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Benefits Legal Update

Interim Final Regulations under Genetic Information Nondiscrimination Act Impact Employer Wellness Programs

On October 1, 2009, the Internal Revenue Service (IRS), the Department of Labor (DOL), and the Centers for Medicare and Medicaid Services (CMS) issued joint final interim regulations under Title I of the Genetic Information Nondiscrimination Act (GINA). The much-anticipated regulations affect group health plans and group health insurance for plan years beginning on and after December 7, 2009, which means they become effective for calendar year plans on January 1, 2010.

Background

The GINA regulations expand protections initially afforded to plan participants under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Title I of GINA prohibits health plans and insurers from: increasing group premiums and contributions based upon genetic information; requesting or requiring any genetic testing; and requesting or obtaining genetic information prior to or in connection with enrollment or for underwriting purposes.

The regulations broadly define "genetic information" to include information about an individual's genetic tests, the genetic tests of that individual's family members, and the manifestation of a disease or disorder in family members of the individual. Such information cannot be collected for underwriting purposes, which is loosely defined to include: (1) rules for, or determination of, eligibility for benefits under the plan or coverage (including changes in deductibles or cost-sharing mechanisms, like completion of a wellness program); (2) calculation of premium or contribution amounts; (3) application of a preexisting condition exclusion; and (4) other activities related to the creation, renewal, or replacement of a contract for health insurance.

Penalties and excise taxes of up to $100 per day for each instance of noncompliance can be assessed against a group health plan. Additionally, improper use or disclosure of genetic information also violates the HIPAA privacy rule, which can result in a fine of $100 to $50,000 or more for each violation.

Wellness Programs

The new regulations may significantly limit the types of information that may be gat from employees participating in an employer's wellness program. Many wellness and disease management programs are designed to require that participants complete a health risk assessment (HRA) prior to enrollment in the plan. Under the new regulations, HRAs that include questions about family medical history or solicit other genetic information cannot be distributed in conjunction with plan enrollment, or at any other time before the employee's effective date of coverage in the plan. Additionally, using the HRA as a screening mechanism for determining participation in such programs or the receipt of other medical benefits violates GINA. The collection of genetic information requested after enrollment does not violate the rules as long as any such genetic information does not impact any future enrollment. Incidental collections of genetic information that could not be reasonably anticipated do not violate GINA.

Under the new regulations, wellness programs that provide incentives for completing HRAs that request genetic information generally violate GINA. Even though prior rules under HIPAA would have permitted such programs, under GINA the incentive is deemed to be for underwriting purposes. For example, plans are no longer permitted to reward employees for participation in an HRA by reducing premiums or deductibles, issuing rebates, or making contributions to a health reimbursement arrangement or flexible spending account in exchange for voluntary participation in an HRA.

The following examples from the regulations highlight typical scenarios in which the use of an HRA may or may not violate GINA:

Example 1: *A group health plan provides a premium reduction to individuals who complete an HRA. The plan requests completion of the HRA after enrollment. Neither the completion of the HRA nor the responses given on the HRA have any effect on an individual's enrollment status or on the enrollment status of the individual's family members. The HRA includes questions about the individual's family medical history.*

The regulations conclude that this example illustrates a violation of the prohibition on the collection of genetic information for underwriting purposes because the HRA includes a request for genetic information (i.e., the individual's family medical history) and because the individual receives a premium reduction for completing the HRA.

Example 2: *The facts are the same as in Example 1 except that t is no premium reduction or other reward for completing the HRA.*

In this example, the plan does *not* violate the prohibition on the collection of genetic information under GINA because, although genetic information is requested, the information is not requested for underwriting purposes (i.e., t is no premium reduction or reward) nor is it requested in conjunction with enrollment.

Example 3: *The facts are the same as in Example 2 except that some individuals 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.*

Because the request for information about the individuals' family medical history could result in the individuals becoming eligible for benefits for which they would not otherwise be eligible, the questions about family medical history on the HRA are a request for genetic information for underwriting purposes and violate GINA.

Conclusion

The new final regulations apply to health plans and insurers regulated by Title I of GINA and do not address employment practices covered under Title II of GINA. Wellness programs that are neither ERISA plans nor group health plans under HIPAA are not subject to these regulations but would likely be required to comply with Title II of GINA. Title II of GINA includes an exception from GINA's prohibition on requesting genetic information if the request is made in connection with a voluntary wellness program; Title I of GINA, as discussed above, does not include such an exception. Because most, if not all, wellness programs are typically tied to a health plan, it remains unclear whether the Title II exception provides sufficient relief for employers, and final regulations have not yet been issued. Title II of GINA is scheduled to become effective November 21, 2009; however, further clarification of GINA's impact on HRAs and wellness programs is required.

Though GINA may severely restrict the use of HRAs in wellness programs, t are still a number of strategies that plan sponsors may utilize to comply with GINA under the final regulations while promoting wellness among employees. If you have any questions about your wellness and disease management programs and compliance with GINA, please contact any of the following

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