

Limitations in GINA Regulations Would Severely Curtail Effectiveness of Wellness Programs

The Interim Final Regulations Prohibit the Use of Benefits or Rewards for Completing Health Risk Assessments

The Departments of Labor, Treasury and Health and Human Services recently issued long-awaited interim final regulations on Title I of the Genetic Information Nondiscrimination Act (GINA). The most troubling aspect about the regulations is the chilling effect they will have on the use of employer-sponsored wellness programs and health risk assessments (HRA) even though such programs have increased in popularity and have strong bipartisan support. Under the interim final regulations governing the insurance aspects of GINA, the use of HRAs and participation in wellness programs would be curtailed by the regulations' implementation of GINA's prohibition against "group health plans" collecting genetic information for "underwriting" purposes or in connection with initial or open plan enrollment. The regulations are effective for plan years beginning on or after December 7, 2009. HR Policy Association will file comments on the regulations, which are due January 5, 2010.

GINA Prohibits Self-Insured Plans from Engaging in "Genetic Discrimination"

Title I of GINA prohibits genetic discrimination by providers of health insurance. Under GINA's discrimination ban, "group health plans", including self-insured employers, are prohibited from adjusting premiums / contributions because of genetic information, requesting an individual or family member undergo a genetic test (unless voluntary test for genetic research), or collecting genetic information—which includes family medical history—for underwriting purposes including prior to or in connection with plan enrollment, although if information is obtained "incidentally" it is not unlawful. Many in the employer community had hoped that the regulations would clarify that collection of family medical history in connection to HRAs and wellness programs would be considered "incidental" under the Act. The agencies, instead, took the opposite approach and adopted a very expansive definition of "underwriting."

Definition of "Underwriting" Interpreted Very Expansively Contrary to the relatively commonly understood meaning of "underwriting", the regulations announce that the term includes reductions in deductibles, premiums or cost-sharing in return for activities such as completing a health risk assessment or participating in a wellness program. Underwriting would also include providing discounts, rebates or payments in kind as a reward for participating in an HRA or wellness program. Thus, as a matter of practice, a plan may not provide a reward for completing an HRA or for participating in a wellness program if the participant is required to provide family medical history—a critical component of almost any assessment. Moreover, wellness programs or HRAs cannot inquire about family medical history prior to or in connection with plan enrollment, regardless of whether it is connected to some type of reward or benefit.

Regulations Leave No Real Viable Options The agencies' guidance indicates that they believe HRAs and wellness programs will continue to be effective in spite of the ban set forth in the regulations. In the regulations, the agencies note that the following options may still be used:

- A wellness program or HRA that does not ask for family medical history and/or other genetic information;
- A wellness program or HRA that asks for family medical history and/or other genetic information but does not offer any type of reward; or
- A program with two HRAs, one that does not request family medical history and *does* provide a reward for participation and another HRA that does inquire as to family medical history but *does not* offer a reward and offering family medical history is completely voluntary.

These options effectively eliminate the ability of employers to provide incentives to employees who participate in an effective wellness program by filling out an HRA. HRAs that do not collect family medical history are generally considered to be incomplete and not sufficient to assist in helping employee plans. Similarly, banning employers from providing incentives to employees for supplying family medical information in connection with HRAs will significantly reduce the number of employees who would participate in wellness programs.

Effective Date of the Regulations & Potential Employer Violations While the regulations are effective for plan years beginning on or after December 7, 2009, many employers have already released HRA questionnaires in preparation for the next plan year before having any knowledge of the regulations. There is a great deal of concern whether questionnaires sent out before the release of the regulations will be considered unlawful. The respective agencies have not yet declared that they will not enforce this aspect of the regulations for the upcoming year.