The Metropolitan
Corporate Counsel®

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Volume 17, No. 11 November 2009

Hot Issues Alerts – Law Firms

2010 Open Enrollment Alert – Under GINA No Good Deed Goes Unpunished

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JONES DAY

The Genetic Information Nondiscrimination Act of 2008 ("GINA") became law on May 21, 2008. GINA was designed, among other things, to prohibit a group health plan or group health insurance issuer from collecting genetic information from or about an individual or family member prior to or in connection with enrollment, or at any time for underwriting purposes. These provisions of GINA are effective for plan years beginning after May 21, 2009 (January 1, 2010 for calendar year group health plans).

On October 1, 2009, the Department of Labor and the Centers for Medicare & Medicaid released interim final rules and the Internal Revenue Service ("IRS") issued temporary and final rules to implement certain provisions of GINA, including the prohibition on the collection of genetic information by group health plans and group health insurance issuers. These rules, which will become effective on December 7, 2009, will have an immediate impact on the information that can be requested, required, or purchased from individuals in connection with enrollment or for underwriting purposes, particularly the continued use of health risk assessments ("HRAs") and wellness programs. HRAs are confidential questionnaires that include questions about an individual's general health and health habits (for example, smoking, drinking and drug usage). In addition to seeking health information about an enrollee, HRAs also commonly ask questions relating to an individual's family medical history for purposes of early detection and treatment of inherited diseases. Because many employers are in the process of soliciting information from employees and their dependents in connection with annual open enrollment, immediate action may be required to comply with the new rules.

What Constitutes The Collection Of Genetic Information?

GINA prohibits a group health plan or a group health insurance issuer from collecting genetic information from an individual or a family member for the purposes of restricting enrollment in a group health plan or for purposes of determining the amounts to be charged to either the individual or the group for coverage or benefits. The word "collect" was not defined in GINA. The regulations broadly define "collect" to mean, with respect to genetic information, to request, require, or purchase such information. Genetic information includes information about an individual's genetic tests (such as DNA, RNA, chromosome, protein or metabolites tests, if the tests detect genotypes, mutations or chromosomal changes), genetic services (for example, counseling, education and the interpretation of genetic information), and manifestation of a disease or disorder by a family member (for example, genetic information that might be learned from family medical history). Genetic information does not include blood tests that are not designed to obtain information relating to genotypes, mutations or chromosomal changes; cholesterol tests; or information about the age or sex of an individual or family member.

Who Are Family Members Under GINA?

Family members of an individual include:

- Any dependents;
- Any first-degree relatives (parents, spouses, siblings and children);
- Any second-degree relatives (grandparents, grandchildren, aunts, uncles, nephews and nieces);
- Any third-degree relatives (great-grandparents, great-grandchildren, great aunts, great uncles, and first cousins); and
- Any fourth-degree relatives (great-great grandparents, great-great grandchildren, and children of first cousins).
- Relatives by affinity (*i.e.*, by marriage or adoption) are treated the same as are relatives who share a common biological ancestor, and relatives who share only one common ancestor (such as half-siblings) are treated the same as are relatives who share full-blood relation (such as siblings who share both parents).

When Is Genetic Information Used For Purposes Of Enrollment Or Underwriting?

One of the more controversial aspects of the regulations relates to the use of genetic information for purposes of enrollment or underwriting. Under the regulations, "enrollment" means initial enrollment or continued enrollment in a group health plan (for example, at the plan's annual open enrollment). As one might expect, "underwriting" includes activities relating to the rating and pricing of a group policy (such as computation of premium or contribution amounts and application of preexisting condition exclusions). The regulations go further, however, and include in the definition of underwriting such things as changing deductibles or other cost-sharing mechanisms, and providing discounts, rebates, payments in kind or other incentives in return for activities such as completing an HRA or participating in a wellness program.

The incidental collection of genetic information in connection with collection of other information does not violate GINA, unless the group health plan or health insurance issuer can reasonably anticipate that genetic information would be collected. In that case, the collection of genetic information will be "incidental" if the individual is explicitly told that he or she should not provide genetic information. Of course, the genetic information collected incidentally may not be used by the group health plan or health insurance issuer for underwriting purposes.

Genetic information (including family history) that is requested by a plan in order to determine whether a benefit provided under the plan to an individual is medically appropriate (for example, a colonoscopy provided to an individual under age 50 on the basis that the individual

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has family members under age 50 with colon cancer) is not treated as being collected for underwriting purposes under the new rules, provided that the plan requests only the minimum amount of genetic information necessary to determine medical appropriateness.

Examples

The following examples from the regulations apply the new rules to some of the more typical situations in which HRAs and rewards are utilized by group health plans today.

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 has 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 (that is, 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 there is no premium reduction or other reward for completing the HRA.*

In this case, the plan does not violate the prohibition on the collection of genetic information under GINA because the information is not requested for underwriting purposes (*i.e.,* there is no premium reduction or any other reward), nor is it requested prior to, or in connection with, enrollment.

