Proposed Rule - Amendments to Regulations Under the Americans With Disabilities Act

Equal Employment Opportunity Commission

29 CFR Part 1630

[DOCKET NO.]

RIN 3046-AB10

Amendments to Regulations Under the Americans With Disabilities Act

AGENCY: Equal Employment Opportunity Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Equal Employment Opportunity Commission (EEOC or Commission) is issuing this proposed rule in response to a decision of the U.S. District Court for the District of Columbia that vacated a portion of an EEOC regulation describing the incentives employers could offer as part of wellness programs that ask about employees' health and/or ask them to undergo medical examinations. Published elsewhere in this issue of the **Federal Register**, the EEOC also is issuing a proposed rule in response to the same decision that vacated a portion of an EEOC regulation implementing Title II of the Genetic Information Nondiscrimination Act (GINA) describing the incentives an employer could offer to an employee whose spouse provides current or past health status information as part of a wellness program.

DATES: Comments regarding this proposed rule must be received by the Commission on or before [insert date 60 days from publication in the Federal Register]. Please see the section below entitled **ADDRESSES** for additional information on submitting comments.

ADDRESSES: You may submit comments, identified by RIN number 3046-AB10, by any of the following methods:

- *Federal eRulemaking Portal*: **http://www.regulations.gov (http://www.regulations.gov) .** Follow the instructions for submitting comments.
- *Fax:* (202) 663-4114. (There is no toll free FAX number). Only comments of six or fewer pages will be accepted via FAX transmittal, in order to assure access to the equipment. Receipt of FAX transmittals will not be acknowledged, except that the sender may request confirmation of receipt by calling the Executive Secretariat staff at (202) 663–7100 (voice) (this is not a toll free number) or (800) 669-6820 (TTY) for individuals who are deaf or hearing impaired.
- *Mail*: Rachel V. See, Acting Executive Officer, Executive Secretariat, Equal Employment Opportunity Commission, U.S. Equal Employment Opportunity Commission, 131 M Street NE., Washington, DC 20507.
- *Hand Delivery/Courier*: Rachel V. See, Acting Executive Officer, Executive Secretariat, Equal Employment Opportunity Commission, U.S. Equal Employment Opportunity Commission, 131 M Street NE., Washington, DC 20507.

Instructions: The Commission invites comments from all interested parties. All comment submissions must include the agency name and docket number or

the Regulatory Information Number (RIN) for this rulemaking. Comments need be submitted in only one of the above-listed formats. All comments received will be posted without change to **http://www.regulations.gov (http://www.regulations.gov)** , including any personal information you provide.

Docket: For access to the docket to read background documents or comments received, go to **http://www.regulations.gov (http://www.regulations.gov) .** Copies of the received comments also will be

available for review at the Commission's library, 131 M Street NE., Suite 4NW08R, Washington, DC 20507, between the hours of 9:30 a.m. and 5:00

p.m., from [insert date] until the Commission publishes the rule in final form, if the Commission's library has reopened to the public.

FOR FURTHER INFORMATION CONTACT: Joyce Walker-Jones, Senior Attorney Advisor, at (202) 921-2663 (this is not toll-free), or (800) 669-6820 (TTY), Office of Legal Counsel, U.S. Equal Employment Opportunity Commission. Requests for this notice in an alternative format should be made to the Office of Communications and Legislative Affairs, (202) 921-3191 (voice) (this is not toll-free) or (800) 669-6820 (TTY).

SUPPLEMENTARY INFORMATION:

This proposed rule applies to wellness programs offered by ADA-covered entities that are considered "employee health programs" under Title I of the Americans with Disabilities Act (ADA).[1] It does not apply to programs that may be provided by entities other than those subject to Title I, such as social service agencies covered under Title II of the ADA,[2] or places of public accommodation subject to Title III of the ADA.[3]

II. Background

A. Introduction

Many employers that provide employee health benefits also offer health promotion and disease prevention activities, known as wellness programs.[4] Wellness programs may be offered as part of an employer's group health plan, may themselves qualify as group health plans, or may be offered even if an employer does not offer a group health plan or health insurance coverage.[5] Many of these programs ask employees to provide information about their medical history, including symptoms, diagnoses, procedures, and outcomes, by completing a health risk assessment and/or undergoing biometric health screenings that measure their risk factors for certain medical conditions.[6] Under the ADA, health risk assessments and biometric screenings are considered disability-related inquiries, which the Commission defines as questions (or a series of questions) that are "likely to elicit information about a disability,"[7] and medical examinations, defined as procedures or tests that seek information about an individual's physical or mental impairments or health.[8]

Other wellness programs, which may include educational classes, onsite exercise facilities, and/or coaching, are designed to help employees meet health goals but do not require them to provide medical information.[9]

Some employers offer incentives to encourage employees simply to participate in a wellness program, while others offer incentives for employees to complete an activity related to a health factor or to achieve health outcomes.[10] Incentives can be framed as rewards or penalties and often take the form of prizes, cash, a reduction or an increase in health care premiums or cost sharing, or payroll deductions.[11]

Wellness programs that do not include disability-related inquiries or medical examinations are not subject to this proposed rule. Employers, however, must make any wellness program available to all employees, provide reasonable accommodations to employees with disabilities, and generally comply with the ADA provisions prohibiting discrimination in the terms, conditions, and privileges of employment. Employers also must protect the confidentiality of medical information[12] obtained and comply with other laws enforced by the EEOC (and, where applicable, other federal agencies) and with laws regulating wellness programs that are part of, or qualify as, group health plans.

B. Brief Overview of the EEOC's Attempts to Regulate Incentives Offered by Wellness Programs Under the ADA

In 2016, after a years-long effort to respond to ongoing stakeholder concerns about whether the ADA allows employers to use incentives to encourage employee participation in wellness programs that obtain medical information, the EEOC issued a final rule to clarify employer obligations. Based on extensive stakeholder input at a meeting the Commission held on wellness programs and comments submitted in response to the proposed rule issued in 2015, the final rule attempted to harmonize and provide consistency with other federal rules authorizing wellness program incentives by adopting a 30 percent incentive limit. Soon after the rule was issued, AARP[13] filed a lawsuit arguing that the incentive limit was too high to give employees a meaningful choice whether or not to participate in wellness programs that required them to disclose medical information to receive a reward or avoid a penalty. The U.S. District Court for the District of Columbia agreed and found that the EEOC failed to provide a sufficient explanation for adopting the 30 percent incentive limit from another federal law. *See AARP v. EEOC*, 267 F. Supp. 3d 14, 29-34, 38 (D.D.C. 2017). As a result of the court's decision, the EEOC removed the incentive section of the ADA regulations at 29 CFR 1630.14(d)(3), effective January 1, 2019. *See* 83 FR 65296 (Dec. 20, 2018).

