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January 28, 2016

Ms. Bernadette Wilson
Acting Executive Officer, Executive Secretariat
U.S. Equal Employment Opportunity Commission
131 M Street, N.E.
Washington, DC 20507

Re: RIN 3046–AB02; Notice of Proposed Rulemaking Regarding How the Genetic Information Nondiscrimination Act Relates to Employer Wellness Programs

Dear Ms. Wilson:

The U.S. Chamber of Commerce (the "Chamber") provides these comments in response to the Notice of Proposed Rulemaking (the "Proposed Rule") that the U.S. Equal Employment Opportunity Commission ("EEOC" or the "Commission") published in the October 30, 2015 edition of the Federal Register. The Proposed Rule purports to set forth obligations and restrictions upon employers who offer wellness program incentives to its employees under the Genetic Information Nondiscrimination Act ("GINA").

The Chamber is the world's largest business federation, representing more than three million businesses and organizations of every size, sector, and region. More than 96 percent of the Chamber's members are small businesses with 100 or fewer employees, 70 percent of which have 10 or fewer employees. Yet, many of the nation's largest companies are also active members. We are particularly cognizant of the problems of smaller businesses, as well as issues facing the business community at large. Besides representing a cross-section of the American business community in terms of number of employees, the Chamber represents a wide management spectrum by type of business and location. Each major classification of American business— manufacturing, retailing, services, construction, wholesaling, and finance—is represented. Also, the Chamber has substantial membership in all 50 states.

As noted in our June 19, 2015 comments submitted in response to the Commission's related rulemaking under the Americans with Disabilities Act (the "ADA Proposed Rule"), the Chamber has long championed the adoption, expansion, innovation, and diversification of workplace wellness programs. For example, the Chamber—as a leader in the U.S. Workplace Wellness Alliance—was instrumental in passing accompanying resolutions in the House and Senate in 2008 recognizing the importance of workplace wellness which designated the first week of April as "National Workplace Wellness Week." Additionally, during the first full week of April, in

commemoration of "National Workplace Wellness Week," the Chamber hosts an annual event highlighting innovations in workplace and community wellness. Our most recent event—held on April 7, 2015—emphasized innovative workplace wellness programs and strategies to influence behavior change, among other wellness-related topics. The Chamber has also issued several publications which promote workplace wellness programs, and such programs were featured in our 2013 report, "*Health Care Solutions from America's Business Community: The Path Forward for U.S. Health Reform*."

Simply put, wellness programs are both effective and popular. Indeed, we are already seeing how wellness programs provide positive benefits for both employers and employees. According to a recent study published in the preeminent journal, *Health Affairs*, authors Katherine Baicker, David Cutler, and Zurui Song calculated a return on investment of $3.27 for medical cost savings and $2.73 for absentee reduction for every dollar spent on wellness programs.[1]

I. Overview

For more than six years, the EEOC has sent confusing signals regarding wellness program incentives. In early 2009, the EEOC indicated that it would follow HIPAA standards for determining voluntariness under the ADA.[2] Roughly three months later, the EEOC rescinded that letter.[3] Since then, the Commission has remained largely silent on what they view as "voluntary" wellness program incentives under the ADA and GINA, yet has filed high-profile lawsuits against employers challenging such incentives.[4] Currently, the EEOC relies on a guidance document issued in 2000, which states that a wellness program is voluntary as long as an employer "neither requires participation nor penalizes employees who do not participate."[5] This guidance predates subsequent legislation and regulations permitting employers to provide financial reward to employees who participate in workplace wellness programs. Given the new law and rules, it would appear that this 2000 guidance has been supplanted. In fact, the EEOC's treatment of and litigation against wellness

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[1] *See Workplace Wellness Programs Can Generate Savings*, available at http://content.healthaffairs.org/content/29/2/304.full.pdf+html.

[2] *See* January 6, 2009 letter, "ADA: Disability Related Inquiries and Medical Exams/Mandatory Clinical Health Risk Assessment" available at http://pdfserver.amlaw.com/cc/WellnessEEOC2009.pdf.

[3] *See* March 2, 2009 letter, "ADA: Disability-Related Inquiries and Medical Examinations; Health Risk Assessment" available at http://www.eeoc.gov/eeoc/foia/letters/2009/ada_disability_medexam_healthrisk.html (last visited March 16, 2015).

[4] The EEOC heretofore has not been successful in these lawsuits. *See e.g.*, *EEOC v Flambeau*, No. 14-cv-638 (W.D. Wisc. Dec 30, 2015). Interestingly, the judge's decision in *Flambeau* is grounded in the "safe harbor" provision of the ADA which EEOC has inappropriately attempted to eliminate in the ADA Proposed rule. *See FDA* v. *Brown* & *Williamson Tobacco Corp.*, 529 U. S. 120, 125 (2000)("Regardless of how serious the problem an administrative agency seeks to address, however, it may not exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'')(internal citations omitted).

