January 28, 2016

Ms. Bernadette B. Wilson, Acting Executive Officer
Executive Secretariat
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; Proposed Rule

Dear Ms. Wilson:

We are pleased to submit these comments on behalf of the College and University Professional Association for Human Resources, the International Public Management Association for Human Resources, the National Public Employer Labor Relations Association, the Associated Builders and Contractors, the National Retail Federation, and the Retail Industry Leaders Association in response to the Equal Employment Opportunity Commission's (EEOC's or Commission's) proposed amendments to the regulations implementing the Genetic Information Nondiscrimination Act of 2008 (GINA) as published in the *Federal Register* on October 30, 2015.[1] The proposal addresses the extent to which GINA permits an employer to offer incentives in connection with a wellness program that utilizes a health risk assessment seeking current or past health status information of an employee's spouse.

Summary of Comments

We are pleased that the Commission has determined that it is appropriate to permit employer wellness programs that collect information about the health status of employees' spouses to utilize the 30 percent incentive limit established by the Affordable Care Act (ACA) for health-contingent wellness programs.[2] However, we have several significant concerns with the manner in which the Commission has proposed authorizing the use of incentives in wellness programs.

[1] Genetic Information Nondiscrimination Act of 2008, Proposed Rule, 80 Fed. Reg. 66,853 (2015) (to be codified at 29 C.F.R. pt. 1635) (hereinafter *GINA Proposal*). The period for submission of public comments was extended until January 28, 2016, pursuant to a notice published on December 7, 2015. 80 Fed. Reg. 75,956.
[2] GINA Proposal, 80 Fed. Reg. at 66,857-58.

In these comments, we address the proposal's failure to adopt incentive limits consistent with those established under the ACA and regulations issued under the Health Insurance Portability and Accountability Act (HIPAA) by the Department of Health and Human Services, Department of Labor, and Department of Treasury (the tri-agency regulations).[3] We are also critical of the Commission's proposal to establish a new "reasonable design" requirement inconsistent with the tri-agency regulations and encourage the Commission to allow greater flexibility in apportioning plan incentives used for employees and spouses.

In addition, these comments express our opposition to any requirement that would mandate that incentives be available to those who do not participate in the wellness program but instead "medically certify" that any issues are under treatment. We also urge the Commission to refrain from rulemaking regarding electronic storage of records and emphasize the need for a significant amount of time for employers to come into compliance with any new requirements.

Statement of Interest

The **College and University Professional Association for Human Resources** (CUPA-HR) serves as the voice of human resources in higher education, representing more than 19,000 human resources professionals and other campus leaders at over 1,900 colleges and universities across the country, including 91 percent of all United States doctoral institutions, 77 percent of all master's institutions, 57 percent of all bachelor's institutions, and 600 two-year and specialized institutions. Higher education employs over 3.7 million workers nationwide, with colleges and universities in all 50 states.

The **International Public Management Association for Human Resources** (IPMA-HR) represents public sector human resource professionals and human resource departments. Since 1906, IPMA-HR has enhanced public sector human resource management excellence through research, publications, professional development and conferences, certification, assessment and advocacy.

The **National Public Employer Labor Relations Association** (NPELRA), a not-for-profit corporation established in 1970, represents public sector and not-for-profit entities and practitioners of labor and employee relations employed therein. NPELRA and its members function as fiduciaries to the interests of the citizens, in part, by advocating the development

[3] Incentives for Nondiscriminatory Wellness Programs in Group Health Plans, Final Rule, 78 Fed. Reg. 33,157 (June 3, 2013) (codified at 26 C.F.R. pt 54; 29 C.F.R. pt. 2590; and 45 C.F.R. pts. 146 & 147) (hereinafter *Tri-Agency Regulations*).

of sound local, state and national policy relative to hiring, compensation, benefits, and employee/labor management relations.

Associated Builders and Contractors (ABC) is a national construction industry trade association representing nearly 21,000 chapter members. Founded on the merit shop philosophy, ABC and its 70 chapters help members develop people, win work and deliver that work safely, ethically, profitably and for the betterment of the communities in which ABC and its members work. ABC's membership represents all specialties within the U.S. construction industry and is comprised primarily of firms that perform work in the industrial and commercial sectors.