Now, five years after its initial rulemaking began on the extent to which employers may incentivize wellness programs under the ADA, the EEOC has more experience but is once again at the same crossroads. This proposed rule addresses the *AARP v. EEOC* court's determination that, because one purpose of the ADA is to prevent employers from forcing employees to disclose medical information that might enable employers to discriminate against them, the EEOC has an obligation to interpret an explicit statutory requirement: an employee's decision to disclose protected information to a wellness program must be "voluntary." This rule also responds to the court's finding that a 30 percent incentive limit is not the appropriate measure for voluntariness and, instead, imposes a de minimis incentive limit for most wellness programs that include disability-related inquiries and/or medical examinations. Finally, the proposed rule recognizes the regulatory and statutory landscape created by Congress and acknowledges that wellness programs that are part of, or qualify as, group health plans already are regulated by other federal laws that allow incentives. The rule, therefore, proposes an exception to the de minimis standard for wellness programs that are part of, or qualify as, group health plans and that require employees to satisfy a standard related to a health factor to receive a reward or avoid a penalty.

III. Applicable Federal Laws

Several federal laws govern wellness programs offered by employers. Wellness programs must comply with Title I of the ADA, Title II of GINA,[14] and other employment discrimination laws enforced by the EEOC. Wellness programs that are part of a group health plan – or provided by a health insurance issuer offering group health insurance coverage in connection with a group health plan – also must comply with the nondiscrimination provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Patient Protection and Affordable Care Act (Affordable Care Act),[15] which is enforced by the Department of Labor (DOL), Department of the Treasury (Treasury), and Department of Health and Human Services (HHS), referred to collectively as "the tri-Departments."[16] A wellness program that is part of a group health plan also must comply with HIPAA's Privacy, Security, and Breach Notification requirements discussed later in this preamble.

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, including "fringe benefits available by virtue of employment, whether or not administered by the covered entity." The ADA also limits the medical information employers may obtain from employees by generally prohibiting them from making disability-related inquiries or requiring medical examinations.[17] The statute, however, provides an exception that allows employers to obtain medical information as part of employee health programs, as long as any disability-related inquiries and medical examinations that are part of these programs are voluntary.[18]

The statute also includes a second provision affecting employee health programs. Known as the "insurance safe harbor," this provision allows insurers and other entities to establish, sponsor, observe, or administer the terms of health and other benefit plans.[19]

Finally, the ADA requires employers to provide reasonable accommodations (modifications or adjustments) to enable individuals with disabilities to have equal access to fringe benefits, such as general health and educational wellness programs, offered to individuals without disabilities.[20] Employers also must comply with other laws the EEOC enforces that prohibit discrimination based on race, color, national origin, sex, religion, compensation, age, or genetic information[21] and are prohibited from retaliating against individuals for engaging in protected EEO activity.

B. HIPAA's Nondiscrimination Provisions

Under PHS Act section 2705,[22] ERISA section 702, and section 9802 of the Code, group health plans and health insurance issuers offering group or individual health insurance coverage are generally prohibited from discriminating against participants, beneficiaries, and individuals in eligibility (including continued eligibility), benefits, or premiums based on a health factor.[23] In connection with group health coverage, an exception to the general rule allows premium discounts, or rebates or modifications to otherwise applicable cost sharing (including copayments, deductibles, or coinsurance), in return for adherence to certain programs of health promotion and disease prevention, commonly referred to as wellness programs.[24] The wellness program exception applies to group health coverage, but generally does not apply to individual market coverage.

On June 3, 2013, the tri-Departments issued final regulations on Incentives for Nondiscriminatory Wellness Programs in Group Health Plans (2013 HIPAA regulations) to implement section 2705 of the PHS Act, enacted as part of the Affordable Care Act, and to amend the 2006 regulations that implemented HIPAA requirements concerning nondiscriminatory wellness programs in group health plans.[25] The 2013 HIPAA regulations distinguish between two types of wellness programs: participatory and health-contingent, and provide guidance with respect to the maximum permissible reward under health-contingent wellness programs offered in connection with a group health plan.[26] For purposes of the 2013 HIPAA regulations, references to an individual obtaining a reward include both obtaining a reward (such as a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism, an additional benefit, or any financial or other incentive) and avoiding a penalty (such as the absence of a premium surcharge or other financial or nonfinancial disincentive).[27]

Participatory wellness programs are those that either do not provide a reward or do not include any condition for obtaining a reward that is based on an individual satisfying a standard related to a health factor. Examples of participatory wellness programs include: programs that reward employees for completing a health risk assessment regarding current health status without any further action (educational or otherwise) required by the employee with regard to the health issues identified as part of the assessment; diagnostic testing programs that provide rewards for participation in the program and do not base any part of the rewards on outcomes; programs that reimburse employees for the costs of participating in, or provide rewards for participating in, smoking cessation programs without regard to whether the employees quit smoking; and programs that provide rewards to employees for attending monthly, no-cost health education classes. The 2013 HIPAA regulations do not impose any limits on rewards provided in connection with participatory wellness programs and only require that they be made available to all similarly situated individuals, regardless of health status.[28]

By contrast, health-contingent wellness programs, which may be either activity-only or outcome-based, require individuals to satisfy a standard related to a health factor to obtain a reward (or require an individual to undertake more than a similarly situated individual to obtain the same reward). Examples include programs that reward employees for walking, dieting, or exercising (activity-only wellness programs) or programs that use biometric screening or a health risk assessment to identify employees with certain medical conditions or risk factors (such as high cholesterol, blood pressure, or blood glucose levels) and reward those at low risk or those who meet certain health outcomes (outcome-based wellness programs).

