ALERT
Willis Employee Benefits Practice

November 2009 – Vol. 2, No. 10 www.willis.com

GINA CHANGES THE HRA RULES

Ever since President Bush signed the Genetic Information Nondiscrimination Act of 2007 (GINA) into law in May 2008, benefits experts have debated the law's effect on health risk assessments (HRAs) used in wellness programs. In October 2009, federal officials issued regulations that help answer this and other questions about GINA's effect on health plans. In short: HRAs are not illegal, but the questions they ask and the way they are conducted will likely have to change for most organizations.

MOST HRAs CAUSE GINA PROBLEMS

HRAs are questionnaires intended to provide an overall picture of respondents' future health risks. HRAs usually include questions regarding health conditions, personal habits and family medical history. Under most wellness programs, health plan participants complete the HRA during the annual enrollment period. In some cases, completing the HRA is a requirement for enrollment in the plan or in a specific plan option or benefit level. More often, the plan provides a discount on premium contributions to those who complete an HRA (or a surcharge to those who don't). In addition, health plans may use the information gathered in HRAs to identify individuals who could benefit from disease management, health coaching or other wellness programs.

GINA affects HRAs because it prohibits health plans and their insurers from engaging in the following practices:

- Collecting (meaning requesting, requiring or purchasing) genetic information prior to or in connection with enrollment or collecting genetic information for underwriting purposes
- Requesting or requiring an individual or family member to undergo a genetic test
- Varying individuals' eligibility, benefits, premiums or contributions based on genetic information
- Increasing the premiums or contributions charged to or for a group's health plan coverage based on genetic information

One of the main sources of conflict stems from the fact that GINA includes family medical history in its definition of genetic information and prohibits health plans from collecting genetic information prior to or in connection with enrollment, or for underwriting purposes. The new regulations explain that enrollment occurs when coverage becomes effective, so HRAs requested during annual enrollment will almost certainly run afoul of the law if they include questions about family members' health conditions. Similarly, if a premium discount or surcharge depends on completion of an HRA that requests family medical history, the plan would violate GINA by using genetic information for underwriting.

Some HRA proponents hoped that the regulations would carve out an exception allowing employers' plans to request family medical history and use it in wellness programs. No such exceptions were provided – but the law does not ban HRAs outright.

Cautionary Note #1. The new regulations address use of HRAs when the reward or penalty for completion relates to a health plan (e.g., reward is a premium or deductible reduction or is available only to health plan participants). HRAs that are tied to other incentives (e.g., gift cards or vacation days available to any employee) are subject to different GINA provisions – the employment discrimination provisions. Proposed regulations from the Equal Employment Opportunity Commission, if finalized, would interpret those provisions to severely restrict use of HRAs that request genetic information. (For information on GINA provisions prohibiting employment discrimination, see Willis' *HR Focus*, June 5, 2008 – "President Signs Genetic Information Nondiscrimination Act of 2007 (GINA).")

HRAs ARE STILL PERMITTED

It appears that health plans providing incentives for completion of HRAs (or requesting completion of HRAs before or in connection with enrollment) can avoid GINA violations if they take two measures:

- Remove all questions that directly or indirectly request genetic information (including questions about family members' health conditions)
- Add a statement to the revised HRA along these lines:

  In answering these questions, you should not include any genetic information. 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.

The regulations do not explicitly say that such HRAs are GINA-compliant, but employers' health plans should be able to provide rewards for completion or impose penalties for non-completion of such HRAs. A plan using a GINA-compliant HRA also should be able to extend disease management, health coaching or other wellness programs to individuals based on their responses. An important caveat, however, is that none of these decisions can be based on any genetic information provided on an HRA, even if the information is provided contrary to instructions.

Cautionary Note #2. Complying with GINA does not assure compliance with other laws, including the nondiscrimination requirements in the Health Insurance Portability and Accountability Act (HIPAA) and the Americans With Disabilities Act (ADA). The effect of the HIPAA rules on wellness programs is discussed in *Employee Benefits Alert*, #128 – "More Guidance, More Flexibility on Wellness Programs." Potential issues with HRAs under the ADA are discussed in *HR Focus*, Issue 24, "EEOC Moves To Oppose Mandatory HRA Screenings."