[5] U.S. Equal Employment Opportunity Commission, *Enforcement Guidance: Disability-Related Inquiries and Medical Examinations of Employees Under the Americans with Disabilities Act (ADA)* at Q. 22 (last visited December 1, 2015).

program incentives contradicts the 2010 legal and 2013 regulatory guidelines that the ACA and its Tri-agency rules have provided, adding confusion and consternation for employers. The Chamber's comments in response to the ADA Proposed Rule explain why the EEOC's approach to addressing wellness program incentives was fundamentally flawed and, which in critical respects, ignored the ADA's statutory language and conflicted with the regulations promulgated by the Departments of Treasury, Labor and Health and Human Services ("Tri-Agency Regulations") in June 2013.[6]

As set forth in greater detail below, while the Chamber is pleased that the EEOC has finally recognized the 30% incentive threshold established by the Affordable Care Act is "not so high as to be coercive" and worked with the Departments of Labor, HHS and Treasury in an attempt to craft compatible rules for wellness program incentives, it remains concerned with certain aspects of the Proposed Rule, including but not limited to, the re-adoption of the "reasonably designed" standard for wellness programs and the incentive allocation structure. If the Proposed Rule is enacted as drafted, it will establish different, more onerous, restrictions on employers providing incentives to their employees and become the *de facto* law of the land regarding wellness program incentives. When multiple federal agencies attempt to regulate some or all of a legislatively favored policy, such as wellness programs, it is the most onerous or restrictive regulation which overwhelms the other regulations, even if issued by agencies with designated expertise. In this situation involving wellness programs, the EEOC lacks the necessary health care policy expertise to impose such restrictions on the regulated community.

This Proposed Rule, in conjunction with the ADA Proposed Rule, will deter employers from innovating and offering workplace wellness programs, contrary to the intent of Congress, the text of the ACA, the Tri-Agency Regulations, the ADA, and the Administration's stated position. While the ACA strengthens and promotes employer-sponsored wellness programs, the Proposed Rule weakens them and impermissibly assumes that the EEOC's interpretation of GINA (and the ADA) becomes the overriding constraint upon wellness programs regardless of what Congress and the Cabinet-level agencies have determined.

With health care costs continuing to rise, along with rates for obesity and other chronic diseases, workplace wellness programs have served as meaningful mechanisms for encouraging and rewarding positive behavior and healthy life choices. Congress was clear in the ACA that such programs should be encouraged. Similarly, the Administration was clear in the Tri-Agency Regulations promulgated to implement that law. Even with regard to litigious action from the EEOC, the White House has reiterated its support for these programs.[7] But apparently these endorsements are irrelevant to the EEOC. Whether through litigation not authorized by the

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[6] 78 Fed. Reg. 33158 (June 3, 2013).

[7] At a White House press briefing on December 3, 2014, Press Secretary Josh Earnest stated that, with regard to the Honeywell case, "as a general matter, . . . the administration, and particularly the White House, is concerned that this… could be inconsistent with what we know about wellness programs and the fact that we know that wellness programs are good for both employers and employees." *See* http://www.whitehouse.gov/the-press-office/2014/12/03/press-briefing-press-secretary-josh-earnest-1232014.

Commission or through the Proposed Rule, the EEOC continues to send a confusing message to employers: reliance on the text of the ACA or the Tri-Agency Regulations cannot protect employers from potentially massive investigations and litigation for offering ACA-compliant wellness programs that provide lawful monetary rewards. Indeed, rather than being supportive of wellness programs as the legislation and government policy clearly compels, the EEOC has embarked on a continuous campaign to saddle wellness programs with onerous requirements not grounded in legislation or the consensus of public policy. This is not appropriate and the result is untenable. Accordingly, we insist that any final rule interpreting the ADA or GINA adopted by the EEOC relating to workplace wellness programs be **harmonized** with the existing federal standards under ACA, HIPAA and the Tri-Agency Regulations.

II. Several Provisions of the Proposed Rule Are Outside the Scope of the EEOC's Limited Jurisdiction and Rulemaking Power

A. The EEOC Has No Authority to Examine Whether a Wellness Program is "Reasonably Designed"

The Proposed Rule defines a previously undefined term—wellness program—while importing certain requirements related to health-contingent wellness program contained in the ACA and the Tri-Agency Regulations promulgated by agencies which actually have the authority to interpret that term. Yet, even the proposed definition strays from the requirements adopted by the ACA and the Tri-Agency Regulations. Under the ACA, a wellness program is a "program of health promotion or disease prevention."[8] Per the ACA and HIPAA, only a health-contingent wellness program must be "reasonably designed," which means:

> The program has a reasonable chance of improving the health of, or preventing disease in, participating individuals and it is not overly burdensome, is not subterfuge for discriminating based on a health status factor, and is not highly suspect in the method chosen to promote health or prevent disease.[9]

Conversely, Section 1635.8(b)(2)(i)(A) of the Proposed Rule provides:

> The health or genetic services, including any acquisition of genetic information that is part of those services, are reasonably designed to promote health or prevent

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[8] 42 U.S.C. § 300gg-4(j)(1)(A). *See* also 26 C.F.R. § 54.9802-1(f) ; 29 C.F.R. § 2590.702(f); 45 C.F.R. § 146.121(f)(2). Participatory wellness programs are those programs where none of the conditions for obtaining a premium discount or rebate or other reward are based on an individual satisfying a standard that is related to a health status factor. 42 U.S.C. § 300gg-4(j)(2). *See* also 26 C.F.R. § 54.9802-1(f) (1)(ii); 29 C.F.R. § 2590.702(f)(1); 45 C.F.R. § 146.121(f)(1). A health-contingent wellness program is one that conditions a premium discount, rebate or reward on an individual satisfying a standard that is related to a health status factor. 42 U.S.C. § 300gg-4(j)(3). *See* also 26 C.F.R. § 54.9802-1(f) (1)(iii); 29 C.F.R. § 2590.702(f)(2); 45 C.F.R. § 146.121(f)(2).

[9] 42 U.S.C. § 300gg-4(j)(3)(B). *See* also 26 C.F.R. § 54.9802-1(f) (3)(iii); 29 C.F.R. § 2590.702(f)(2)(ii); 45 C.F.R. § 146.121(f)(2)(ii).

> disease. A program satisfies this standard if it has a reasonable chance of improving the health of, or preventing disease in, participating individuals, and it is not overly burdensome, is not a subterfuge for violating Title II of GINA or other laws prohibiting employment discrimination, and is not highly suspect in the method chosen to promote health or prevent disease.[10]

As with the ADA Proposed Rule, there are multiple concerns with this approach. This regulatory sleight of hand appears to be an effort to actually define "wellness programs," a term that Congress and the Administration have already defined in the ACA and the Tri-Agency Regulations, respectively. Now, the EEOC proposes to adopt a new definition, which it conceded was only "similar." While the EEOC is the designated agency to enforce the ADA and GINA, it has been delegated no authority to adjust or disregard the definition of wellness programs statutorily granted to the Tri-Agencies. The EEOC must administer its laws consistent with direction of the Congress. It cannot adjust the definition of wellness programs in order to shoehorn its own views of wellness program design into the regulations it is proposing. Introducing a "similar" definition means that the EEOC intends to adopt a different standard than the one adopted by Congress in the ACA or the Departments of Labor, Treasury and HHS in the Tri-Agency Regulations.

Moreover, the Preamble's interpretation of the "reasonably defined" requirement is concerning. The EEOC states that one purpose of the requirement is to make the Proposed Rule "consistent" with the ADA Proposed Rule.[11] As noted in our June 19, 2015 comments, the EEOC lacks the authority to make such a change under the ADA, and proposing a change in the Proposed Rule merely compounds the error.

Second, by importing the "reasonable design" requirement, the Proposed Rule imputes the burdens previously associated only with health-contingent wellness programs to all "wellness programs," which exceeds what is required under the ACA and the Tri-Agency Regulations. Under the Proposed Rule, even participatory wellness programs would have to be reasonably designed, and the agency that would determine whether any particular wellness program was "reasonably designed" would be the EEOC. For example, would an employer offering a gym membership reimbursement (a classic participatory wellness program) be "reasonably designed" to promote health or prevent disease? What would the EEOC's analysis be for such a wellness program? The EEOC could argue that it may not be "reasonably designed" because an individual must actually use a gym membership to promote health and prevent disease.

Third, the Proposed Rule introduces new concepts to its reasonable design requirement in the Preamble. In fact the EEOC almost defiantly states in the Preamble that it is proposing six substantive changes to the GINA regulations which relate to the standard of "reasonable design:" While some of these changes are less egregious than others, of particular concern are the two new

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[10] Proposed Rule, 80 Fed. Reg. at 66,861.
[11] Proposed Rule, 80 Fed. Reg. at 66,856.

requirements that a workplace wellness program (1) must provide follow-up information or advice and after collecting information on a health questionnaire;[12] and (2) must not impose as a condition of obtaining a reward, an overly burdensome amount of time for participation, require unreasonably intrusive procedures, or place significant costs related to medical examinations on employees.[13] What does the EEOC consider an overly burdensome amount of time for participation or unreasonably intrusive procedures? What are "significant" costs and would that depend on the employee's and/or spouse's income? These concepts simply introduce more confusion and uncertainty into wellness program design and administration which were largely resolved by the Tri-Agency Regulations.

