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GINA Regulations Released – Prohibiting Discrimination in Health Plans Based on Genetic Information and Revising Privacy Rules

On Friday, October 2, 2009, the Departments of Labor, Treasury, and Health and Human Services (HHS) released an advanced copy of the [interim final regulations](#) under Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA) implementing the rules in GINA that prohibit group health plans and health insurance issuers from discriminating based on genetic information. HHS also released [proposed regulations](#) amending its Privacy Rule as required by GINA to preclude the use of genetic information for health plan or health insurance underwriting. Both sets of regulations will be published in the Federal Register on Wednesday, October 7, 2009.

Nondiscrimination Rules

Effective for plan years beginning after May 21, 2009, GINA prohibits employer-sponsored group health plans and health insurers providing group and individual health insurance from:

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

Under the regulations, genetic information means:

- The individual's genetic tests;
- The genetic tests of family members;
- The manifestation of a disease or disorder in family members; or
- Any request for, or receipt of, genetic services or participation in clinical research that includes genetic services, by the individual or a family member.

Genetic information does not include information about the sex or age of any individual; it does include—with respect to a pregnant woman, an individual who is utilizing an assisted reproductive technology, or a family member—genetic information of any fetus carried by the pregnant woman or of any embryo legally held by the individual or family member. The regulations provide definitions for the terms: “genetic test,” “family member,” “manifestation” or “manifested,” and a number of other terms necessary for application of the rules. The group health plans subject to these rules are plans that are subject to the special enrollment, nondiscrimination and other requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), that is, most plans providing general medical benefits, but not plans providing excepted benefits such as stand-alone dental and vision plans, most health flexible spending account plans, and long-term care plans.

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Prohibition on Adjusting Rates

GINA and the regulations expand the prohibitions against discrimination based on health factors that were enacted in HIPAA by prohibiting group health plans and health insurance issuers from adjusting premium or contribution amounts for a group health plan, or a group of similarly situated individuals, on the basis of genetic information and extend this prohibition to the individual insurance market. The preamble to the regulations states that this prohibition is distinct from the prohibition on requesting or requiring an individual to undergo a genetic test and the prohibition on collecting genetic information. Thus, even when a plan or issuer has lawfully obtained genetic test results or other genetic information, the plan or issuer is prohibited from using that information to discriminate.

The regulations provide that this prohibition does not limit the ability of a plan or issuer to increase the premium or contribution for a group health plan based on the manifestation of a disease or disorder of an individual enrolled in the plan. However, a plan or issuer may not use the manifested disease or disorder of one individual as genetic information about other group members, such as the individual's family members, to further increase the premium or contribution amount.

Limitation on Requesting or Requiring Genetic Testing

GINA generally prohibits plans and issuers from requesting or requiring individuals or their family members to undergo a genetic test. The three exceptions to this prohibition are for certain health care professionals, for determinations regarding payment, and for research.

The regulations make clear that this restriction is not intended to limit the ability of a health care professional who is providing health care services to an individual to request that the individual undergo a genetic test. The regulations say that, for example, a physician may recommend that an individual whose mother has Huntington's disease undergo a genetic test for the disease.

Under the payment exception, if a plan conditions payment for an item or service based on its medical appropriateness, and its medical appropriateness depends on the genetic makeup of a patient—for example, if a particular treatment may not be effective for a person with a particular gene mutation—the plan is permitted to condition the payment for the item or service on the outcome of a genetic test. The plan may also refuse payment if the individual does not undergo the genetic test. However, a plan may request only the minimum amount of genetic information necessary to make a determination regarding payment.

The regulations also say that, for research purposes, a plan may request, but not require, that a participant or beneficiary undergo a genetic test, provided that:

- The request for research complies with federal and state law for the protection of participants in the research study;
- The plan makes the request in writing and clearly indicates that compliance is voluntary and that noncompliance will have no effect on eligibility for benefits or premium amounts;
- No genetic information collected can be used for underwriting purposes; and
- The plan provides notice to the applicable federal agencies.

Prohibition on Collection of Genetic Information

Under GINA, plans and issuers cannot request, require or buy genetic information, including family history, for underwriting purposes or prior to or in connection with enrollment. The preamble to the regulations provides that the definition of underwriting is broader than merely activities relating to rating and pricing a group policy; it also includes 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.

