ERIC

The ERISA Industry Committee

January 26, 2016

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Acting Executive Officer
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Equal Employment Opportunity Commission
131 M Street, NE
Washington, DC 20507

RE: RIN 3046-AB02 (Amendments to Regulations under the Genetic Information Nondiscrimination Act of 2008)

Ladies and Gentlemen:

The ERISA Industry Committee is pleased to respond to the request for comments on the notice of proposed rulemaking regarding Title II of the Genetic Information Nondiscrimination Act ("GINA"). The proposed rulemaking was published by the Equal Employment Opportunity Commission (the "Commission") in the *Federal Register* on October 30, 2015.

ERIC'S INTEREST IN THE PROPOSED RULEMAKING

The ERISA Industry Committee ("ERIC") is the only national trade association advocating solely for the employee benefit and compensation interests of the country's largest employers. ERIC supports the ability of its large employer members to tailor health, retirement and compensation benefits for millions of employees, retirees and their families.

ERIC's members, which sponsor some of the largest private group health plans in the country, are committed to, and known for, providing high-quality, affordable health care. Our members expend considerable resources to maintain plans that cover many disparate populations across a wide range of geographic areas and that operate in all states and territories. These plans provide health care to millions of workers and their families with a high standard of cost containment and effectiveness.

Over time, it has become increasingly difficult for ERIC members to continue to deliver high-quality health benefits to their employees due to spiraling costs and extensive regulation. Despite these challenges, the promotion of wellness for each and every worker – and his or her family – continues to be of paramount importance for large employers. Effective workplace wellness programs can provide significant benefits both inside and outside the workplace; workers who do not need to worry about the health of themselves or their family members are happier and more productive employees.

As you are aware, ERIC has met and communicated with the Commission on several occasions to discuss how the Affordable Care Act ("ACA"), Title II of GINA, and Title I of the Americans with Disabilities Act ("ADA") affect employer-sponsored wellness programs.[1] These interactions are an important means to enable the government to understand how their actions affect the employee benefits community.

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[1] See, e.g., prior ERIC communications to the EEOC of March 8, 2011 and February 17, 2012, and ERIC's June 18, 2015 comment letter on the proposed ADA Title I regulations.

Continuing in this tradition, ERIC supports the Commission's efforts to clarify its rules describing how Title II of GINA impacts these programs. ERIC members are encouraged by the Commission's clarifications confirming that GINA does not preclude inducements for the completion of a health risk assessment ("HRA") by an employee's spouse.[2] ERIC members are especially encouraged by the Commission's attempts to align the GINA Title II permissible inducement limits with the ACA incentive limits (the "ACA rules") issued by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services (collectively "the Departments").[3]

ERIC members have continuing concerns, however, about different facets of the proposed rulemaking, particularly insofar as the Commission's rules impose different, and possibly conflicting, standards vis-à-vis the ACA rules issued by the Departments. Of principal concern are the inducement limits themselves – the Commission's inducement limits for HRAs are categorically inconsistent with the ACA rules, which do not impose incentive limits for participatory wellness programs, including HRAs. Moreover, the inducement limits for HRAs are simply not necessary to protect the "voluntary" nature of a wellness program, because the Commission's rules require such inducements to be paid *whether or not* an employee or the employee's spouse answers questions regarding genetic information.

Assuming the Commission believes that an inducement limit for HRAs is necessary, another concern relates to the "apportionment" rule. ERIC members believe that the apportionment rule is also inconsistent with the ACA rules and may have the perverse effect of permitting greater inducements for spouses and lesser inducements for employees. Another concern relates to the "reasonable design" rule, which ERIC members believe may lead to non-uniform interpretation and enforcement. Another concern relates to the ongoing lack of clarity regarding the impact of GINA Title II on incentives related to tobacco usage. Finally, ERIC members have additional concerns about each of the specific questions on which the Commission requested comments in the proposed rulemaking. Our recommendations and suggestions below emanate from these concerns.

