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# Health Risk Assessments in a Protected Environment

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This article discusses the use and collection of genetic information for Health Risk Assessments and wellness programs under the Genetic Information Nondiscrimination Act of 2008 (GINA), Public Law 110-233. Title I of GINA was enacted to prohibit discrimination with respect to health insurance on the basis of genetic information. Recently, three federal agencies, the U.S. Departments of Treasury, Labor, and Health and Human Services, issued interim final regulations which govern the use and collection of genetic information by health insurance issuers and group health plans. Many employers use health risk assessment tools in wellness programs to assist them in developing personal health improvement plans. Often these health risk assessment tools are used in disease management programs to control costs, maintain quality of care and the continuation of coverage. The health plan actuary uses claims data and demographic information for the development of the group ratings. The many disciplines that use health risk assessments need to evaluate their programs for compliance with these new federal regulations.

GINA prohibits group health plans and health insurance carriers in the group and individual markets from using genetic information to increase

premiums or contribution amounts to the individual or the group. However, nothing in the regulations limits group rating based on health factors, review of claims experience and the blending of the rate. Health insurers and group health plans may increase premiums or contribution amounts for the entire group health plan based on the manifestation of the disease or disorders of individuals who are enrolled under the plan. A disease is considered manifested when a health care professional has made a diagnosis based on an examination, symptoms or test results; but a disease is not manifested if a diagnosis is based principally on genetic information. It is permissible for the plan to include the cost of genetic testing or genetic services with the aggregate costs of the plan for purposes of determining premiums. Lastly, the plan is not permitted to increase premiums by using information about a manifested disease of one individual as genetic information about other members of the group, e.g. similarly situated individuals or dependent children.

Individuals and family members cannot be required nor requested by health insurers or group health plans to undergo genetic testing. However, a health care professional may still recommend and order a genetic test for the individual. Insurers and plans are permitted to obtain and use genetic test results to

determine if payment for services is appropriate. A plan is permitted to condition the payment for a service on the outcome of a genetic test to determine the appropriateness of certain courses of treatment. The plan is permitted to request a participant to undergo a genetic test under the research exception, so long as all the conditions of the research exception are met. Naturally, the plan cannot mandatorily require the individual to participate in the research, and no collected or acquired genetic information can be used for underwriting purposes.

Genetic information cannot be collected prior to or in connection with enrollment or at any time for underwriting purposes. The regulations define genetic information as information about an individual's genetic tests or tests of family members, the manifestation of a disease or disorder in family members which is disclosed in a family medical history or the fact that a request was made by the individual or family member for genetic services such as testing, counseling or education. This broad definition makes the collection of genetic information, including a family medical history, subject to the federal regulations.

Wellness programs that reward individuals for completing health risk assessments and disclosing genetic information and family medical history information would be in violation of the regulations. However, as long as no rewards are offered, a plan can collect genetic information after enrollment through the health risk assessment process. Similarly, a plan can offer rewards for completing the health risk assessment so long as genetic information is not solicited. So, a plan could administer two distinct health risk assessments after enrollment in the plan: one with the option for a reward without soliciting genetic information, and the option for soliciting genetic information without a reward incentive.

GINA does not allow the collection of genetic information for underwriting purposes. In addition to insurance rating or pricing a group policy, underwriting purposes are broadly defined to include eligibility rules for benefits, computation of

premiums or contribution amounts, the use of preexisting condition exclusions, changes in deductibles, cost-sharing mechanisms, discounts, rebates, payments in kind or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program. Health insurers and group health plans will have to conduct compliance reviews to ensure that genetic information is not being used prior to or in connection with enrollment or for underwriting purposes.

However, the regulations allow plans to collect genetic information which happens to be incidental to the collection of other information, so long as the genetic information is not used for underwriting purposes. In order to qualify for this incidental collection exception, the collection form must contain an explicit statement to inform the individual that genetic information should not be provided.

Further, a plan may request genetic or family medical history information to make determinations regarding payment of a claim. Payment can be limited or denied for an actual claim submission based upon a determination of whether the provided care was medically appropriate and indicated. This payment exception process would not be considered an underwriting purpose.

The administrative agencies believe that implementing underwriting safeguards will reduce the fears of individuals from the health coverage-related consequences of undergoing genetic testing and participating in research studies that examine genetic information. More genetic testing will lead to greater knowledge of genetic disorders, earlier diagnosis and treatment of individuals predisposed to developing certain diseases and the development of new discoveries and treatments.

The administrative agencies are also cognizant of the fact that curtailment of genetic information for use by the underwriter could increase the potential for adverse selection in the insurance market. Individuals having prior knowledge of genetic testing results could influence the timing and purchasing



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of health coverage. Individuals with low genetic risk factors might forgo health coverage. Those individuals at risk of contracting a serious medical condition could benefit from obtaining health coverage. If the ability to accurately assess the medical risks is compromised, then plans may be forced to raise premiums for all insureds. Experience data will need to be monitored.

The administrative agencies expect that the premiums for health care coverage will increase to offset increased costs as genetic testing and associated expenditures increase. However, the direct cost of testing could be offset by lower costs associated with the treatment of manifested diseases.

To assure compliance with the provisions contained in the federal regulations, plans may need to modify the operations of their health risk assessment programs, conduct training sessions with underwriters, conduct compliance reviews, coordinate with outside vendors, modify enrollment application forms and practices, update training manuals, and amend

policies and procedures. The health plan actuary should determine that genetic information is not used for group rating purposes. Plans will need to advise health care providers and others that the portions of the medical records dealing with genetic information and family medical history information should be removed or redacted prior to submission to the plan. These internal safeguards are recommended to assure compliance with the federal regulations.

Health Risk Assessments are used by health insurance carriers, group health plans, and employers to motivate individuals to improve their health and lifestyle, in connection with enrollment or for underwriting purposes. Health insurers, group health plans, and employers will need to redesign their incentive programs, enrollment processes and underwriting purposes to comply with the legislative and administrative mandates under the Genetic Information Nondiscrimination Act. Since the health risk assessment is the centerpiece of wellness programs and disease management programs, health insurance issuers, group health plans and employers will need to strive to achieve high levels of participation and

to promote employee health and wellness in a protected environment.

*This article is written for informational purposes only and should not be construed as legal advice. ■*

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