



585/22

The ERISA Industry Committee

November 18, 2009

The Honorable Timothy Geithner
Secretary
U.S. Department of Treasury
1500 Pennsylvania Avenue N.W.
Washington, DC 20220

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue S.W., Room 639G
Washington, DC 20201

The Honorable Hilda Solis
Secretary
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

Dear Secretary Geithner:
Secretary Sebelius:
Secretary Solis:

Attached is a letter submitted yesterday by the ERISA Industry Committee ("ERIC") through the federal eRulemaking Portal concerning a request for comments on the interim final rules implementing sections 101 through 103 of the Genetic Information Nondiscrimination Act of 2008 ("GINA"). The request was published by the Departments of Labor, Health and Human Services, and the Treasury (collectively, the "Departments") in the *Federal Register* on October 7, 2009.

The interim final regulations place a number of new and unforeseen restrictions on health risk assessments that request family medical history, and on employees' participation in disease management programs. As ERIC explains in its comments, these restrictions are not consistent with the statute, and they will severely impair the effectiveness of workplace wellness programs.

In addition to our substantive concerns, the effective date of the regulation will also have a profoundly negative—and we believe unintended—impact on company wellness programs. The regulation was released more than four months after the statutory deadline for publication; by this time, companies had already completed the drafting, preparation, printing, and possibly dissemination of their open enrollment materials for 2010.

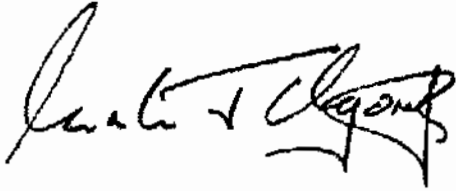
GINA, as enacted, was intended to prevent discrimination on the basis of genetic information. We support the goals of GINA and the intent of much of the regulation under Title I. We cannot, however, support a regulation that would severely weaken the value of wellness programs both for ourselves and our employees.

The ERISA Industry Committee
November 18, 2009

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ERIC appreciates the opportunity to provide these comments on the interim final regulations. If the Departments have any questions concerning our comments, or if we can be of further assistance, please let us know.

Sincerely,



Mark J. Ugoretz
President

- cc: Phyllis Borzi, Assistant Secretary, Employee Benefits Security Administration,
U.S. Department of Labor (via e-mail)
- Robert Kocher, MD, Special Assistant to the President, National Economic
Council, The White House (via fax to (202) 456-4796)
- Ezekiel Emanuel, MD, Special Advisor for Health Policy, Office of the Director,
Office of Management and Budget (via fax to (202) 395-3174)

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The
ERISA
Industry
Committee

November 17, 2009

Submitted through the Federal eRulemaking Portal

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5653
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Attention: RIN 1210-AB27

Ladies and Gentlemen:

The ERISA Industry Committee ("ERIC") is pleased to submit this response to the request for comments on the interim final rules implementing sections 101 through 103 of the Genetic Information Nondiscrimination Act of 2008 ("GINA"). The request was published by the Departments of Labor, Health and Human Services, and the Treasury (collectively, the "Departments") in the *Federal Register* on October 7, 2009.

The interim final rules implement provisions of GINA that prohibit group health plans from discriminating on the basis of genetic information. GINA provides that a group health plan may not (1) increase premiums or contributions for a group based on the genetic information of individuals in the group, (2) request or require an individual or family member to undergo a genetic test, or (3) request, require, or purchase genetic information prior to or in connection with enrollment or for underwriting purposes.

ERIC's Interest in the Interim Final Rules

ERIC is a nonprofit association committed to the advancement of the employee retirement, health, incentive, and welfare benefit plans of America's largest employers. ERIC's members sponsor group health plans that provide comprehensive health benefits directly to some 25 million active and retired workers and their families. ERIC has a strong interest in proposals that affect its members' ability to deliver high-quality, cost-effective benefits.

Many ERIC members have taken the lead in developing voluntary wellness programs. Some of the most effective programs are designed to address each participant's personal health needs. In many programs, each participant is encouraged to complete a health risk assessment ("HRA") that provides family medical history, evaluates the individual's health status, and identifies any conditions that merit observation or intervention. Employees are much more likely to complete an HRA if they receive an incentive to do so. A recent survey of 694 employers found that 64% offered employees an incentive to complete an HRA, and that the rate of participation increased significantly in programs that offered incentives.¹

Based on the information in the health risk assessment, medical professionals retained by the employer design a program to address the individual's personal health needs. The HRA often serves as the entry point for the employer's wellness program, where individuals are offered incentives to improve or maintain their health (for example, by reducing their weight or exercising regularly). Individuals with chronic conditions might be offered the opportunity to participate in a disease management program. As required by the Health Insurance Portability and Accountability Act,² the information collected in the HRA remains confidential: it is not shared with the employer.