There are five requirements for health-contingent wellness programs under the 2013 HIPAA final regulations. First, individuals eligible for a health-contingent wellness program must be given the opportunity to qualify for a reward at least once per year. Second, the total reward offered to an individual under all health-contingent wellness programs (including activity-only and outcome-based) with respect to the plan cannot exceed 30 percent of the total cost of employee-only coverage under the plan, taking into account both employee and employer contributions toward the cost of coverage.[29] (If the program is designed to prevent or reduce tobacco use, the reward cannot exceed 50 percent of the total cost of coverage.) Third, the program must be reasonably designed to promote health or prevent disease. Fourth, the full reward under the program must be available to all similarly situated individuals unless the program allows a reasonable alternative standard (or waiver of the standard) for obtaining the reward for any individual for whom the standard is unreasonably difficult to satisfy because of a medical condition.[30] Fifth, the plan or issuer must disclose the availability of a reasonable alternative standard to qualify for the reward (and if applicable, the possibility of a waiver of the standard) in all plan materials that provide details regarding the wellness program, and in the case of an outcome-based program, when disclosing to an individual that he or she did not satisfy an initial outcome-based standard.[31]

Finally, the 2013 HIPAA regulations recognize that compliance with HIPAA's nondiscrimination rules (as amended by the Affordable Care Act), including the wellness program requirements, is not determinative of compliance with any other provision of any other state or federal law, including, but not limited to, the ADA, Title VII of the Civil Rights Act of 1964, and GINA.[32]

IV. Interaction of HIPAA's Nondiscrimination Provisions (as Amended by the Affordable Care Act), the ADA, and GINA, and the Efforts by Courts and the EEOC to Reconcile These Laws

A. HIPAA, the Affordable Care Act, GINA, and the ADA

When Congress passed HIPAA in 1996, it included language authorizing the use of incentives as a means to promote health and disease prevention but did not impose a specific incentive limit.**[33]** In 2001, noting the limited data regarding the practices of wellness programs, the tri-Departments issued a proposed rule to implement HIPAA specifying three alternative percentages for wellness program incentive limits (10, 15, and 20 percent) and welcomed comments to help determine the standard for the final regulations.**[34]**

Around the same time, the EEOC issued guidance to answer questions about when employers may make disability-related inquiries and/or conduct medical examinations of employees.**[35]** In answer to a question about whether the ADA's general prohibitions on obtaining health information from employees applied to voluntary wellness programs, the guidance stated, consistent with the statute and regulations, that inquiries and examinations are permitted as long as participation is in fact voluntary, and any medical records acquired as part of the program are kept confidential and separate from personnel records. Although the guidance did not explicitly address incentives, it stated that a wellness program is "voluntary" as long as an employer "neither requires participation nor penalizes employees who do not participate."**[36]** Because neither the statute nor the EEOC regulations define the term "voluntary" or address the extent to which incentives are allowed, the 2000 guidance was the EEOC's first official position on what it meant for a wellness program to be voluntary.**[37]**

In 2006, the tri-Departments published joint regulations implementing the nondiscrimination and wellness provisions of HIPPA, including a provision allowing incentives of up to 20 percent of the cost of employee-only coverage for participation in health-contingent wellness programs offered in connection with a group health plan.**[38]** The incentivization of wellness programs, including those with health risk assessments and/or biometric screening, begged the question of whether and how such programs could conform with the ADA's requirement that an employee's disclosure of medical information pursuant to an employee health program must be "voluntary."**[39]** The preamble to the 2006 HIPAA regulations also acknowledged that compliance with HIPAA's nondiscrimination rules, including the incentive provisions, was not determinative of compliance with any other state or federal law, including the ADA and GINA, and stated that those with questions about the applicability of other laws should contact legal counsel or other government agencies such as the EEOC. Thus, immediately after the tri-Departments issued their regulations, the Commission began receiving inquiries about how employers could provide limited incentives for wellness programs without running afoul of the EEOC's guidance indicating that employers could neither require participation nor penalize employees who did not participate. In 2008, in an attempt to clarify what level of incentives are permitted under the ADA, the EEOC's Office of Legal Counsel issued an informal discussion letter stating that participation in a wellness program is "voluntary" if the incentive offered does not exceed the 20 percent limit set forth in HIPAA.**[40]**

The passage of GINA in 2008 once again linked the issues of voluntariness, incentives, and the protection of medical information. In 2010, the EEOC issued regulations implementing Title II of GINA, which included a statutory prohibition on incentives in return for genetic information when requested as part of employer-provided health and genetic services, including wellness programs. The EEOC's 2010 GINA rule, however, did not address the question of whether this provision applied to incentives offered to employees in return for the employees' family members providing information about their own manifestations of disease or disorders as part of a wellness program because the Commission received no comments raising this issue in response to the proposed rule. It was only after the 2010 GINA regulations were issued that the question was brought to the EEOC's attention.**[41]**

Notwithstanding the different purposes of HIPAA, the ADA, and GINA, Congress passed the Affordable Care Act in 2010 and permitted further incentivization of wellness programs by increasing the allowable incentive to 30 percent of the total cost of coverage (or 50 percent to the extent the wellness program is designed to prevent or reduce tobacco use) under the plan for health-contingent programs that are part of, or qualify as, group health plans and authorized the tri-Departments to increase the maximum permissible incentive to as much as 50 percent if the tri-Departments determine that such an increase is appropriate. Congress, however, did not expressly indicate how the Affordable Care Act related to other federal laws and, specifically, did not add any statutory language addressing how the Affordable Care Act should be reconciled with the "voluntary" standard in the ADA. Congress also left untouched the ADA's long-standing safe harbor provision, which allows insurers and other entities to "establish, sponsor, observe, or administer the terms of health and other benefit plans."

In 2013, the tri-Departments issued final regulations under section 2705 of the PHS Act regarding nondiscriminatory wellness programs in group health coverage that, among other things, implemented the Affordable Care Act, and expressly acknowledged that compliance with HIPAA, as amended by the Affordable Care Act, is not determinative of compliance with other applicable laws, including the ADA.**[42]**

B. Lawsuits Challenging Wellness Programs

Courts also have struggled with the applicability of the ADA and GINA to employer wellness programs and have issued conflicting rulings about whether the ADA's "safe harbor" for certain insurance-related practices applies and, in one case, determining that incentives and voluntariness are separate issues entirely.**[43]** In 2012, the first federal court of appeals to address wellness program incentives considered whether a participatory program that included a surcharge for employees who declined to complete a health risk assessment and undergo biometric screening violated the ADA. The court held that because the wellness program was a "term" of the employer's health plan, it was protected by the ADA's safe harbor provision and, therefore, the court did not need to address the issue of whether the program was voluntary. *See Seff v. Broward County*, 778 F. Supp. 2d 1370, 1373 (M.D. Fla. 2011), *aff'd*, 691 F.3d 1221 (11th Cir. 2012).