COMMENTS

I. INDUCEMENT LIMITS FOR HRAS

The proposed regulations clarify that an employer-sponsored wellness program may offer limited wellness program inducements (financial or in-kind; positive or negative) to employees and their spouses who complete an HRA. The proposed regulations note that such inducements are subject to a maximum limit – the inducement may not exceed 30 percent of the total annual cost of the coverage under the plan in which the employee and any dependents are enrolled. Thus, where an employee and his or her spouse are enrolled in a plan that costs $14,000, the employer may not offer a wellness program inducement in excess of $4,200 (30% of $14,000).

The preamble indicates that the inducement limits for HRAs are intended to parallel the

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[2] For purposes of this letter, we use the term "HRA" in the same manner as the Commission does in its proposed regulations. Thus, an HRA includes a medical questionnaire, a medical examination, or both, that seeks information about an employee or spouse's receipt of health or genetic services as part of an employer-sponsored wellness program. See 80 Fed. Reg. 66853, at 66855 (October 30, 2015).

[3] 78 Fed. Reg. 33158 (June 3, 2013) (final regulations affecting wellness programs under the ACA) and 74 Fed. Reg. 51664 (October 7, 2009) (interim final regulations affecting wellness programs under Title I of GINA).

limitations applicable to health-contingent wellness programs under the ACA. But this attempt at alignment misses a critical point – under the ACA rules, HRAs are not health-contingent wellness programs subject to incentive limits. To the contrary, the ACA rules characterize HRAs as participatory wellness programs, which are *not* subject to incentive limits.

The ACA rules define participatory wellness programs as programs that either do not provide a reward that is, or do not include any conditions for obtaining a reward that are, based on an individual satisfying a standard related to a health factor. Examples in the final regulations include: A program that reimburses employees for all or part of the cost for membership in a fitness center; a program that reimburses employees for the costs of participating, or that otherwise provides a reward for participating, in a smoking cessation program without regard to whether the employee quits smoking; and a program that provides a reward to employees who complete an HRA regarding current health status, without any further action (educational or otherwise) required by the employee with regard to the health issues identified as part of the assessment.[4]

When drafting the ACA rules, the Departments considered whether participatory wellness programs – including HRAs – should be subject to incentive limits. Their reasoned determination was that limitations were not needed for "participatory" wellness programs because they posed no risk of discrimination under the ACA based on employees' health factors. ERIC members are encouraged that the Commission has similarly concluded that there is no risk of discrimination under GINA Title II with respect to the very limited genetic information solicited by an HRA.

It may be that the Commission believes that incentive limits for HRAs are somehow necessary to reinforce the principle that the GINA Title II exception applies only to "voluntary" wellness programs. But it is hard to reconcile how an incentive limit operates to accomplish that goal where, as here, the Commission's regulations have always required HRA inducements to be paid *whether or not* the participant answers questions regarding genetic information. If participants may choose to collect an inducement without answering questions about genetic information, ERIC members are hard pressed to understand how such "payable in any event" inducements cause a wellness program to be involuntary.

While ERIC members appreciate the Commission's effort to align its proposed GINA Title II regulations with the existing ACA rules, the Commission's conflicting decision to limit inducements for HRAs greatly complicates the administration of ACA-compliant wellness programs. ERIC members believe there is no reason for the Commission to impose inducement limits for HRAs, and urges the Commission to eliminate these requirements.[5]

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[4] 29 CFR §2590.702(f)(1).

