Employee Benefits and Executive Compensation - Health Law Advisory: DOL, Treasury and HHS Issue Joint Interim Final Rule under Title - of the Genetic Information Nondiscrimination Act of 2008 (Relating to Group Health Plans and Health Insurance Issuers)

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The Genetic Information Nondiscrimination Act of 2008 (GINA) was signed into law on May 21, 2008. The law's purpose is to ensure that genetic information is not used to discriminate against individuals in matters of employment or for insurance underwriting purposes. GINA Title I amends the Employee Retirement Income Security Act of 1974, the Public Health Service Act, the Internal Revenue Code, and the Social Security Act to prohibit discrimination in health coverage based on genetic information, and to expand upon the protections established under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA already contains robust non–discrimination rules that prohibit a group health plan or group health insurance issuer from imposing preexisting condition exclusions based on genetic information. But GINA goes further. GINA prohibits group health plans, health insurance issuers in the group and individual markets, and issuers of Medicare supplemental policies from discriminating based on genetic information, and from collecting such information.

On October 1, 2009, the Department of Labor's Employee Benefits Security Administration, the Treasury Department, and the Department of Health and Human Services issued a joint interim final rule (the "interim final rule") implementing the provisions of GINA Title I. Under the interim final rule, group health plans and health insurance issuers in both the group and individual markets must not request, require, or buy genetic information for underwriting purposes, or prior to and in connection with enrollment. In addition, plans and issuers are generally prohibited from asking individuals or family members to undergo a genetic test. These requirements will force employers and group health plans to either make major modifications to their health risk assessment programs or abandon them altogether. The interim final rule takes effect for plan years commencing on or after December 7, 2009.

This client advisory explains the key features of the interim final rule, with a particular focus on health risk assessment.

Definitions

Much of the interim final rule consists of new definitions that either implement GINA's substantive provisions or endeavor to mesh new requirements with the health care portability and privacy provisions of HIPAA. Some of the more important definitions include:

- **Genetic Information. "**Genetic information" is defined as information about an 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." Information about the sex or age of an individual is not genetic information for this purpose. GINA does, however, apply to genetic information about a fetus or embryo.
- **Manifestation or Manifested. "**Manifestation" of a disease is important for three different purposes under GINA. First, a plan or insurance carrier may increase the premium or contribution amount for a group health plan based on the manifestation of a disease or disorder in an individual who is enrolled in the plan. Second, the definition of genetic information for an individual includes information about the manifestation of a disease or disorder in family members of such individual. Finally, the definition of genetic test excludes an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition. 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. A disease, disorder, or pathological condition is not manifested, however, if a diagnosis is based principally on genetic information.
- **Family Member.** The definition of "family member" is important for two reasons. First, the definition of genetic information for an individual includes information about the manifestation of a disease or disorder in family members of the individual. Second, a plan or health insurer generally may not request or require an individual or family member of the individual to undergo a genetic test. The statute defines a family member as any individual who is a dependent or who is a first–, second–, third–, or fourth–degree relative of the individual or of the dependent of the individual.
- **Genetic Services.** "Genetic services" means a genetic test, genetic counseling, or genetic education.
- **Genetic Test.** A "genetic test" is any analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if it detects genotypes, mutations, or chromosomal changes. But a genetic test does not include an analysis of proteins or metabolites "that does not detect genotypes, mutations, or chromosomal changes, or an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could be reasonably detected by a health care professional with appropriate training and expertise in the field of medicine involved." A blood glucose test, for example, is not a genetic test.
- **Underwriting Purposes.** The term "underwriting purposes" includes, with respect to group health plan coverage, rules for and determinations of eligibility (including enrollment and continued eligibility), computation of premium or contribution amounts, and application of preexisting condition exclusions. It also covers rules for changing deductibles or other cost–sharing mechanisms, or providing discounts, rebates, payments in kind, or other premium differential mechanisms, in return for activities such as completing a health risk assessment (HRA) or participating in a wellness program.

Interim Final Rule: Individual Market Rules

GINA regulates group health plans and health insurance issuers (*i.e.*, carriers) that sell health insurance in both the group and individual markets. In the individual market, GINA imposes new restrictions under which individual market issuers are barred from discriminating on the basis of genetic information. Specifically, individual market issuers may not collect genetic information prior to or in connection with enrollment, or at any time for underwriting purposes. The interim final rule defines the term "collect" as being a substitute for the longer phrase "request, require or purchase," which is used in the statute.

Unlike their group market counterparts, individual market issuers were not subject to HIPAA's nondiscrimination requirements. GINA's requirements, therefore, are new to this sector of the insurance market. Individual health insurance policies can no longer use genetic information as a basis for making eligibility or premium determinations, or for imposing preexisting condition exclusions. They may continue to establish rules for eligibility, increase premiums, and impose preexisting condition exclusions based on the manifestation of a disease or disorder in an individual, or in a family member covered under the policy that covers the individual. But they cannot use a manifestation of a disease or disorder in one individual as genetic information and apply that information to family members, covered under the same policy or another policy, to further increase premiums.