The **National Retail Federation** (NRF) is the world's largest retail trade association, representing discount and department stores, home goods and specialty stores, Main Street merchants, grocers, wholesalers, chain restaurants and Internet retailers from the United States and more than 45 countries. Retail is the nation's largest private sector employer, supporting one in four U.S. jobs – 42 million working Americans. Contributing $2.6 trillion to annual GDP, retail is a daily barometer for the nation's economy.

Retail Industry Leaders Association (RILA), the trade association of the world's largest and most innovative retail companies, product manufacturers, and service suppliers, promotes consumer choice and economic freedom through public policy and industry operational excellence. RILA's members provide millions of jobs and operate more than 100,000 stores, manufacturing facilities and distribution centers domestically and abroad.

GINA and Wellness Plans

Since Congress first contemplated extending employment nondiscrimination provisions to cover employees' genetic information, it has always included intended to ensure that employer provided genetic services would not be adversely affected.[4] Early in the Congressional consideration of the legislation that would become GINA, the exception for employer-provided genetic services was expanded to explicitly protect employer-provided health services, including wellness programs.[5] These provisions were enacted as Section 202(b)(2) of GINA[6] and create an exception to GINA's mandate that employers refrain from requesting, requiring, or purchasing the genetic information of employees.

[4] See H.R. 2457, 106th Cong., 1st Sess., § 202(a)(3)(B).
[5] See S. 318, 107th Cong., 1st. Sess, § 203(a)(3)(B), S. 1995, 107th Cong., 2nd Sess., § 202(b)(2), H.R. 1910, 108th Cong., 1st Sess. § 202(a)(3)(B).
[6] Section 202(b)(2) describes the exception for employer wellness programs. Sections 203(b)(2), 204(b)(2), and 205(b)(2) govern programs of employment agencies, labor organizations, and training programs, respectively.

The Commission's regulations already construe the statutory requirements very narrowly. While they permit the use of incentives in connection with wellness programs, they do not permit any incentive for an individual to provide genetic information as part of such a program.[7] In other words, the Commission's regulations interpret GINA as prohibiting an employer from offering an incentive to fill out a health risk assessment that includes a question about family medical history unless the family medical history questions are identified as optional and the incentive is available to the employee regardless of whether he or she answers the questions.

Because GINA defines "genetic information" so broadly, there is a risk that collection of current health status information from an employee's spouse could be considered protected genetic information of the employee. However, such a reading is in tension with GINA's exception designed to ensure that employers are able to offer effective genetic services, health services, and wellness programs to their employees and family members. If current health status of spouses or family members is not considered by health care professionals or genetic counselors implementing employer-provided health or genetic services, including wellness programs, it is questionable that such services could be effective at all.

To date, the Commission has not provided guidance as to whether an employer violates GINA when a spouse of an employee is awarded an incentive for participating in a wellness program that includes collecting information on the current or past health status of the spouse. While this question is an important issue, especially for employers that extend wellness programs to employees' spouses, it is just one facet of the broader question regarding the regulation of wellness programs. As the Commission considers whether and how it will move forward with this proposal and the proposed revisions to ADA regulations,[8] it is imperative that the Commission carefully consider the extent to which its regulations could create a significant disincentive toward employer use of wellness programs, an outcome inconsistent with the ACA.

The Commission's Proposal Correctly Recognizes Incentives for Spousal Participation in Wellness Programs Are Not Inherently Inconsistent with GINA

The Commission proposes adding a new Section 1635.8(b)(2)(iii) to its regulations implementing GINA expressly recognizing that corporate wellness programs that include inquiries, such as health risk assessments, about current or past health status of employees' spouses may offer incentives. In the preamble to its proposal, the Commission states that

[7] 29 C.F.R. § 1635.8(b)(2)(ii).

