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Office of Health Plan Standards and Compliance Assistance
Attn: RIN 1210-AB27
Employee Benefits Security Administration, Room N-5653
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Dear Department Officials:

The purpose of this letter is to submit the following comments regarding the Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance Coverage and Group Health Plans (the "Interim Final Rules") issued by the Department of Labor, the Department of Treasury and the Department of Health and Human Services (collectively, the "Agencies") on October 7, 2009. We understand that this letter will be shared with the Department of Treasury and the Department of Health and Human Services.

For the reasons discussed below, we believe that the Interim Final Rules interpret the definition of "underwriting purposes" more expansively than what is intended under Title I of GINA. We respectfully request that the Agencies reconsider and revise the definition of "underwriting purposes" in the Interim Final Rules to specifically authorize group health plans to –

- Offer rewards and other incentives to plan participants who complete health risk assessments (HRAs) that include questions which request genetic information, including questions about family medical history; and

- Use HRAs that collect genetic information through family medical history questions or otherwise to identify and enroll individuals in the plan's disease management program.

I. Revise the definition of "underwriting purposes" to allow rewards to be provided to health plan participants as an incentive for completing an HRA.

Prior to GINA, group health plans commonly provided monetary and other incentives to health plan participants in return for completing HRAs that contain questions about family medical history.[1] For most employers, HRAs are an integral part of their wellness program as they serve as a gateway for steering participants towards appropriate wellness activities. It is well-established that HRA completion rates increase significantly when a reward is offered to those who complete it. Moreover, few would deny the importance of wellness and disease management programs as a cost-effective way of containing spiraling health care costs.

Under the Interim Final Rules, a group health plan may not provide a reward to participants as an incentive for completing an HRA because these activities fall within the definition of "underwriting purposes." The Interim Final Rules define "underwriting purposes" much more expansively than the definition contained in Title I of GINA, and as a result many common wellness practices are now prohibited. Yet, there is nothing in GINA or the legislative history which suggests that this expanded definition is appropriate or intended by Congress. The Interim Final Rules characterize the changes to the definition of "underwriting purposes" as a "clarification," but a comparison of the relevant sections from the definition in GINA and the Interim Final Rules shows just how much broader the new definition is.

Definition of "Underwriting Purposes": The term "underwriting purposes" is defined in relevant part with respect to any group health plan to include –

Title I of GINA	The Interim Final Rules
(A) rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage;	(A) rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage ***(including changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program)***;
(B) the computation of premium or contribution amounts under the plan or coverage;	(B) the computation of premium or contribution amounts under the plan or coverage ***(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***;

[1] For simplicity, we will assume in the remainder of this letter that all HRAs include questions about family medical history and thus can be viewed under the Interim Final Rules as collecting genetic information.

There is nothing in GINA or the legislative history which indicates that Congress intended the definition of "underwriting purposes" to be interpreted to restrict the use of rewards in connection with HRAs. Given the prevalence of this practice, if Congress had intended to eliminate this types of activity by including it within the definition of "underwriting purposes" it would have drafted the statute to address this issue or at a minimum there would be some discussion in the legislative history regarding this intent.

Moreover, the legislative history actually supports the conclusion that existing HRA reward practices should be allowed to continue. In particular, the legislative history indicates that –

- Congress supports using genetic information to identify beneficial medical treatments (as is done with HRAs and wellness programs);[2]

- Congress does not intend to change the existing established practices of employers in controlling health care costs;[3]

- Congress is concerned about the actual use of genetic information to deny eligibility to participate in a health plan or to raise the premium rates, but the focus is on situations where the genetic information itself results in a denial of coverage or increased premium not the situation where a reward is given for voluntarily completing an HRA regardless of the outcome.[4]

While the Agencies have indicated that they do not believe that they have the ability to carve out an exception for wellness and disease management programs, there is nothing in the statute or

