



AMERICAN BENEFITS

COUNCIL

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Submitted electronically via <http://www.regulations.gov>

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Acting Executive Officer
Executive Secretariat
U.S. Equal Employment Opportunity Commission
131 M Street, NE
Washington, DC 20507

**Re: Amendments to Regulations Under the Americans With Disabilities Act
(RIN 3046-AB01)**

Dear Ms. Wilson:

We write on behalf of the American Benefits Council (“Council”) to provide comment in connection with the proposed rule (“Proposed Rule”) published in the Federal Register on April 20, 2015 by the Equal Employment Opportunity Commission (“EEOC”). The Proposed Rule would amend the regulations and interpretive guidance implementing Title I of the Americans with Disabilities Act (“ADA”) as they relate to employer wellness programs. Specifically, the Proposed Rule provides guidance on the extent to which employers may use incentives to encourage employees to participate in wellness programs that include disability-related inquiries and/or medical examinations.

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

The prospect of a healthier workforce has compelled a growing number of companies to develop and implement wellness strategies. The trend is particularly

strong among large employers. According to the Kaiser Family Foundation's Employer Health Benefits 2014 Annual Survey, 98 percent of large U.S. companies (with 200 or more workers) and 73 percent of smaller U.S. companies offered at least one wellness program in 2014.¹ The remarkable take-up of these programs by employers and employees, combined with the capacity and incentives for growth, make wellness an area of tremendous promise for the future of health care and employer-sponsored benefits. The Council believes that public policy should generally support private sector investment in wellness by giving all employers the flexibility they need to administer these programs.

The Council appreciates the EEOC's recognition of the importance of wellness programs and the existing regulatory framework that protects consumers, and notes the Patient Protection and Affordable Care Act ("ACA") was amended on a bipartisan basis to endorse and expand Health Insurance Portability and Accountability Act of 1996 ("HIPAA")-compliant wellness programs.

Notwithstanding employers' increasing interest in establishing wellness programs, a great deal of legal uncertainty exists with respect to the application of both the ADA and the Genetic Information Nondiscrimination Act ("GINA") to these programs. To address this, the Council's recent public policy strategic plan, [*A 2020 Vision: Flexibility and the Future of Employee Benefits*](#), notes that "A critical component of encouraging employers to offer meaningful wellness programs is consistent federal policy that promotes the health of Americans and is aligned across multiple agencies and Congress." Unfortunately, existing guidance from the EEOC is not clear regarding what constitutes a voluntary wellness program for purposes of the ADA and questions remain regarding how GINA applies to various aspects of some common wellness program designs. The proposed rule serves as a first step in addressing the uncertainty, though additional clarifications are necessary.

We support the EEOC's statement in the preamble to the Proposed Rule that it believes that "it has a responsibility to interpret the ADA in a manner that reflects both the ADA's goal of limiting employer access to medical information and HIPAA and the ACA provisions promoting wellness programs." We believe, however, that the Proposed Rule deviates in some material respects from HIPAA and does so in a manner that is inconsistent with HIPAA, the ACA, and Congress' intent. As a result, we urge the EEOC to revise the Proposed Rule, as discussed in greater detail below, to give greater effect to HIPAA and its existing regulatory regime.

In order to provide for consistent federal policy, it is important for stakeholders to be fully aware of the strong regulatory protections applicable to employees that are already in effect under HIPAA. Accordingly, this letter begins with a discussion of the

¹ Kaiser Family Foundation, [Employer Health Benefits 2014 Annual Survey – Wellness Programs and Health Risk Assessments](#) 196 (2014)

current legal and regulatory landscape regarding wellness programs followed by specific comments with respect to the EEOC's Proposed Rule as briefly described here:

- When an employee and spouse (or dependent) are enrolled in other than self-only coverage, and both are eligible to participate in the wellness program, the maximum incentive limit for purposes of the ADA should be the same as that which applies for purposes of HIPAA – in other words, 30 percent of the cost of the other-than-self-only coverage in which the employee and spouse (or dependent) are enrolled. The Proposed Rule unnecessarily deviates from HIPAA in a manner that is confusing and administratively complex to administer.
- The Council strongly discourages implementing an affordability standard in connection with any incentive limitation. Imposition of such an affordability standard is contrary to the goal of consistent policy, ill-suited to wellness programs, and could lead to some employers ceasing to offer wellness programs and to increased health and premium costs for employees.
- The Council urges the EEOC to allow all tobacco-related programs to use the higher 50 percent incentive limitation permitted by HIPAA regardless of whether the program uses a biometric screen or diagnostic test. We believe the line-drawing engaged in by the EEOC here is unduly restrictive and that the EEOC has the authority to permit all tobacco-related programs to utilize a 50 percent incentive limitation.
- As permitted by existing federal law, employers should continue to be able to encourage wellness program participation by allowing access to certain employer-sponsored health coverage only to those who participate in the employer's wellness program (as allowed by existing federal law and regulations).
- Clarification is needed regarding the application of any incentive limitation to stand-alone wellness programs. Moreover, employers who sponsor such stand-alone wellness programs should be able to use meaningful incentives in connection with their programs to encourage wellness program participation.
- The Council urges the EEOC not to require a new notice to be issued to employees with regard to a wellness program that is part of a group health plan. Adequate notice is already required pursuant to the HIPAA privacy rules. In addition, any final rulemaking should not require prior, written, and knowing confirmation of voluntary participation in a wellness program.
- Clarification is needed regarding the confidentiality requirement that is included in the Proposed Rule and its intersection with the HIPAA privacy rules. The

Council believes that the limitations imposed by HIPAA with regard to group health plans are sufficient to limit employer access to protected health information. With regard to wellness programs that are not part of a group health plan, entering into a contract with a wellness provider pursuant to which the provider maintains such data should be sufficient to ensure that any confidentiality requirement is satisfied.

- The Council believes that the bona fide benefit plan safe harbor should be available in the context of wellness programs where the spirit of the safe harbor is satisfied, consistent with the statute and federal case law.
- The Council urges that any final rulemaking not take effect for a minimum of 12 months after issuance, given that decisions regarding benefit design (including with respect to wellness program design) are made well in advance of the beginning of a plan year. Moreover, the Council encourages the EEOC to make clear that employers do not run the risk of enforcement action based upon this rulemaking project until the applicability date of any final rulemaking has passed.
- The Council urges that timely guidance be issued with respect to the applicability of GINA to wellness programs. Timely guidance is needed to resolve potential issues related to the sponsoring of spousal Health Risk Assessment (“HRAs”) by employers.

