



December 17, 2009

Amy Turner  
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 20010  
Attention: RIN 1210-AB27

**Re: Comments on Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance Coverage and Group Health Plans**

Dear Ms. Turner:

We are writing on behalf of the American Benefits Council ("Council") and the HR Policy Association ("HRPA") to comment on the Interim Final Rules for Prohibiting Discrimination Based on Genetic Information ("Interim Final Rules" or "Rules"). The Interim Final Rules were issued by the Department of Labor, Department of Health and Human Services, and Department of Treasury on October 7, 2009 (74 Fed. Reg. 51664). The Rules address the Genetic Information Nondiscrimination Act ("GINA"). The Preamble to the rules states that a response submitted to one agency will be shared with the other agencies and that commenters should not submit comments to more than one agency.

The Council is a public policy organization representing principally Fortune 500 companies and other organizations that assist employers of all sizes in providing benefits to employees. Collectively, the Council's members either sponsor directly or provide services to retirement and health plans that cover more than 100 million Americans.

HRPA represents the senior human resource executives of over 280 of the largest employers doing business in the United States. Representing every major industrial sector, HRPA's members employ over 12 percent of the United States' private sector workforce or some 10 million employees in the United States and 18 million worldwide.

All of our companies operate employee welfare benefit programs, and most sponsor wellness programs that include health risk assessments ("HRAs") and disease management

programs. Many of our members have been leading innovators in developing these programs, which are an important component of employers' strategies to engage employees to improve health status and workforce productivity and reduce health care costs. A key goal of these programs is to identify and target effective interventions for increasingly prevalent and costly chronic conditions. According to recent studies, about 75% of the country's \$2.5 trillion in health care spending is related to four chronic diseases: obesity, diabetes, heart disease and cancer. These conditions are considered preventable because they are caused by behaviors like unhealthy diets, inadequate exercise and smoking.<sup>1</sup>

We are particularly concerned about the significant restrictions the Rules impose on employers' ability to effectively use HRAs and disease and case management programs to improve employee health. HRAs are used to identify risks or conditions within an employee population and target interventions for at-risk individuals, such as disease management strategies. Typical features of an HRA design include collection of family medical history with the use of rewards to encourage employees to complete an HRA. Family medical history is requested because of its significant value in assessing participant health risks and as a predictor of chronic disease.<sup>2</sup> Incentives are offered because, as it has been our members' long experience, incentives significantly increase HRA participation rates.

The Interim Final Rules interpret GINA to permit group health plans to either include family medical history questions on an HRA *or* offer an incentive to complete the HRA, but not both. As a result, plans are forced to sacrifice the accuracy of risk assessment by not requesting family medical history or forgo greater participation in HRAs by not offering rewards. The effect of the Rules is to significantly undercut the effectiveness of HRAs for improving health and reducing costs.

As discussed below, we believe that the statute could be read in a manner that would allow these programs, as currently structured, to remain intact. We urge the agencies to adopt these alternative interpretations in final rules. It is apparent from our discussions that it may take some time to issue final rules. Therefore, in the meantime, it is critical that the agencies issue guidance as soon as possible granting employers and plans the following relief:

- A period of time to make any necessary modifications without the risk of penalty or excise taxes;
- Guidance concerning how to make "corrections" for family medical history information already requested; and
- Clarification of key issues.

We appreciate the opportunity to offer our comments and your willingness to consider the issues that we raise.

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<sup>1</sup> "Health Care Savings Could Start in the Cafeteria", *New York Times* (November 29, 2009).

<sup>2</sup> According to the U.S. Department of Health & Human Services, Surgeon General's Family Health History Initiative, family health history is a powerful screening tool for a range of common diseases, including heart disease, cancer, and diabetes, as well rare diseases that run in families. <http://www.hhs.gov/familyhistory/>

We have divided our comments into three sections – (I) alternative interpretations of certain statutory provisions; (II) suggestions concerning enforcement and correction measures; and (III) other key issues where our members seek clarification.