Adopting a new definition with new and undefined characteristics will cause unnecessary confusion for employers. Further, this definition is inconsistent with standards promulgated by the agencies which have clear jurisdiction and expertise on health care policy. Moreover, although the EEOC is obviously well-versed in federal anti-discrimination laws, the EEOC cannot possibly know whether or when a wellness program is "reasonably designed." Such a question is simply beyond the expertise of the Commission. Therefore, the EEOC must restrict itself to adopting the statutory and Tri-Agency definition, not synthesizing and restating it in different language.

Finally, by including "or other laws prohibiting employment discrimination" in the proposed definition, it appears as if the Proposed Rule attempts to promulgate a regulation that encompasses statutes, such as Title VII, where the EEOC lacks authority to issue regulations.[14] Indeed, it seems to indicate that if a wellness program somehow discriminates under Title VII, then any related inquiries would not be voluntary under GINA. Additionally, the EEOC seems to be attempting to create a regulatory "catch all" that can be used to regulate any wellness program that ***may*** implicate another statute not addressed by these regulations. That type of circular analysis appears to be a bald and impermissible attempt to regulate under Title VII or to promulgate an open-ended regulation not anchored in the authorizing statute.

The EEOC simply does not have the statutory authority or the health care expertise to determine whether a wellness program is "reasonably designed" or to overrule the ACA or the Tri-Agency Regulations on what wellness programs have to be "reasonably designed" or what that entails. The EEOC's only jurisdiction is to determine whether a wellness program is voluntary, not to weigh in on wellness program design and any final rule should recognize that limitation. The EEOC should merely state the obvious—that any wellness program meeting the requirements of the

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[12] "Collecting information on a health questionnaire without providing follow-up information or advice would not be reasonably designed to promote health or prevent disease." Proposed Rule, 80 Fed. Reg. at 66,857.

[13] "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" Proposed Rule, 80 Fed. Reg. at 66,857.

[14] *See* 42 U.S.C. § 2000e-12(a), granting the EEOC authority only to issue procedural regulations related to Title VII.

ACA and HIPAA are acceptable "wellness programs" under GINA, and that spousal medical inquiries or examinations which are part of it, must be voluntary.

B. The Proposed Rule's Prohibition Against Incentives Where Spouses Are Not Included in the Elected Coverage and For Dependents

The Proposed Rule permits employees to take advantage of the maximum 30% incentive only where his or her spouse is covered by the employer's group health plan, and prohibits such incentives either for dependents or where a spouse does not participate in the health plan.[15] This approach is problematic for several reasons. First, it perpetuates the misguided principle set forth in the ADA Proposed Rule that an employee may only receive an incentive up to 30% of self-only coverage regardless of what plan the employee enrolls in, such as plus 1 or family coverage. As noted in our June 19, 2015 comments, limiting the incentive calculation to the cost of self-only coverage versus the cost of the chosen coverage clearly conflicts with the ACA and the Tri-Agency Regulations, which permit an employee incentive to be based on the total cost of chosen coverage.

Second, this allocation structure would lead to some curious results. For example, if a female employee chooses family coverage for herself and three children, while her husband has separate health coverage through his employer, the female employee, mother of three, would be penalized by the Proposed Rule's restrictions and her maximum incentive would be limited to 30% of self-only coverage. Moreover, a single mother with three children and family coverage would likewise be prevented by the Proposed Rule from reaping the full benefits of the ACA, namely, a permissible incentive based on the total cost of chosen coverage. Is it really the EEOC's intent to limit incentives for single mothers?

These examples demonstrate why it is improper to address wellness program incentives in this manner. Any permissible incentive calculation should be based on the total cost of coverage chosen by the employee, rather than a multistep calculation limited by the cost of employee-only coverage. Congress made that determination in amending HIPAA through the ACA. Calculating whether an inquiry is voluntary under the ADA based upon the cost of a plan that the employee is not enrolled in is misguided and could lead to absurd results. The EEOC should modify any final rule to base the incentive calculation on the total cost of the coverage chosen by that employee, as contemplated by the ACA and HIPAA.

Moreover, the proposed regulations ignore the fact that if an employer offers health care coverage to employees' dependents, that coverage must continue to be offered to employee's children up to age 26, pursuant to the ACA. Given that the health conditions of children (regardless of age) contribute to the cost of health care and therefore coverage, there is as much incentive for these dependents/children to participate in wellness programs as there is for employees or spouses. The EEOC's position is an arbitrary rule untethered to the statutory GINA language, as no such

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[15] Proposed Rule at Section 1635.8(b)(2)(i)(A)(iii).

limitation to the wellness program exception to requesting, requiring, or purchasing genetic information exists. The restriction should be eliminated from any final rule for this reason, but also because GINA contains an absolute prohibition on using genetic information in employment decisions, which is sufficient to protect the employee's interest in such cases.