EFFECTIVE DATES

For calendar year plans, these GINA provisions – and the new regulations interpreting them – are effective January 1, 2010. For plans operating on other plan years, the provisions may already be effective (they apply to plan years starting on or after May 21, 2009), but the new regulations will not be effective until next year (they apply to plan years starting on or after December 7, 2009). For example, a plan with a June 1 plan year became subject to GINA on June 1, 2009 but will not be subject to the new regulations until June 1, 2010. It is difficult to say, however, what leeway such plans may have in the interim, and employers sponsoring such plans may wish to comply with the regulations as soon as possible.

Cautionary Note #3. In November 2009, many calendar-year plans have already distributed their annual enrollment materials for 2010, including any HRAs they request or require. If the HRAs include questions about family medical history, those requests for genetic information will not violate GINA because they are made before GINA becomes effective for those plans. Starting January 1, 2010, however, it will be illegal to vary premiums, contributions, benefits or eligibility based on genetic information, even if requesting the information was legal. As a result, cautious employers may want to forego applying incentives for HRA completion if their HRAs include requests for family medical history or other genetic information, or if the HRAs do not warn respondents to avoid providing genetic information as described above.

GINA requirements generally apply to the same plans that are subject to the nondiscrimination requirements in HIPAA, and the same exemptions apply, including:

- Stand-alone dental-only and vision-only plans
- Health flexible spending accounts offered under cafeteria plans, provided certain conditions are met
- Coverage for on-site medical clinics

Plans covering fewer than two current employees at the start of the plan year are exempt from the HIPAA nondiscrimination rules, but are not exempt from GINA's requirements. (Some experts contend that this provision makes health plans providing benefits only to retirees exempt from HIPAA nondiscrimination compliance.) In addition, self-insured nonfederal governmental plans cannot opt out of GINA's requirements in the same way they can with respect to most HIPAA nondiscrimination requirements.

GINA also requires the Department of Health and Human Services (HHS) to revise its HIPAA privacy rules so that using genetic information for underwriting purposes is no longer permitted. HHS has issued proposed regulations that, if finalized, will implement this requirement. (We will address those HHS rules in future publications after the rules are finalized.)

While HHS' proposed revisions to the HIPAA privacy rules are not binding, employers that are making changes to HIPAA privacy and security materials to comply with other recent changes to the rules may consider adopting changes based on these proposed regulations at the same time. (For information on recent changes to the HIPAA privacy and security rules, see Willis' *Employee Benefits Alert*, Vol. 2, No. 9 – "New HIPAA Requirements: Breach Notification.")

FAMILY MEDICAL HISTORY *CAN* BE REQUESTED

HRAs may in fact include a request for family medical history or other genetic information, but only under requirements so strict the HRAs would likely have little value. Here are the conditions under which an HRA could request family medical history (all four must be met):

- The HRA is requested after enrollment (meaning after the effective date of coverage) and is not requested in connection with enrollment
- The HRA clearly states that completing the HRA is voluntary
- There is no reward or penalty for completing or not completing the HRA
- No disease management or health coaching program and no enhanced benefits will be provided based on the responses provided in the HRA

THE MEDICAL APPROPRIATENESS EXCEPTION

One of the main purposes of requesting family medical history on an HRA is to help ensure that those predisposed to certain conditions receive appropriate disease management, health coaching or other services. It may be possible to partially accomplish this goal under a narrow exception to the prohibition on health plans requesting and using genetic information. The law allows health plans to collect genetic information that is needed to determine whether benefits requested for an item or service should be provided under the rules of the plan.

This exception would apply to disease management, health coaching or other wellness services offered as plan benefits *available only on request and only when medically appropriate*. If these (and other) requirements are met, the plan could ask individuals voluntarily seeking the wellness services to provide genetic information needed to determine medical appropriateness. A plan would violate GINA, however, if it asked all plan participants to provide family medical history and then offered disease management services to those whose information indicated that the services would be medically appropriate. It is unlikely that employers will find the medical appropriateness exception a useful substitute for collecting family medical history on an HRA.

ACT NOW

Employers whose wellness programs have included HRAs should review their practices in light of the new regulations. They should consider removing any HRA questions that might be interpreted as requesting family medical history or other genetic information. They should also consider adding instructions telling respondents not to provide such information. In addition, employers should review their health plan practices more broadly to determine if genetic information is involved at all (e.g., using one family member's diagnosis with a genetically linked condition as a risk factor for another family member when setting rates). While most plans do not explicitly use genetic information, employers may find some practices that should be discontinued before GINA becomes effective.

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