Workplace wellness programs are popular and increasingly widespread. In 2009, 78% of large employers surveyed offered wellness programs to their employees, and 83% of large employers surveyed offered disease management programs to eligible individuals; 67% of all employers surveyed said that they intended to expand or improve their wellness programs in the future.³ Employees value these programs, and they benefit from the programs' emphasis on identifying and addressing health problems before the problems become more serious and more costly to treat.

¹ PricewaterhouseCoopers Health and Well-Being Touchstone Survey at 28–30 (May 2009), http://pwchealth.com/cgi-local/hregister.cgi?link=reg/PwC_2009_health_and_well-being_Touchstone_survey_results.pdf.

² 45 C.F.R. §§ 164.500–164.534. GINA § 105 directs the Department of Health and Human Services to amend the HIPAA Privacy Rule to provide additional protection for genetic information. The Department published a proposed amendment at 74 *Fed. Reg.* 51698 (Oct. 7, 2009).

³ PricewaterhouseCoopers Survey, *supra*, at 7, 29, 32. The Departments, relying on a Kaiser Family Foundation survey from 2008, estimate that approximately 30,000 group health plans offer wellness and disease management programs that provide an incentive to complete an HRA. 74 *Fed. Reg.* at 51672 n. 19. The Departments have underestimated the impact of the interim final regulations on these programs in two respects. First, the PricewaterhouseCoopers Survey shows that the percentage of surveyed employers offering incentives to complete an HRA increased from 57% in 2008 to 64% in 2009, so that data drawn from a 2008 survey necessarily understates the number of plans affected. Second, a more important measure of the regulations' impact is the number of *participants* affected. Since wellness and disease management programs offering HRA incentives are much more prevalent among large employers (those with 5,000 or more employees), the affected plans cover a disproportionately large percentage of all group health plan participants. PricewaterhouseCoopers Survey, *supra*, at 28, 29, 32.

Urgent Request for Delayed Implementation

The interim final regulations place a number of new and unforeseen restrictions on health risk assessments that request family medical history, and on employees' participation in disease management programs. As ERIC explains below in its comments on specific provisions, these restrictions are not consistent with the statute, and they will severely impair the effectiveness of workplace wellness programs. Employers do not have time to bring their group health plans into compliance by January 1, 2010, when the new restrictions are scheduled to become effective for most plans. Accordingly, ERIC urges the Departments to announce as soon as practicable that the effective date of certain provisions in the interim final regulations will be delayed by at least twelve months.

The provisions whose effective date should be delayed are (1) the definition of "underwriting purposes," to the extent that the definition prohibits a group health plan from offering *any* incentive to an employee merely to complete a health risk assessment (see Comment 1, below) or prevents a group health plan from using information provided in a health risk assessment to determine a participant's eligibility for a voluntary disease management program (see Comment 2, below); and (2) the definition of "enrollment," to the extent that the definition applies to the period after the participant has completed the enrollment process but before the effective date of coverage (see Comment 3, below). The delay will give the Departments an opportunity to understand how these provisions will affect workplace wellness programs and to address the legal and practical concerns that ERIC identifies in this letter.

The statute required the Departments to issue final regulations interpreting Title I of GINA no later than May 21, 2009.⁴ This deadline recognized the long lead time that employers require in order to implement any change that affects their group health plans. Large employers ordinarily finalize the design of their group health plans for the next calendar year no later than June or July, so that the plans' third-party administrators will have time to program software systems, revise administrative manuals, and train customer service representatives to administer the benefits properly. Employers also must prepare participant communications and open enrollment materials, and must create internet-based tools, to help employees understand the new benefit options and make appropriate choices concerning their family's health coverage for the upcoming year. Many employers commence open enrollment for the upcoming year in October or earlier.

