

New GINA Regulations Would Affect Certain Group Health Plans, Wellness Programs

Title I of the Genetic Information Nondiscrimination Act of 2008 (“GINA”) prohibits discrimination based on genetic information in group health plans and health insurance issuers. The Secretaries of Labor, Treasury and Health and Human Services have issued regulations (“Regulations”) to implement Title I of GINA which, among other things, affect wellness programs that seek information about participants’ family history and reward those who provide that information. (These [regulations](#) can be found at <http://www.dol.gov/federalregister/HtmlDisplay.aspx?DocId=23182&AgencyId=8&DocumentType=2>.) While GINA is effective for plan years beginning after May 21, 2009, the Regulations apply to group health plans and health insurance issuers for plan years beginning on and after December 7, 2009.

GINA builds on existing protections concerning genetic information and nondiscrimination that exist under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). We focus here on the effects of GINA’s enhancements as clarified by the Regulations on wellness programs. The Equal Employment Opportunity Commission continues to develop final regulations to implement the portion of GINA relating to employment. See [Genetic Information Nondiscrimination Act Regulations Expected: Are Your Wellness Programs Ready?](#)

Impact on Wellness Programs

Many wellness programs are part of a group health plan where the program reward is in the form of a premium or cost sharing reduction, rather than a cash payment. For example, a program may provide that if a participant takes a health risk assessment (“HRA”), he or she would be rewarded with a premium discount or waiver of a deductible. GINA adds to the legal challenges these programs already face.

Title I of GINA prohibits group health plans and health insurance issuers from “requesting, requiring or purchasing genetic information prior to or in connection with enrollment, or at any time for underwriting purposes.” As under Title II of GINA, Title I defines “genetic information” to include, among other things, information about “the manifestation of a disease or disorder in family members of such individual.” The Regulations broadly define “underwriting purposes” to include activities beyond rating and pricing a group policy. That is, “underwriting purposes” under the Regulations also means rules for eligibility for benefits and the computation of premium or contribution amounts. GINA prohibits the collection of genetic information to determine eligibility for benefits or provide rewards in the form of premium or contribution discounts. This means that wellness programs would violate GINA when they seek information regarding family medical history, a common feature of HRAs, and reward participants who provide that information. The same is true even if the rewards are not based on the outcome of the assessment.

For example, assume a group health plan provides a premium reduction to enrollees who complete an HRA (which includes questions about the individual’s family medical history) that is to be completed after

enrollment. The Regulations would conclude that the HRA includes a request for genetic information (i.e., the family medical history) and because completing the HRA results in a premium reduction, the request for genetic information is for underwriting purposes. **Thus, the request violates the Regulations.** On the other hand, if there were no premium reduction or other award for completing the HRA, there would be no violation of the prohibition with respect to collecting genetic information.

Sponsors of group health plans and health insurance issuers may need to modify their wellness programs, including HRAs, to eliminate the collection of genetic information (including questions concerning manifestation of disease in family members). Alternatively, group health plan sponsors and health insurance issuers could achieve compliance by eliminating the rewards under the programs concerning genetic information.

Other Provisions of the Regulations

In addition to the provisions affecting wellness programs, the Regulations provide additional guidance concerning GINA's application to group health plans and health insurance issuers. Some key provisions include:

- GINA and the Regulations expand HIPAA's ban on health factor discrimination by prohibiting group health plans (and health insurance issuers offering health coverage) from using genetic information to adjust premium or contribution amounts. This is a change from prior law, which allowed plans and issuers to adjust premium or contribution amounts for a group health plan or group of similarly situated individuals based on genetic information and other health factors.
- GINA and the Regulations also provide that the prohibition on adjusting premiums or contributions based on genetic information does not limit the ability of a plan or issuer to increase the premium or contribution amount for a group health plan based on the "manifestation" of a disease or disorder of an individual enrolled in the plan. The Regulations provide that a disease, disorder, or pathological condition 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. However, a disease, disorder or pathological condition is not manifested if a diagnosis is based principally on genetic information.
- The Regulations contain a definition of genetic information that restates and reorganizes the statutory provisions. Genetic information is defined, with respect to an individual, 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 (i.e., family medical history), or
 - any request of or receipt by the individual or family members of genetic services.

Genetic information does not include information about the sex or age of an individual. The Regulation also clarifies how GINA applies to genetic information about a fetus or embryo.

- GINA generally prohibits plans and issuers from requesting or requiring individuals or their family members to undergo a genetic test. The Regulations describe three exceptions to this rule: for certain health care professionals, for determinations regarding payment and for research.
- The Regulations clarify that if an individual seeks a benefit under a plan or coverage, the plan or coverage may limit or exclude the benefit based on whether the benefit is medically appropriate (and a determination of whether the benefit is medically appropriate is not within the meaning of underwriting purposes).

Take Away

The Regulations apply to the individual health insurance market, group health plans and health insurance issuers. While the Regulations do not apply to employers, many employers have a wellness program as part of their group health plans. Accordingly, employers should act now to determine if their wellness programs violate GINA and the Regulations.