> The EEOC has determined that extending the 30 percent limit established by the Affordable Care Act for health-contingent wellness program inducements in return for health information about the health status (but not the genetic information) of spouses promotes GINA's interest in limiting access to genetic information and ensuring that inducements are not so high as to be coercive, and thus prohibited.[9]

The Commission's proposal also acknowledges that health care laws encourage the use of incentives in connection with employer-provided wellness programs, describing the balance between those laws and GINA in this way:

> Although information about the manifestation of a disease or disorder in spouses or children is genetic information protected by GINA, adopting a very narrow exception that permits inducements only for a spouse's current or past health status strikes the appropriate balance between GINA's goal of providing strong protections against employment discrimination based on the possibility that an employee may develop a disease or disorder in the future or may face discrimination because a family member is expected to become ill in the future, and the goal of the wellness program provisions of the Health Insurance Portability and Accountability Act (HIPAA), as amended by the Affordable Care Act, of promoting participation in employer-sponsored wellness programs.[10]

We support the Commission's efforts to amend its GINA regulations to explicitly permit the use of incentives in wellness programs that may ask about the health status of employees' spouses and we support the Commission's recognition that public policy as established by Congress promotes participation in employer-sponsored wellness programs. However, as explained below, we have several concerns with the limitations that the Commission has proposed.

Permissible Incentive Limits Should Mirror Those Adopted under Tri-Agency Regulations

The Commission asserts that its proposed incentive limit "generally parallels" the incentives established in the ACA. However, the Commission's proposal departs in important ways from the approach embraced by Congress and will create a disincentive for employers to continue to use wellness programs. We strongly disagree with the Commission's departure from the incentive limits established by Congress and the agencies with responsibility for

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[8] Amendment to Regulations Under the Americans With Disabilities Act, Proposed Rule, 80 Fed. Reg. 21,659 (Apr. 20, 2015) (to be codified at 29 C.F.R. pt. 1630). (hereinafter *ADA Proposal*).
[9] GINA Proposal, 80 Fed. Reg. at 66,857-58.
[10] GINA Proposal, 80 Fed. Reg. at 66,856.

interpreting health care law and urge the Commission to revise its proposal to mirror the tri-agency regulations.

Tri-Agency Regulations and the ACA

When Congress enacted the ACA, it was mindful of a regulatory regime established in 2006 by the Departments of Health and Human Services, Labor, and Treasury that, among other things, regulated the use of incentives in wellness programs. In the ACA, Congress generally endorsed the tri-agency regulatory framework that had been established, including different treatment of participatory wellness programs and health-contingent wellness programs.

Under the tri-agency regulations, participatory wellness programs are programs that are made available to all similarly situated individuals and that do not either provide a reward 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 of participatory wellness programs include an employer subsidizing the cost of gym membership for all employees or an employer that provides an incentive to all employees who complete a health risk assessment regardless of any health issues identified.

In contrast, health-contingent wellness programs require employees to satisfy a standard related to a health factor to obtain a reward. According to the preamble accompanying the tri-agency regulations, most wellness programs are participatory. Under the tri-agency regulations, there is no incentive limit for such programs because the availability of the program to all similarly situated individuals, regardless of health status, ensures that the general prohibition against discrimination based on a health factor is not implicated.[11] It should be emphasized that genetic information is included within the statutory definition of health-status related factors.[12]

While retaining this framework, Congress significantly expanded the extent to which wellness plans could use rewards, including both incentives and penalties, to encourage participation. The legislative compromise that led to this expansion was made after the Senate Health, Education, Labor, and Pensions (HELP) Committee heard significant testimony about the success of existing wellness programs and how further use of incentives could play an important role in health care reform.[13] In response, the HELP Committee approved, on a

[11] Tri-Agency Regulations, 78 Fed. Reg. at 33,161.
[12] See 42 U.S.C. § 300gg-4(a)(6)(Public Health Service Act); 29 U.S.C. § 1182(a)(1)(f)(Employee Retirement Income Security Act (ERISA)); and 26 U.S.C. §9802(a)(1)(f)(Internal Revenue Code (IRC)).
[13] See, for example, *Healthcare Reform Roundtable (Part I), Hearing Before the Senate Comm. on Health, Education, Labor, and Pensions*, 111th Cong., 1st Sess. (June 11, 2009).

bipartisan basis, an amendment to increase the incentive limit from 20 percent of the total cost of health care coverage to 30 percent. The Committee also empowered the three agencies to increase the incentive limit to as high as 50 percent if they determine such an increase "is appropriate." This compromise survived the legislative process and has been codified into law.[14]

By enacting the ACA and largely codifying and expanding upon the approach originally adopted in the tri-agency regulations, Congress intended to create an environment that would encourage greater use of such programs.