BACKGROUND REGARDING LAWS AND GUIDANCE APPLICABLE TO WELLNESS PROGRAMS

Application of HIPAA to Wellness Programs

1. HIPAA Provides Robust Protections Against Discrimination in the Context of Wellness Programs

HIPAA sets forth a substantial regulatory regime that operates to impose significant restrictions on the ability of wellness programs to discriminate against employees. HIPAA generally prohibits a group health plan from requiring any individual (as a condition of enrollment or continued enrollment under the plan) to pay a premium or contribution which is greater than such premium or contribution for a similarly situated individual enrolled in the plan on the basis of any health factor specified in the statute in relation to the individual or to an individual enrolled under the plan as a dependent of the individual.²

² 42 U.S.C. § 300gg-4(b)(1); 26 U.S.C. § 9802(b)(1); 29 U.S.C. § 1182(b)(1).

The prohibition on discrimination in premiums and contributions, however, is not to be construed to prevent a group health plan from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.³ These programs are commonly referred to as wellness programs. In order for a wellness program to not be subject to the prohibition on discrimination in premiums and contributions, it must satisfy certain requirements.

These requirements, which vary depending on the design of the wellness program, have traditionally been set forth in regulations. These regulations were largely codified as part of the ACA. Among other things, the ACA provides that the reward for health-contingent programs (as described below) cannot exceed 30 percent of the cost of employee-only coverage under the plan (or, if dependents may participate in the wellness program, 30 percent of the cost of coverage in which the employee and dependents are enrolled).⁴ The ACA granted discretion to the Secretaries of Labor, Health and Human Services, and the Treasury to increase the reward to up to 50 percent of the cost of coverage.⁵

The fact that Congress chose to codify then existing HIPAA wellness regulations as part of the ACA affirms Congress' strong support for employer-sponsored wellness programs. Moreover, it plainly demonstrates Congress' belief that the HIPAA regulations in effect at the time of the ACA struck the correct balance between federal policy, employer interests and employee protections.

Following the enactment of the ACA, final regulations implementing the ACA's wellness program provisions were published in the Federal Register on June 3, 2013.⁶ The regulations outline two main categories of wellness programs: (i) participatory programs and (ii) health-contingent programs.

Participatory programs are defined to be those that either do not provide a reward or do not include any conditions for obtaining a reward that are based on an individual satisfying a standard that is related to a health factor.⁷ Participatory programs are generally not subject to regulation under HIPAA if participation in the program is made available to all similarly situated individuals, regardless of health status.⁸

³ 42 U.S.C. § 300gg-4(b)(2); 26 U.S.C. § 9802(b)(2); 29 U.S.C. § 1182(b)(2).

⁴ See 42 U.S.C. § 300gg-4.

⁵ Id.

⁶ Incentives for Nondiscriminatory Wellness Programs in Group Health Plans, 78 Fed. Reg. 33,158 (June 3, 2013).

⁷ 45 C.F.R. § 146.121(f)(1)(ii); 26 C.F.R. § 54.9802-1(f)(1)(ii); 29 C.F.R. § 2590.702(f)(1)(ii).

⁸ 45 C.F.R. § 146.121(f)(2); 26 C.F.R. § 54.9802-1(f)(2); 29 C.F.R. § 2590.702(f)(2).

Health contingent programs are defined to be those that require an individual to satisfy a standard related to a health factor to obtain a reward.⁹ Health-contingent programs are subject to a host of robust requirements under the HIPAA regulations. These participant-protective requirements focus on five areas: (i) frequency of opportunity to qualify; (ii) size of reward; (iii) reasonable design; (iv) uniform availability and reasonable alternative standards; and (v) notice of availability of reasonable alternative standard.

- ***HIPAA requires that participants have a meaningful opportunity to qualify for the reward.*** Pursuant to HIPAA, all individuals eligible to participate in health-contingent programs must be given a meaningful opportunity to qualify for any reward under a program – at minimum, at least once per year.¹⁰
- ***HIPAA imposes significant limits on the amount of any reward that can be granted.*** The general rule is that the reward for any health-contingent program, together with the reward for other health-contingent wellness programs with respect to the plan, must not exceed 30 percent of the total cost of employee-only coverage under the plan (the default percentage specified in the ACA).¹¹ However, if, in addition to employees, any class of dependents (such as spouses, or spouses and dependent children) may participate in the wellness program, the reward must not exceed the applicable percentage of the total cost of the coverage in which an employee and any dependents are enrolled.¹² The cost of coverage is based on the total amount of employer and employee contributions towards the cost of coverage for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage.¹³

The Secretaries of Labor, Health and Human Services, and the Treasury exercised their discretion to increase the limit on rewards to 50 percent of the relevant cost of coverage described above to the extent that the excess is in connection with a program designed to prevent or reduce tobacco use.¹⁴

⁹ 45 C.F.R. § 146.121(f)(1)(iii); 26 C.F.R. § 54.9802-1(f)(1)(iii); 29 C.F.R. § 2590.702(f)(1)(iii). A health-contingent wellness program may be an activity-only wellness program or an outcome-based wellness program. Activity-only programs require an individual to perform or complete an activity related to a health factor in order to obtain a reward but do not require the individual to attain or maintain a specific health outcome. 45 C.F.R. § 146.121(f)(1)(iv); 26 C.F.R. § 54.9802-1(f)(1)(iv); 29 C.F.R. § 2590.702(f)(1)(iv). Outcome-based programs require an individual to attain or maintain a specific health outcome (such as not smoking or attaining certain results on biometric screenings) in order to obtain a reward. 45 C.F.R. § 146.121(f)(1)(v); 26 C.F.R. § 54.9802-1(f)(1)(v); 29 C.F.R. § 2590.702(f)(1)(v).

¹⁰ 45 C.F.R. § 146.121(f)(3)(i), (f)(4)(i); 26 C.F.R. § 54.9802-1(f)(3)(i), (f)(4)(i); 29 C.F.R. § 2590.702(f)(3)(i), (f)(4)(i).

¹¹ 45 C.F.R. § 146.121(f)(3)(ii), (f)(4)(ii), (f)(5); 26 C.F.R. § 54.9802-1(f)(3)(ii), (f)(4)(ii), (f)(5); 29 C.F.R. § 2590.702(f)(3)(ii), (f)(4)(ii), (f)(5).

¹² Id.

¹³ Id.

¹⁴ 45 C.F.R. § 146.121(f)(5); 26 C.F.R. § 54.9802-1(f)(5); 29 C.F.R. § 2590.702(f)(5).