## **I. Alternative Interpretation of Certain Statutory Provisions**

GINA creates ERISA sections 702(d)(1) and (2), which provide that a group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request, require, or purchase genetic information (including information about the manifestation of disease or disorder of a family member) for underwriting purposes, or prior to enrollment or coverage in connection with such enrollment. As relevant here, the statutory definition of "underwriting purposes" under ERISA § 733(d)(9) includes: (i) rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage ("Eligibility Rule"); and (ii) the computation of premium or contribution amounts under the plan or coverage ("Premium or Contribution Rule"). There is no statutory definition of "enrollment" that would clarify the circumstances under which genetic information will be considered to be collected prior to enrollment or coverage in connection with such enrollment ("Prior to Enrollment Rule").

The Interim Final Rules go beyond GINA to broadly define "underwriting purposes" to include, for purposes of the Eligibility Rule, "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" and, for purposes of the Premium or Contribution Rule, "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." 29 CFR 2590.702-1(d)(1)(ii)(A); (B).

Thus, under the Interim Final Rules, an HRA that requests family medical history and provides any type of reward, including enrollment in a disease management program where a participant is not seeking benefits, arguably violates the GINA statute. Informally, the agencies have said they think this prohibition should apply to "any reward," regardless of the type or value, even *de minimis* incentives.

Further, the Interim Final Rules broadly provide that genetic information may not be collected prior to the effective date of coverage or in connection with the rules for eligibility that apply to an individual. 29 CFR 2590.702-1(d)(1). Thus, under the Interim Final Rules, an HRA with family medical history questions that is provided to and completed by a new plan participant during open enrollment arguably violates the GINA statute, even if such HRA is completed after the participant has elected his/her medical options, and even if completion of the HRA does not affect his/her eligibility for coverage.

While these are three possible interpretations of the statute, we do not think they are the only interpretations. Indeed, alternative interpretations are possible, as described below. We urge the agencies to adopt these alternative interpretations consistent with the statute, which would allow employers and plans to continue to administer HRAs and disease and case management programs as currently structured. Moreover, the anti-discrimination provisions of GINA would

not be trivialized, nor would it impair the agencies' ability to enforce such provisions, by adopting the interpretations suggested below.

**A. *Eligibility Rule***

The Interim Final Rules, consistent with the statute, prohibit the collection of genetic information (which includes the manifestation of disease or disorder of a family member) for underwriting purposes. However, the Rules define "underwriting purposes" with respect to eligibility more broadly than the statute requires. In particular, an Example under the Rules indicates that merely enrolling an individual who has completed an HRA with family medical history questions in a disease management program violates the Eligibility Rule unless the individual is affirmatively seeking benefits. CFR 2590.702-1(d)(3), Example 4.

This interpretation is one, but not the only, possible interpretation. An alternative interpretation would recognize that, where family medical history is requested as part of an HRA and is used *for the purpose* of providing early intervention (*e.g.*, coaching or disease management), eligibility for benefits or coverage under the group health plan is not affected. Individuals who participate in coaching and disease management programs are eligible for the same benefits under the group health plan as individuals who do not participate in these programs. Further, coaching and disease management programs are not benefits in and of themselves. Rather, they are services under which an individual receives assistance with accessing benefits that are otherwise available to them under the group health plan. A coaching or disease management program merely offers more targeted access to benefits.

Even if coaching and disease management are viewed as benefits or coverage within the meaning of the GINA statute, completing an HRA and providing family medical history information is only one of many ways to access these programs. Since eligibility for the programs is not contingent on providing HRA/family medical history information, requesting and using the information to enroll an individual in a program should not be viewed as impacting *eligibility* for benefits (all employees are generally *eligible* for such programs). Rather, provision of family medical history is simply one of many ways that an individual can be automatically *enrolled* in such program. Other ways that individuals may be enrolled can include reviews by the health plan of actual claims experience of the individual, physician referral or individual request.