Example 3*: The facts are the same as in Example 2, except that 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 (for example, early detection and management of diabetes).*

Because the request for information about the individual's family medical history could result in the individual's becoming eligible for benefits for which the individual would not otherwise be eligible, the questions about family medical history on the HRA are a request for genetic information for underwriting purposes which is prohibited under GINA.

Example 4: *A group health plan waives its annual deductible for enrollees who complete an HRA. The HRA is to be completed after enrollment and has no effect on the enrollment status of the individual or any family member. The HRA does not include any direct questions about the enrollee's genetic information, including family medical history. However, the last question reads, "Is there anything else relevant to your health that you would like us to know or discuss with you?"*

Under the regulations, the HRA violates GINA because it does not explicitly state that enrollees should not provide genetic information when responding to the final question. Plans and issuers can avoid this result by including the following statement on the HRA: "In answering this question, you should not include any genetic information related to genetic testing, genetic services, genetic counseling, or genetic diseases for which you believe you may be at risk." Even if the statement is included, neither the plan nor the issuer may use any genetic information that enrollees voluntarily provide on the HRA for underwriting purposes.

What Penalties Are Imposed For Violations?

GINA amended the Internal Revenue Code, the Employee Retirement Income Security Act of 1974 ("ERISA") and the Public Health Services Act to include statutory penalty schemes that are similar but not identical. Under all three laws, unless the plan is under examination, no penalties are imposed if the entity otherwise liable for the penalties did not know, and exercising "reasonable diligence" would not have known, of a failure to comply with GINA. It is important, therefore, for employers, plans and issuers to periodically audit plan operation to determine whether any violations have occurred and to correct any known violations within 30 days.

In most other cases, substantial penalties may be imposed if a group health plan or group health insurance issuer collects genetic information prior to or in connection with enrollment, or at any time for underwriting purposes. Depending on the applicable statute, the penalties may be imposed on the employer, plan sponsor, the health insurance issuer offering health insurance coverage in connection with a group health plan or, in the case of a multiemployer plan, the plan. The statutory penalties are equal to $100 per individual, per day of violation, unless the violation is corrected within generally 30 days of the date the entity otherwise liable for the penalty knows, or exercising reasonable diligence would have known, of the violation. For most plans, if the government agency charged with enforcement (*i.e.,* the Department of the Treasury, Department of Labor or Department of Health and Human Services) discovers a violation that has not been corrected, the minimum penalty increases to $2,500 per individual (for insignificant violations) and $15,000 per individual (for significant violations). The reasonable diligence and 30-day correction exceptions described above are not available if a government agency discovers a violation that hasn't been corrected. In the case of unintentional failures relating to single employer plans, the above-described penalties will be limited to the lesser of 10 percent of the aggregate amount paid by the employer for group health plans during the prior taxable year or $500,000.

The government agency charged with enforcement has the discretion to waive part or all of the penalties for failures that are due to reasonable cause, and not to willful neglect, to the extent that the payment of the tax would be excessive relative to the failure involved.

What Should Employers Do?

Many employers are using HRAs together with rewards or other incentives in connection with annual open enrollment periods that are currently underway or that will begin shortly (open enrollment for calendar year group health plans commonly runs from October through December). If the plan or health insurance issuer could obtain genetic information (such as family medical history) in connection with an HRA that is part of the enrollment process, and if rewards or incentives will be paid or the information obtained will be used to provide additional benefits to individuals or family members, the arrangement may run afoul of the newly issued regulations. At a minimum, employers and health insurance issuers should review their HRAs and wellness programs to determine whether genetic information is being collected or might be obtained in connection with the HRA. On the basis of that review, employers and health insurance issuers may find it necessary to rethink and redesign their HRAs and wellness programs, as well as the incentives or additional benefits that are provided in connection with the completion of HRAs or participation in wellness programs.

The new rules suggest a few practical redesign opportunities. For example, the new rules permit plans and issuers to continue to obtain important health-risk assessment information that relates only to the individual enrollee, as long as the enrollee is explicitly advised not to provide genetic information (see disclaimer language above in Example 4). The new rules also permit plans and issuers to continue to collect genetic information after the individual has enrolled in the plan, as long as no reward or additional benefits are provided and the information is not used for underwriting purposes. Finally, the new rules specifically approve the use of two HRAs by a plan or issuer, one that includes questions that do not seek genetic information and one that seeks genetic information. Neither HRA is required prior to or in connection with enrollment. A reward or incentive is provided for completing the HRA that does not seek genetic information and no reward or incentive is provided for completing the HRA that seeks genetic information.

Because open enrollment season is occurring now, immediate coordination among employers and group health plan issuers may be needed in order for the plan to obtain important information designed to improve the health and wellness of employees and, at the same time, ensure compliance with the new rules.

Stay Tuned For Future Developments

The new regulations are not finalized yet and they could be revised based upon comments that the agencies receive from employers, group health plan sponsors and insurers. Employers should also stay tuned to the health care reform process currently underway in Congress. Some of the proposals currently before Congress support or mandate robust preventive medicine measures, including the sponsorship of wellness programs, as a means of reducing future health care costs for all Americans. If individuals will not take the time to complete HRAs or participate in wellness programs without meaningful incentives, a potential conflict may be created between the new GINA rules and the goals contained in these health care reform measures.