In 2014, the EEOC filed a trio of lawsuits challenging employers' offering of wellness programs under the ADA. These lawsuits had varying

(W.D. Wis. 2015) (holding that the employer's health assessment and testing requirement did fall within the ADA's safe harbor), aff'd on other grounds, 846 F.3d 941 (7th Cir. 2017) with *EEOC v. Orion Energy Systems, Inc.*, 208 F. Supp. 3d 989 (2016)**[44]** (rejecting the employer's argument that the ADA's statutory safe harbor provision for insurance plans immunizes wellness programs from ADA scrutiny, and holding that the safe harbor would not apply even absent EEOC's 2016 regulations taking the position it was inapplicable). Having decided that the safe harbor did not apply, the court in *Orion* turned to the issue of whether the wellness program was "voluntary," noting that Congress had not defined what constitutes a "voluntary" medical examination or inquiry. In reaching its conclusion that the wellness program did not violate the ADA, the court stated:

> [E]ven a strong incentive is still no more than an incentive; it is not compulsion. Orion's wellness initiative is voluntary in the sense that it is optional. An employee is not required to participate in the program and is instead given a choice: either elect to complete the [health risk assessment] as part of the health program or pay the full amount of the health benefit premium. A corporation is not required to fully pay for an employee's health insurance—indeed, it is not required to provide health insurance at all—and it is not unlawful to give an employee a choice regarding her health benefits provided the choices are among lawful alternatives. There may be strong reasons to comply with an employer's wellness initiative, and the employee must balance the considerations in deciding whether to participate or not. But a "hard choice is not the same as no choice." *See* ***United States v. Martinez–Salazar*, 528 U.S. 304, 315, 120 S.Ct. 774, 145 L.Ed.2d 792 (2000) (https://1.next.westlaw.com/Link/Document/FullText?findType=Y&serNum=2000034157&pubNum=0000780&originatingDoc=I98326af0800d11e6b8b9e1ce282dafae&refType=RP&fi=co_pp_sp_780_3 (sc.History*oc.UserEnteredCitation)#co_pp_sp_780_315)** . [The employee] made a choice about what was truly important to her. She chose to forego the medical examination and pay the full amount of her health benefit premium. This choice may have been difficult, but is a choice nonetheless. Sometimes hard choices need to be made.**[45]**

208 F. Supp. 3d at 1001.

C. Response to Requests for Guidance from Employers, Insurance Groups, Congress, and Members of the Public

In response to continued urging by the EEOC stakeholders to provide additional guidance on how employers could avoid discrimination under the ADA and GINA in offering incentives to encourage employees to participate in wellness programs, the Commission held a public meeting in May 2013. Experts representing business, advocacy groups, and health insurance issuers described the confusion that resulted from the different applicable laws and asked the EEOC to clarify the key requirements of the ADA and GINA and how they interact with the Affordable Care Act.**[46]**

In April 2015, after extensive coordination with other federal agencies, the Commission issued a proposed rule to provide guidance regarding the extent to which employers may use incentives to encourage employees to participate in wellness programs that obtain health information. In the preamble to the 2015 proposed rule, the Commission noted that its interpretation of the term "voluntary" in the ADA's disability-related inquiries and medical examinations provision was "central to the interactions between the ADA and HIPAA's wellness program provisions, as amended by the Affordable Care Act." 80 FR 21659, 21662 (April 20, 2015). The proposed rule also stated:

> A plausible reading of "voluntary" in isolation is that covered entities can only offer de minimis awards or penalties to employees for their participation in wellness programs that include disability-related inquiries and medical examinations. That reading, however, would make many wellness programs incentives tied to the disclosure of health information or the completion of medical examinations expressly permitted by HIPAA impermissible under the ADA.

Id.

Although acknowledging that it was clear that compliance with the standards in HIPAA is not determinative of compliance with the ADA, the proposed rule concluded that adopting a 30 percent incentive level was the "best way to effectuate the purposes of the wellness program provisions of both laws." *Id*.

The preamble to the 2015 proposed rule solicited comments from members of the public about a wide range of issues, including wellness programs in general and particular practices that might violate the ADA or other laws enforced by the EEOC. The preamble to the proposed rule also invited comments on how the Commission should define what it means for a wellness program that includes disability-related inquiries or medical examinations to be voluntary and whether there were any methods, other than those mentioned in the proposed rule, by which the Commission could effectuate the intent of both the "voluntary" requirement in the ADA and the provisions of the Affordable Care Act intended to encourage workplace health promotion and disease prevention. Additionally, the Commission asked whether the proposal to require employers to provide a notice informing employees why their medical information was being collected and how it would be used should apply only to wellness programs that offered more than a de minimis incentive and, if so, how the Commission should define "de minimis." *Id.* at 21664.

During the 60-day comment period, the Commission received nearly 2,750 public comments from a wide spectrum of stakeholders. Disability advocacy groups generally expressed concerns that, in proposing to allow employers to offer incentives up to a maximum of 30 percent of the total cost of self-only coverage for both participatory and health-contingent wellness programs, EEOC was abandoning its position that a voluntary wellness program that includes disability-related inquiries and/or medical examinations cannot involve penalties. Employer and industry groups commented that the proposed rule's limitations on incentives were inconsistent with the tri-Department rules because the proposed rule calculated the incentive level differently than the HIPAA regulations. Members of Congress also commented that the EEOC has no statutory or jurisdictional authority to cap the maximum permitted incentive limit at 30 percent and should tie the maximum limit to the percentage permitted under HIPAA, as amended by the Affordable Care Act. Finally, some commenters gave examples of incentives that might be considered de minimis but did not identify a reasoned principle or a dollar amount that could be used as the basis for defining which incentives are de minimis and which are not.**[47]**

D. 2016 Final ADA Rule on Wellness Programs

In May 2016, after consideration of all of the public comments on its proposed rule, EEOC issued a final rule to amend its ADA regulations, at 29 CFR Section 1630.14(d), "Other Acceptable Examinations and Inquiries," and the accompanying interpretive guidance (also known as the Appendix) as they relate to employer wellness programs (2016 rule). *See* 81 FR 31126 (May 17, 2016). The rule applied to all wellness programs that included disability-related inquiries and/or medical examinations, whether they were offered only to employees enrolled in an employer-sponsored group health plan, offered to all employees regardless of whether they were enrolled in such a plan, or offered as a benefit of employment by employers that did not sponsor a group health plan or group health insurance. The 2016 rule stated what it meant for a wellness program to be "voluntary" and clarified that the use of incentives (financial or in kind), whether in the form of a reward or penalty, would not render the program involuntary if the maximum allowable incentive available generally did not exceed 30 percent of the total cost of self-only coverage. The rule also enhanced confidentiality protections and stated that compliance with regulations regarding wellness programs, including the limit on incentives, did not relieve a covered entity from complying in all respects with the nondiscrimination provisions of other federal laws.