Proposal Inappropriately Includes Participatory Wellness Programs Within Incentive Limits

As with its proposed revision of ADA regulations, the Commission's proposal is not limited to incentives provided in connection with health contingent wellness plans but instead includes incentives for participatory wellness programs. Health contingent wellness programs and participatory wellness programs operate very differently and the Commission is wrong to treat them the same for purposes of its GINA regulations.

Instead of following the tri-agency approach, the EEOC's proposal would count incentives from both participatory wellness programs and health contingent wellness toward the 30-percent limit. The Commission recognizes this inconsistency but makes no meaningful attempt to justify the departure. In the preamble to the proposal, the Commission states that "EEOC believes that employers will be able to comply with both the wellness requirements under the [ACA] and these regulations."[15] The issue of whether it is *possible* for employers to comply with both sets of regulations is beside the point. Employers could simply cease offering wellness programs and be in compliance with both sets of regulations. The more appropriate question is whether the Commission can or should impose limitations on the use of participatory wellness programs that were explicitly rejected by the agencies responsible for implementing the HIPAA and the ACA.[16]

The Commission has not included within either of its proposals any meaningful justification for this unwise departure. We strongly recommend that the Commission revisit this approach to ensure that its regulations mirror the types of incentives permitted under the tri-agency regulations.

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[14] See 42 U.S.C. § 300gg-4(j)(3)(A).
[15] GINA Proposal, 80 Fed. Reg. at 66,858.
[16] See, for example, Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, Final Rules, 71 Fed. Reg. 75,014, 75,017-18 (Dec. 13, 2006) (codified at 26 C.F.R. pt. 54; 29 C.F.R. pt. 2590; and 45 C.F.R. pt. 146).

Smoking Cessation Programs Generally Not Impacted Under GINA; However, Regulations Should Permit Higher Incentives If Authorized Under Tri-Agency Regulations

Under its proposal, the Commission notes in a footnote that GINA is unlikely to apply to smoking cessation programs as such programs are unlikely to request genetic information and therefore would not be covered by the GINA regulations.[17] We agree with this assessment and support the inclusion of such a statement in the final rule or its preamble.

While we agree with the Commission's assessment with respect to smoking cessation programs, neither this proposed rule nor the proposed ADA regulations acknowledge that the ACA permits a higher incentive for certain types of wellness programs if the Secretaries of Health and Human Services, Labor, and Treasury determine that such an increase is appropriate. To date, the Secretaries have only authorized a higher incentive for smoking cessation programs. However, they retain the authority to do so in the future. Neither the Commission's proposed revision to its ADA regulations or the current proposal provide a mechanism to increase the permissible incentive limitation should the Secretaries make such a determination in the future. The Commission should include a mechanism to ensure that employers may use higher incentives where otherwise authorized under law.

The Proposed Regulation Impermissibly and Inappropriately Seeks to Regulate Health Program Design

The proposal seeks to add a requirement that any "employee health program" must be "reasonably designed to promote health or prevent disease." Such a provision was also included as part of the Commission's proposed ADA regulations. We recommend that the Commission decline to add such a provision to the GINA regulations as the matter of health program design is more properly regulated by the three agencies responsible for the tri-agency regulations. In addition, the proposal breaches firewalls that Congress established in GINA. If the Commission nevertheless decides to incorporate a reasonable design standard then it should explicitly state that the requirement is to be interpreted consistently with the tri-agency standard.

Reasonable Design of Wellness Plans More Properly Regulated in Tri-Agency Regulations

Employers are generally comfortable with the reasonable design requirement that was enacted as part of the ACA and implemented in the tri-agency regulations. However, they have significant concerns with the Commission's proposed reasonable design standard in the ADA and GINA regulations for four reasons. First and foremost, the Commission has no

[17] GINA Proposal, 80 Fed. Reg. at 66,858 n.24.

particular expertise with the design of health programs and systems and the assessment of whether such programs are reasonably designed. The Commission should therefore defer to the agencies that have expertise in such matters, in particular the Departments of Health and Human Services, Labor, and Treasury.