- ***HIPAA requires wellness programs to be reasonably designed to promote health or prevent disease.*** HIPAA requires that a health-contingent program reflect meaningful health considerations. Specifically, the program must be reasonably designed to promote health or prevent disease.¹⁵ A program satisfies this standard if, based on the facts and circumstances, 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 discriminating based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease.¹⁶
- ***HIPAA requires uniform availability and reasonable alternative standards to ensure equal access to rewards.*** The full reward must be available to all similarly situated individuals.¹⁷ In addition, with respect to health-contingent programs, HIPAA requires that a reasonable alternative standard be offered in many circumstances (or that the otherwise applicable standard be waived) that would enable individuals who cannot satisfy the otherwise applicable standard due to a health factor to earn the full reward earned by others who satisfy the otherwise applicable standard.¹⁸ The requirements for offering a reasonable alternative standard differ depending on whether a program is an activity-only program or an outcome-based program.¹⁹

In addition to the exception for wellness programs described above, HIPAA also provides an exception for “benign discrimination.”²⁰ Pursuant to such exception, HIPAA does not prevent a group health plan from establishing more favorable rules for eligibility for individuals with an adverse health factor, such as disability, than for individuals without the adverse health factor.²¹

¹⁵ 45 C.F.R. § 146.121(f)(3)(iii), (f)(4)(iii); 26 C.F.R. § 54.9802-1(f)(3)(iii), (f)(4)(iii); 29 C.F.R. § 2590.702(f)(3)(iii), (f)(4)(iii).

¹⁶ Id.

¹⁷ 45 C.F.R. § 146.121(f)(3)(iv), (f)(4)(iv); 26 C.F.R. § 54.9802-1(f)(3)(iv), (f)(4)(iv); 29 C.F.R. § 2590.702(f)(3)(iv), (f)(4)(iv).

¹⁸ Id.

¹⁹ Id.

²⁰ 45 C.F.R. § 146.121(g); 26 C.F.R. § 54.9802-1(g); 29 C.F.R. § 2590.702(g).

²¹ Id.

2. HIPAA Mandates that Individuals Be Informed of Their Privacy Rights

The HIPAA privacy rule applies robust standards to protect individuals' protected health information ("PHI"). Among other things, the privacy rule requires that covered entities, which may include group health plans, provide a notice of privacy practices to individuals that sets forth individuals' privacy rights and the limited uses and disclosures of their PHI.²²

The covered entity must provide a notice that is written in plain language and that contains certain required elements.²³ Although much more detail as to the requirements is set forth in the regulations, the notice must generally include a prescribed header, specific descriptions of the types of uses and disclosures that the covered entity may make (including sufficient detail to place the individual on notice of such uses and disclosures), and a statement of the individual's rights with respect to PHI and a brief description of how the individual may exercise those rights.²⁴ It must also include statements regarding the covered entity's duties with respect to the PHI.²⁵

The notice of privacy practices must be made available to anyone who requests it.²⁶ The notice of privacy practices must automatically be provided to individuals covered by the plan (although one notice to a named insured or covered employee will suffice for all dependents covered through that named insured or covered employee).²⁷

The notice must generally be provided (i) no later than the compliance date for the health plan, to individuals then covered by the plan, (ii) thereafter, at the time of enrollment, to individuals who are new enrollees, or (iii) upon request.²⁸ The notice must also be provided following a material revision thereto.

A covered entity that maintains a website that provides information about the covered entity's customer services or benefits must prominently post the notice on the web site and make the notice available electronically through the web site.²⁹ The notice may be provided by email if the individual agrees and such agreement has not been withdrawn.³⁰

²² 45 C.F.R. § 164.520(a).

²³ 45 C.F.R. § 164.520(b).

²⁴ Id.

²⁵ Id.

²⁶ 45 C.F.R. § 164.520(c).

²⁷ Id.

²⁸ Id.

²⁹ Id.

³⁰ Id.

The Department of Health and Human Services has issued a model notice, but use of the model notice is not mandatory.

3. HIPAA Prohibits Employers from Using and Disclosing Protected Health Information Except in Very Limited Circumstances

Under the HIPAA privacy rule, a group health plan, as covered entity, may only use or disclose PHI in very limited circumstances described in regulations. In this regard, HIPAA only allows an employer, in its role as plan sponsor, to receive PHI from its group health plan in very limited circumstances; specifically, to (i) receive PHI from the group health plan for enrollment and disenrollment purposes, (ii) receive PHI from the group health plan for plan administration functions provided the plan sponsor certifies to the group health plan that its plan documents have been amended to restrict permitted uses and disclosures of PHI, and (iii) receive summary health information (generally de-identified PHI) for obtaining premium bids and modifying, amending or terminating the group health plan.³¹ Thus, HIPAA thoroughly limits the instances in which an employer as plan sponsor may obtain or receive PHI, including in connection with any related wellness program.

Application of the ADA to Wellness Programs

1. Statute and Prior Guidance

Congress enacted the ADA in 1990 to prohibit discrimination against individuals with disabilities. In relevant part, Title I of the ADA prohibits discrimination against individuals on the basis of disability “in regard to . . . employment compensation . . . and other terms, conditions, and privileges of employment,”³² including “fringe benefits available by virtue of employment, whether or not administered by the covered entity.”³³ The prohibition against discrimination includes medical examinations and inquiries.³⁴ Specifically, an employer³⁵ “shall not require a medical examination and shall not make inquiries of an employee as to whether such employee is an individual with a disability or as to the nature or severity of the disability, unless such examination or inquiry is shown to be job-related and consistent with business necessity.”³⁶ The statute goes on to provide in relevant part that an employer “may conduct voluntary medical examinations, including voluntary medical histories, which are part of an employee health program available to employees at that work site.”³⁷

³¹ 45 C.F.R. § 165.504(f).

³² 42 U.S.C. § 12112(a).

³³ 42 U.S.C. § 12112(b).

³⁴ 42 U.S.C. § 12112(d)(1).

³⁵ The prohibition applies to “covered entities,” which include employers, employment agencies, labor organizations, and joint labor-management committees. 42 U.S.C. § 12111(2).

³⁶ 42 U.S.C. § 12112(d)(4)(A).

³⁷ 42 U.S.C. § 12112(d)(4)(B).

Until the issuance of the Proposed Rule, described below, there has been very limited guidance in terms of what constitutes a “voluntary medical examination” within the meaning of the foregoing paragraph. This informal, limited guidance has provided only that a program is “voluntary” if the employer neither requires participation nor penalizes employees who do not participate.³⁸

The limited guidance as to what constitutes a “voluntary” medical examination as permitted by the ADA, created substantial uncertainty for employers, particularly with regard to what level of reward might comply with the ADA.

In addition to the exception for voluntary medical exams, the ADA also provides an exception to the general prohibition on discrimination for bona fide benefit plans. Specifically, the prohibition on discrimination described above “shall not be construed to prohibit or restrict”³⁹ an employer from establishing, sponsoring, observing or administering the terms of a bona fide benefit plan that are based on underwriting risks, classifying risks, or administering such risks that are based on or not inconsistent with state law.⁴⁰ In 2012, the Eleventh Circuit upheld a district court decision in *Seff v. Broward County*,⁴¹ which ruled that a wellness program could utilize the safe harbor in certain circumstances.

2. Summary of Proposed Rule

The Proposed Rule was published in the Federal Register by the EEOC on April 20, 2015 and provides guidance on the extent to which employers may use incentives to encourage employees to participate in wellness programs that include disability-related inquiries and/or medical examinations, among other things.⁴²

The Proposed Rule outlines the following topics/requirements with respect to “employee health programs,” which include wellness programs: (i) reasonable design; (ii) voluntary requirement; (iii) level of incentive that may be offered under a voluntary program; (iv) notice requirement for voluntary programs; and (v) confidentiality.

