



Benefits Alert

Legal developments affecting employee benefits

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New GINA regs curtail health risk assessments

By Brian Kopp and Kate Ulrich Saracene

The departments of Labor, Health and Human Services, and the Treasury jointly released interim final regulations under Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA), which governs the use of genetic information by group health plans and insurers. The regulations impose significant limitations on the use of health risk assessments (HRAs) making many current practices illegal.

Congress enacted GINA in response to a concern that employers, insurers, and benefit plans might collect and misuse genetic information. Genetic information is broadly defined to include family medical histories. Because virtually all HRAs request information about an individual's family medical history and are frequently used as part of a wellness feature in an employer's medical plan, most HRAs are subject to GINA's rules.

Specifically, if an HRA includes questions about family medical history or solicits other genetic information, the new regulations prohibit group health plans and insurers from

soliciting participation in the HRA in conjunction with plan enrollment, or at any other time before the employee's effective date of coverage in the plan;

linking any incentives to the completion of the HRA (For example, plans are no longer permitted to 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.); or

using the HRA as a screening mechanism for determining participation in disease management programs or the receipt of other medical benefits.

In other words, plans may solicit family medical history or other genetic information in an HRA only 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). This is a significant reduction in the scope of how many HRAs are currently in use.

The regulations also clarify that the use of open-ended questions, which may implicitly request genetic information, is problematic. For example, questions such as, "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?”, may elicit genetic information in the response. Such questions must now be accompanied by statements specifically instructing participants not to provide any genetic information; otherwise, the HRA will be subject to the additional restrictions outlined above.

The regulations become effective for plan years commencing on or after December 7, 2009.

Following are some excerpted examples from the new regulations illustrating their impact on HRAs:

Example 1:

Facts. A group health plan provides a premium reduction to enrollees who complete a health risk assessment. The health risk assessment is requested to be completed after enrollment. Whether or not it is completed or what responses are given on it has no effect on an individual’s enrollment status, or on the enrollment status of members of the individual’s family. The health risk assessment includes questions about the individual’s family medical history.

Conclusion. In this Example 1, the health risk assessment includes a request for genetic information (that is, the individual’s family medical history). Because completing the health risk assessment results in a premium reduction, the request for genetic information is for underwriting purposes. Consequently, the request violates the prohibition on the collection of genetic information....

Example 2:

Facts. The same facts as Example 1, except there is no premium reduction or any other reward for completing the health risk assessment.

Conclusion. In this Example 2, the request is not for underwriting purposes, nor is it prior to or in connection with enrollment. Therefore, it does not violate the prohibition on the collection of genetic information....

Example 3:

Facts. A group health plan requests that enrollees complete a health risk assessment prior to enrollment, and includes questions about the individual’s family medical history. There is no reward or penalty for completing the health risk assessment.

Conclusion. In this Example 3, because the health risk assessment includes a request for genetic information (that is, the individual’s family medical history), and requests the information prior to enrollment, the request violates the prohibition on the collection of genetic information.... Moreover, because it is a request for genetic information, it is not [a permitted] incidental collection of genetic information....

Example 4:

Facts. The facts are the same as in Example 1, except there is no premium reduction or any other reward given for completion of the health risk assessment. However, 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. Other people may become eligible for the disease management program based solely on their answers to questions about their individual medical history.

Conclusion. In this Example 4, the request for information about an individual’s family medical history could result in the individual’s being eligible for benefits for which the individual would not otherwise be eligible. Therefore, the

questions about family medical history on the health risk assessment are a request for genetic information for underwriting purposes and are prohibited....

Example 5:

Facts. A group health plan requests enrollees to complete two distinct health risk assessments (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. In this Example 5, 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 the prohibition on the collection of genetic information....

Example 6:

Facts. A group health plan waives its annual deductible for enrollees who complete an HRA. The HRA is requested to be completed after enrollment. Whether or not the HRA is completed or what responses are given on it has no effect on an individual's enrollment status, or on the enrollment status of members of the individual's family. The HRA does not include any direct questions about the individual'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?"

Conclusion. In this Example 6, the plan's request for medical information does not explicitly state that genetic information should not be provided. Therefore, any genetic information collected in response to the question is not within the incidental collection exception and is prohibited....

Example 7:

Facts. Same facts as Example 6, except that the last question goes on to state, "In answering this question, you should not include any genetic information. That is, please do not include any family medical history or any information related to genetic testing, genetic services, genetic counseling, or genetic diseases for which you believe you may be at risk."

Conclusion. In this Example 7, the plan's request for medical information explicitly states that genetic information should not be provided. Therefore, any genetic information collected in response to the question is within the incidental collection exception. However, the plan may not use any genetic information it obtains incidentally for underwriting purposes.

The above rules apply to health plans and insurers regulated by Title I of GINA. In March 2009, the Equal Employment Opportunity Commission (EEOC) issued proposed regulations pursuant to Title II of GINA, which regulates employers. Title II of GINA includes an exception from GINA's prohibition on requesting genetic information if the request is made in connection with a voluntary wellness program. (Title I of GINA does not include such an exception.) Given that wellness

programs are typically tied to a health plan, it is not clear if anything is really left of the exception. We hope for clarification when the EEOC issues final regulations.

If you would like more information about the topics covered in this alert, please contact your regular Nixon Peabody attorney or:

David S. Foster at 415-984-8331 or dfoster@nixonpeabody.com

Christian D. Hancey at 585-263-1147 or chancey@nixonpeabody.com

Sherwin Kaplan at 202-585-8224 or skaplan@nixonpeabody.com

Brian Kopp at 585-263-1395 or bkopp@nixonpeabody.com

Thomas J. McCord at 617-345-1337 or tmccord@nixonpeabody.com

Steven C. Mindy at 585-263-1106 or smindy@nixonpeabody.com

Eric Paley at 585-263-1012 or epaley@nixonpeabody.com

Kate Ulrich Saracene at 585-263-1438 or ksaracene@nixonpeabody.com