Interim Final Rule: Group Market Rules

The interim final rule establishes three general prohibitions that apply to group health plans and to health insurance issuers in the group market:

- ***A group health plan or group market health insurance issuer may not increase premiums or contributions based on genetic information.***
  This rule represents a major departure from prior law. As interpreted by the interim final rule, GINA prohibits group health plans and health insurance issuers from adjusting premium or contribution amounts for a group health plan or group of similarly situated individuals on the basis of genetic information. Prior law allowed plans and issuers to adjust premium or contribution amounts for the group health plan or a group of similarly situated individuals (but not for individuals within the group) based on genetic information, as well as other health factors. Since the enactment of GINA, a plan or issuer is prohibited from using that information to discriminate, even when the plan or health insurance issuer has lawfully obtained genetic test results or other genetic information (e.g., where the acquisition that took place prior to GINA's effective date). Nothing in GINA or elsewhere prohibits the adjustment of premiums or contributions based on the manifestation of a disease or disorder of an individual enrolled in the plan, although manifestation of a disease or disorder in one individual does not allow for further increases in the premiums or contributions of anther individual.
- ***A group health plan or group market health insurance issuer may not request or require an individual or family member to undergo a genetic test.***
  GINA generally prohibits plans and issuers from requesting or requiring individuals or their family members to undergo a genetic test. There are three exceptions to this prohibition: for certain health care professionals, for determinations regarding payment, and for research. Thus, a health care professional who is providing health care services to an individual may request that the individual undergo a genetic test. To do so, however, the health care professional must

actually be providing health care services to the individual. Under the second exception, a plan or carrier may obtain and use the results of a genetic test to make a determination regarding payment. For this purpose, however, plans and insurance issuers are only permitted to request the minimum amount of information necessary to make the payment determination. In addition, where the appropriateness of a certain course of treatment depends on an individual's genetic makeup, a plan or health insurance issuer may condition payment on medical appropriateness that depends on the outcome of a genetic test. Lastly, a group health plan or group health insurance issuer may request—but not require—that a participant or beneficiary undergo a genetic test in connection with certain research–related activities.

- ***Requesting, requiring or purchasing genetic information prior to or in connection with enrollment, or at any time for underwriting purposes.***
  Plans and health insurance issuers may not collect genetic information, either for underwriting purposes or prior to or in connection with enrollment. Where group health plans are concerned, "underwriting purposes" includes rules for and determinations of eligibility (including enrollment and continued eligibility), computation of premium or contribution amounts, and application of preexisting condition exclusions.

Impact on Health Risk Assessments

As mentioned, GINA prohibits plans and issuers from collecting genetic information for underwriting purposes or prior to or in connection with enrollment. The collection of genetic information with respect to an individual is considered prior to enrollment if it takes place before the individual's effective date of coverage under the plan or health insurance coverage. If a plan collected genetic information with respect to an individual after initial enrollment (and not for underwriting purposes), and the individual later dropped coverage but then re–enrolled in the plan, the collection of genetic information after the initial enrollment would not be considered prior to the re–enrollment. Special rules expressly permit the collection of genetic information subsequent to an initial enrollment, but before a subsequent annual re–enrollment, provided that the subsequent enrollment is unaffected.

HRAs routinely ask about an individual's family medical history and are frequently used as part of a wellness feature in an employer's medical plan. While the regulators acknowledged comments urging a broad exemption for HRAs and wellness programs, they felt constrained by the express terms of the statute: GINA prohibits collecting genetic information for underwriting purposes, and "underwriting purposes" is defined broadly to include rules for eligibility for benefits and the computation of premium or contributions amounts. As a result, wellness programs that provide rewards for completing HRAs that request genetic information, including family medical history, violate the prohibition against requesting genetic information for underwriting purposes. This is so even if rewards are not based on the outcome of the assessment.

The interim final rule does, however, allow for the collection of genetic information through an HRA as long as no rewards are provided *and* if the request is not made prior to or in connection with enrollment. A plan or issuer can also provide rewards for completing an HRA as long as the HRA does not collect genetic information. Several examples appear in the interim final rule, and they can be summarized as follows:

- An HRA may not solicit information about family medical history or other genetic information in conjunction with plan enrollment, or at any time before the employee's effective date of coverage in the underlying group health plan. As a result, plans may no longer 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.
- An HRA may not be used as a screening mechanism for determining participation in disease management programs or the receipt of other medical benefits.
- An HRA may ask questions about family medical history or other genetic information if **(i)** no rewards are provided for participation in the HRA, **(ii)** the request is made *after* the effective date of coverage and is not made in connection with enrollment in the plan, and **(iii)** completion of the HRA does not qualify an individual for any additional benefits (*e.g.*, participation in a disease management program).

The interim final rule also bars the use of open–ended questions that may indirectly gather genetic information. According to the regulators, responses to questions like "Have you had any laboratory tests in the last two years?" or "Is there anything else relevant to your health that you would like us to know or discuss with you?" can result in the collection of genetic information. Therefore, the interim final rule requires that these and similar questions be accompanied by statements specifically instructing participants not to provide any genetic information, in order to avoid a violation.

Conclusion

While the interim final rule interprets GINA broadly, the three agencies have not strayed from the text of the law as mediated by its legislative history. Nevertheless, the impact on HRAs is unfortunate. While not barring HRAs outright, the interim final rule effectively guts their usefulness. When combined with the concerns recently raised by the Equal Employment Opportunity Commission about whether health risk assessments raise issues under the Americans with Disabilities Act (here), the net result is to take HRAs off the table until Congress chooses to get involved.

For assistance in this area, please contact one of the attorneys listed below or any member of your Mintz Levin client service team.

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