- ***Reasonable Design.*** The Proposed Rule provides that an employee health program, including any disability-related inquiries or medical examinations that are part of such program, must be reasonably designed to promote health or

³⁸ See, e.g., EEOC Enforcement Guidance on Disability-Related Inquiries and Medical Examinations Under the Americans with Disabilities Act (ADA) at Q&A 22 (July 27, 2000); EEOC Informal Discussion Letter (Jan. 18, 2013); EEOC Informal Discussion Letter (June 24, 2011).

³⁹ 42 U.S.C. § 12201(c).

⁴⁰ 42 U.S.C. § 12201(c)(2).

⁴¹ 691 F.3d 1221 (11th Cir. 2012).

⁴² Amendments to Regulations Under the Americans with Disabilities Act, 80 Fed. Reg. 21,659 (proposed Apr. 20, 2015).

prevent disease.⁴³ A program satisfies this standard if it has a reasonable chance of improving the health of, or preventing disease in, participating employees, and it is not overly burdensome, is not a subterfuge for violating the ADA or other laws prohibiting employment discrimination, and is not highly suspect in the method chosen to promote health or prevent disease.⁴⁴

- ***Voluntary Requirement.*** The Proposed Rule provides that an employee health program that includes disability-related inquiries or medical examinations (including disability-related inquiries or medical examinations that are part of a health risk assessment (“HRA”)) is voluntary as long as a covered entity, such as an employer:
 1. Does not require employees to participate;
 2. Does not deny coverage under any of its group health plans or particular benefits packages within a group health plan for non-participation, or limit the extent of benefits (except as allowed with regard to certain incentives for wellness programs that are part of a group health plan, as detailed below) for employees who do not participate;
 3. Does not take any adverse employment action or retaliate against, interfere with, coerce, intimidate, or threaten employees within the meaning of section 503 of the ADA; and
 4. Where a health program is a wellness program that is part of a group health plan, provides employees with a notice (“Notice”) that provides certain information outlined below.⁴⁵

- ***Level of Incentive That May Be Offered Under a Voluntary Program.*** The Proposed Rule provides that the use of incentives (financial or in-kind) in an employee wellness program that is part of a group health plan, whether in the form of a reward or penalty, together with the reward for any other wellness program that is offered as part of a group health plan, will not render the program involuntary if the maximum allowable incentive available under the program (whether health-contingent or participatory) does not exceed 30 percent of the total cost of employee-only coverage.⁴⁶ It is unclear in the Proposed Rule as to whether the EEOC intended for the 30 percent of the total cost of the employee-only coverage to also apply where dependents and spouses are eligible to participate in the wellness program. As described above, the existing HIPAA

⁴³ 29 C.F.R. § 1630.14(d)(1) (as proposed).

⁴⁴ Id.

⁴⁵ 29 C.F.R. § 1630.14(d)(2) (as proposed).

⁴⁶ 29 C.F.R. § 1630.14(d)(3) (as proposed).

rules are different. They permit rewards up to 30 percent of the total cost of employee-only coverage in the plan, or, if spouses and dependents may participate, up to 30 percent of the total cost of coverage in which the employee, spouse and/or dependents are enrolled. In addition, the HIPAA rules allow for rewards of up to 50 percent of the relevant cost of coverage where the excess over 30 percent is attributable to a smoking cessation program, unlike the Proposed Rule.

The Interpretive Guidance issued with the Proposed Rule provides that tobacco-related programs that do not involve a medical examination or a disability-related inquiry would not be subject to the limit specified in the Proposed Rule and could, therefore, utilize the higher 50 percent limit available for tobacco-related programs under HIPAA.⁴⁷ Such a program would include a simple “yes/no” question regarding use of tobacco but would not include, for example, a blood test for the presence of nicotine.⁴⁸ Tobacco cessation programs that use nicotine testing therefore, would be subject to the 30 percent limit on rewards, which is less than the 50 percent reward permitted under HIPAA.

- ***Notice Requirement for Voluntary Programs.*** In order for a wellness program to be “voluntary,” the Proposed Rule would require that an employer issue a Notice to employees that (i) is written so that the employee from whom medical information is being obtained is reasonably likely to understand it; (ii) describes the type of medical information that will be obtained and the specific purposes for which the medical information will be used; and (iii) describes the restrictions on the disclosure of the employee’s medical information, the employer representatives or other parties with whom the information will be shared, and the methods that the covered entity will use to ensure that medical information is not improperly disclosed (including whether it complies with the HIPAA privacy requirements).⁴⁹
- ***Confidentiality.*** The Proposed Rule provides that, with certain exceptions, information obtained via the wellness program regarding the medical information or history of any individual may only be provided to an ADA covered entity in aggregate terms that do not disclose, or are not reasonably likely to disclose, the identity of any employee.⁵⁰ Existing regulations already provide that medical records developed in the course of providing voluntary health services to employees, including wellness programs, must be maintained

⁴⁷ Appendix to 29 C.F.R. § 1630.14(d)(1) (as proposed).

⁴⁸ Id.

⁴⁹ 29 C.F.R. § 1630.14(d)(2)(iv) (as proposed).

⁵⁰ 29 C.F.R. § 1630.14(d)(6) (as proposed).

in a confidential manner and must not be used for any purpose in violation of the ADA.⁵¹

COUNCIL COMMENTS PERTAINING TO THE PROPOSED RULE

Clarification Is Needed Regarding Determination and Application of the Incentive Limitation

As discussed above, the ADA generally prohibits employers and other covered entities from requiring a medical examination and making inquiries of an employee as to whether he or she has a disability or as to the nature or severity of a disability, but there is an exception for “voluntary medical examinations.”⁵² This exception is available only if the examination is “voluntary.” As contemplated by the Proposed Rule and as discussed above, multiple requirements must be satisfied in order for a medical examination or disability-related inquiry to be voluntary for purposes of the exception.

One of the Proposed Rule’s requirements to satisfy the voluntary exception is that an employer must not deny coverage under any of its group health plans or particular benefits packages within a group health plan for non-participation, or limit the extent of benefits for employees who do not participate.⁵³ However, a program that is part of a group health plan may “limit the extent of benefits” for employees who do not participate by using an incentive (financial or in-kind) that, together with the reward for any other wellness program that is offered as part of a group health plan, does not exceed 30 percent of the total cost of employee-only coverage.⁵⁴

1. Consistency with HIPAA Is Urged

The Council appreciates that the EEOC has proposed to define what level of reward is permitted with respect to wellness programs under the ADA in order to qualify for the exception for voluntary medical examinations, and urges the EEOC to adopt a structure similar to that included in the ACA. The Proposed Rule is ambiguous and should be clarified in final regulations to ensure that employers remain able to utilize the full reward permitted by HIPAA and the ACA while still complying with the ADA.

