellness program.

Prohibition Against Collecting Genetic Information – Effect on Use of Health Risk Assessments

Perhaps the most significant impact of the regulations is their effect on wellness and disease management programs that provide incentives to employees who complete HRAs and on group health plans that require completion of HRAs prior to or during open enrollment. The regulations prohibit a group health plan from collecting genetic information for underwriting purposes. Group health plans also may not collect an individual’s genetic information prior to that individual’s effective date of coverage or in connection with rules for eligibility. Most HRAs contain questions concerning family medical history, which constitutes genetic information. Consequently, group health plans that provide incentives for completing HRAs, that require completion of HRAs in connection with enrollment, or that use HRAs as a means of identifying individuals who would benefit from certain disease management programs will need to revise their practices in order to comply with the regulations.

Examples in the regulations suggest steps that a group health plan can take to help ensure compliance with the GINA regulations’ prohibitions against collecting genetic information. When requesting completion of HRAs after (and unrelated to) enrollment, a group health plan could remove the reward or incentive for completing the HRA. Alternatively, the group health plan could prepare two separate HRAs, one containing only questions about the individual’s medical history, excluding genetic tests (the completion of which would result in a reward or incentive), and the other containing family medical history questions and questions about the individual’s genetic tests (the completion of which would be voluntary). Regardless of when a group health plan requests completion of the HRA, the plan could also choose to delete questions that involve family medical history or that concern an individual’s genetic tests, although this may diminish the usefulness of the HRA.

There is a medical appropriateness exception to the prohibition against a group health plan’s collection of genetic information. The prohibition does not apply if an individual is seeking benefits under the plan and the plan conditions the benefit upon a determination of medical appropriateness and the medical appropriateness of the benefit depends on the individual’s genetic information.

Prohibition Against Increasing Premiums or Contribution Amounts

The regulations prohibit a group plan from adjusting premiums or contribution amounts for the plan on the basis of genetic information. Consequently, group health plans may not use genetic tests or a manifested disease or disorder of one individual to increase the premium or contribution amounts of the individual or his or her family members. However, group health plans may increase premium or contribution amounts for the entire group health plan based on a manifested disease or disorder of one plan member.

Prohibition Against Requesting or Requiring Genetic Testing

Under the regulations, a group health plan may not request or require an individual or his or her family member to undergo genetic testing. This general rule is subject to several exceptions. Most notably, a group health plan may obtain and use the results of a genetic test to make a payment determination as long as it only requests the minimum amount of information necessary to make the determination. The regulations incorporate the standard set forth in the HIPAA Privacy Rule to determine what is the minimum amount of information necessary.

Action Points

In light of the GINA regulations’ impending effective date, plan sponsors and those administering group health plans should take the following actions:

- Review and make necessary changes to health risk assessments and to programs using these assessments to ensure compliance with the prohibition against collection of genetic information for underwriting purposes.
- Review and make necessary changes to enrollment procedures to ensure compliance with the prohibition against collection of genetic information in connection with or prior to enrollment.
- Review and make necessary changes to group health plan documents and procedures to ensure compliance with the prohibition against requesting or requiring genetic testing.