Importantly, the purpose of providing an incentive to an individual who fills out a voluntary HRA and participates in coaching or disease management programs is not to *limit* eligibility or benefits for such individuals. Instead, it is to assist those individuals who may be at risk for an adverse health condition to access benefits under the group health plan sooner than they might otherwise do so and in a more efficient, targeted manner. Interpreting the statute in a manner that would allow individuals protected by GINA to participate in such programs would also be consistent with the HIPAA nondiscrimination rules, which specifically permit more favorable treatment of individuals with adverse health factors. *See* 29 CFR § 2590.702(g).

## **B. Premium or Contribution Rule**

The Interim Final Rules prohibit the collection of genetic information (which includes the manifestation of disease or disorder of a family member) for underwriting purposes. However, the Rules define "underwriting purposes" with respect to computing premiums or contribution amounts more broadly than required by GINA. Moreover, the Rules fail to give proper consideration to the "purpose" of incentives that are provided. An alternative interpretation, however, would give proper weight to the statutory phrase "for the purpose of underwriting" and recognize that the only time a plan or health insurance issuer should be viewed as collecting family medical history information *for the purpose* of computing contributions or premiums is if the plan or health insurance issuer is actually using that information to discriminate against the individual by taking into account the family medical history information that was supplied (*e.g.*, by increasing their premiums or reducing coverage in some fashion based on the family medical history).

In contrast, where the HRA is voluntary and the incentive/reward is provided to anyone that fills out the HRA (as described above), it is clear that plans and health insurance issuers are *not* giving a premium discount or reward *for the purpose of underwriting*. Indeed, the incentive is available to everyone in the same amount and is realized by simply filling out the form. No adjustment to premiums or contributions is made in response to the information that is actually provided on the form (*i.e.*, the content of the form and the answers to the family medical history questions). Therefore, any discount or reward for filling out the form is *not for the purpose* of computing a contribution or premium-- even if the incentive is in the form of a minimal premium discount, and especially if the incentive has nothing to do with the premium or contribution. Rather, it is *for the purpose* of getting individuals to complete the form (and, depending on the answers, to receive additional services as described in A, above).

We also urge the agencies to consider the common meaning of the term "underwriting," in construing the statute. The commonly understood meaning of the term "underwriting" refers to the act of taking an individual's medical history into account when determining, among other things, how much to charge for coverage and what coverage will be made available. Providing a premium discount for the act of completing a form does not involve "underwriting" as that term is commonly understood.

## **C. Prior to Enrollment Rule**

The Interim Final Rules interpret the statute as prohibiting a group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, from collecting genetic information with respect to any individual prior to that individual's *effective date of coverage* under that plan or coverage, and in connection with the rules for eligibility that apply to that individual. The Rules further provide that the determination of whether a plan or issuer is collecting information before the individual's effective date of coverage is made at the time of collection. The fact that a future enrollment may occur does not mean that genetic information was collected before the enrollment (*i.e.*, collection of genetic information after the initial enrollment would not be considered prior to the reenrollment in the case of an individual who drops coverage or in the case of an annual reenrollment period).

An alternative interpretation would: (i) interpret the statutory phrase “prior to such individual’s enrollment under the plan or coverage in connection with such enrollment” to read “prior to such individual’s enrollment under the plan” or “prior to enrollment in coverage,” and (ii) provide that, as long as information is requested after a participant has selected a medical plan option, and as long as a participant need not complete an HRA in order to be enrolled in the plan, an HRA with family medical history questions that is completed by any participant during the open enrollment period does not violate the statutory prohibition against requesting genetic information prior to enrollment.