Second, it appears from the Commission's proposed revisions to both ADA and GINA regulations that the Commission intends that its reasonable design standard be harder to meet than the standard set in the tri-agency regulations. The ACA makes clear that the purpose of the reasonableness determination is not prescriptive. This was emphasized during the rulemaking process that led to the current tri-agency regulations, as the agencies stated that while the standard was drafted to prevent abuse, it was otherwise designed to be easy to satisfy in order to allow experimentation in diverse ways of promoting wellness.[18]

However, the Commission's proposed revision of both the ADA and GINA regulations includes new provisions that raise questions about whether the Commission intends to follow a permissive approach and indicates that the EEOC may be intending a new, narrower standard of reasonable design. For example, the preamble states that "Collecting information on a health questionnaire without providing follow-up information or advice would not be reasonably designed to promote health or prevent disease."[19] This is similar to an example the Commission proposed to be included as part of the ADA's interpretative guidance.[20]

As we stated in our comments on the ADA proposal, it is unlikely that an employer would collect information on a health questionnaire without using it. However, such an occurrence has no bearing on whether the employer's wellness program is reasonably designed. Any number of circumstances could explain the employer's failure to use the information in the manner originally intended, for example the employer's decision to abandon or change the wellness program after the information has already been collected. Conduct that would not violate the tri-agency regulations should never be construed to violate any reasonable design standard set by the Commission.

Third, the Commission's proposed reasonable design requirement is inconsistent with the tri-agency regulations because it seeks to apply the reasonable design requirement to a broader class of wellness programs. Under the tri-agency regulations, as mandated by the ACA, the reasonable design requirement applies to health-contingent wellness programs, not

[18] See Public Health Service Act, 42 U.S.C. § 2705(j)(3)(B) and Incentives for Nondiscriminatory Wellness Programs in Group Health Plans, Proposed Rule, 77 Fed. Reg. 70,619, 70,625 (Nov. 26, 2012) (to be codified at 26 C.F.R. pt. 54, 29 C.F.R. pt. 2590, and 45 C.F.R. pts. 146 & 147).
[19] GINA Proposal, 80 Fed. Reg. at 66,857.
[20] ADA Proposal, 80 Fed. Reg. at 21,668.

to participatory wellness programs. The Commission has no authority to extend the reach of the reasonable design requirement beyond that set by Congress.

A fourth and related concern that employers have with the proposed reasonable design component of the proposed regulations is that even if the Commission proposed regulatory language identical to that used in the tri-agency regulations, the Commission might interpret those regulations inconsistently with the manner in which those same requirements are interpreted by the Departments of Health and Human Services, Labor, and Treasury. If the Commission ultimately decides to retain the reasonable design requirement it should explicitly state that it intends the provision to be interpreted consistent with the tri-agency rules to help mitigate the chance that the Commission would later make inconsistent interpretations.

Reasonable Design Standard Appears To Be Backdoor Attempt to Breach GINA's Firewalls

A key consideration of Congress in enacting GINA was the creation of several firewalls to ensure that the EEOC would not be permitted to enforce or interpret health care laws. Two key firewall provisions are included within Section 209 of GINA. Section 209(a)(2)(B) of GINA states that nothing in Title II [of GINA] shall be construed "to provide for enforcement of, or penalties for violation of, any requirement or prohibition applicable to any employer" or other covered entity under certain enumerated sections of health law, described below. A companion provision, Section 209(c), states that Title II of GINA does not prohibit group health plans and health insurance issuers offering group health insurance coverage in connection with a group health plan from engaging in any activity authorized under the enumerated statutory provisions.