The Departments published the interim final regulations on October 7, more than four months after the statutory deadline and at a time when most of ERIC's members had started (and some had nearly completed) their annual enrollment for 2010. Although the Departments had previously requested general information from

⁴ Pub. L. No. 110-233, §§ 101(f)(1), 103(f)(1).

the public on Title I of GINA,⁶ the Departments took the unusual step of publishing final regulations without first publishing proposed regulations. As a result, the publication of the interim final regulations revealed for the first time that the Departments had interpreted GINA to restrict workplace wellness programs in ways that employers could not have anticipated. It simply is not possible for large employers to redesign their benefit programs, eliminate incentives previously promised to their employees, recall and reissue printed communications, coordinate with outside vendors, and take the other steps that would be necessary to comply with the new restrictions by January 1, 2010.

Employers face civil penalties and excise taxes up to \$500,000 per year for violations of the GINA rules, even if the violations are due to reasonable cause.⁶ Although the penalties and excise taxes can be waived in cases where the employer could not discover the violation by exercising reasonable diligence, there is no similar relief for violations that occur because employers have insufficient time to comply with the new restrictions. The financial penalty for non-compliance is self-executing: employers who are not able to bring their group health plans into compliance by January 1, 2010, will be required to report and pay the excise tax on their own initiative.⁷ Accordingly, the Departments cannot address the unfair compliance burden imposed on employers by exercising appropriate enforcement discretion.

Because the Departments did not previously issue the regulations in proposed form, employers have not had an opportunity to comment on the new restrictions imposed by the regulations, to explain the many harmful effects these restrictions will have on workplace wellness programs, or to seek answers to the important questions that remain unresolved. Significantly, the public comment period for the regulations closes in January 2010, a month *after* the regulations become effective. ERIC anticipates that it will take a substantial amount of time for the Departments to review the comments submitted and develop appropriate modifications to the regulations. Accordingly, ERIC urges the Departments to delay the effective date of the underwriting and enrollment provisions ERIC has identified until the Departments have an opportunity to understand how the regulations will affect workplace wellness programs. Although ERIC has proposed a delay of at least twelve months as the minimum period the Departments will require to address the problems associated with these provisions, ERIC notes that a two-year delay would be more appropriate, so that employers will have sufficient time to bring their group health

⁶ See 73 *Fed. Reg.* 60208 (Oct. 10, 2008).

⁶ ERISA § 502(c)(9); I.R.C. § 4980D(c).

⁷ See *Treas. Reg.* § 54.4980D-1, 74 *Fed. Reg.* 45997 (Sept. 8, 2009) (final regulation identifying the form used to report the excise tax under I.R.C. § 4980D and establishing a reporting deadline). Employers who fail to report and pay the excise tax by the deadline will owe interest and additional penalties. See I.R.C. § 6651.

plans into compliance with any new restrictions before they begin to develop their plan designs and enrollment materials for the first plan year affected by the restrictions.

ERIC does not make this request lightly. ERIC recognizes that the Departments have worked diligently, under difficult conditions, to collect relevant information and to provide guidance to group health plans affected by GINA. ERIC's members are committed to GINA's goal of ensuring that group health plans do not collect or use genetic information inappropriately, but they believe that this goal can be achieved without sacrificing programs designed to improve their workers' health. If the Departments delay the effective date of the provisions ERIC has identified, employers still must administer their group health plans in compliance with a reasonable, good-faith interpretation of Title I of GINA. Accordingly, delaying the effective date will not deprive group health plan participants of the protection that the statute was designed to provide.

Comments on "Underwriting" Restrictions

GINA prohibits a group health plan from requesting, requiring, or purchasing genetic information for underwriting purposes. The statute defines "underwriting purposes" as rules for determining eligibility (including enrollment and continued eligibility) for coverage or benefits; the computation of premiums or contributions; the application of pre-existing condition exclusions; and other activities related to the creation, renewal, or replacement of health insurance or benefits.

1. The regulations should state that a reward for completing a health risk assessment is not "underwriting."

Medical underwriting is the process by which a health plan or insurer evaluates the health risk associated with an individual to determine whether the individual should be denied initial or renewal coverage; whether certain conditions should be excluded from coverage; or whether the individual's premiums, deductibles, or costs should be increased.⁸ For example, a group health plan would engage in medical underwriting if the plan charged a participant a higher premium because she had the BRCA2 gene mutation associated with breast cancer, or if the plan denied a participant coverage because his father had a hereditary condition such as Huntington's Disease.