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[2] H.R. Rep. No. 110-28, pt. 1 at 38 (2007) ("The second exception--which preserves employer-sponsored wellness programs--is necessary to achieve the bill's stated goal of encouraging employees to take advantage of genetic technologies and opportunities to improve human health without fear of discrimination by their employer."); S. Rep. 110-48, at 26 ("Since health insurance issuers typically treat underwriting as a separate business function and process from coverage decisions and medical management, the committee believes that this important layer of protection will not adversely impact the delivery of patient care and health care improvement activities."); H.R. Rep. No. 110-28, pt. 3 at 27 (2007) ("The appropriate use of genetic information offers enormous opportunities to save lives and prevent the onset of disease."); Rep. Schwartz (Pa.): "In additional to the great medical potential they are exploring, genetic information also has the potential to reduce health care costs with better prevention and disease management." 154 Cong. Reg. H2974 (daily ed. May 1, 2008).

[3] S. Rep. No. 110-48, at 19 (2007) ("[T]he 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"); Id., at 35 ("While the legislation adds to the substance of these existing requirements, it does not add any major new concepts or requirements .... Based on these factors, the committee has determined that there will be negligible regulatory impact with respect to group health plans.").

[4] Sen. Kennedy (Ma.): "The bill before us provides comprehensive protections. It prohibits health insurers from using a patient's genetic information to deny health insurance coverage or raise premiums." 154 Cong. Reg. S3364 (daily ed. April 24, 2008). Rep. Pelosi (Ca.): "This legislation prevents health insurers from adverse coverage or pricing decisions based on a person's genetic predisposition toward a disease. 154 Cong. Reg. H2961 (daily ed. May 1, 2008).

legislative history that requires or even suggests such an expansive definition of "underwriting purposes" is warranted. We urge the Agencies to revise the definition of "underwriting purposes" to provide a carve-out for rewards which are offered to participants who complete an HRA.

II. Revise the definition of "Underwriting Purposes" to allow HRAs to be used in connection with disease management programs.

Another common employer practice is to use HRAs to identify and enroll eligible individuals in a plan's disease management program. The Interim Final Rules also prohibit this practice because the HRA is viewed as collecting information for the purposes of determining eligibility for benefits under the plan (e.g., the disease management program) which falls within the definition of "underwriting purposes." The Interim Final Rules do, however, allow the plan to send information about the disease management program to participants and if an individual requests enrollment in the disease management program, the plan may require the participant to submit genetic information to determine whether program is "medically appropriate." The key appears to be that an individual must formally apply for a disease management program and if the individual is refused participation he or she can submit genetic information to prove eligibility. We believe that this distinction cuts too fine of a line and is not supported by GINA.

Disease management programs are not separate plans with separate eligibility requirements that must be met by participants in order to participate. Rather, disease management programs are part of the existing health plan and all participants of the health plan are typically already eligible for the disease management program. The HRA is simply used as a tool to determine whether the disease management program is medically appropriate for a particular individual. This is similar to determining whether a particular service is medically necessary under the plan. For example, all plan participants are eligible for all the services provided by the plan, such as chiropractic services, but those services will only be paid for by the plan upon a showing that they are medically necessary. Similarly, all plan participants are typically eligible for a disease management program, but those services again are only provided if they are medically appropriate. As a result, we do not believe that it is appropriate to interpret the definition of "underwriting purposes" to include the use of an HRA to identify individuals for whom participation in a disease management program is medically appropriate when that program is already part of the health plan.

Alternatively, if the Agencies are unwilling to revise the definition of "underwriting purposes" to exclude use of HRAs in connection with disease management programs, we respectfully request that the Interim Final Rules be revised to allow the plan to treat the HRA as the participant's application for enrollment in the disease management program (together with appropriate written disclaimers that inform the individual that the HRA is an application). This approach would allow the plan to rely on the medically appropriateness exception in using the genetic information that is provided in the HRA to determinate if the individual is eligible for the disease

management program. This would be helpful to employers and their group health plans as it eliminates the additional step of requiring participants to contact the plan to formally request enrollment.

We appreciate the opportunity to submit these comments and urge your careful consideration of our recommendations. If you have any questions, please feel free to contact me.

Sincerely,

Mark L. Stember

Martha L. Sewell