C. The EEOC's Allocation Mechanism Perpetuates the EEOC's Missteps Taken in the Proposed ADA Rule

Section 1635.8(b)(2)(i)(A)(iv) provides an allocation mechanism for determining the maximum permissible incentive for spousal participation in a wellness program. The Proposed Rule states that:

> The maximum amount of the inducement for an employee's spouse to provide information about current or past health status may not exceed 30 percent of the total cost of coverage for the plan in which the employee is enrolled less 30 percent of the total cost of self-only coverage.[16]

This allocation mechanism, however, also presents concerns. First, the allocation is based on the employee incentive with respect to self-only coverage, a problem described above. Second, this allocation seemingly disregards how employers are currently offering incentives. In the majority of cases, employers offer an equal incentive to employees and their spouses to participate in a wellness program. The proposed allocation mechanism has the potential to turn that structure on its head, as illustrated perfectly by the EEOC's own example.[17] Rarely would an employer offer an $1,800 incentive to an employee and a $2,400 incentive to the participating spouse. It simply does not make business sense to incentivize a spouse more than an employee or to penalize an employee based on the voluntary choices of his or her spouse.

Finally, the Proposed Rule does not address how this allocation mechanism will be analyzed by the EEOC. Would the EEOC review the incentive calculation itself, or the manner in which the incentive was paid? Administratively, would the employer be required to issue separate incentive payments to the employee and the spouse?

Overall, as written and in conjunction with the ADA Proposed Rule, the EEOC would be establishing a more complex regulatory scheme related to wellness program incentives which would likely become the *de facto* law of the land. As the EEOC lacks the expertise and the statutory authority to do so, the EEOC should harmonize its regulations with the ACA and the Tri-Agency Regulations.

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[16] Proposed Rule, 80 Fed. Reg. at 66,861.
[17] Proposed Rule, 80 Fed. Reg. at 66,861.

D. Restricting Smoking Cessation Benefits to the 30% Maximum Incentive Rule

In addition to the above concerns, the Chamber has several concerns with establishing a 30% maximum incentive rule. First, the Proposed Rule limits permissible incentives to 30% of the total cost of chosen coverage for all wellness programs—participatory or health-contingent—subject to the restrictions discussed above. That limitation, however, conflicts with the level of permissible incentives under HIPAA, as amended by the ACA. First, for participatory wellness programs, no incentive limit exists.[18] For health-contingent wellness programs, HIPAA provides:

> If, in addition to employees or individuals, any class of dependents (such as spouses or spouses and dependent children) may participate fully in the wellness program, such reward shall not exceed **30 percent of the cost of the coverage in which an employee or individual and any dependents are enrolled.**[19] (emphasis added.)

Second, the ACA and the Tri-Agency Regulations did not establish a hard cap for incentive levels. Instead, Congress granted authority to the Secretaries of Labor, HHS and Treasury to increase that limit up to 50% of the cost of coverage. Specifically, the ACA provided as follows:

> The Secretaries of Labor, Health and Human Services, and the Treasury may increase the reward available under this subparagraph to up to 50% of the cost of coverage if the Secretaries determine that such an increase is appropriate.[20]

In fact, that is exactly what the Secretaries did in promulgating the Tri-Agency Regulations. Not only did the Tri-Agency Regulations adopt the 30% baseline limit for incentives related to health-contingent wellness programs, but the Secretaries actually increased the permissible reward to 50% for smoking cessation programs based on the flexibility granted to them by Congress. The Proposed Rule fails to account for the possibility that the Secretaries may modify the standard in the future. If the EEOC includes such a hard cap in a final rule, then the practical effect is that employers and employees alike will again be confronted with conflicting rules for permissible wellness program incentives should the Secretaries modify the percentages. An agency cannot just disregard an existing regulation and/or quickly create a different one. The regulatory process is time consuming and there are no guarantees on any particular outcome. To bring its regulation into alignment with the ACA and the Tri-Agency regulations, the EEOC should adopt a flexible "HIPAA Standard" for permissible incentives.

Third, the Proposed Rule limits incentives for smoking cessation programs to 30% where an employer conducts a medical examination to confirm whether that employee's spouse actually

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[18] 42 U.S.C. § 300gg-4(j)(2).
[19] 42 U.S.C. § 300gg-4(j)(3)(A).
[20] 42 U.S.C. § 300gg-4(j)(3)(A).

smokes.[21] Where an employer merely asks whether an employee is a smoker, then it would be permissible for that employer to offer a 50% incentive because the ADA is not implicated in such a scenario.

One major cost driver for employee health insurance is smoking-related diseases and complications. The Proposed Rule would restrict the rewards available for employers to encourage its workforce to stop smoking. It strains credulity to suggest that an employer would offer the maximum incentive permitted, indeed encouraged, by the ACA where it could not confirm that an employee or spouse did not smoke and would have to rely on each individual's statement. If an employer asked employees or spouses whether they smoke, and offered a larger rebate if they simply answered no, it is simply unreasonable to believe that all employees would answer truthfully.