⁸ See H.R. Rep. No. 28 Part 2, 110th Cong., 1st Sess. 28 (2007) ("If an individual applies for a Medigap policy after the open enrollment period, the company is permitted to use medical underwriting. *This means that the company can use an individual's medical history to decide whether or not to accept the application and how much to charge for the policy.*" [Emphasis added.]

A primary concern of Congress when it enacted GINA was to prevent discrimination in group health coverage based on genetic information.⁹ Congress regarded medical underwriting as “inherently discriminatory,”¹⁰ since underwriting permitted a group health plan to charge higher premiums, limit or deny coverage, or otherwise apply adverse rules based on the greater actual or perceived risk associated with certain genetic information. In order to prevent this type of discrimination, GINA prohibited group health plans from collecting or using genetic information for underwriting purposes. The report of the Senate Committee on Health, Education, Labor, and Pensions explained, “Since one of the purposes of this legislation is to prevent discrimination in premium rates, this provision prohibits a plan or issuer from using or disclosing genetic information for purposes of underwriting, determining eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or benefits.”¹¹

The interim final regulations adopt a definition of “underwriting purposes” that goes well beyond both the language and the intent of the statute. As defined in the regulations, “underwriting purposes” includes “changes in deductibles or other cost-sharing mechanisms . . . [or] 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 preamble of the regulation explains, “[W]ellness programs that provide rewards for completing HRAs that request genetic information, including family medical history, violate the prohibition against requesting genetic information for underwriting purposes.”¹² Accordingly, if a group health plan offers a participant an incentive to complete a health risk assessment that requests family medical history, the incentive is regarded as prohibited “underwriting” even if the genetic information is requested after enrollment and has no effect on the individual’s costs or coverage.¹³

This definition of “underwriting” ignores the fact that the reward for completing a health risk assessment has nothing to do with any increased risk associated with the genetic information collected in the HRA. As the regulation itself

⁹ See Pub. L. No. 110-233, § 2(5): “Federal law addressing genetic discrimination in health insurance and employment is incomplete in both the scope and depth of its protections. . . . Therefore Federal legislation establishing a national and uniform basic standard is necessary to fully protect the public from discrimination and allay their concerns about the potential for discrimination, thereby allowing individuals to take advantage of genetic testing, technologies, research, and new therapies.”

¹⁰ See H.R. Rep. No. 28 Part 1, 110th Cong., 1st Sess. 25 (2007); S. Rep. No. 48, 110th Cong., 1st Sess. 3 (2007).

¹¹ S. Rep. No. 48 at 25–26.

¹² 74 *Fed. Reg.* at 51668.

¹³ See *Treas. Reg.* § 54.9802-3T(d)(3), Example 1; 29 C.F.R. § 2590.702-1(d)(3), Example 1.

acknowledges, the individual is being rewarded for an *activity*—that is, for filling out an HRA that includes family medical history—regardless of what the HRA reveals about the individual's genetic makeup. An individual whose family medical history indicates a predisposition to diabetes or heart disease will receive exactly the same reward as an individual whose family medical history reveals no increased risk of any disease or medical condition. Because the reward for completing the HRA is unrelated to any increased risk that the genetic information contained in the HRA might disclose, the reward cannot be considered a form of “underwriting” as that term is commonly understood or as it was understood by Congress when it enacted GINA.

The preamble of the interim final regulations points out that earlier versions of GINA included exceptions for wellness programs in both the Title I health coverage provisions and the Title II employment provisions, whereas the legislation as enacted included an exception for wellness programs only in Title II.¹⁴ The difference is easily explained, however, by the fact that Title I does not prohibit group health plans from collecting genetic information in all circumstances: instead, it limits the plans' ability to collect this information prior to enrollment or for underwriting purposes. As ERIC has demonstrated, the concept of “underwriting,” properly construed, does not prohibit group health plans from offering incentives to complete an HRA that includes family medical history, as long as the genetic information collected does not affect the employee's coverage. Significantly, the Title I exception for wellness programs appeared in a different provision concerning genetic testing; the exception was later deemed unnecessary because the provision permitted any health care professional (whether or not employed by a group health plan or wellness program) to request that an individual undergo a genetic test. Despite Congress's evident desire to preserve workplace wellness programs,¹⁵ the legislation's drafters did not feel that a similar exception was necessary in the underwriting provision of Title I. In contrast, Title II of GINA generally prohibits an employer from collecting genetic information for *any* purpose, and thus requires an exception in order to preserve employment-based wellness programs that are maintained separately from group health plans.