Finally, the 2016 rule explained that the ADA's "safe harbor" provision, at 29 CFR 1630.16(f), did not apply to wellness programs even if they were part of an employer's health plan because it would render the ADA statutory "voluntary" requirement superfluous. The 2016 rule also stated that it disagreed with *Seff v. Broward County* and *EEOC v. Flambeau, Inc.*[48] because there was insufficient evidence that the employer or its health plan used data from employees' health risk assessments and biometric screenings to determine insurability or to calculate insurance rates based on risks associated with certain conditions – the practices the safe harbor provision was intended to permit. *Id.* at 31131.[49]

V. AARP Lawsuit

On October 24, 2016, AARP filed a complaint in the U.S. District Court for the District of Columbia arguing that both the ADA and GINA rules' 30 percent incentive limits were inconsistent with requirements of the ADA and GINA and that employees would feel coerced to disclose medical information to receive a reward or avoid a penalty. Although the court denied AARP's motion for a preliminary injunction, it ultimately ruled that the EEOC failed to provide a reasoned explanation for its decision to adopt the 30 percent incentive limits and remanded both rules to the Commission for reconsideration. *AARP v. EEOC*, 267 F. Supp. 3d 14, 29-34, 38 (D.D.C. 2017). Following a motion by AARP to alter or amend the court's summary judgment order, the court vacated the incentive sections of both the ADA and GINA rules, effective January 1, 2019. *AARP v. EEOC*, 292 F. Supp. 3d 238, 241 (D.D.C. 2017). *See* 83 FR 65296 (Dec. 20, 2018).

With respect to the ADA rule, the court found sufficient evidence to support EEOC's conclusion that regulation is needed in this area to clarify whether employers may use incentives to increase employee participation in wellness programs that obtain medical information. However, the court was unpersuaded by EEOC's explanation that it adopted the 30 percent incentive limit for all wellness programs to harmonize the ADA's requirements with HIPAA regulations governing wellness programs. 267 F. Supp. 3d at 30. The court noted that Congress imposed the 30 percent limit in a different context and that, unlike the ADA, HIPAA does not contain an explicit "voluntary" requirement. The court also pointed out that the ADA rule extended the 30 percent incentive limit to both participatory and health-contingent wellness programs and calculated the incentive level differently than the HIPAA regulations. Thus, the court concluded that the "ADA rule does not, in fact, achieve EEOC's desired harmony with HIPAA." *Id.*

In response to the court's decision, the EEOC amended the ADA regulations to remove the incentive section at 29 CFR 1630.14(d)(3).

VI. This Proposed Rule

The Commission now proposes amendments to provisions in two sections of the ADA regulations: 29 CFR 1630.14(d), medical examinations and inquiries specifically permitted, and 1630.16(f), health insurance, life insurance, and other benefit plans (known as the "safe harbor"), and to the interpretive guidance accompanying these sections. Revisions to these sections explain how the ADA's voluntary requirement and safe harbor provisions apply when determining the extent to which employers may offer incentives for employees to participate in wellness programs that obtain medical information.

The Commission recognizes that the issue of voluntariness can be viewed differently, as the various case law outcomes demonstrate. One view is that, as the court in *Orion* concluded, voluntariness and incentives are separate issues and that "even a strong incentive is still no more than an incentive." *See EEOC v. Orion Energy Systems, Inc.*, 208 F. Supp. 3d at 1001. Under this analysis, deciding whether to forego an award or be penalized for not providing health information is a choice. Alternatively, another view is that the voluntariness of a wellness program must be determined, at least in part, by deciding what level of incentives offered to employees for their health information fails to give them a meaningful choice.

This rule adopts the view that allowing too high of an incentive would make employees feel coerced to disclose protected medical information to receive a reward or avoid a penalty and, therefore, states that most wellness programs that include disability-related inquiries and/or medical examinations may offer no more than de minimis incentives to encourage employees to participate. Unlike the 2016 rule, this rule proposes that the ADA's statutory safe harbor provision applies to a subset of wellness programs. Accordingly, under the new proposed rule, health-contingent wellness programs that are part of, or qualify as, group health plans to which the tri-Department wellness regulations apply are an exception to the de minimis standard. Accordingly, this proposed rule interprets the safe harbor as permitting health-contingent wellness programs that are part of, or qualify as, group health plans to offer the maximum allowed incentive under the 2013 HIPAA regulations (currently 30 percent of the total cost of coverage or 50 percent to the extent the wellness program is designed to prevent or reduce tobacco use), as long as they comply with the five HIPAA requirements for such plans.

Proposed Section 1630.14(d)(1): Types of Employee Wellness Programs (previously Employee Health Program)

The 2016 rule explained that the term “health program,” as used in the statute, included wellness programs and stated that any health program that included disability-related inquiries and/or medical examinations had to be “reasonably designed to promote health or prevent disease.” The proposed rule explains that, for purposes of these regulations, a wellness program is a program of health promotion or disease prevention that includes disability-related inquiries or medical examinations. It also describes the two types of wellness programs that are considered employee health programs under the ADA: participatory and health-contingent, and provides guidance with respect to the maximum permissible incentive for each type of program. In addition, the proposed rule deletes the requirement that an employee health program under the ADA must be “reasonably designed to promote health or prevent disease.”

We are proposing this change because we believe that the de minimis incentive standard will make it unlikely that an employee will choose to participate in a program that requires providing medical information unless the employee believes the program has some value in promoting health or preventing disease.**[50]** Additionally, health-contingent wellness programs that are part of, or that qualify as, group health plans will be permitted to offer limited incentives that are more than de minimis in exchange for an employee’s medical information only if they satisfy the five requirements for health-contingent wellness programs under PHS Act section 2705 and the 2013 HIPAA final regulations, one of which is that programs “must be reasonably designed to promote health or prevent disease.” Health-contingent programs that fail to satisfy any of the five requirements will be able to offer only de minimis incentives. For this reason, the Commission concludes that the provision in the 2016 rule expressly imposing a “reasonably designed” requirement on wellness programs that include disability-related inquiries or medical examinations is no longer necessary.

