



701 Pennsylvania Ave. N.W., Suite 700
Washington, D.C. 20004-2694
(202) 737-5980 • (202) 478-5113 (fax)
dmaa@dmaa.org • www.dmaa.org

Impact of the Genetic Information Nondiscrimination Act (GINA) Interim Final Rule on Wellness and Disease Management Programs

Frequently Asked Questions

What is GINA?

On May 21, 2008, President George W. Bush signed the Genetic Information and Nondiscrimination Act (GINA) into law. The legislation, which passed the House by a 414-1 vote and won unanimous Senate approval after more than a decade of debate, sought to end discrimination in insurance and employment based on genetic information. As signed into law, GINA defined “underwriting purposes” in a traditional manner, including for “the computation of premium or contribution amounts under the plan or coverage.”

However, a joint interim final regulation on GINA from the departments of Health and Human Services, Labor and the Treasury unexpectedly expanded the “underwriting purposes” definition. The Oct. 7, 2009, regulation added, after the “computation of premium” language:

“(including 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)”

The interim final rule is scheduled to take effect Dec. 7, 2009. The agencies will accept comments on it through Jan. 5, 2010.

What is DMAA’s position on GINA?

DMAA fully supports GINA’s goal of guarding against the improper use of genetic information in hiring practices and in the provision and pricing of health insurance. But we oppose elements of the Oct. 7, 2009, interim final rule that would severely limit the use of health risk assessments (HRAs) and access to wellness and disease management services, which improve lives and increase value in health care.

How does the interim final rule impede the ability to conduct wellness and disease management programs?

The interim final rule impedes wellness and disease management programs by:

- Prohibiting collection of family medical history through an HRA for stratification and enrollment in wellness and disease management programs; and
- Defining “underwriting” to include the use of HRAs in connection with premium discounts, rebates and other incentives commonly employed with success to increase wellness program participation.

By limiting the collection of family medical history for enrollment in wellness and disease management programs, the regulation forces employers, health plans and others to either end incentives or remove questions about family medical history from health risk assessments. Both options come at a cost: Without incentives, wellness and disease management participation declines. Without family medical history, the effectiveness of HRAs and, consequently, wellness and disease management programs suffers.

A third option, establishing two health risk assessments – one with questions about family medical history and one without – adds a burdensome layer of complexity, inconveniences participants and increases the cost of care. Further, genetic information collected under this scheme still could not be used to match participants with disease management services, regardless of the use of incentives.

Can’t wellness and disease management programs be just as effective without soliciting family history and other genetic information?

Family health history, such as that typically collected through an HRA, is an important predictor of chronic disease risk and essential to wellness and prevention efforts. The Centers for Disease Control and Prevention Office of Public Health Genomics, in its frequently asked questions about family history, says:

“Family history is one of the most important risk factors for health problems like heart disease, stroke, diabetes and cancer. (A risk factor is anything that increases your chance of getting a disease.)”¹

Prohibiting collection of family history in HRAs increases the chance that those who could benefit most from prevention and disease management might fall through the cracks. This, in turn, could lead to a greater incidence of chronic disease and higher health care spending, as these individuals develop costly conditions that might otherwise have been prevented.

The alternative – collecting genetic information without providing incentives for program participation – could have the same effect. Without incentives, program participation likely would decline sharply. Again, programs would fail to reach those most in need of services and poorer outcomes and increased costs would result. Particularly troubling is the regulation’s apparent inclusion of disease management as a benefit under the definition of underwriting purposes. As such, family history could not be used – even absent incentives – to identify appropriate candidates for these valuable programs.

¹ <http://origin.cdc.gov/genomics/famhistory/resources/faq.htm> (accessed Oct. 22, 2009)

How would DMAA change the regulation to resolve these concerns?

DMAA has asked the three federal agencies with regulatory jurisdiction to immediately impose a moratorium on the interim final rule's implementation and enforcement. Further, DMAA has asked for the creation of a joint-agency panel to respond to concerns about the rule.

DMAA also has asked Congress to clarify the law's intent with respect to the underwriting definition and consider providing a safe harbor for health risk assessments that use family history to stratify participants into wellness and disease management programs.

Do other stakeholders share DMAA's concerns?

Yes. DMAA is working closely with other organizations, including those representing employers and health plans, to raise awareness of the chilling effect the interim final rule will have on access to wellness and disease management programs. This regulation will be particularly burdensome on employers, who overwhelmingly support wellness programs. A 2008 survey by the National Association of Manufacturers and the ERISA Industry Committee found that 77 percent of employers offer formal health and wellness programs and that the use of incentives is on the rise, with 71 percent offering some form of incentive for program participation. Respondents to a 2009 DMAA industry survey of program providers and purchasers identified incentives as among the top four critical components of population health management and wellness programs. A majority of respondents called incentives essential to program success.