If promulgated, the Proposed Rule will cause fewer people to have the maximum allowable resources to assist them to stop smoking. That is a perverse policy decision to impose, given the health issues caused by smoking. The EEOC should defer to the health policy experts, like HHS, on how best to reduce smoking, as the EEOC has no expertise in the area. It is improper for the EEOC to promulgate a rule that limits an employer's ability to incentivize nonsmoking when Congress and other Cabinet-level agencies have proactively created such incentives.

III. Additional Concerns

A. Prior, Knowing, Voluntary and Written Authorization

GINA prohibits employers from requesting, requiring, or purchasing genetic information with respect to an employee or family members unless an exception applies.[22] One exception permits an employer to request such information pursuant to services offered as part of a wellness program.[23] According to the statute, the "employee" must provide prior, knowing, voluntary and written authorization.[24] Under existing regulations, the EEOC expanded that requirement to any "individual" from which the employer requests genetic information.[25] Pursuant to those regulations, "prior knowing, voluntary, and written authorization" means that the authorization is written in a manner so that the individual is likely to understand it and must describe how the information will be used and the disclosure restrictions.[26]

The Preamble of the Proposed Rule provides:

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[21] Proposed Rule, 80 Fed. Reg. at 66,858, n. 24.
[22] 42 U.S.C.§ 2000ff-2(b) In addition, it absolutely prohibits employers from using genetic information in employment decisions 42 U.S.C § 2000ff-1.
[23] 42U.S.C. § 2000ff-1(b)(2)(A)
[24] 42 U.S.C. § 2000ff-1(b)(2)(B)
[25] 29 CFR § 1635.8.
[26] 29 CFR § 1635.8(b).

> The HRA, which may include a medical questionnaire, a medical examination (e.g., to detect high blood pressure or high cholesterol), or both, must otherwise comply with paragraph (b)(2)(i) in the same manner as if completed by the employee, including the requirement that the spouse provide prior knowing, voluntary, and written authorization when the spouse is providing his or her own genetic information, and the requirement that the authorization form describe the confidentiality protections and restrictions on the disclosure of genetic information. The employer also must obtain authorization from the spouse when collecting information about the spouse's past or current health status, though a separate authorization for the acquisition of this information from the employee is not necessary.[27] (emphasis added.)

Read literally, this language requires an employer to obtain authorization from the spouse twice -- once related to a spouse's own genetic information and once for the spouse's past or current health status information. This language raises some practical concerns as it seems to assume that the *employee* is providing either genetic information or current/past health status *regarding his/her spouse* to the employer. In such a case, the Proposed Rule appears to contemplate that employers cannot accept that information in the absence of spousal authorization. Such a requirement seems unreasonably intrusive into its employee's marital relations.

Generally speaking, however, that is not how we understand that our members request information pursuant to a wellness program. Each individual -- the employee and the spouse -- is generally given separate HRAs or subjected to separate medical examinations, each of which is voluntary. In these circumstances, a single authorization that complies with GINA should be sufficient to satisfy the requirements under GINA regarding voluntariness. As noted in our June 19, 2015 comments, no parallel requirement exists in the ADA for employees.

Overall, this language from the Preamble creates a significant amount of confusion as to what type of authorization is required, how many authorizations must be obtained, and creates additional unnecessary barriers to wellness program design and administration.

B. In-Kind Incentives

The ACA provides the following definition for the term "reward":

> A reward may be in the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance) the absence of a

[27] Proposed Rule, 80 Fed. Reg. at 66,857.

> surcharge, or the value of a benefit that would otherwise not be provided under the plan.[28]

The Proposed Rule provides the following:

> A covered entity may not offer an inducement (financial or in-kind) whether in the form of a reward or penalty, for individuals to provide genetic information, except as described in paragraphs (b)(2)(iii) and (iv)…[29]

The Preamble provides the EEOC's view of "in-kind" incentives.

> "[I]nducements include both financial and in-kind inducements, such as time off awards, prizes, or other items of value, in the form of either rewards or penalties.[30]

In addition to exceeding the statutory definition for reward under the ACA, the EEOC does not provide any sort of *de minimis* exception for potential "prizes" distributed by an employer. For example, an employer that offers a 30% premium reduction in accordance with the ACA and the ADA under the Proposed Rule, yet also provides employees with a key chain, stress ball, refrigerator magnet, or highlighter would presumably violate the Proposed Rule. Notably, none of these "prizes" is taxable, and compliance with the Proposed Rule would require all employers to consider such value in its voluntariness analysis. That result is patently absurd.