The specifically enumerated statutory provisions referenced in these firewall provisions include key sections of the Public Health Service Act (PHSA).[21] In particular, GINA references Section 2702(b)(1) of the PHSA, which is today codified at 42 U.S.C. Section 300gg-4(b)(1). It is this provision that address discrimination against individual participants and beneficiaries in premium contributions under the PHSA. Moreover, Section 300gg-4 contains additional provisions that explain how the provisions of 300gg-4(b)(1) are to be interpreted. These include a long standing rule of construction that the provision shall not be construed to:

> prevent a group health plan, and a health insurance issuer offering group health insurance coverage, from establishing premium discounts or rebates or modifying

[21] While only the PHSA is discussed above, GINA also explicitly references analogous sections of ERISA and the IRC. See 42 U.S.C. § 2000ff-8(a)(2)(B).

otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.[22]

It was also this section of the PHSA that Congress amended when it passed the ACA to explicitly authorize the use of incentives in wellness programs. When Congress did so, it added subsections to the end of Section 300gg-4 further describing the types of programs that would be considered programs of health promotion and disease prevention. It was these sections that added to the PHSA the requirement that certain wellness programs be "reasonably designed to promote health or prevent disease."[23]

Together, these provisions express the intent of Congress that it is not the Commission that should enforce and interpret health care law. Instead, that is the domain of the Departments of Health and Human Services, Labor, and Treasury. While the Commission certainly has the ability to enact regulations interpreting Section 202(b)(2) of GINA, that authority does not extend to the regulation of the design of programs of health promotion or disease prevention regulated under the PHSA.

In sum, we do not believe it is necessary or appropriate for the Commission to include a reasonable design standard as part of its GINA or ADA regulations and we recommend that the Commission remove this provision from its final rules. If, however, the Commission decides to retain a reasonable design standard, it should make it clear that the standard is the same as that used under the tri-agency regulations and that compliance with the tri-agency standard will constitute compliance with the Commission's regulations.

Any Reasonable Apportionment of Award Among Family Members Should Be Permissible

The Commission's proposal includes restrictive rules governing how incentives used for employees and spouses are to be apportioned. Under the proposal, the maximum share of the incentive attributable to the employee's participation in a covered wellness program is 30 percent of the cost of self-only coverage. The remainder of the incentive, equal to 30 percent of the total cost for the plan in which the employee and any dependents are enrolled, minus 30 percent of the total of self-only coverage, may be provided for the spouse providing information to a wellness program about his or her current or past health status.

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[22] 42 U.S.C § 300gg-4(b)(2)(B). ERISA and the IRC include analogous rules of construction. 29 U.S.C. § 1182(b)(2)(B); 26 U.S.C. § 9802(b)(2)(B).

[23] 42 U.S.C. § 300gg-4(j)(3)(B). While the ACA included such amendments to the PHSA, it did not make corresponding amendments to ERISA or the IRC. As explained in the tri-agency regulations, "The wellness program exception to the prohibition on discrimination under PHS Act section 2705 applies with respect to group health plans (and any health insurance coverage offered in connection with such plans), but does not apply to coverage in the individual market." Tri-Agency Regulations, 78 Fed. Reg. at 33,159.

There are several problems with the proposed approach. First, as the Commission's own example illustrates, apportioning incentives in this way could often create a situation in which a greater portion of the incentive may be apportioned to a spouse than to an employee. For many employers, this approach will seem backwards and counterintuitive.

Second, by setting an incentive limit on employees that is not directly tied to a health plan that the employee participates in, the proposed apportionment does not account for situations where an employer has several different health plans available. Of course, as noted later in these comments, the apportionment method also makes little sense when the employee or spouse are not enrolled in any health plan that the employer offers.

If the incentive limit is to be measured with reference to the total cost of health insurance premiums, we recommend the Commission use the same apportionment approach discussed in the preamble to the tri-agency regulations. In addressing comments that the agencies received on the apportionment issue in its rulemaking, and in particular, addressing the administrative challenging in apportioning incentives among covered family members, the agencies stated:

> …these final regulations do not set forth detailed rules governing apportionment of the reward under a health-contingent wellness program. Instead, plans and issuers have flexibility to determine apportionment of the reward among family members, as long as that method is reasonable. Additional subregulatory guidance may be provided by the Departments if questions persist or if the Departments become aware of apportionment designs that appear unreasonable.[24]

We urge the Commission to adopt a similar approach. Allowing plans and issuers and employers the flexibility to apportion incentives will likely significantly reduce administrative burdens imposed by the rule.