This alternative interpretation makes sense from an administrative standpoint. It is most efficient for plans or health insurance issuers to provide an HRA for completion during the time that participants are focused on and receiving other information about benefits. Administering the HRA at any other time of year would not only result in additional mailing expenses and/or email traffic, but would also interrupt the workdays of employees at a time that they are not focused on benefits, reducing the likelihood that they will complete the HRA. Further, the approach in the Rules that allows an HRA to be provided during open enrollment to an existing enrollee but not to a new enrollee would be expensive and cumbersome to administer. It would require plans and health insurance issuers to create an entirely new system for treating these two groups separately when, for all other purposes, they are treated as a single group.

## **II. Enforcement & Correction Measures**

Congress mandated that the agencies issue regulations by May 21, 2009, the effective date of Title I of GINA (which applies to plan years beginning on or after May 21, 2009). The agencies missed this deadline and did not issue the Interim Final Regulations until October 7, 2009. This meant that GINA was effective for a number of health plans whose plan years had already begun. It also meant that many other plans were in the middle of their annual enrollment periods and had already set up their HRA and wellness programs for the 2010 plan year (and in many cases, requested and received back HRA responses). As such, health plans are extremely concerned about how to make “corrections” going back or looking ahead. In addition, health plans are concerned about trying to understand the full impact of the Rules, implementing them system-wide (which usually involves multiple vendors), educating their workforce and vendors, and educating plan participants. Meanwhile, numerous other laws also are becoming effective, such as the Mental Health Parity and Addiction Equity Act, Michelle’s Law, the end of the ARRA COBRA subsidy, and the new self-reporting requirement under Code § 4980D. *See* Treas. Reg. § 54.4980D-1, 74 Fed. Reg. 45997 (Sept. 8, 2009). We request that the agencies consider the timing of these requirements and issue guidance related to how these new Rules will be enforced.

### ***A. Interim Nonenforcement Period***

As noted above, the prohibitions in the Interim Final Rules related to HRAs and disease management programs impacted many employers during open enrollment (or after their plan years already had begun). This means that many HRA and disease management programs already were underway or had been completed by the time the Interim Final Rules were issued. Thus, health plans need time to work toward compliance.

We request that the agencies grant a period of nonenforcement for group health plans that are working toward compliance with the regulations, similar to the approach recently taken by the Department of Health and Human Services ("HHS") in the HIPAA privacy context, and similar to many other examples noted below. In the Preamble to the HIPAA security breach rules, HHS noted that commenters were concerned that the effective date (which was mandated by statute) did not allow enough time to implement the new requirements and said:

We also recognize that it will take covered entities and business associates time to implement the processes and procedures necessary to comply with this subpart . . . [B]ased on the concerns described above, and based on some ambiguity within the statute, we will use our enforcement discretion to not impose sanctions for failure to provide the required notifications for breaches that are discovered before 180 calendar days from the publication of this rule, or February 22, 2010. During this initial time period - after this rule has taken effect but before we are imposing sanctions - we expect covered entities to comply with this subpart and will work with covered entities, through technical assistance and voluntary corrective action, to achieve compliance.

74 Fed. Reg. 42756 - 42757 (Aug. 24, 2009).

Federal agencies have adopted a similar approach for a number of other regulatory requirements where the affected parties were in good faith working toward compliance of a new requirement.<sup>3</sup> Likewise, the agencies should adopt a nonenforcement period so that plan sponsors and administrators have time to review and effectively implement these new Rules. We recommend that the nonenforcement period extend to the first plan year beginning on or after May 21, 2010, so that all health plans, regardless of their plan year, have the same opportunity to design their plans on a *prospective* basis while taking these new rules into consideration.