C. Wellness Programs That Are Not Part of a Group Health Plan

The Proposed Rule limits incentives for wellness programs that are part of a group health plan to 30% of the total cost of employee-only coverage or the cost of chosen coverage where a spouse participates in the insurance plan. However, the Proposed Rule does not provide any guidance related to what is voluntary vis-à-vis stand-alone wellness programs, i.e., those that are not part of a group health plan. Whether this omission was intentional or not, it again reflects a lack of commitment to address wellness program incentives in a holistic manner.

Some wellness programs are part of group health plans, and others are not. Failing to set forth the EEOC's position on permissible wellness program incentives for stand-alone wellness programs yet again leaves employers and employees without guidance on how to determine the voluntariness of medical inquiries. Will the EEOC use a 30% standard as it does for wellness program incentives that are part of a group health plan? Will it be something less? If so, what would the basis for that be, as such a rule would clearly conflict with HIPAA and the ACA.

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[28] 42 U.S.C. 300gg-4(j)(3)(A).
[29] Proposed Rule, 80 Fed. Reg. at 66,861.
[30] Proposed Rule, 80 Fed. Reg. at 66,858.

D. Effective Date

The EEOC has stated that it intends to finalize both the ADA Proposed Rule and this Proposed Rule in February 2016. However, the comments for this Proposed Rule are not due until January 28, 2016. Recognizing that the February 2016 date is aspirational only, the EEOC must consider two concerns when contemplating an effective date for any final rule. First, if the EEOC promulgates a final rule, is must allow employers enough time to redesign and implement health plans, including wellness programs, in a reasonable and comprehensive manner. For example, if a regulation is finalized in the summer months, then it is likely too late in the process for an employer to redesign its plan for the upcoming plan year to be ready for an open enrollment period in the fall. Practically speaking, much of the design and marketing plan will have been submitted for printing well before open enrollment, and nearly be impossible to change, if enough time to implement the new regulations is not provided.

Second, the EEOC has waited almost seven years to address the issue, and then only did so in a piecemeal manner, despite being pressed by Congress, the Administration, the regulated community and individuals. The EEOC therefore should commit to issuing wellness program regulations under the ADA and GINA simultaneously. In addition, the EEOC should suspend such investigations and cease litigation which allege that incentives violate the ADA and/or GINA until the final rules under both the ADA and GINA are promulgated and in effect.

IV. The EEOC Underestimates the Burden Associated with the Requirements of the NPRM

The Commission claims that the proposed rule is not economically significant (does not exceed $100 million per year in cost impact) and also is not subject to special analysis requirements under the Unfunded Mandates Act. The Commission's compliance cost calculations recognize only one category of cost impact: initial year training of human resource managers. The Commission estimates the amount of this one-time cost to be $38,638,670. The Commission's analysis and estimation of compliance cost is inaccurate and incomplete, and its conclusions are inaccurate regarding economic non-significance and inapplicability of Unfunded Mandates Act.

A. The Commission's Training Costs Estimate is Inaccurate

The Commission's estimate of the opportunity cost of training human resource management staff ($49.41 per hour, based on BLS wage data) reflects only the hourly wage component and fails to consider the full opportunity cost, including overhead and lost profit contribution of reallocating productive labor to non-productive regulatory compliance training activity. Based on review of fully loaded hourly rates paid by the government to private contractors for professional labor, a markup of direct labor by a factor of at least three is an appropriate estimate of the full opportunity cost, implying an hour rate of $148.23 for the full opportunity cost, including overhead and profit contribution of human resource management professional labor diverted to regulatory compliance training. Using the same parameters assumed by the Department (1 hour training time, 3 staff

receiving training, and 260,667 affected employers), the corrected training cost would be $115,915,860.

Second, the Commission's calculation of training cost considered only the time and cost associated with the staff receiving training, but failed to include any cost for the person delivering the training. Assuming that each of the 260,667 affected employers identified by the Commission pay $180 for the training unit (equivalent to the fully loaded including overhead cost of a manager/trainer at a basic wage of $60 per hour) the trainer cost would be $46,920,000, bringing the sum total of training cost (trainees plus trainer) to $162,835,860.

Finally, the Commission's estimate of one hour for the necessary training is not supported by evidence. This is a subject that the Commission should investigate by empirical research rather than making unfounded supposition. If, for example, the training required on average two hours of staff and trainer time, the total training cost would be $325,671,720. Given the sensitivity of the training cost to the time parameter, it is incumbent upon the Commission to provide a sound empirical basis for its assumption, based on surveys of training providers or in-house experiments using its own staff resources.

These considerations demonstrate that the initial cost of the proposed regulation is clearly greater than the threshold defining an economically significant regulation proposal, triggering both the obligation to submit its regulatory cost/benefit analysis to the Office of Information and Regulatory Affairs ("OIRA") for review and triggering analysis obligations under the Unfunded Mandates Act.