ERIC is not alone in reaching the conclusion that GINA permits an employer group health plan to reward participants for providing genetic information, as long as the plan does not use the genetic information to deny enrollment, set premiums, or make other benefit-related decisions. A report prepared for Congress by the

¹⁴ 74 *Fed. Reg.* at 51669 n. 12.

¹⁵ See S. Rep. No. 48 at 19 (“the committee is also aware that some health plans go beyond the insurance function and engage in wellness and disease management programs; and *the committee does not wish to discourage such efforts.* Thus, section 101(b) makes it clear that this legislation does not limit the authority of a health care professional who is employed by or affiliated with the group health plan or health insurance issuer who is providing health care services to the enrolled individual as part of a wellness program from notifying such individual about the availability of a genetic test or providing information about the genetic test.” [Emphasis added])

Congressional Research Service, a nonpartisan agency within the Library of Congress, explains the “underwriting” restriction as follows:

If an employer adjusted a premium contribution amount according to participation in a wellness program but did not utilize collected genetic information in this decision, it would comply with GINA statutory provisions [B]y definition, in order to violate GINA’s provisions, an employer would have to use the collected information to determine premium amounts. *Simply using the fact of participating in a wellness program to determine premium contributions does not appear to meet the definition of “underwriting purposes” under the Act.* [Emphasis added.]¹⁶

Confidential health risk assessments permit group health plans to develop wellness programs tailored to each individual’s health needs. Like other large employers, the federal government has recognized this fact: the Federal Employee Health Benefits Program (“FEHBP”), which is not subject to Title I of GINA, offers employees an incentive to complete a health risk assessment that requests family medical history.¹⁷ The description of the program’s “Blue Health Assessment” states, “By entering your personal health information *and family medical history*, you’ll receive personalized health-related recommendations to improve or maintain your health and wellness.” [Emphasis added.]¹⁸

If group health plans are prohibited from offering participants incentives to complete confidential HRAs that include family medical histories, these programs will become far less effective. Nothing in Title I of GINA or in its legislative history suggests that Congress intended to impose such a restriction. It is ironic that the interim final regulations have interpreted GINA in a way that undermines wellness programs at a time when pending health reform measures emphasize the importance of preventive care and workplace wellness programs, and even mandate wellness benefits

¹⁶ Amanda K. Sarata, “Employer Wellness Programs: Health Reform and the Genetic Information Nondiscrimination Act,” CRS Report R40791, at 6 (August 31, 2009).

¹⁷ Blue Cross recently announced that it would waive the co-payments on annual physical exams for participants in the Blue Cross and Blue Shield Government-wide Service Benefit Plan (FEP) who complete the “Blue Health Assessment” as part of their 2010 benefits package. “Federal Employee Program (FEP) Focuses on Health and Wellness in 2010” (Sept. 29, 2009), <http://www.bcbs.com/news/bcbsa/fep-focuses-on-health-and-wellness-in-2010.html>. The FEP covers more than half of the 8 million federal employees and retirees (and their families) who participate in the FEHBP.

¹⁸ <https://fepa.careenhance.com/portal/site/fepa>.

for Medicare beneficiaries.¹⁹ ERIC urges the Departments to correct this unjustified interpretation.²⁰

2. The regulations should make clear that determining eligibility to participate in a voluntary disease management program is not “underwriting.”

If a group health plan offers a disease management program, the plan often uses family medical history to identify individuals who might benefit from the program. For example, individuals who are at risk of developing diabetes might be eligible for a disease management program that seeks to prevent or delay the onset of the disease through diet, exercise, monitoring blood sugar levels, and other interventions. If a participant’s voluntary health risk assessment discloses a family history of diabetes, a health professional might contact the participant, provide information about the plan’s voluntary disease management program for those at risk of developing diabetes, and recommend that the individual consider participating in the program.

Because the plan in this example uses family medical history to determine the participant’s eligibility for the disease management program, the interim final regulations treat the plan as collecting genetic information for prohibited “underwriting purposes.”²¹ The interim final regulations prohibit this use of genetic information even if the information is collected after the participant’s enrollment in the group health plan, and even if the group health plan offers no incentive to the individual who provides the information.