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<sup>3</sup> See *Mental Health Parity; Interim Rules HIPAA Mental Health Parity Act; Proposed Rule*, 62 Fed. Reg. 66931, 66956 (Dec. 22, 1997) (under certain circumstances no enforcement action will be taken against group health plans that in good faith attempt to comply with certain sections of Act); *FTC Enforcement Policy: Identity Theft Red Flags Rule*, 16 CFR 681.2, available at <http://www.ftc.gov/os/2008/10/081022idtheftredflagsrule.pdf>, (Oct. 22, 2008) (delaying the implementation of the Red Flag rule from November 1, 2008 to May 1, 2009 to allow covered entities to adopt appropriate programs); *Telemarketing Sales Rule*, 69 Fed. Reg. 67287, 67290 (Nov. 14, 2004) (FTC "will forbear from bringing any enforcement action for violation" of the Telemarketing Sales Rule against certain telemarketers pending completion of review of policy); *Modifications to the Electronic Data Transaction Standards and Code Sets*, 68 Fed. Reg. 8381, 8384 (Feb. 20, 2003) (reserving authority to "penalize noncompliance" with the standards to those entities that fail to make reasonable efforts to comply during an interim period); *Notice and Request for Comments on Annual Reporting Enforcement Policy*, 62 Fed. Reg. 11929 (March 13, 1997) (SOP 92-6 guidelines applicable after December 15, 1995, but absent guidance, the Department would not reject annual reports of multiemployer plans filed for the 1996 and 1997 plan years solely for failure to follow SOP 92-6; relief extended to 1998 plan years. See Notice on Annual Reporting Policy, 62 Fed. Reg. 65506 (Nov. 25, 1998)); *Technical Release No. 92-01*, DOL Enforcement Policy for Welfare Plans with Participant Contributions (May 28, 1992) (announcing limited enforcement policy to provide relief while Department continued to consider issues).

## **B. *Adopt a Formal Policy of "Good Faith Compliance"***

As previously mentioned, GINA required agencies to issue regulations by May 21, 2009, and the agencies missed this deadline by nearly 5 months. Consequently, plans were forced to make design decisions without the guidance of the new Rules in interpreting this new statutory regime. For many plans, the plan year is already underway. Accordingly, we request that the agencies formally adopt a rule that penalties will not be issued if a plan has acted in "good faith compliance" with the statute. This policy should remain in effect at least through the time final rules are issued.

The agencies followed a similar approach under the HIPAA portability rules. In those rules, the agencies stated that they "intend to issue further regulations . . . and that in no event would the Departments take any enforcement action against a plan or issuer that had sought to comply in good faith with Section 9802 of the Code, Section 702 of ERISA, and Section 2702 of the PHS Act before the additional guidance is provided." 66 Fed. Reg. 1379 (Jan. 8, 2001); 62 Fed. Reg. 16902 (Apr. 8, 1997).

In addition, we request that the agencies formally adopt the approach they have provided informally; namely, that they will work with health plans to make corrections before imposing penalties. This would mean that plans could not ignore the new requirements, but that they should be working toward compliance, and the agencies will issue compliance assistance guidance to help them do this.

This approach would be similar to that taken by HHS in the privacy context. In its regulations regarding HIPAA privacy enforcement, HHS states that it will "attempt to reach a resolution of the matter satisfactory to the Secretary by informal means. Informal means may include demonstrated compliance or a completed corrective action plan or other agreement." If not resolved through informal means, the Secretary may impose penalties. *See* 45 CFR§ 160.312. In its recently published enforcement regulations (where HHS formally adopted the new penalty structure in the HITECH Act), HHS again indicated that it would take this approach, "Notwithstanding these revisions, the Secretary may continue to use discretion in providing technical assistance, obtaining corrective action, and resolving possible noncompliance by informal means where the possible noncompliance is due to reasonable cause or in the event a person did not reasonably know that the violation occurred." 74 Fed. Reg. 56123, 56128 (Oct. 30, 2009).

## **C. *Correction for Prior Collections***

We have received numerous questions from health plans that had collected family medical history prior to the delayed release of the Interim Final Rule. In some cases, plan years had already begun so they were forced to make decisions on how to interpret GINA without the Interim Final Rules as guidance. Some had already collected information and had begun to provide an incentive, such as a premium credit for the plan year in place currently (before the Interim Final Rules were issued). For others, their plan year had not started (*e.g.*, for those that start January 1), but they had collected family medical history in advance of the upcoming plan year. These plans have concerns about what they should do with the information they already have. Generally, these plans have made "corrections" going forward and removed family medical



history questions from their HRAs or do not provide any incentives in connection with an HRA. Further, plans are particularly concerned due to the new self-reporting requirement under the excise tax rules, forcing them to decide whether they have a reportable violation or whether their correction measures are sufficient. *See* Code § 4980D; Treas. Reg. § 54.4980D-1.