As discussed in more detail in the background section above, Congress provided, as part of a bipartisan amendment to the ACA, that rewards for health-contingent programs could not exceed 30 percent of the cost of employee-only coverage under the plan (or, if dependents may participate in the program, 30 percent of the cost of

⁵¹ 29 C.F.R. § 1630.14(d)(4)-(5) (as proposed to be renumbered by the Proposed Rule).

⁵² 42 U.S.C. § 12112(d)(4).

⁵³ 29 C.F.R. § 1630.14(d)(2)(ii) (as proposed).

⁵⁴ Id.; 29 C.F.R. § 1630.14(d)(3) (as proposed).

coverage in which the employee and dependents are enrolled) – Congress gave the Secretaries of Labor, Health and Human Services, and the Treasury authority to increase the amount to 50 percent.⁵⁵ The Secretaries of Labor, Health and Human Services and the Treasury subsequently exercised their regulatory discretion to increase the maximum incentive to 50 percent of the relevant cost of coverage so long as the excess over 30 percent is attributable to a program designed to prevent or reduce tobacco use.⁵⁶

Unlike HIPAA, the Proposed Rule bases the limit on the cost of employee-only coverage even if a spouse and/or dependents may participate. In addition, unlike HIPAA, the Proposed Rule would apply the limit to participatory programs.

The HIPAA limit is a clearly defined standard, endorsed by Congress and the tri-agencies, to which employers that offer health-contingent programs already adhere. Alignment with HIPAA is strongly urged, not only from the perspective of administrative ease, but also because such alignment would be consistent with congressional intent. In this regard, the Council strongly contends that the following aspects of the Proposed Rule’s incentive limit should be modified to more closely align with HIPAA as follows:

- First, unlike the Proposed Rule, HIPAA provides that the maximum reward may be determined based on the total cost of coverage in which an employee and any dependents enroll in cases where dependents may participate in the wellness program. The Council believes the ADA’s limited jurisdiction, which extends only to employees, does not in fact restrict the EEOC from fashioning a rule that provides, *with respect to an employee*, that a wellness program is “voluntary” if the program complies with HIPAA’s incentive limitations; in other words, that the available incentive is no more than 30 percent of the cost of the coverage in which the employee is enrolled, including 30 percent of the cost of family coverage if the employee and the spouse (or dependent) are both eligible to participate in the wellness program. In the interest of consistent federal policy, to help reduce the administrative costs and burdens of compliance on employers, and to foster the maintenance and establishment of wellness programs in accordance with the ACA and stated congressional intent, the Council urges the EEOC to adopt this clarification as part of any final rulemaking.
- Second, per the language of the ACA and as discussed above, the Secretaries of Labor, Health and Human Services, and the Treasury have the discretion to increase the permitted HIPAA limit up to 50 percent of the cost of relevant coverage. The Secretaries have already exercised this discretion by allowing

⁵⁵ See 42 U.S.C. § 300gg-4.

⁵⁶ 45 C.F.R. § 146.121(f)(5); 26 C.F.R. § 54.9802-1(f)(5); 29 C.F.R. § 2590.702(f)(5).

incentives up to 50 percent if the reward in excess of 30 percent is related to programs designed to prevent or reduce tobacco use. In the future, the Secretaries could exercise permitted discretion to allow the use of incentive awards beyond the current 30 percent threshold with respect to other types of wellness programs as well. The incentive limit in the Proposed Rule, however, would be set at a static, unchanging 30 percent of employee-only coverage. Thus, even if the regulators permit the use of such increased rewards for purposes of HIPAA, the Proposed Rule would continue to limit incentives for purposes of the ADA to no more than 30 percent of employee-only coverage. This discrepancy would make it difficult for employers to realize the full potential provided by the HIPAA rules.

For the above reasons, the Council encourages the EEOC to provide in final rulemaking that the permitted reward under the ADA is the maximum reward permitted under HIPAA, as may be determined from time to time by the Secretaries of Labor, Health and Human Services, and the Treasury. As the EEOC notes in the preamble to the Proposed Rule, the EEOC's stated intent is to interpret the ADA consistent with HIPAA and the ACA. Not allowing the ADA limit to align with the HIPAA limit is effectively overriding the HIPAA limit, as Congress intended that it be available to employers when it largely codified the HIPAA wellness program regulations as part of the ACA.

2. Final Rules Should Not Adopt an Affordability Standard in Connection with Incentive Limits

As discussed above, the Proposed Rule sets forth a limit on permitted incentives in the form of a percentage of the cost of self-only coverage.⁵⁷ The EEOC also requests comment as to whether, to be considered "voluntary" under the ADA, the incentives provided with respect to a wellness program may not be so large as to render health insurance coverage unaffordable under the ACA. The EEOC requests specific input on whether it would be appropriate for the EEOC to provide that incentives offered to promote participation in wellness programs "must not render the cost of health insurance unaffordable to employees within the meaning of 26 U.S.C. 36B(c)(2)(c) as implemented by 26 C.F.R. 54.4980H-5(e)."

The Council strongly opposes the inclusion of an affordability standard in any final regulations or other wellness plan guidance for several reasons. The affordability test in the ACA and implementing regulations was established for the specific purposes of determining eligibility for premium assistance for coverage offered in the health insurance exchanges and for assessing penalties under the employer shared responsibility provision of the ACA.⁵⁸ The affordability rules, which are

⁵⁷ 29 C.F.R. § 1630.14(d)(3) (as proposed).

⁵⁸ See 26 U.S.C. § 36B; 26 U.S.C. § 4980H.

administratively complex and in the early years of implementation, were not intended to be applied in other contexts, such as the one contemplated by the EEOC, and would unnecessarily complicate the rules applicable to wellness programs and lead to confusion for the regulated community.

Applying such a standard again, in the context of wellness plans, would impose an additional, substantial administrative burden on employers. This is because it would effectively cause employers to engage in an individualized determination with respect to each and every wellness program participant. Alternatively, an employer would need to set the incentive amounts based on its lowest paid worker or class of workers. The practical effect of such an alternative is that employers would then be unable to design programs to be most effective within the parameters provided by HIPAA. In addition, an affordability standard would require that employers utilize a completely different method for calculating reward limits than is used under HIPAA.