¹⁹ See, e.g., H.R. 3962, 111th Cong., 1st Sess. § 2301(a) (2009); S. 1679, 111th Cong., 1st Sess. § 302 (2009) (establishing a fund for national investment in prevention and wellness programs); H.R. 3926 at § 2301(a), S. 1679 at § 303 (creating a task force to encourage and expand preventive services); S. 1679 at § 327 (establishing a demonstration project to “test the impact of providing at-risk populations who utilize community health centers . . . an individualized wellness plan that is designed to reduce risk factors for preventable conditions as identified by a comprehensive risk-factor assessment”); H.R. 3962 at § 112 (directing the Labor Department and Department of Health and Human Services to make wellness program grants to support small employers that establish workplace wellness programs); S. 1679 at § 326 (confirming that group health plans and insurers “may offer incentives to an individual who voluntarily participates in a wellness program that is reasonably-designed to promote health or prevent disease”); S. 1796, 111th Cong., 1st Sess. § 1901(a) (2009) (confirming that workplace wellness programs may offer incentives up to 30% of the annual cost of health coverage), S. 1679 at § 334 (directing the Centers for Disease Control and Prevention to conduct an educational campaign “to make employers, employer groups, and other interested parties aware of the benefits of employer-based wellness programs” and to provide technical assistance for workplace wellness programs); and S. 1796 at § 2001 (requiring Medicare to cover a personalized prevention plan and an annual wellness visit for all Medicare beneficiaries).

²⁰ To the extent that the Department of Health and Human Services has incorporated a similar definition of “underwriting purposes” in its proposed amendment to the HIPAA Privacy Rule, ERIC urges the Department to correct that definition as well. See 45 C.F.R. § 164.501 (proposed), 74 *Fed. Reg.* 51709 (Oct. 7, 2009).

²¹ Treas. Reg. § 54.9802-3T(d)(3), Example 4; 29 C.F.R. § 2590.702-1(d)(3), Example 4.

In order to comply with the interim final regulations, the group health plan in this example must ignore the information it has otherwise lawfully obtained, which identifies participants who might benefit from its disease management program. Instead, the group health plan may do no more than publicize the disease management program to all participants and hope that the individuals who might benefit will identify themselves, understand on their own the importance of the program to their continued health, and apply for admission.

Nothing in GINA requires this result. As the interim final regulations recognize, GINA permits a group health plan to use genetic information to determine whether a benefit or service is medically appropriate.²² Accordingly, a group health plan may use genetic information to determine whether an individual is eligible to participate in a disease management program.²³ The only difference between conduct prohibited and conduct permitted under the interim final regulations is a question of timing. If the plan uses genetic information on its own initiative to determine whether the participant is eligible for the disease management program, the plan's use of genetic information is prohibited. In contrast, if the plan waits until the participant applies for admission to the disease management program and then uses genetic information to determine whether he is eligible, the plan's use genetic information is permitted. This artificial distinction bears no relationship to the concept of "underwriting."

As explained above, GINA prohibits the use of genetic information for "underwriting purposes" in order to protect group health plan participants from adverse treatment based on the actual or perceive risk associated with certain genetic conditions. If, instead, a group health plan extends additional benefits (such as participation in a disease management program) to individuals with certain conditions that have not yet manifested themselves as a disease or disorder, the plan does not engage in prohibited "underwriting" when it uses family medical history or other genetic information to determine whether an individual is eligible for the additional benefits. As long as participation in the disease management program or other additional benefit is completely voluntary, it should make no difference whether the participant "seeks" the benefit on his own or whether the plan identifies him as an eligible individual based on information he provides in a health risk assessment.

Experience has shown that without the encouragement of a health professional, many participants who would benefit from participation in a disease management program will never enroll. Accordingly, the position taken in the interim final regulations is not only unnecessary, it is potentially damaging to the health of

²² Treas. Reg. § 54.9802-3T(d)(1)(iii); 29 C.F.R. § 2590.702-1(d)(1)(ii). Although the statutory exception relates only to genetic tests, the interim final regulations expand the exception to permit group health plans to use the minimum amount of genetic information necessary to make determinations regarding payment. This expansion is appropriate and consistent with the purposes of GINA, and should be retained.

²³ Treas. Reg. § 54.9802-3T(e), Example 4; 29 C.F.R. § 2590.702-1(e), Example 4.

plan participants. ERIC urges the Departments to make clear that a plan will not be deemed to collect genetic information for “underwriting purposes” when the plan uses the information to identify participants eligible for additional benefits provided on a voluntary basis.

