



INTERIM FINAL RULES - THE GENETIC INFORMATION NONDISCRIMINATION ACT (GINA)

October 2009

*On October 7, 2009 The Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (IRS) published interim final rules for Title I of GINA. The regulations become effective for plan years beginning on or after December 7, 2009 (January 1, 2010 for calendar year plans). In conjunction with this guidance, HHS issued a proposed rule that clarifies the HIPAA nondiscrimination requirements as it relates to genetic information. This **Insights** will review the impact these regulations have on group health plans and in particular the significant limitations imposed on the use of Health Risk Assessments (HRAs) in connection with wellness initiatives.*

BACKGROUND

The Genetic Information Nondiscrimination Act (GINA) was signed into law on May 21, 2008 and prohibits employers, insurers, and health plan sponsors from using or collecting genetic information to discriminate against employees and family members with respect to:

- ◆ Plan eligibility and contribution requirements (Title I); and
- ◆ Employment-related decisions such as hiring, promotions, and firing (Title II).

Title I of GINA, which basically expands the existing protections under the HIPAA nondiscrimination and privacy rules, applies to group health plans sponsored by private employers, unions, public employers; issuers in the group and individual health insurance markets; and issuers of Medicare supplemental (Medigap) insurance. Title I of GINA is effective for plan years beginning on or after May 21, 2009 (January 1, 2010 for calendar year plans). The Title II employment provisions take effect on November 21, 2009.

AN OVERVIEW OF THE GINA REGULATIONS

Group health plans are generally prohibited from determining eligibility, benefits, premiums, contributions or setting preexisting condition limitations based on any health factor, including genetic information. Like most federal laws, GINA does not mandate coverage for

genetic tests and services, but instead establishes rules when these benefits are covered. GINA and the recently issued clarifying regulations, prohibit a group health plan from discriminating based on genetic information or utilizing this information for underwriting purposes.

More specifically, GINA prohibits:

- ◆ Increasing group premiums or contributions 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.

KEY DEFINITIONS

The regulations contain a number of key definitions. A person's **genetic information** includes:

- ◆ Personal or family member genetic tests,
- ◆ The manifestation of a disease or disorder in family members (including data gathered in a family medical history), or
- ◆ Any request or receipt of genetic services (e.g. counseling, education, genetic tests, etc.) or participation in clinical research by the individual or a family member.

Genetic test generally means an analysis of human DNA, RNA, chromosomes, proteins or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes. **Family member** is broadly defined to include any first, second, third or fourth degree relative by affinity (marriage or adoption) or consanguinity (blood relative) and offers protections to unborn children, as well. A disease, disorder, or pathological condition is considered **manifested** when an individual has been or could reasonably be diagnosed by an appropriate healthcare professional, but the condition would not be

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considered manifested if the determination is made principally on the reliance of genetic information. For example, Person A has a family medical history of diabetes. Person A begins to exhibit the symptoms of diabetes and is then diagnosed with diabetes. The condition would be considered manifested because the diagnosis was based on Person A's symptoms and not on the family medical history (genetic information).

GENETIC TESTING

GINA generally does not allow a plan to request or require an individual or any family member to undergo genetic testing. However, there are three circumstances where a plan may request or require a genetic test and not run afoul of the GINA regulations. A plan may:

- ◆ Require and allow a genetic test upon the recommendation of a qualified healthcare professional who is providing treatment and services to the individual,
- ◆ Obtain and use the results of a genetic test or family medical history to determine or condition a claim payment based on medical appropriateness for which the outcome of a genetic test is needed (as long as the plan only uses the minimum necessary information to make the determination), or
- ◆ Request, but not require an individual to undergo a genetic test for research purposes if certain conditions outlined in the regulations are observed. For example, participation must be voluntary and refusal to participate in the study will not result in a loss of healthcare benefits.

GENETIC INFORMATION - ENROLLMENT AND UNDERWRITING RESTRICTIONS

The interim final regulations describe the statutory prohibitions against plans or issuers collecting genetic information, either for underwriting purposes or prior to or in connection with enrollment. The regulations greatly expand the meaning of underwriting purposes to not only include rating and pricing activities, but to incorporate such practices as changing deductibles or other cost-sharing mechanisms, providing discounts, rebates of any kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment (HRA) or participating in a wellness program. Furthermore, the collection of genetic information (such as requesting a family medical history) with respect to "enrollment" not only refers to initial enrollment but is expanded to include "annual open enrollment", as well.