Proposed Section 1630.14(d)(2):Voluntary

This provision retains the requirements from the 2016 rule that an employer: may not require employees to participate; may not deny coverage under any of its group health plans or particular benefits packages within a group health plan; generally may not limit the extent of such coverage; and may not take any other adverse action against employees who decline to participate in an employee health program or fail to achieve certain health outcomes. The proposed rule also identifies as unlawful several other employer actions that also were prohibited under the 2016 rule. An employer may not retaliate against, interfere with, coerce, intimidate, or threaten employees in violation of Section 503 of the ADA, at 42 U.S.C. 12203 (*e.g.*, by coercing an employee to participate in an employee health program or threatening to discipline an employee who does not participate).

Additionally, a wellness program that asks participants to provide medical information must not impose any condition that would adversely affect the terms, conditions, or privileges of employment of any employee who does not want to participate. Accordingly, this rule states employers generally may offer no more than de minimis incentives (*e.g*, a water bottle or gift card of modest value) to encourage employees to take part in a wellness program that includes disability-related inquiries and medical examinations. The interpretive guidance includes examples of the type of incentives that would violate this principle.

The Commission invites comments on the types of incentives that should and should not be considered de minimis. For example, should de minimis incentives include additional examples other than a water bottle and a gift card of modest value? Would it be helpful to provide examples of incentives other than those given in the interpretive guidance (*e.g*., a paid annual gym membership or free airline tickets) that would violate the de minimis limit?

Where the safe harbor provision applies as an exception to the de minimis incentive limit – allowing instead the maximum incentive permitted under HIPAA for certain health-contingent wellness programs – such programs still must adhere to all the other requirements of voluntariness specified in the rule. This includes, for example, not requiring employees to participate; not denying coverage under any group health plans or particular benefits packages within a group health plan; generally not limiting the extent of such coverage; not taking any other adverse action against employees who decline to participate in an employee health program or fail to achieve certain health outcomes; and not engaging in retaliation or interference in violation of the ADA.

Allowing only de minimis incentives for participatory wellness programs does not conflict with the wellness program provisions in HIPAA, as amended by the Affordable Care Act, or the 2013 HIPAA regulations implementing those statutory provisions. Rather, it harmonizes the ADA and HIPAA requirements. The wellness program provisions in HIPAA and the Affordable Care Act aim to provide wellness programs with flexibility, while protecting individuals from wellness programs that may be a subterfuge for discrimination on the basis of a health factor. The ADA is similarly concerned with prohibiting discrimination based on a disability, but also extends protections to employees without disabilities to prevent employers from forcing employees to disclose health information when they otherwise would choose not to do so. For this reason, the ADA explicitly states that an employee’s decision to disclose medical information as part of a wellness program must be voluntary.

Because the Commission is now proposing a de minimis incentive standard for most wellness programs, it no longer believes that it is necessary to require employers to issue a unique ADA notice that describes, among other things, the type of medical information that will be obtained and the purposes for which the information will be used. 29 CFR 1630.14(d)(2)(iv). Although the Commission believes that the applicability of the de minimis incentive standard makes it unlikely that an employee will choose to participate in a program that requires providing medical information unless the employee understands how the information will be used and protected, the Commission invites comments on whether notice should be required even where the program is allowed to offer no more a de minimis incentive.**[51]** Additionally, as an assurance for employees, this proposed rule also provides that, regardless of whether notice is given, employers may not condition participation in a wellness program on an employee allowing information to be disclosed to a third party. Finally, unlike the plain language of the provision in Title II of GINA governing information requested in connection with health or genetic services provided by an employer,**[52]** the ADA does not include a notice or authorization requirement. The ADA simply states that any disability-related inquiries or medical examinations that are part of a wellness program

Proposed Section 1630.14(d)(3))(previously Section 1630.14(d)(4)): Confidentiality

The proposed rule retains all of the confidentiality protections from the 2016 rule, including the exceptions for disclosure, and states that medical information collected through a wellness program may be provided to a covered entity only in aggregate terms that do not disclose, or are not reasonably likely to disclose, the identity of specific individuals, except as needed to administer the health plan (where the wellness program is part of such plan) and except as permitted under § 1630.14(d)(3)(i). Where a wellness program is part of a group health plan, the individually identifiable health information collected from or created about participants is protected health information under the HIPAA Privacy, Security, and Breach Notification Rules. *See* 45 CFR part 160 and Part 164. These rules apply to HIPAA covered entities, which include group health plans, and generally safeguard protected health information maintained by or on behalf of such entities.

Proposed Section 1630.14(d)(4)(previously Section 1630.14(d)(5)): Relationship to Other EEOC Laws

This section retains the language from the 2016 rule and explains that compliance with the requirements of this section of the regulations does not relieve a covered entity from the obligation to comply with other federal nondiscrimination laws.

Proposed Section 1630.14(d)(5)(previously Section 1630.14(d)(6)): Safe Harbor

For the reasons explained later in this preamble, the Commission has revised this section and the interpretive guidance to provide that the ADA "safe harbor" provision applies to programs that offer incentives to employees who answer disability-related questions and/or undergo medical examinations as part of a health-contingent wellness program if the program is part of, or qualifies as, a group health plan and complies with the five nondiscrimination requirements under HIPAA.**[54]** This proposed section lists four factors that the Commission believes are helpful in determining when a wellness program is part of a group health plan for purposes of the ADA wellness rule: (1) the program is only offered to employees who are enrolled in an employer-sponsored health plan; (2) any incentive offered is tied to cost-sharing or premium reductions (or increases) under the group health plan; 3) the program is offered by a vendor that has contracted with the group health plan or issuer; and (4) the program is a term of coverage under the group health plan.**[55]** We welcome comments on whether different or additional factors would be more useful.