Comments on Enrollment Restrictions

3. The regulations should clarify that “enrollment” means the process of enrolling in a group health plan, not the effective date of coverage.

GINA prohibits a group health plan from collecting genetic information prior to or in connection with an individual’s enrollment in the plan. The legislative history indicates that this restriction reflected Congress’s broader concern that group health plans would use genetic information to deny participants coverage or increase the cost of their coverage. For example, the report of the House Committee on Education and Labor observed:

The Committee believes that if a covered entity is barred from using or disclosing genetic information for purposes of underwriting, it should not be able to collect such information in the first place as part of the underwriting, application, or some other preenrollment process or interaction.²⁴

The interim final regulations define “enrollment” as the individual’s “effective date of coverage” under the plan.²⁵ This definition goes well beyond the language and purpose of the statute.

Most group health plans conduct open enrollment during the fall for the coverage period beginning on the following January 1. Many large employers have automated the annual enrollment process. A participant may log on to a confidential internet site and provide the information necessary to enroll in the group health plan. Once the participant has submitted the enrollment information and has been accepted by the plan (but before the new period of coverage becomes effective), the internet site might offer a screen that allows the participant to complete a voluntary health risk assessment that includes family medical history. Similarly, if the participant submits a paper enrollment form, the administrator might send to each participant who enrolls in the plan (before the new period of coverage becomes effective) a voluntary health risk assessment that includes family medical history.

In both cases described in the preceding paragraph, the participant’s enrollment in the group health plan is complete, and the terms of his participation in the plan are fixed, before the plan requests genetic information. The voluntary HRA is

²⁴ H.R. Rep. No. 28 Part 1 at 34; *see also* S. Rep. No. 48 at 26.

²⁵ Treas. Reg. § 54.9802-3T(d)(2)(i); 29 C.F.R. § 2590.702-1(d)(2)(i).

presented before the participant's group health plan coverage becomes effective so that any information gathered in the HRA can be used to design a wellness program that will meet the individual's personal health needs and will complement the individual's group health plan coverage when it becomes effective. An HRA completed after the individual's group health plan coverage has become effective will be less valuable to the individual: at a minimum, it will delay the time when the individual can participate fully in the related wellness program. In addition, in the case of electronic enrollment, the time immediately after the participant enrolls in the plan (but before he logs off of the system) is often the only time when it is practical to offer him the opportunity to complete an on-line health risk assessment.

The interim final regulations should be revised to indicate that "enrollment" means what it says: the process of enrolling in a group health plan. Once the participant's enrollment is complete and the terms of his participation in the group health plan are fixed, it is not necessary to extend the period during which the plan is prohibited from collecting genetic information. GINA prohibits a group health plan from collecting genetic information at any time "in connection with" the individual's enrollment. Accordingly, any genetic information collected after a participant enrolls in the group health plan, but before his coverage becomes effective, may be used only for purposes permitted under GINA. The current definition in the regulations, which prohibits any collection of genetic information until after the effective date of coverage, imposes substantial administrative costs and inconvenience on group health plans without any corresponding benefit to participants.

Additional Comments on Effective Date

The interim final regulations are scheduled to become effective on January 1, 2010, for most group health plans. For the reasons explained above, ERIC has requested that the Departments delay the effective date of certain provisions for at least twelve months. ERIC offers below several additional comments on the effective date of the regulations and related transition issues.

4. The regulations should clarify that GINA does not prohibit rewards provided after the effective date of the regulations for genetic information collected before the effective date.

At present, most group health plans that include voluntary health risk assessments offer employees incentives to complete the HRAs.²⁶ The incentive often takes the form of a reduction in premiums or contributions, a waiver of the deductible, or other financial benefits associated with the employee's participation in the group health plan. For voluntary HRAs offered in connection with the coverage period that begins January 1, 2010, employees generally are completing the HRAs now (or have already completed them) as part of the annual enrollment process. The annual

²⁶ See note 1, *supra*, and accompanying text.

enrollment materials, which were printed and distributed long before the Departments published the interim final regulations, promised employees that they would receive a reward in 2010 (such as a reduction in their 2010 health contributions) for completing the voluntary HRA in the fall of 2009.