Finally, under the affordability rules of Code section 4980H, an employer need only offer affordable coverage with respect to one of its benefit packages.⁵⁹ Thus, it is unclear how an affordability requirement for purposes of the ADA would apply to all of the employer's benefit offerings. Additionally, affordability is based solely on the cost of "self-only" coverage for purposes of Code section 4980H.⁶⁰ It is, therefore, unclear as to what would qualify as "affordable" with respect to family coverage for purposes of the ADA. Moreover, the affordability requirement of Code section 4980H does not apply to small employers, nor does it apply to retirees or employees working less than a Code section 4980H full-time schedule.⁶¹

The Council further notes that the vast majority of wellness programs are sponsored by larger sized employers who are currently subject to the employer shared responsibility provisions of Internal Revenue section 4980H. Quite significantly, the regulations underpinning the employer shared responsibility provisions require employers to take account of wellness program incentives in determining whether they are offering affordable coverage for purposes of Code section 4980H. More specifically, these regulations require employers, when determining the affordability of the coverage offered, to assume that the wellness incentive will not be earned by the participant. This rule has already adversely affected employers' ability to use wellness program incentives as they might otherwise see fit, which many fear may result in decreased wellness program participation and reduced health outcomes for employees (and as applicable, their spouses and dependents). Given the existence of these rules, the Council believes imposing an affordability standard for purposes of the ADA is unnecessary and would only serve to further limit employer flexibility to the detriment of employers and employees alike.

⁵⁹ See 26 U.S.C. § 4980H and the regulations issued thereunder.

⁶⁰ Id.

⁶¹ Id.

In summary, while Code section 4980H imposes an affordability requirement with respect to employer-sponsored coverage and deems wellness program incentives unrelated to tobacco as unearned, the rules are ill-suited for use by the EEOC for purposes of the ADA. We strongly recommend that the final regulations not impose an additional affordability requirement on employer-sponsored wellness programs for purposes of the ADA.

3. All Tobacco-Related Programs Should Be Permitted to Use a 50 Percent Incentive Limit, Consistent with HIPAA

The Interpretive Guidance issued with the Proposed Rule provides that tobacco-related programs that do not constitute a medical examination or a disability-related inquiry are not subject to the incentive limit set forth in the Proposed Rule.⁶² This means such programs effectively may utilize the higher limit under HIPAA applicable to programs designed to prevent or reduce tobacco use. Per the Interpretive Guidance, such a program would include asking a simple “yes/no” question regarding whether an individual uses tobacco.⁶³ However, it appears that, under the Proposed Rule, using biometric screening or another approach to test for the presence of nicotine or tobacco would require the use of the lower Proposed Rule incentive limit of 30 percent of the cost of self-only coverage.⁶⁴

The Council requests that final regulations permit rewards related to tobacco cessation to track the limit under the HIPAA regulations – i.e., up to 50 percent of the cost of self-only coverage (or enrolled coverage where spouses and dependents may participate) – even if the program goes beyond asking a “yes/no” question. As discussed in the background section above, HIPAA provides a number of safeguards on such programs, including reasonable alternative standards required with respect to wellness programs designed to prevent or reduce tobacco use.

Screening for tobacco use is a very common wellness program component. Increasing participation rates in tobacco cessation programs benefits employees and employers by improving health, increasing productivity, and lowering health care costs. Accurately identifying the prevalence of tobacco use is a key step in implementing a successful cessation program. Based on Council member feedback, self-certification is not as effective as nicotine testing for identifying prevalence and implementing successful cessation strategies.

Given (i) HIPAA’s existing safeguards with respect to tobacco cessation programs (including with respect to biometric screenings and other tests), (ii) recent statutory

⁶² Appendix to 29 C.F.R. § 1630.14(d)(1) (as proposed).

⁶³ Id.

⁶⁴ Id.

endorsement of higher reward levels, and (iii) the greater effectiveness of biometric screening when compared to self-certification in increasing participation rates, the Council urges the EEOC to provide that wellness programs may offer rewards as permitted by HIPAA with regard to tobacco cessation programs, whether the programs involve self-certification or something more. Any final rulemaking should not prohibit or limit, or persuade employers to cease sponsoring, valuable plan designs that are intended to prevent or reduce tobacco use as permitted by HIPAA.

4. Clarification Is Needed Regarding Application of Incentive Limit to Wellness Programs that Are Not Part of a Group Health Plan

The Proposed Rule's limit on incentives (i.e., 30 percent of the cost of employee-only coverage) appears to apply only to wellness programs offered in connection with a group health plan.⁶⁵ In many situations, wellness programs are offered other than in connection with a group health plan. We see no policy reason for distinguishing between wellness programs offered as part of a group health plan and those that are not for purposes of the ADA. The Council thus requests that the EEOC clarify in the final rule that employers are permitted to use material rewards in connection with their wellness programs regardless of whether such programs are, or are not part of, a group health plan.

To ensure that employers have sufficient flexibility to design and administer wellness programs that include effective incentives, the Council recommends the adoption of certain safe harbor rules that would be available for use by employers with respect to wellness programs offered not in connection with a specific group health plan. More specifically, the Council urges the EEOC to include in any final rule the following safe harbors:

- If the employer sponsors any unrelated major medical plan for any employee, the wellness program incentive is no more than 30 percent of the cost of the applicable coverage (i.e., self-only or other-than-self-only) for the lowest-cost option for such coverage.
- If the employer does not sponsor any major medical plan for any employee, the wellness program incentive is no more than 30 percent of the cost of self-only coverage for the Blue Cross Blue Shield standard option under the Federal Employees Health Benefits Plan ("FEHBP").

5. Clarification Regarding What Constitutes a "De Minimis" Incentive May Be Necessary

⁶⁵ 29 C.F.R. § 1630.14(d)(2)(ii) (as proposed); 29 C.F.R. § 1630.14(d)(3) (as proposed).

The preamble to the Proposed Rule states that “[a] plausible reading of ‘voluntary’ is that covered entities can...offer de minimis rewards.”⁶⁶ In the event that the EEOC does not permit the meaningful incentive amounts as set out in the safe harbors described above with respect to stand-alone wellness programs (i.e., wellness programs that are not part of a group health plan), employers will need at a minimum, clarification regarding what would constitute a de minimis incentive.

6. The “Voluntary” Requirement Should Not Prohibit Employers from Encouraging Wellness Program Participation Based on Access to Other Employer-Sponsored Medical Plan Coverage

Under the Proposed Rule, in order to satisfy the voluntary requirement, a covered entity could not, among other things, deny coverage under any of its group health plans (or particular benefits packages within a group health plan) for non-participation, or limit the extent of benefits (except for certain permitted incentives) for employees who do not participate.⁶⁷

The Council is very concerned that this new requirement could significantly disrupt existing wellness programs and require employers to adopt less effective wellness program structures. Under current HIPAA rules, employer may provide comprehensive major medical coverage to their employees and, at the same time, provide employees with enhanced coverage if they fulfill certain wellness program requirements. Employers do this to encourage participation in wellness program activities and also to tailor benefit packages to employees based on their specific health needs – often in accordance with the “benign discrimination” exception under HIPAA, which, as discussed in the background section above, allows more favorable benefits to be provided to employees with adverse health factors.⁶⁸

We are concerned that the “voluntary” requirement as set out in the proposed rule would prohibit existing plan designs that are effective in increasing participation rates by offering enhanced benefits coverage to employees who participate in wellness programs. We also note that the effective economic value of the enhanced coverage is likely not to exceed 30 percent of the cost of self-only coverage with respect to the “base” or default major medical coverage. Accordingly, the Council strongly urges the EEOC to allow these program designs, especially where the employer is otherwise offering “base” comprehensive major medical plan coverage regardless of wellness program participation.