The Commission Should Not Mandate Full Incentive Payments Based on Medical Certification

In the preamble to the proposal, the Commission invites comments on whether employers that offer incentives to encourage the spouses of employees to disclose information about current or past health must also offer similar incentives to those who choose not to disclose such information if a medical professional certifies that the spouse is under a

[24] Tri-Agency Regulations, 78 Fed. Reg. at 33,162.

physician's care and any medical risks are under active treatment. The preamble to the Commission's proposed ADA regulations include a similar invitation for comments.

We urge the Commission to decline to adopt such a provision. The medical certification standard would limit an employer's ability to design wellness programs. A statement that medical risks are under treatment does not in any way help an employer to design health and wellness plans that are relevant to its workforce—a fundamental reason why employers choose to offer incentives for employee and family member participation in wellness programs. In addition, the language appears to inappropriately allow any medical professional to make such a certification regardless of their competency to assess the medical risks and treatment being undertaken by an employee's spouse.

Further, as we noted in our comments on the proposed revision to ADA regulations, standards adopted under the tri-agency regulations require that employers either waive requirements to receive an incentive or make a reasonable alternative standard available for employees for whom it is unreasonably difficult to satisfy the standard due to a medical condition or for employees for whom it is medically inadvisable to attempt to satisfy the standard. This framework is sufficient to ensure that individuals can earn the full amount of incentive even if an impairment makes it more difficult to meet the requirements of a health contingent wellness program.

For these reasons, we encourage the Commission to decline to take such an approach.

The Commission Should Not Use This Rulemaking to Opine On Lawfulness of Electronic Record Storage Methods

In the preamble to the proposal, the Commission invites comments as to whether its revised rule should include more specific guidance to employers regarding how to implement the requirements of GINA's confidentiality provisions for electronically stored records. If so, the Commission invites comments on what procedures are needed to ensure the confidentiality of genetic information with respect to electronic records stored by employers.

It may be that the issue of electronic record security is an appropriate issue for the Commission to examine, but rulemaking is the wrong forum. Instead, the Commission should consider holding a public meeting on the topic to gather more information about the many technical and practical aspects to the problem. It may be that after sufficient study the Commission is able to offer some helpful guidance, or direct employers toward helpful resources, but the Commission should refrain from rulemaking in this area.

The Commission Should Not Limit Employer Wellness Program Questions to Matters Directly Supporting Specific Wellness Activities

In the preamble to the proposed rule, the Commission invites comments on whether the regulation should 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. The Commission should refrain from further restricting the use of wellness programs.

GINA was crafted to encourage employers to offer health and genetic services, not to limit their use. Further limiting the types of inquiries that wellness programs may make is inconsistent with this statutory goal. In addition, GINA's existing restrictions governing employer provided health and genetic services are sufficient to ensure that individually identifiable genetic information is not transmitted to the employer. These provisions are also backed-up by GINA's anti-discrimination and confidentiality provisions. There is simply no need for the Commission to impose such additional limitations on employer wellness programs.

The Proposed Rule Does Not Account for Wellness Programs Outside of Group Health Plans

In the preamble to the proposal, the Commission invites comments on whether employers offer or are likely to offer wellness programs outside of group health plans that use incentives to encourage employees' spouses to provide information about a current or past health status as part of a health risk assessment and whether the GINA regulations should allow incentives provided as part of such programs.

There are a wide variety of wellness plans that operate outside of an employer's group health plan. For example, an employer may host health screenings for employees or provide vaccination services. Similarly, subsidized gym memberships (or even an on-site gym) are commonly available outside of group health plans. Many employers also offer access to weight loss, diabetes control, nutritional/healthy eating, and smoking cessation programs outside of health plans. In addition, some employers provide free access to healthy beverages and snacks while others, particularly in the retail sector, report offering store discounts on healthy foods. Retail employers also report utilizing store gift card incentives for enrolling and participating in wellness programs offered outside of group health plans.

Many such programs are available to employees as well as to spouses and other family members. Some involve a health risk assessment or other questionnaire that asks one or more

questions about current or past health status. Any of these could be impacted by the Commission's proposed rule, but the Commission provides no guidance on how the rules should be applied with respect to such programs.