The interim final regulations treat a reward associated with the collection of genetic information as a prohibited collection for “underwriting purposes.” ERIC has explained above why this interpretation is at odds with the statute, the legislative history, and the accepted definition of “underwriting.” It is not an interpretation that employers could reasonably have foreseen; and the interim final regulations were published far too late for employers to adjust their group health plan enrollment materials and procedures. Nevertheless, the interim final regulations appear to prohibit a group health plan from providing a premium reduction or other financial benefit in 2010, after the regulation becomes effective, even if the participant was promised this reward for completing a voluntary HRA in 2009 that included family medical history.

Applying this restriction in 2010 is unfair to employees and serves no purpose. The genetic information has already been collected, under a reasonable, good-faith interpretation of the statutory requirements: although group health plans can alter the way in which they use the information, they cannot alter the fact that they have collected it. Employees have completed the HRAs during the 2009 enrollment period in the expectation that they would receive the promised reward when their health plan coverage became effective in 2010. To force group health plans to break this promise and deny employees the reward in 2010 accomplishes nothing except to harm the individuals whom GINA is supposed to protect. If the Departments do not delay the effective date of this restriction, ERIC urges the Departments to make clear that group health plans may provide rewards in 2010 for genetic information collected during 2009, before the regulations became effective.

- 5. The regulations should clarify that program eligibility established on the basis of genetic information collected before the effective date of GINA remains valid.**

GINA generally prohibits the collection of genetic information for underwriting purposes. The interim final regulations define this concept very broadly (and, in ERIC’s view, inappropriately) to include any situation in which an individual receives a reward for completing an HRA that includes family medical history, and any situation in which genetic information is used to determine eligibility for a benefit (unless the participant was actively seeking a benefit that is conditioned on medical appropriateness). These rules appear to apply to any use of genetic information after

the effective date of the interim final regulations, even if the genetic information was lawfully collected before the effective date.²⁷

As explained above, group health plans that include disease management programs often condition a participant's eligibility for those programs on certain risk factors, including a family history that indicates an increased risk of developing a disease or adverse health condition. Once an individual qualifies for participation in a disease management program, the individual usually remains eligible from year to year: the program does not require participants to provide an annual demonstration that they remain at risk for the condition addressed by the disease management program.

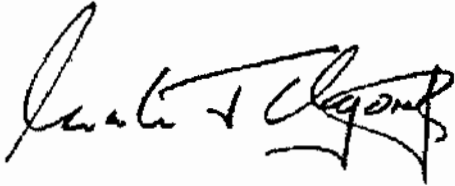
In many cases, the information used to establish an individual's eligibility for the disease management program was collected years ago, long before GINA was enacted. The employer has no way of determining now whether the individual's eligibility for the program was based on family medical history collected in an HRA for which the individual received an incentive, or whether the individual was "seeking benefits" under the disease management program before the eligibility determination was made. In most disease management programs, it is likely that participants will have established their eligibility through a variety of means, some of which would have complied with GINA and the interim final regulations if those rules had been in effect at the time, and some of which would not have complied.

If group health plans are required to determine that the eligibility of any individual to continue participating in a disease management program after 2009 was established by a method that would have complied with the interim final regulations, the plans will have no alternative other than to force all participants in the program to re-establish their eligibility for the program. Forcing all participants to re-qualify for the disease management program would be expensive and disruptive, and would serve no purpose. Instead, such a rule would require group health plans to collect genetic information again that they have already obtained by lawful and appropriate means. To avoid this costly and futile exercise, the Departments should make clear that eligibility for a disease management program or other continuing benefit that was based on a collection of genetic information before the effective date of the interim final regulations remains valid after the effective date.

²⁷ See 74 Fed. Reg. at 51667 ("[E]ven when a plan or issuer has lawfully obtained genetic test results or other genetic information (for example, an acquisition that took place prior to GINA's effective date), the plan or issuer is still prohibited—under GINA and paragraph (b) of these interim final regulations—from using that information to discriminate.") Although this statement is directed at the provision of GINA prohibiting group-based discrimination in premiums, nothing in the regulations suggests that a different principle would apply to the underwriting provision.

ERIC appreciates the opportunity to provide these comments on the interim final regulations. If the Departments have any questions concerning our comments, or if we can be of further assistance, please let us know.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark J. Ugoretz". The signature is stylized with a large initial "M" and a prominent horizontal stroke across the middle.

Mark J. Ugoretz
President