⁶⁶ 80 Fed. Reg. at 21,662.

⁶⁷ 29 C.F.R. § 1630.14(d)(2)(ii) (as proposed).

⁶⁸ 45 C.F.R. § 146.121(g); 26 C.F.R. § 54.9802-1(g); 29 C.F.R. § 2590.702(g).

Clarification Is Needed Regarding New Proposed Notice Requirement

As discussed above, the ADA's exception to the prohibition on disability-related inquiries and medical examinations for employee health programs applies only if the medical examination is "voluntary."⁶⁹ The voluntary standard, as proposed, includes a requirement that, with regard to a wellness program that is part of a group health plan, a notice be provided to employees that clearly explains what medical information will be obtained, how the medical information will be used, who will receive the medical information, the restrictions on its disclosure, and the methods the covered entity uses to prevent improper disclosure of medical information.⁷⁰

1. The New Proposed Notice Is Unnecessary and Administratively Burdensome

The Council requests that final regulations not include new notice requirements. The proposed notice requirement would, under the Proposed Rule, apply with respect to wellness programs offered in connection with group health plans. Group health plans generally are already subject to the requirements of HIPAA's privacy provisions – requirements that are fully protective of participant interests and set forth significant detail regarding the uses and disclosures of PHI.⁷¹ Moreover, HIPAA's notice requirements are the product of a careful and well-considered balancing by the Executive Branch of various public interests. To impose additional notice obligations results in unnecessary costs and burdens on employers and health plans. Accordingly, we believe such additional notice requirements should not be included as part of final rulemaking.

We note that federal regulators already require employer-sponsored group health plans to issue more than 40 separate notices, disclosures and reports⁷² to plan participants and/or the federal government. As a result, the Council and its members have become increasingly concerned that plans – as well as participants and beneficiaries – are suffering under the weight of these notice and disclosure

⁶⁹ 42 U.S.C. § 12112(d)(4)(B).

⁷⁰ 29 C.F.R. § 1630.14(d)(2)(iv) (as proposed).

⁷¹ 45 C.F.R. § 164.520.

⁷² Medicare Part D creditable coverage notices to Medicare-eligible individuals, and to CMS; HIPAA privacy notice, privacy notice reminder, and notice of breach; HIPAA special enrollment notice; notice of alternative standards under outcomes-based wellness program; COBRA general notice, election notice, notice of unavailability of COBRA coverage, notice of early termination of COBRA coverage, notice of insignificant premium shortfall; ACA-related notices related to grandfathered status, right to designate primary care provider, availability of marketplace coverage, wellness programs (TBD), Form 1095-C, Form 1094-C, coverage rescissions, insignificant premium shortfall related to employer offer of coverage under shared responsibility regulations, expatriate coverage qualifying as minimum essential coverage, coverage values on Form W-2, PCORI fee submission, transitional reinsurance fee submission, summary of benefits and coverage, mid-year material change to summary of benefits and coverage; claims and appeals notices including notice of external review process, notice of adverse benefit determination, notice of final internal adverse benefit determination, preliminary notice regarding request for external review, notice of final external review decision; notices related to Women's Cancer Rights Act, Michelle's Law, USERRA coverage, and premium assistance under Medicaid or CHIP; notice of cancellation of coverage for nonpayment during FMLA leave; notice of comparable contributions to HSAs; ERISA-required disclosures and reports including Form 5500, summary annual report, provision of plan documents on request, summary plan description, notice of material reduction in benefits, and notice of material modification; Form M-1 for multiple employer plans.

requirements and fear that important notices effectively are being diluted or rendered “lost” to participants by reason of these many notices and disclosures. Absent extraordinary need, it seems sound public policy would dictate that additional, duplicative notice requirements, such as that proposed in the Proposed Rule, should not be imposed.

To the extent a notice requirement is made part of any final rule we request that the notice not be required to identify the types of medical information that will be obtained. This may vary from year to year, depending on whether a wellness program’s design is modified annually, and it would impose a significant cost burden on employers to have to revise and redistribute the notice each year.

In addition, we urge the EEOC not to require a description of the specific purpose for which the medical information will be used. This is arguably already satisfied by the HIPAA notice requirements, and requiring duplicative disclosure would necessitate unnecessary printing and mailing costs. Moreover, under HIPAA, covered entities are required to have policies to ensure that PHI is held and disclosed in compliance with HIPAA, but it does not require disclosure of compliance methods to individuals. We request that detail regarding the method of compliance not be required to be disclosed to individuals. Lastly, if the final regulations include a new notice requirement, the EEOC should provide a voluntary, model notice for employers to use at their discretion.

2. Prior, Written and Knowing Confirmation of Voluntary Participation Is Unnecessary and Administratively Burdensome

The EEOC has specifically requested comments regarding whether the proposed notice requirement should also include a requirement that employees participating in wellness programs and that are part of a group health plan, provide prior, written, and knowing confirmation that their participation is voluntary. The Council does not believe such a requirement should apply. Employers sponsor wellness programs because of the significant benefits to not only the employer but also to the employees in the form of improved health, reduced health cost, and reduced absenteeism. For these reasons, employers work hard to encourage and increase participation in wellness programs. Requiring that participants provide prior, written, and knowing confirmation that their participation is voluntary would create a barrier to participation in beneficial wellness programs, would increase the costs and burdens associated with establishing and administering wellness programs, and would reduce their effectiveness in improving health and enhancing productivity. Moreover, as discussed above, HIPAA already imposes very significant notice requirements with respect to wellness programs, and additional disclosure is not needed.

3. Application of Notice Requirement to Wellness Programs that Use Only De Minimis Incentives

The Proposed Rule requests comments as to whether the proposed notice requirement should apply only to wellness programs that offer more than de minimis rewards or penalties to employees who participate (or decline to participate) in wellness programs that ask them to respond to disability-related inquiries and/or undergo medical examinations, and, if so, how the EEOC should define “de minimis” for this purpose.

As discussed above, the Council recommends that the proposed notice requirement not be included in any final rulemaking. As such, there would be no need for a definition of “de minimis” for this purpose. If a notice requirement is included in the final rule, then the Council supports not imposing the notice requirement where the incentive available is “de minimis.”