The safe harbor provision, as set forth in the statute and in the current ADA regulation, states, in pertinent part, that an insurer or any entity that administers benefit plans is not prohibited from "establishing, sponsoring, observing or administering the terms of a bona fide benefit plan based on underwriting risks, classifying risks, or administering such risks that are based on or not inconsistent with state law." 42 U.S.C. 12201(c)(2); 29 CFR 1630.16(f)(2). A separate subsection permits a covered entity to "establish, sponsor, observe, or administer the terms of a bona fide benefit plan that is not subject to State laws that regulate insurance." 42 U.S.C. 12201(c)(3); 29 CFR 1630.16(f)(3).

The 2016 rule on wellness programs took the position that the ADA safe harbor provision applied only in situations where "sound actuarial data" or "reasonably anticipated experience" concerning risks associated with health conditions were used to determine insurability or to set insurance rates, not to the practice of offering incentives for employees to answer disability-related questions or undergo medical examinations as part of a wellness program. *See* 81 FR at 31130-31. The practice of applying actuarial data or reasonably anticipated experience to estimate risk and determine insurability or to set rates based on a health condition can fairly be said to constitute "underwriting risks" as that term is understood in the insurance industry.**[56]** But the ADA safe harbor allows for more than underwriting risks. It also allows "classifying risks"**[57]** and "administering risks." 42 U.S.C. 12201(c)(2); 29 CFR 1630.16(f)(2). The Commission's earlier interpretation that the safe harbor was limited only to those situations involving the application of sound actuarial data or reasonably anticipated experience to determine insurability or insurance rates rendered the terms "classifying risks" and "administering risks" superfluous, interpreting them as necessarily and always having the same meaning as "underwriting risks."

A wellness program that is part of, or that qualifies as, a group health plan will be considered to be "classifying risks" and "administering risks" when it offers incentives in exchange for employees to engage in certain activities and achieve goals aimed at reducing health risks provided that the program actually uses the aggregate data it obtains to help employees improve their health. For example, a program that includes a physical examination and biometric screening can be beneficial in identifying key health indicators related to chronic disease that can be measured and tracked over time, including blood pressure, cholesterol levels, and blood sugar. Employers then can take steps to help employees manage their specific risk factors and use the data to create future benefit plans. **[58]**

By contrast, a wellness program that simply uses a health risk assessment that relies on self-reporting may not give employers an accurate picture of a particular's employee's health or the health of the workforce and, therefore, may not provide the type of quantifiable data needed to classify or administer risks.**[59]** Similarly, the Commission does not believe that a program that simply requires employees to undergo biometric screening without tracking their results or requiring them to achieve health goals in order to earn a reward or avoid a penalty is able to classify or administer risks. Indeed, a recent study indicates that such programs do not result in differences in health measurements (such as improved blood glucose levels) or lower health care costs to employers, and we are aware of no studies that have reached a contrary conclusion.**[60]**

Finally, the portion of the safe harbor referring to "underwriting risks, classifying risks, and administering risks" applies only to group health plans that are subject to state laws governing insurance – that is, insured health plans. A third subsection of the safe harbor provision applies to self-insured group health plans, such as plans that are sponsored by private entities and subject to ERISA, the Code, and/or the PHS Act.**[61]** This subsection allows employers to "establish, sponsor, observe, or administer the terms of a bona fide benefit plan that is not subject to State laws that regulate insurance." 42 U.S.C. 12201(c)(3); 29 CFR 1630.16(f)(3). The 2016 rule governing wellness programs did not address this subsection specifically, but it is clear that the safe harbor allows wellness programs that are part of a self-insured group health plan to offer incentives that are

The Commission invites comments from employers, insurance providers, and vendors regarding how employers use the information from participatory programs that simply require employees to complete a health risk assessment or undergo biometric screening without requiring employees to achieve any particular health outcomes.. The Commission also invites comments on what kind of information employers obtain from health risk assessments and biometric screenings and how they actually use the aggregate data they collect.

Proposed Section 1630.16(f): Safe Harbor

The proposed revision adds a subparagraph related to health-contingent wellness programs that are part of a group health plan or are themselves group health plans. This section explains that a program that requires an employee to satisfy a standard related to a health factor to earn a reward or avoid a penalty is permissible under this section as long as it complies with the five HIPAA nondiscrimination requirements, as amended by the Affordable Care Act, and otherwise complies with the requirements in § 1630.14(d)(2)(i)-(iii) of this part.

The interpretive guidance describes these requirements and includes examples of permissible incentives. The proposed revision also states that covered entities must comply with other federal nondiscrimination laws.

Regulatory Procedures

*Executive Order 13563**[62]** and Executive Order 12866**[63]***

This proposed rule has been drafted and reviewed in accordance with Executive Order 13563 and Executive Order 12866.

Executive Order 13563 directs agencies to propose or adopt a regulation only upon a reasoned determination that its benefits justify its cost (recognizing that some benefits and costs are difficult to quantify); to tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives; and to select, from among alternative regulatory approaches, including the alternative of not regulating, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity).

Executive Order 12866 directs agencies to submit a regulatory impact analysis for those regulatory actions that are “economically significant” within the meaning of section 3(f)(1). A regulatory action is economically significant under section 3(f)(1) if it is anticipated (1) to “[h]ave an annual effect on the economy of $100 million or more,” or (2) to “adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.” Executive Order 13563 reaffirms the principles established by Executive Order 12866, and further emphasizes the need to reduce regulatory burden to the extent feasible and permitted by law.

Pursuant to Executive Order 12866, the EEOC has coordinated this proposed rule with the Office of Management and Budget. Under section 3(f)(1) of Executive Order 12866, the EEOC has determined that the proposed regulation will not have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities.

Although a detailed benefit-cost assessment of the proposed regulation is not required, the Commission recognizes that providing some information on potential benefits and costs of the rule may be helpful in assisting members of the public in better understanding the potential impact of the proposed rule. In this regard, the Commission notes that the rule will significantly aid compliance with Title I of the ADA and with HIPAA, as amended by the Affordable Care Act, by employers that offer wellness programs that include disability-related inquiries and/or medical examinations. Currently, employers face uncertainty as to whether providing incentives permitted by HIPAA will subject them to liability under the ADA. This rule will clarify that offering de minimis incentives to employees to respond to questions on a health risk assessment or undergo biometric screenings that are part of a participatory wellness program is permitted as long as the program is voluntary. The rule also will clarify that a health-contingent wellness program that is part of, or qualifies as, a group health plan may offer incentives to an employee to satisfy a standard related to a health factor as long as it complies with HIPAA nondiscrimination requirements, as amended by the Affordable Care Act, and provisions of this proposed rule that prohibit an employer from requiring an employee to participate, denying health coverage, or taking adverse actions against employees who do not participate.