B. The Commission Ignored Basic Familiarization Costs

The Commission identified 782,000 employers with 15 or more employers who are potentially affected by the proposed rule. To calculate the training cost element of regulatory compliance, the Commission reduced this number to an estimated 260,667 employers who sponsor wellness programs that are open for participation by spouses and, therefore, most likely affected by the proposed new rule. <u>The Commission failed to consider that employers cannot know whether or not they are among the most likely affected subset unless they have initially taken time to review the rule</u>. If 782,000 employers on average devote one hour to read and understand the rule (including, perhaps time and cost to consult with attorney's and human resource plan consultants), at a fully loaded opportunity cost rate (including overhead and foregone profit) of $189 per hour for senior manager time, the basic familiarization cost would total $147,798,000. Adding this amount to the corrected training cost described above, brings the total initial annual cost of the proposed rule to $473,469,720. Adding familiarization cost for the five million employers with fewer than 15 employees who must at least review the rule sufficiently to determine that their employment levels are below the applicability threshold would result in greater cost: just five minutes of management time to determine that employers with fewer than 15 employees are exempt would add $78.5 million to initial compliance cost. Worse, the Commission's assertion that employers with fewer than 15 employees are unaffected does not appear until page 8 of the Federal Register notice, about

thirty minutes reading time into the preamble, which implies over $400 million in familiarization burden imposed on very small employers to discover their exemption. EEOC should inform the potentially affected public of this exception (and its legal basis) earlier and more prominently in regulatory text and preamble to minimize the familiarization burden on very small employers.

C. The Commission Ignored the Costs Associated With Employers' Compliance Review of their Wellness Programs

For employers who sponsor wellness programs that may be affected by the proposed rule, estimated as 260,667 employers by the Commission, each will need to conduct a careful review of its existing program, identify whether or not its program is compliant with the rule, and, if not, identify changes needed to bring the program into compliance. The compliance review and verification activity will be complex and time consuming, involving the coordination of effort among human resource management professionals, accountants, and legal staff. Input from outside legal counsel, actuaries and other consultants may be needed, especially to ensure the accuracy of complex calculations regarding the value of incentives and the ratio of such value to applicable health insurance costs. Even a *de minimus* average cost of $1,200 per each of the subject 260,667 employers would result in a total program review cost of $312,800,000. This is an illustration to show the serious potential magnitude of this cost element. Anecdotal evidence from our interviews with potentially affected employers suggests that the actual amount may be many times greater. The Commission should give serious consideration to this important element of compliance by conducting surveys, field studies or other research to obtain a realistic empirical estimate of this cost element. It should be noted that program review is not a one-time cost. Affected employers will need to continually review their program compliance as health insurance benefit costs change, as the composition of their covered employee groups change, and as the value of monetary and in-kind wellness program participation incentives change.

D. The Commission Ignored Wellness Program Revision Costs

For those employers who find that their existing program is not compliant with the rule, further significant costs will be required to redesign the program and implement changes identified as needed, or to terminate the program. Significant renegotiation of contracts with service providers and labor union collective bargaining agreements may be necessary. The proportion of the 260,667 potentially affected employers whose program is already compliant versus the proportion not compliant and likely to trigger significant revision cost is a critical parameter for a realistic estimate of the cost burden of the proposed rule. The Commission has not presented any survey results or other research regarding this key baseline compliance parameter. It is essential that the Commission fill this critical information gap before proceeding further with this rulemaking. To promulgate a regulation without knowledge of this critical economic impact parameter would be capricious. In the absence of data regarding the baseline compliance parameter, a default assumption that all 260,667 employers identified in the Commission's calculations would need to make significant program adjustments suggests additional hundreds of million dollars in regulatory compliance cost.

* * *

The Commission's regulatory proposal is clearly an economically significant one. The Commission has not conducted the economic impact research needed to reasonably inform its regulatory decisions. The failures described above are magnified by the failure of the Commission to consider alternative regulatory approaches, including the alternative of no new regulation, and by the failure of the Commission to describe in any meaningful or quantitative terms the putative benefits of a regulation, which should be shown to exceed the likely compliance costs.

V. Conclusion

The Proposed Rule, in many respects, conflicts with the ACA, the Tri-Agency Regulations and adopts positions that exceed the EEOC's jurisdiction. Congress and the Administration recognized the clear benefits of wellness programs, but the EEOC did not in its Proposed Rule. Instead, the EEOC's Proposed Rule will chill employers from offering such programs, impose roadblocks to a healthier American public, and potentially, take money away from American workers. Therefore, the Proposed Rule should be withdrawn, and if necessary, re-proposed based on the comments received.

Thank you for your consideration of these comments. As always, please contact us if you have questions or would like to discuss our comments on this important matter.

Sincerely,

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