Clarification Is Needed Regarding Confidentiality Requirements

Existing EEOC regulations provide that medical records developed in the course of providing voluntary health services to employees, including wellness programs, must be maintained in a confidential manner and must not be used for any purpose in violation of the ADA.⁷³ The Proposed Rule would add that, with certain exceptions, information obtained via the wellness program regarding the medical information or history of any individual may only be provided to an ADA covered entity in aggregate terms that do not disclose, or are not reasonably likely to disclose, the identity of any employee.⁷⁴

As discussed above, the HIPAA privacy rule allows a plan sponsor to (i) receive PHI from the group health plan for enrollment and disenrollment purposes, (ii) to receive PHI from the group health plan for plan administration functions provided the plan sponsor certifies to the group health plan that its plan documents have been amended to restrict permitted uses and disclosures of PHI, and (iii) to receive summary health information (generally de-identified PHI) for obtaining premium bids and modifying, amending or terminating the group health plan.⁷⁵

The Interpretive Guidance that accompanies the Proposed Rule provides that a wellness program that is a part of a HIPAA covered entity “likely will” be able to comply with the Proposed Rule’s confidentiality requirements by complying with HIPAA.

⁷³ 29 C.F.R. § 1630.14(d)(4)-(5) (as proposed to be renumbered by the Proposed Rule).

⁷⁴ 29 C.F.R. § 1630.14(d)(6) (as proposed).

⁷⁵ 45 C.F.R. § 164.504(f).

The Council requests that the EEOC clarify in future guidance that compliance with HIPAA's privacy rule satisfies any confidentiality requirements included in final regulations. Moreover, given that stand-alone wellness programs (i.e., wellness programs not offered in connection with a group health plan) are not subject to HIPAA's privacy requirements, and further given that stand-alone wellness programs often will not provide what is commonly considered to be "medical care," the Council urges the EEOC not require stand-alone wellness programs comply with the confidentiality requirement described in the Proposed Rule.

The Proposed Rule Should Make Clear that the Bona Fide Benefit Plan Safe Harbor Applies in the Context of Wellness Programs, as Supported by Federal Case Law

While the ADA generally prohibits an employer's ability to make disability-related inquiries or to require medical examinations, it provides two exceptions: (1) for voluntary medical examinations that are part of an "employee health program" available to employees at the work site (as generally addressed by the Proposed Rule); and (2) under the bona fide benefit plan safe harbor, which, among other things, provides an exception from the prohibition on medical examinations and inquiries. These exceptions are discussed in more detail in the background section above.

In a footnote to the preamble to the Proposed Rule, the EEOC states that it "does not believe that the ADA's 'safe harbor' provision . . . is the proper basis for finding wellness program incentives permissible."⁷⁶ It does not provide reasoning or justification for this position. In *Seff v. Broward County*,⁷⁷ the Eleventh Circuit upheld a district court's ruling that the bona fide benefit plan safe harbor is permitted to be used in the wellness program context. The Council contends that *Seff v. Broward County* was correctly decided and the bona fide benefit plan safe harbor should be available where appropriate in the wellness context.

Sufficient Time Is Needed Before Final Rules Become Effective

The Council urges that any final rulemaking not take effect for a minimum of 12 months after issuance. Given that decisions regarding benefit design, including wellness program design, are made well in advance of the beginning of a plan year, employers need sufficient time to implement final regulations to make plan design changes and systems modifications and to develop employee communications.

An Enforcement Safe Harbor Is Needed Prior to the Effective Date of Final Rules

The Council requests that the EEOC clarify that employers will not be subject to EEOC enforcement action based on this rulemaking project before the applicability date

⁷⁶ 80 Fed. Reg. at 21,662, n. 24.

⁷⁷ 691 F.3d 1221 (11th Cir. 2012).

of any final regulations. Q&As issued concurrently with the Proposed Rule state that, “[w]hile employers do not have to comply with the proposed rule, they may certainly do so. It is unlikely that a court or the EEOC would find that an employer violated the ADA if the employer complied with the NPRM until a final rule is issued.”⁷⁸ This statement does not affirmatively establish whether the EEOC could find that an employer has violated the ADA if it does not comply with the Proposed Rule *prior to* the issuance/applicability date of any final rulemaking.

Employers cannot be expected to conform their wellness programs to a Proposed Rule that will change, perhaps substantially, before becoming final. Such conformance would require significant time, administrative burden, and expense. Moreover, to the extent that wellness program designs are already in place for this plan year or next plan year, it would be difficult, if not impossible, for employers to make changes with regard to the recently issued Proposed Rule.

The Council proposes that the EEOC provide, until the application date, a “safe harbor” or similar transition period for plans that are in compliance with existing federal regulations governing wellness programs. This is of critical concern for employers where there has been a longstanding lack of guidance in terms of how the ADA applies to wellness programs. Although the Council appreciates the issuance of the Proposed Rule, it should not create a “catch-22” for employers who have tried their best to understand what the ADA requires of wellness programs in the absence of regulatory guidance. For such plans, compliance with existing laws and regulations should suffice in terms of EEOC enforcement unless and until any final rulemaking becomes effective as described above.

TIMELY GINA GUIDANCE REGARDING WELLNESS PROGRAMS IS NEEDED

Nondiscrimination laws other than the ADA may have implications for wellness programs.⁷⁹ One such law is GINA.⁸⁰ Relevant for these purposes, Title II of GINA generally prohibits employers from requesting, requiring, or purchasing genetic information of an employee.⁸¹ An employee’s “genetic information” includes information relating to the manifestation of a disease or disorder in a spouse.⁸² There is an exception for collecting genetic information as part of a voluntary wellness program, but it is unclear how those regulations apply in the context of a spousal HRA.⁸³

⁷⁸ Questions and Answers about EEOC’s Notice of Proposed Rulemaking on Employer Wellness Programs, Q&A-10 (Apr. 20, 2015).

⁷⁹ The Proposed Rule cites other federal nondiscrimination statutes.

⁸⁰ Pub. L. No. 110-233 (2008).

⁸¹ 42 U.S.C. § 2000ff-1.

⁸² *Id.*

⁸³ *Id.*

Spousal HRAs are a common feature of employer-sponsored wellness programs, particularly where an employee's spouse is also participating in the underlying plan. In such cases, spousal HRAs are used not for purposes of collecting genetic information about an employee, but rather for purposes of assisting the spouse himself/herself with his or her health. In this regard, it is very important that if the EEOC proceeds with issuing regulations pertaining to GINA, it provide a safe harbor for spousal HRAs. A contrary rule would cause employers to cease to utilize such wellness designs, which would make unavailable important benefits for employees and spouses enrolled in major medical coverage.

* * *

It is the Council's hope that this letter has reinforced the imperative to support and strengthen the efforts of employers to be effective in their role of advancing the health of their employees and their family members. As the Council's *A 2020 Vision* states, employer-sponsored benefit plans are now being designed with the express purpose of giving each worker the opportunity to achieve personal health and financial well-being. The ability to offer and incentivize robust wellness programs is a fundamental aspect to increasing personal health.

Thank you for considering these comments submitted in response to the Proposed Rule. If you have any questions or would like to discuss these comments further, please contact us at (202) 289-6700.

Sincerely,



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