The specific facts of each situation makes a "one size fits all" correction measure impractical, but it would be helpful if the agencies gave examples of the types of activities a plan could undertake to correct itself for prior collections. In addition, we request that the agencies adopt an enforcement policy for prior collections that says that if a health plan makes a good faith effort to put itself in the same position it would have been if it had not collected the information or provided some incentive, it will not be considered to have violated GINA. Examples of possible correction measures could include destroying, purging, or not using any family medical history information already obtained, returning the information, or allowing individuals to "re-take" their HRA, without asking family medical history questions.

### **III. Key Issues for Clarification**

Under the Interim Final Regulations, there are some areas causing particular confusion for employers and health plans. As noted in Section I, we recommend that the agencies modify their current interpretation of GINA regarding HRAs. However, to the extent that the agencies retain the current rules, we request that the agencies clarify their interpretation of the following issues, possibly in additional Q&As or technical guidance.

#### **A. *Incentives that do not impact premiums or contributions should not be considered "rewards" under the Interim Final Rules.***

GINA prohibits the collection of genetic information that is used for "underwriting purposes," which is defined to include rules for "computation of premium or contribution amounts." ERISA § 733(d)(9). The Interim Final Rule expands this definition to include "discounts, rebates, payments in kind, or other premium differential mechanisms." 29 CFR § 2590.702(d)(1)(ii)(B). The Preamble says this prohibition means "any reward." 74 Fed. Reg. 51669.

As discussed in Section I, providing a reward for merely completing an HRA (where information is not used to limit eligibility or benefits) should be permissible under GINA. However, under the interpretation currently in the Interim Final Rules, we are receiving a number of questions about what types of incentives constitute prohibited "rewards." Our members provide a variety of incentives, from premium credits or cash payments to more incidental incentives, such as gift cards, lottery tickets, or t-shirts.

The GINA statute says that a plan cannot vary "premium or contribution amounts," but does not address other types of rewards. Thus, a broad reading of the term "reward" does not seem supported by the statute, which expressly addressed the type of plan feature it intended to limit. We request clarification that a health plan is permitted to offer incentives that are not tied to premiums or contribution amounts (*i.e.*, that these types of incentives are outside the scope of GINA).

**B. *A health plan should be able to use family medical history to invite participants to enroll in disease management programs.***

Examples in the Rules suggest that if a health plan identifies an individual for a disease management program based on family medical history requested as part of an HRA, this may be prohibited because it is deemed an eligibility determination for an additional benefit. 29 CFR § 2590.702(d)(3), Example 4. As discussed in Section I, we believe this Rule is an overly broad interpretation of the statute. However, if this Rule is unchanged, clarification regarding its application is necessary. Informally, regulators have said that a health plan could identify potential candidates for disease management based on family medical history and *invite* them to join the program (leaving the decision up to the individual whether to join). Regulators also have said that the plan could advertise the disease management programs and encourage those with certain family medical history traits to join. Elsewhere, the Rules are clear that once an individual seeks a benefit, the plan is permitted to request genetic information to substantiate whether the benefit is medically appropriate. 29 CFR § 2590.702(c)(4).

Many health plans use HRA information to determine what types of disease management programs to offer and to identify potential candidates for disease management. For example, if an employee indicates that he has high cholesterol, along with a family medical history of heart attacks, he may be invited to join a disease management program related to heart disease. This may be a program he may not be aware of without the invitation. Even if the program is advertised, he may not be aware of its benefits to his risk factors in particular.