[5] If the Commission decides to retain incentive limits for HRAs, we suggest several clarifications to the regulations. First, the regulations should be restructured in a manner that clarifies three principles: (1) the general rule (no inducements permitted); (2) the exceptions to that rule (inducements permitted for HRA completion by an employee, or by both an employee and spouse); and (3) the terms and conditions applicable to those exceptions (incentives must be provided in any event, spouse must be enrolled, spouse must provide authorization, incentives are limited to specific percentages and, if retained, the apportionment rule). Currently these three principles are spread across three subparagraphs of the proposed regulations - §1635.8(b)(2)(ii), (iii) and (iv). Second, the regulations should clarify that it is permissible for employers to determine the "cost" of coverage for employees and spouses by reference to the cost of the coverage tier in which the employee and the spouse are actually enrolled. Many employers offer three tiers of coverage – employee only, employee plus children and employee plus family. In this 3-tier design, the maximum limitation should be applied to the cost of the employee plus family coverage tier. Third, the regulations should clarify that in the case of a self-insured health plan it is permissible for employers to

II. THE APPORTIONMENT RULE

The proposed regulations include a further surprise that is inconsistent with the ACA rules – for GINA Title II purposes, the overall inducement limit must be *apportioned* between the employee and the spouse, and the employee's share of the overall limit cannot exceed 30 percent of the cost of employee-only coverage. The preamble suggests that this apportionment rule is necessary because the Commission's proposed regulations under Title I of the ADA limit the maximum incentive for voluntary wellness programs to 30 percent of the cost of employee-only coverage.

ERIC members believe strongly that the apportionment rule is unnecessary in the context of the GINA Title II exception for wellness programs. There are at least three persuasive reasons for this view.

- First, the wellness program exception under Title I of the ADA is more limited than the GINA Title II exception – the ADA Title I exception is relevant only for employees, not for employees and spouses. Thus, in the ADA Title I context, the question of how to determine the appropriate limit on inducements for an employee and spouse never arises.

- Second, the apportionment rule is inconsistent with the limitations applicable to health-contingent wellness programs under the ACA rules.[6] The ACA rules recognize that different limitations are appropriate, without apportionment, depending on whether the employee is enrolled in an employee-only tier of coverage or whether the employee and the employee's spouse are enrolled in a higher tier of coverage (e.g., employee plus spouse or employee plus family).

- Third, the apportionment rule is inconsistent with common plan designs that provide uniform HRA inducements for both an employee and the employee's spouse. The apportionment rule will have the strange effect of permitting greater inducements for spouses than for employees, because of the significant cost differentials between employee-only coverage and higher tiers of coverage. Employers should be allowed to apportion permissible inducements as they see fit, without being forced into an arbitrary and unnecessary apportionment rule.

In the absence of a compelling legal rationale, ERIC members believe that the apportionment rule should be eliminated.

III. REASONABLE DESIGN REQUIREMENT

The proposed regulations add a new "reasonable design" requirement to the GINA Title II wellness program exception. As drafted, this requirement is almost word-for-word the same as the reasonable design requirement applicable to health contingent wellness programs under the ACA rules. The criteria for satisfying the reasonable design requirement, however, are not specified. While the ACA rules indicate that satisfaction of the reasonable design requirement is

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determine the "cost" of coverage by reference to the cost of health care continuation coverage under COBRA, minus the 2% administrative fee.

[6] Where an employee and spouse both participate in a health-contingent wellness program, the ACA rules limit the reward to 30 percent of the cost of the coverage in which the couple is enrolled, *and no apportionment is required*. See, e.g., 29 CFR §2590.702(f)(3), (4) and (5).

"based on all the relevant facts and circumstances," the proposed regulations do not take this approach. Instead of providing a rule in the proposed regulations, the preamble describes three wellness programs that would not satisfy the reasonable design requirement:

> Collecting information on a health questionnaire without providing follow-up information or advice would not be reasonably designed to promote health or prevent disease. Additionally, a program is not reasonably designed to promote health or prevent disease if it imposes, as a condition of obtaining a reward, an overly burdensome amount of time for participation, requires unreasonably intrusive procedures, or places significant costs related to medical examinations on employees. A program is also not reasonably designed if it exists merely to shift costs from the covered entity to targeted employees based on their health.[7]