If an individual seeks a benefit under a group health plan, the plan may limit or exclude the benefit based on whether the benefit is medically appropriate, and the determination of whether the benefit is medically appropriate is not considered to be for underwriting purposes. Accordingly, if a plan conditions a benefit that an individual is seeking on its medical appropriateness, and the medical appropriateness depends on genetic information, then the plan is permitted to condition the benefit on the genetic information.

The regulations provide several examples generally illustrating that any reward given for the completion of an HRA that solicits information about the individual's family history violates GINA. Plans may collect genetic information through HRAs so long as the information is provided voluntarily and a reward is not provided, and plans may offer a reward so long as the HRA does not collect genetic information, but plans are not permitted to offer a reward if the HRA asks about family history or other genetic information.

The regulations also include examples in which information provided in HRAs is used to determine eligibility for a disease management program. If an enrolled individual seeks a benefit under a disease management program, the genetic information may be used to determine whether the benefit is medically appropriate. However, the regulations prohibit a plan from basing eligibility for a disease management program on family medical information provided in an HRA because the questions about genetic information in the HRA are a request for genetic information for underwriting purposes.

Also, an incidental collection of genetic information will not violate the non-collection rule as long as the collection form warns that genetic information should not be provided if it should reasonably be expected that persons responding to the form will be likely to include family medical history or other genetic information in their responses.

The interim final regulations will be effective 60 days after publication in the Federal Register on October 7, 2009. Therefore, for health plans, the regulations will apply to plan years beginning after that date.

Privacy Rules

As noted above, GINA also required HHS to revise the HIPAA Privacy Rule to clarify that genetic information is health information and that group health plans, health insurance issuers and issuers of Medicare supplemental policies may not use or disclose genetic information for underwriting purposes. The HHS Office of Civil Rights has issued a proposed regulation to make these changes and related conforming changes to the Privacy Rule.

Under the existing Privacy Rule, the definition of health information was sufficiently broad to encompass genetic information, and HHS had confirmed in a Frequently Asked Question on its Web site that this information was considered health information. The proposed regulations would add an explicit statement to that effect to the regulations themselves.

The proposed regulations would also add a specific prohibition on the use or disclosure of genetic information for underwriting purposes by a health plan or health insurance issuer. The definitions of the terms “underwriting purposes,” “genetic information,” “genetic test,” “manifestation” and so on are the same as in the nondiscrimination regulations issued by the Departments of Labor, Treasury and HHS. HHS noted in the preamble that the definition of a group health plan that is subject to the nondiscrimination rules is narrower than the definition of a health plan that is subject to the Privacy Rules and said that the Agency had chosen to write the proposed regulations to make all health plans that are required to comply with the Privacy Rule subject to the prohibition on use or disclosure of genetic information for underwriting purposes. The preamble also pointed out that a plan or insurance issuer cannot obtain an authorization to be able to use the genetic information for underwriting purposes – there is no exception to the prohibition on the use or disclosure of the information for this purpose. Because the definition of underwriting purposes in the proposed regulations would overlap with certain aspects of the definitions of the terms “payment” and “health care operations” in the prior final regulations, the proposed regulations include changes to these definitions to eliminate any explicit overlap and to clarify that the prohibition on use of genetic information for underwriting controls if an activity could still be considered both for payment or a health care operation and as being for underwriting purposes. Other conforming changes to the existing regulations were also proposed.

The proposed regulations would require plans and insurance issuers to revise their Notices of Privacy Practices to include a statement that genetic information cannot be used or disclosed for underwriting purposes. The Privacy Rule generally requires plans to issue an updated notice within 60 days of a material change to the notice. HHS indicated that it understands that this timing may be burdensome and that distributing revised notices may be costly. Thus, HHS solicited comments on ways to mitigate these burdens, such as by allowing a revised notice to be distributed with annual open enrollment materials or allowing a specific extension of time in this instance.

The amendments to the Privacy Rule are proposed to be effective 180 days after final regulations are published in the Federal Register. Comments are due on the proposed regulations within 60 days after publication in the Federal Register.



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