

## **New GINA Regulations Severely Hamper Health Risk Assessments**

**October 16, 2009**

New interim final regulations issued under the Genetic Information Nondiscrimination Act of 2008 (GINA) require employers to quickly evaluate and implement the new regulations before the 2010 plan year, especially with regard to wellness programs that utilize traditional health risk assessments (HRAs) that are linked to financial incentives, enrollment, or disease management programs. The Department of Labor, Department of Treasury, and Health and Human Services jointly published these three interim final regulations under Title I of GINA on October 7, 2009. The regulations can be found online at [http://www.morganlewis.com/documents/FederalRegister\\_InterimFinalGINARegs\\_07oct09.pdf](http://www.morganlewis.com/documents/FederalRegister_InterimFinalGINARegs_07oct09.pdf).

### **GINA Overview**

GINA prohibits discrimination based on genetic information and builds on the existing genetic nondiscrimination protections established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Specifically, Title I of GINA prohibits group health plans and health insurers (with some very limited exceptions) from taking the following actions:

- Increasing group premiums or contribution amounts based on genetic information
- Requesting or requiring individuals or their family members to undergo a genetic test
- Requesting, requiring, or purchasing genetic information prior to or in connection with enrollment, or at any time for underwriting purposes

The new regulations further define the scope and restrictions of these GINA prohibitions. To view a discussion of the original GINA legislation, see the Morgan Lewis LawFlash “New Law Prohibits Employers from Considering Genetic Information in Making Employment Decisions,” available at [http://www.morganlewis.com/pubs/LEPG\\_GeneticInformation\\_LF\\_22may08.pdf](http://www.morganlewis.com/pubs/LEPG_GeneticInformation_LF_22may08.pdf).

### **Genetic Information**

The new regulations broadly define the term “genetic information” to include information about an individual’s genetic test or the genetic tests of family members, the manifestation of a disease or disorder or any family medical history, and any request for genetic services. “Family members” include dependents, including all relatives to the fourth degree, whether related by blood, marriage, or adoption.

## **Prohibition on Adjusting Group Rates**

The new regulations expand HIPAA's nondiscrimination provisions by prohibiting group health plans and health insurers from adjusting premiums or contribution amounts for a group health plan of similarly situated individuals based on genetic information. Prior to these new regulations, group health plans and insurers could adjust premiums and/or contribution amounts based on genetic information as well as other health factors. Now, even when a group health plan or insurer has lawfully obtained genetic test results or other genetic information, GINA prohibits the group health plan or insurer from using that information to adjust premiums or contributions.

The new regulations clarify that GINA does not limit the ability of a group health plan or insurer to use a manifested disease or disorder of an individual enrolled in the group health plan to adjust the premium or contribution amount for the entire group health plan. Moreover, a group health plan or insurer may consider costs associated with providing benefits for covered genetic tests or genetic services when determining the costs of coverage under the plan.

## **Prohibition on Genetic Testing**

GINA generally prohibits group health plans and insurers from requesting or requiring individuals or their family members to undergo genetic testing. The new regulations provide three exceptions to this prohibition:

- A healthcare professional who is providing healthcare services to an individual may request the individual to undergo a genetic test
- A group health plan or insurer can obtain and use the results of a genetic test to make a determination regarding payment
- A group health plan or insurer is permitted to request an individual or covered dependent to undergo a genetic test in very limited circumstances involving research, as long as certain conditions and requirements are met

## **Prohibition on Collection of Genetic Information**

GINA prohibits group health plans and insurers from collecting genetic information in either of the following situations:

- Prior to or in connection with enrollment
- For underwriting purposes

### ***Collecting Genetic Information Prior to or in Connection with Enrollment***

The regulations clarify that a collection of genetic information with respect to an individual is considered collected prior to enrollment if an employer collects the genetic information before the individual's effective date of coverage under the plan. The determination of whether the employer collects the information before an individual's effective date of coverage is made at the time of collection. Any renewal of coverage or reenrollment would be treated the same as initial enrollment for this purpose. As a result, while a plan or insurer could collect genetic information after initial enrollment (under limited circumstances), the plan or insurer cannot use the information at a subsequent enrollment. This prohibition applies regardless of whether there is any financial incentive associated with the

collection, and may call into question plans that condition enrollment on the completion of a traditional HRA.

### ***Collecting Genetic Information for Underwriting Purposes***

The final interim regulations broadly define “underwriting purposes” to mean rules for the determination of eligibility (including enrollment and continued eligibility), computation of premium or contribution amounts, and application of preexisting condition exclusions. This definition 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 an HRA or participating in wellness programs. The new regulations clarify that offering reduced premiums or other rewards for providing genetic information is an impermissible “underwriting.”

The regulations provide an exception for receiving genetic information incidentally to the collection of other information as long as the information is not used for underwriting purposes. However, employers that use enrollment forms with questions that may elicit genetic information incidental to the process should explicitly include language on the form stating that employees should not provide genetic information in order to take advantage of the incidental collection exception.

### ***Impact on HRAs and Wellness Programs***

The prohibition on collecting genetic information for underwriting purposes described above severely impacts HRAs and wellness programs. A wellness program that provides rewards for completing an HRA that requests genetic information, including family medical history, violates the prohibition against requesting genetic information for underwriting purposes, even if the rewards or incentives are not based on the outcome of the assessment. There is no exception to this rule, regardless of the amount of the reward or incentive or whether the HRA meets the HIPAA wellness plan requirements. Simply put, an HRA that is tied to an incentive or an award cannot ask or collect any genetic information.

Further, GINA prohibits using an HRA to determine whether a participant is eligible for a disease management program if the HRA elicits family medical information—even if the HRA does not otherwise contain a financial reward or incentive.

However, a plan and insurer can still collect genetic information through a second voluntary HRA. The second HRA should be distinct and separate from the HRA containing the award or incentive. The second HRA must not trigger an award or incentive and must clearly state that completion is wholly voluntary and will not affect the award or incentive given for completion of the first HRA. The second HRA also cannot be used prior to or in connection with enrollment or, apparently, for making a determination regarding whether a disease-management program is medically appropriate for the individuals.

### **Next Steps**

Because the new interim final regulations are effective for plan years beginning on or after December 7, 2009 (which, practically, means January 1, 2010 for calendar year plans) employers have very little time to ensure that HRAs that currently elicit family medical history do not violate GINA. Because most employers have by now settled on their 2010 plan design and operation, any employers with HRAs must immediately begin to analyze and possibly modify the operation of those HRAs.

Morgan Lewis has experience in the design and operation of HRAs, and would be please to assist you with an analysis of your company's risks under GINA.

If you have questions or would like more information on any of the issues discussed in this LawFlash, please contact any of the following Morgan Lewis attorneys:

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