Programs Offering Only De Minimis Incentives Should Not Be Covered by Regulation; De Minimis Rewards Should Not Be Counted Toward Any Incentive Limit

The Commission proposes deleting the term "financial" as a modifier for the types of incentives that may be offered in connection with wellness programs. In the preamble to its proposal, the Commission states that its intent is to make clear that the limitations apply to both financial and in-kind incentives, "such as time-off awards, prizes, or other items of value, in the form of either rewards or penalties." The Commission states that it intends that its regulations apply to all such incentives. In addition, the Commission also seeks comment on whether the incentive limits should apply only to wellness programs that offer more than de minimis rewards or penalties.

Token or de minimis incentives are commonly used in connection with wellness programs and should not be considered in determining whether incentive limits are met. For example, novelty items such as coffee mugs, t-shirts, or gift cards for coffee or a meal are commonly used by some employers as part of an effort to create a wellness culture[25] and cannot fairly be said to be coercive in any meaningful way. The inclusion of such items will often be difficult to quantify and could lead to a situation where an employer unintentionally violates the incentive limit if, for example, it already utilized incentives at the maximum level and then provides an additional novelty item it received through a promotion.

If a wellness program only utilizes de minimis incentives, it should be exempt from the Commission's proposed requirements. Similarly, de minimis incentives should not be counted toward the 30 percent incentive limit.

New Examples Help Illustrate Application of Rule

The Commission's proposal includes a new example to be added to Section 1635.8(c)(2) of its regulations. The example shows that it does not violate GINA when an employer seeks information about the current or past health status of a family member who is covered by the employer's group health plan and is completing a health risk assessment on a voluntary basis in connection with the family member's receipt of health or genetic services

[25] SOEREN MATTKE ET AL., RAND CORPORATION, WORKPLACE WELLNESS PROGRAMS STUDY: FINAL REPORT 71-72 (2013), available at http://www.dol.gov/ebsa/pdf/workplacewellnessstudyfinal.pdf (last accessed Jan. 28, 2016).

offered by the employer in compliance with the Commission's regulations. We support the inclusion of the example in the regulations.

Employers Will Need Appropriate Time to Adjust to New Requirements

The proposal does not identify how long a time period EEOC plans to provide between finalization of the rules and the date that employers must come into compliance. We urge the Commission to consider that its regulations may necessitate significant changes in plan design. Significant lead time is necessary to implement changes in plans, including designing new systems and creating and printing materials in advance of a new plan year.

This was recognized by the Departments of Health and Human Services, Labor, and Treasury when they finalized the tri-agency regulations. Those regulations were finalized on June 3, 2013 but did not apply to group health plans and group health insurance issuers until the beginning of the next plan year after January 1, 2014.[26] Accordingly, the Commission should consider either a significant delay before the effective date or a phased-in effective date, requiring compliance with the start of a new plan year after an appropriate period of time, such as one year, to allow for revision of plans and system updates.

Further Evidence that the Commission Has Incorrectly Characterized the Insurance Safe Harbor in its Proposed ADA Regulations

In our comments on the Commission's proposed ADA regulations, we detailed our reasons for believing that the Commission has erroneously construed the insurance safe harbor
codified at 42 U.S.C. Section 12201(c) and the Commission's belief that the Eleventh Circuit Court of Appeals incorrectly decided that the provision applied to an employer wellness program in *Seff v. Broward County*.[27] In particular, our comments focused on the Commission's lack of regulatory authority to interpret this section of the ADA, the legislative history and statutory construction of the provision, and the fact that the Commission's interpretation is simply not the best reading of the ADA.

Since our comments were filed, another federal court has now joined the Eleventh Circuit. In *EEOC v. Flambeau*, the Federal District Court for the Western District of Wisconsin ruled that the insurance safe harbor may exempt certain wellness programs from the ADA, expressly rejecting the position that the EEOC took in litigation. We revisit the

[26] Tri-Agency Regulations, 78 Fed. Reg. at 33,168.
[27] 691 F.3d 1221 (11th Cir. 2012).

issue now to urge the Commission to again review its interpretation of the insurance safe harbor.

Thank you for your consideration of these comments. Please do not hesitate to contact us if we may be of further assistance as the Commission proceeds to consider these important issues.

Sincerely,

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