ERIC members have several concerns with this approach. As a matter of form, significant regulatory requirements should be specified in the regulations themselves, not in a preamble to the regulations. Further, the examples do not provide concrete guidance that would help to understand usage of phrases such as "overly burdensome amount", "unreasonably intrusive procedures", and "significant costs". Most significantly, the lack of an explicit determination standard – even a facts and circumstances standard – may, and most likely will, lead to inconsistent interpretation and enforcement. Employers may believe that a wellness program is reasonably designed for purposes of the ACA rules, only to encounter disagreement among, and possible enforcement actions initiated by, different EEOC Field Offices attempting to enforce the GINA Title II rules.

To ameliorate these concerns, ERIC members suggest that the Commission consider revising the reasonable design requirement. Most importantly, the Commission should consider adopting the same reasonable design determination standard utilized in the ACA rules; namely, that satisfaction of the reasonable design requirement is based on all the facts and circumstances. This will have the effect of aligning the reasonable design standard in the GINA Title II regulations with the reasonable design standard applicable to health contingent wellness programs under the ACA rules.

Second, the Commission should delete the preamble examples that attempt to illustrate non-reasonable designs. If the Commission believes strongly that examples of "non-reasonable" designs are important, the examples should be included in the regulations with additional factual content to clearly illustrate why a particular design is unreasonable.

IV. RESPONSES TO COMMISSION'S REQUEST FOR COMMENTS

In the preamble, the Commission requested written comments on seven specific questions. We reiterate each of those questions below, accompanied by ERIC's comments. At the outset, we also note that many of these questions involve topics that are beyond the scope of the proposed rulemaking, and beyond the scope of 29 CFR §1635.8. If the Commission intends to more broadly revisit the content of its GINA Title II regulations, we suggest that it consider doing so through a formal Request for Information.

Question #1 – Certification from medical professionals. *Whether employers that offer inducements to encourage the spouses of employees to disclose information about current or past health must also offer similar inducements to persons who choose not to disclose such*

[7] 80 Fed. Reg. 66853 at 66857 (October 30, 2015).

information, but who instead provide certification from a medical professional stating that the spouse is under the care of a physician and that any medical risks identified by that physician are under active treatment.

ERIC members oppose, as strongly as possible, the notion that the GINA Title II rules require inducements to be offered to employees, or to both employees and spouses, merely because one or both people provide a "certification" from a medical professional. A certification from a physician is in no way comparable to the identification of an individual's risk factors and encouragement to participate in wellness programs that are designed to mitigate these risks. Providing an alternative path to rewards will do nothing but maintain the status quo for participants and their families, who will be deprived of the opportunity to take control of their health.

Further, the ACA rules do not impose this requirement, and adding such a requirement in the GINA Title II context would create a further inconsistency between the ACA rules and the GINA Title II rules.

More broadly, the question misconstrues a key value of HRAs. Employers seek information about the health of an individual employee and his or her spouse in order to identify broad demographic risks so that wellness-related activities can be tailored for the population as a whole. To use a specific example, one ERIC member noted that their HRA results revealed two broad population risks – stress and healthy eating. This employer used these results in two ways – first, by developing seminars focused on resilience and dealing with work stress, and second, by working with its cafeteria vendors to offer healthier food and label it as such.

Receiving a doctor's certification as an alternative to an HRA would not generate any of these benefits as it provides no information about population risks and, moreover, imposes costs on both the employer and the employee and his or her spouse (such as the cost of the doctor visit, for example.)

If the HRA process is to be successful at identifying health risks, and encouraging the reduction or mitigation of those risks, then employers need to be able to condition inducements on an employee's (or spouse's) completion of an HRA. The Commission's regulations already permit a person to obtain an HRA inducement without answering questions regarding genetic information, and those regulations have correspondingly diminished the potential effectiveness of the HRA process. There is no reason to further dilute the HRA process by offering inducements merely because a person submits a certification from his or her physician.