GINA AND HEALTH RISK ASSESSMENTS

The new regulations greatly curtail the design and use of wellness tools such as Health Risk Assessments, however, a plan sponsor or insurer may continue to use Health Risk Assessments under the following guidelines:

- ◆ Employees may complete an HRA that asks for a family medical history as long as the request is voluntary and there is no reward offered for this information.
- ◆ A reward for completing an HRA may be offered, but genetic information and a family medical history may not be requested. Furthermore, the HRA must plainly state that the employee should not offer or divulge any genetic information when completing the HRA. In particular, open-ended questions that simply ask if someone would like to share any additional information not specifically requested would violate GINA, as an employee may inadvertently share genetic information when a question is posed in this manner.
- ◆ If an individual completes an HRA, and as a result of completing the HRA seeks a benefit under a disease management program, only personal genetic information may be used to determine whether the program is medically necessary. The regulations specifically prohibit using family medical history data to determine eligibility for a disease management program because this is considered information for underwriting purposes.

In addition, recent guidance from the Equal Employment Opportunity Commission (EEOC) suggests that certain disability-related questions on HRAs could violate the protections under the Americans With Disabilities Act (ADA). Consequently, HRAs must be reviewed and carefully crafted to comply with all of the laws and regulations that impact these questionnaires.

EXAMPLES

The regulations offer the following examples to help clarify the provisions of GINA:

- ◆ **Example 1** - A group health plan provides a premium reduction to members who complete a Health Risk Assessment after enrollment. Whether or not the HRA is completed or what responses are given has no effect on an individual's enrollment status, or on the enrollment status of the individual's family members. The HRA includes family medical history questions. **Conclusion** - The HRA includes a request for genetic information (family medical

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history). Because completing the HRA results in a premium reduction, the request for genetic information is for underwriting purposes and violates GINA.

- ◆ **Example 2** - The same facts as Example 1, except there is no premium reduction or other reward for completing the HRA. **Conclusion** – This does not violate GINA because the request is not for underwriting purposes, nor is it prior to or in connection with enrollment.
- ◆ **Example 3** - A group health plan requests enrollees to complete two distinct HRAs after and unrelated to enrollment. The first HRA instructs the individual to answer only for the individual and not for the individual's family. The first HRA does not ask about any genetic tests the individual has undergone or any genetic services the individual has received. The plan offers a reward for completing the first HRA. The second HRA asks about family medical history and the results of genetic tests the individual has undergone. The plan offers no reward for completing the second HRA and the instructions make clear that completion of the second HRA is wholly voluntary and will not affect the reward given for completion of the first HRA. **Conclusion** - No genetic information is collected in connection with the first HRA, which offers a reward, and no benefits or other rewards are conditioned on the request for genetic information in the second HRA. Consequently, the request for genetic information in the second HRA is not for underwriting purposes, and the two HRAs do not violate GINA and the prohibition on the collection of genetic information
- ◆ **Example 4** - A group health plan offers a diabetes disease management program to individuals for whom it is medically appropriate based on whether the individuals have or are at risk for diabetes. The program provides enhanced benefits related only to diabetes for individuals who qualify for the program. The plan sends out a notice to all participants that describes the diabetes disease management program and explains the terms for eligibility. Individuals interested in enrolling in the program are advised to contact the plan to demonstrate that they have diabetes or that they are at risk for diabetes. For individuals who do not currently have diabetes, genetic information may be used to demonstrate that an individual is at risk. **Conclusion** - The plan may condition benefits under the disease management program upon a showing by an individual that the individual is at risk for diabetes, even if such

showing may involve genetic information, provided that the plan requests genetic information only when necessary to make a determination regarding whether the disease management program is medically appropriate for the individual and only requests the minimum amount of information necessary to make that determination.

- ◆ **Example 5** - Same facts as Example 4, except the plan includes a questionnaire that asks about the occurrence of diabetes in family members as part of the notice. **Conclusion** - The plan violates GINA because the requests for genetic information are not limited to those situations in which it is necessary to make a determination regarding whether the disease management program is medically appropriate for the individual.

SUMMARY

GINA and the recently issued regulations are quite complex and require careful analysis to determine whether the collection, use or request for genetic information is in compliance with the law. Carriers and insurers must align administrative and underwriting processes and procedures to make sure the request for and use of genetic information is within stipulated guidelines. Plan sponsors should review HIPAA privacy policies and wellness initiatives such as Health Risk Assessments, to make sure the necessary use and restrictions are properly disclosed and administered.

ADDITIONAL INFORMATION

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