We request the agencies clarify that inviting an individual to join a disease management program based on family medical history would not violate the Rules. Specifically, we request that the agencies formalize their oral guidance that a health plan is permitted to target the invitation for a disease management program to those it knows have a particular family medical history, based on HRA results. For example, we request guidance that the health plan may direct an individual to disease management based on family medical history, as long as it is the individual who then seeks enrollment.

**C. *Health care professionals who work with a health plan's wellness program should fall under the health care professional exception.***

The Interim Final Rules state that nothing limits the authority of a health care professional who is providing health care services to an individual to request the individual undergo a genetic test. 29 CFR § 2590.702(c)(2). The examples state that an HMO physician who advises a patient still would be considered a health care professional under this exception, even though the physician also works for the plan (*i.e.*, the HMO). 29 CFR § 2590.702(c)(3), Example 2.

Health plans provide a variety of disease management programs. Many offer coaching or counseling programs by nurses or other trained professionals. These may be part of on-site screenings (for example, for cholesterol, weight, or blood pressure), or more ongoing, comprehensive services for a particular health condition. As part of these programs, the health care professional may ask about family medical history in order to better understand results or offer feedback or recommendations. We request that the agencies clarify that these types of

services also would fall under the health care professional exception, even where part of a health plan's wellness program. Further, we request clarification that any reward provided for participating in wellness programs involving these types of coaching services should not fall under the prohibition of requesting family medical history.

***D. Plans should have flexibility in distinguishing HRAs that do not seek family medical history.***

The Interim Final Rule provides an example where a group health plan requests enrollees to complete "two distinct" HRAs. One that asks family medical history but does not provide an incentive and another that does not ask family medical history but does provide an incentive. The example says that this approach would be permissible. 29 CFR § 2590.702(d)(3), Example 5.

We have received several questions from members about how to make sure two HRAs are "distinct." Administering two HRAs is unduly burdensome and could be confusing to participants. It should be possible for an HRA to have two distinct sections. One that asks family medical history and one that does not, so as long as it is clear that only one section will be connected with the incentive and that completion of the section that includes family medical history is wholly voluntary and not connected to the incentive. We request confirmation of this interpretation in the form of additional examples illustrating approaches that health plans can take while remaining compliant with the Interim Final Rules, so plans have a better understanding of the types of activities that would be permitted.

***E. Information gathered from dependents on their own HRA should not constitute genetic information.***

The Interim Final Rules state that information about dependents would not be considered "genetic history" with respect to that dependent, but may be considered "genetic information" with respect to a family member. 29 CFR § 2590.702(a)(3).

We have received questions about how this rule would apply, as a practical matter, to HRAs offered to both employees and dependents. For example, a health plan may offer an incentive to both an employee and spouse for completing an HRA. Even if the HRA does not request family medical history, the plan arguably would be collecting family medical history about the employee by simply asking health questions of the spouse (of her own manifested conditions). Would the act of offering an HRA to dependents, even if the HRA does not ask family medical history, be considered a request of family medical history so that an incentive is prohibited? GINA indicates that a plan may adjust the premium for an employee based on the manifestation of a disease of a covered individual, but that information cannot also be used as genetic information about other group members. ERISA § 702(b)(3)(B). Based on this premise, we think that each HRA should be considered on its own and, as long as the HRA does not request family medical history, a reward is permitted, even if the HRA is given to more than one family member. We request that this point be clarified.

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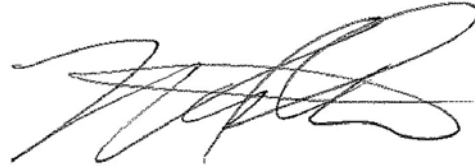
Thank you for giving us the opportunity to comment on the new Interim Final Rules under GINA and highlight questions from employer health plans as they work toward compliance. We look forward to further clarification.

If we can be of further assistance, please contact Kathryn Wilber at 202-289-6700 or [kwilber@abcstaff.org](mailto:kwilber@abcstaff.org).

Sincerely,



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