Question #2 – Authorization requirements. *Should the proposed authorization requirement apply only to wellness programs that offer more than de minimis rewards or penalties to employees whose spouses provide information about current or past health status as part of a HRA? If so, how should the Commission define "de minimis"?*

The meaning of this question is not completely evident. The authorization requirements are a long-standing component of the Commission's GINA Title II regulations; the only "change" in the proposed regulations is to impose the same authorization requirements for an employee's spouse who is completing an HRA.

If the Commission is asking whether the existing authorization requirements should be modified for all purposes under the GINA Title II wellness program exception, then ERIC members strongly favor such an approach. Similar to our comments on the Commission's ADA Title I

proposed regulations, ERIC members believe that the GINA Title II requirement to obtain a prior, individual authorization for wellness programs that are part of a group health plan is overkill. Existing laws, particularly the ACA, ERISA and HIPAA, already require extensive disclosures about the details of an employer-sponsored group health plan; these disclosures are furnished to employees and their families at multiple times and in multiple formats (e.g., new hire kits, summary plan descriptions, summaries of benefits and coverage, open enrollment communications, etc.).

Rather than focus on an arbitrary de minimis standard, ERIC encourages the Commission to focus more broadly on whether the existing authorization requirements serve a functional purpose. In our view, an employee's decision, or a family's decision, to participate in a wellness program that is part of a group health plan should serve as sufficient confirmation that the employee's or family's decision was voluntary.

Question #3 – Inappropriate cost-shifting. *Which best practices or procedural safeguards ensure that employer-sponsored wellness programs are designed to promote health or prevent disease and do not operate to shift costs to employees with spouses who have health impairments or stigmatized conditions?*

This question assumes that employer-sponsored wellness programs shift costs in a discriminatory manner; this is not true. ERIC members do not shift costs to employees, or to employees with spouses, who have health impairments or stigmatized conditions, and they do not wish to do so. In addition, doing so in the context of a group health plan would violate the ERISA rules prohibiting discrimination in eligibility, contributions and premiums based on health status, triggering enormous IRS excise tax penalties and likely DOL enforcement action. Such actions could also violate other federal laws, including ADA and GINA.

The *sine qua non* of employer-sponsored wellness programs is that these programs operate to provide additional resources and support to participants and beneficiaries with health problems, not to discriminate against them. Restricting an employer's flexibility to best tailor wellness programs to their workforces would discourage innovative approaches to health improvement and, ultimately, would serve only to force additional administrative and financial challenges on employers who strive to help their employees achieve better health outcomes.

Question #4 – Storage of electronic records. *Given that, in contrast to the status quo when the ADA was enacted, most employers today store personnel information electronically, and in light of increasingly frequent breaches to electronically stored employment records, should the rule include more specific guidance to employers regarding how to implement the requirements of 29 CFR 1635.9(a) for electronically stored records? If so, what procedures are needed to achieve GINA's goal of ensuring the confidentiality of genetic information with respect to electronic records stored by employers?*

Question #5 – Disclosure safeguards for spousal information. *In addition to any suggestions offered in response to the previous question, are there best practices or procedural safeguards to ensure that information about spouses' current health status is protected from disclosure?*

Question #6 – Minimum necessary standard. *Given concerns about privacy of genetic information, should the regulation restrict the collection of any genetic information by a workplace wellness program to only the minimum necessary to directly support the specific wellness activities, interventions, and advice provided through the program – namely information collected through the program's HRA and biometric screening? Should programs be prohibited*

from accessing genetic information from other sources, such as patient claims data and medical records data?

All three of these questions are similar in the sense that they assume potential gaps in the Commission's existing regulations, particularly 29 CFR §1635.9. The simple truth for ERIC members is that there are no gaps. For the last 15 years, employer-sponsored group health plans have been subject to HHS regulations regulating the confidentiality and security of protected health information under the Health Insurance Portability and Accountability Act ("HIPAA"). Under the HIPAA regulations, employer-sponsored group health plans, including wellness programs that are part of such plans, must comply with highly detailed requirements relating to the uses, disclosures and security of protected health information. Failure to comply with the HIPAA regulations can trigger civil monetary penalties and, potentially, civil and/or criminal lawsuits. [8]

With very few exceptions, employers do not maintain records of protected health information in-house; this information is managed, held, transmitted and stored by third-party administrators and other service providers. In the parlance of the HIPAA regulations, these administrators and service providers are "business associates" who are themselves subject to the HIPAA requirements, both legally and contractually. A similar dynamic exists with respect to employer-sponsored wellness programs – employers use service providers to operate their wellness programs, to collect information submitted as part of an HRA, and to communicate with employees (and spouses) where the HRAs reveal potential medical issues or concerns. These service providers are also business associates subject to the HIPAA requirements.

In many respects, the HIPAA regulations *are* the best practice that the Commission seeks to identify. The HIPAA regulations already provide detailed rules regarding the security standards for protecting and storing electronic protected health information. The HIPAA regulations already impose a "minimum necessary" standard on uses and disclosures of protected health information. In short, there is no need for the Commission to create a separate set of rules to protect the limited amount of genetic information that may be collected as part of an HRA process because that information is already amply protected by the HIPAA regulations.

ERIC urges the Commission to "go slow" with respect to these questions, and to consider a simpler approach: namely, to identify actual gaps where the HIPAA regulations might not protect and secure genetic information and, to the extent such gaps exist, require compliance with the HIPAA regulations as a proxy for protecting and securing that information. We emphasize, however, that a group health plan's compliance with the HIPAA regulations should be sufficient to satisfy any concerns about the confidentiality and security of genetic information that may be collected as part of an HRA process.

Question #7 – Inducements outside of group health plans. *Whether employers offer (or are likely to offer in the future) wellness programs outside of a group health plan or group health insurance coverage that use inducements to encourage employees' spouses to provide information about current or past health status as part of a HRA, and the extent to which the GINA regulations should allow inducements provided as part of such programs.*

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[8] We note that under 29 USC §1635.11(d), the Commission's GINA Title II regulations *do not apply* to genetic information that is protected health information subject to the HIPAA privacy regulations. Our broader point is that wellness programs that are part of employer-sponsored group health plans are always subject to the HIPAA privacy regulations, so there is no need for the Commission to develop duplicative confidentiality and security rules for these programs.

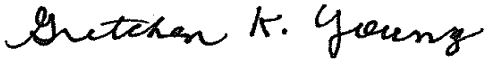
Most ERIC members currently offer HRA inducements only under wellness programs that are part of a larger group health plan. As a technical matter, the ACA rules apply only to wellness programs that are, or a part of, a group health plan. But the breadth of the ACA rules has the effect of applying at least some nondiscrimination requirements to nearly all wellness programs.

The GINA Title II exception for wellness programs does not differentiate between wellness programs that are part of a group health plan from those that are not. Logically, the Commission could choose to adopt exactly the same rules for wellness programs offered inside or outside of a group health plan. Or the Commission could choose to adopt different rules for such programs, although the legal and practical rationale for doing so is not clear.

A better use of Commission resources would be to evaluate whether to further align the GINA Title II regulations with the ACA regulations, focusing on whether the GINA Title II regulations should be more flexible for participatory wellness programs than for health-contingent wellness programs. As suggested earlier in these comments, ERIC members strongly believe that the GINA Title II regulations should not impose inducement limits on participatory wellness programs.

ERIC appreciates the opportunity to provide comments on the Commission's notice of proposed rulemaking. If you have questions concerning our comments, or if we can be of further assistance, please contact us at (202) 789-1400.

Sincerely,



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