The Commission does not believe the costs to employers associated with the rule are significant. Under HIPAA, as amended by the Affordable Care Act, incentives of up to 30 percent of the total cost of coverage in which an employee is enrolled are permitted for health-contingent wellness programs (or up to 50 percent to the extent the program is designed to prevent or reduce tobacco use). This rule permits the same level of incentives as HIPAA does for health-contingent wellness programs that are part of, or qualify as, a group health plan. It differs from HIPAA’s wellness program incentives in that it permits only de minimis incentives for health-contingent wellness programs that are not part of group health plans as well as for all participatory wellness programs.

Although employers will face initial start-up costs to train human resources staff and others on the revised rule, the Commission notes that it conducts extensive outreach and technical assistance programs, many of them at no cost to employers, to assist in the training of relevant personnel on EEO-related issues. For example, in FY 2019, the agency's outreach programs reached more than 295,600 workers, employers, their representatives, and advocacy groups at more than 3,800 education, training, and outreach events conducted by the EEOC. We expect to put information about the revisions to the ADA regulations in our outreach programs in general and to continue to offer ADA-specific outreach programs which will, of course, include information about the revisions once the proposed rule becomes final. We also will post technical assistance documents on our website explaining the revisions to the ADA regulations, as we do with all of our new regulations and policy documents.**[64]**

We estimate that there are approximately 1,275,000 employers with 15 or more employees subject to Title I of the ADA**[65]** and, of that number, one half to two thirds (637,500 to 850,000) offer some type of wellness program.**[66]** Assuming that 50 percent of those programs (using the highest estimate of 850,000) ask employees to complete a health risk assessment and/or undergo biometric screening, we assume that approximately 425,000 employers will be covered by the proposed rule.**[67]** We further estimate that the typical human resources professional will need to dedicate, at most, 60 minutes to gain a satisfactory understanding of the revised regulations, which are less complicated than the 2016 rule because the majority of wellness programs can offer only a de minimis incentive, and the allowable incentive for those programs that are permitted to offer a more than de minimis completely align with the already familiar rules governing incentives for health-contingent wellness programs under HIPAA, as amended by the Affordable Care Act. We also estimate that the median hourly pay rate of a human resources professional is approximately $54.47. *See* Bureau of Labor Statistics, Occupational Employment and Wages, May 2018 at **http://www.bls.gov/oes/current/oes113121.htm (http://www.bls.gov/oes/current/oes113121.htm)**. Assuming that an employer will train up to three human resources professionals/managers on the requirements of this rule, we estimate that initial training costs will be approximately $66,449,250.**[68]**

We welcome comments on this and all of our conclusions concerning the benefits and burdens of the proposed revisions.

Paperwork Reduction Act

Because this proposal removes the previous notice requirement, it contains no new information collection requirements subject to review by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

Regulatory Flexibility Act

Title I of the ADA applies to all employers with 15 or more employees, approximately 1,255,000 of which are small firms (entities with 15-500 employees) according to data provided by the Small Business Administration Office of Advocacy. *See* Data by Enterprise Employment Size, US and states, totals at **https://www.census.gov/data/tables/2016/econ/susb/2016-susb-annual.html (https://www.census.gov/data/tables/2016/econ/susb/2016-susb-annual.html)**.

The Commission certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small entities because it imposes no reporting burdens and only minimal costs on such firms. The proposed rule simply clarifies that employers that offer wellness programs are free to adopt certain types of incentives without violating the ADA. It does not require any action on the part of covered entities, except to the extent that those entities created documentation or forms that cite to the ADA for the proposition that the entity is unable to offer incentives to employees for answering disability-related inquiries or undergoing medical examinations and now will have to change those forms to indicate what levels of incentives are permissible. We do not have data on the number or size of businesses that may need to alter documents relating to their wellness programs. However, our experience with enforcing the ADA, which required all employers with 15 or more employees to remove medical inquiries from application forms, suggests that revising questionnaires to eliminate or alter an instruction would not impose significant costs.

To the extent that employers will expend resources to train human resources staff and others on the revised rule, we reiterate that the EEOC conducts extensive outreach and technical assistance programs, many of them at no cost to employers, to assist in the training of relevant personnel on EEO-related issues. For example, in FY 2019, the agency's outreach programs reached more than 295,600 workers, employers, their representatives, and advocacy groups at more than 3,800 education, training, and outreach events conducted by the EEOC. We expect to put information about the revisions to the ADA regulations in our outreach programs in general and to continue to offer ADA-specific outreach programs which will, of course, include information about the revisions once the proposed rule becomes final. We will also post technical assistance documents on our website explaining the revisions to the ADA regulations, as we do with all of our new regulations and policy documents.

We estimate that the typical human resources professional will need to dedicate, at most, 60 minutes to gain a satisfactory understanding of the revised regulations, which are less complicated than the 2016 rule because the majority of wellness programs can offer only a de minimis incentive and the allowable incentive for those programs that are permitted to offer a more than de minimis incentive completely align with the already familiar rules governing incentives in wellness programs under HIPAA, as amended by the Affordable Care Act. We further estimate that the median hourly pay rate of a human resources professional is approximately $54.47. *See* Bureau of Labor Statistics, Occupational Employment and Wages, May 2018 at **http://www.bls.gov/oes/current/oes113121.htm (http://www.bls.gov/oes/current/oes113121.htm)**. Assuming that small entities have between one and five human resources professionals/managers, we estimate that the cost per entity of providing appropriate training will be between approximately $54.47 and $272.35. The EEOC does not believe that this cost will be significant for the impacted small entities. We urge small entities to submit comments concerning the EEOC’s estimates of the number of small entities affected, as well as the cost to those entities.

Unfunded Mandates Reform Act of 1995

This proposed rule will not result in the expenditure by state, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

The Congressional Review Act (5 U.S.C. 801 et seq.) generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. A major

to result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, or innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. 5 U.S.C. § 804(2). The EEOC has determined that this rule is not a major rule. The EEOC will submit a copy of the final rule to each House of the Congress and to the Comptroller General of the United States, as required.

List of Subjects in 29 CFR Part 1630

Equal employment opportunity, Individuals with disabilities.

For the reasons set forth in the preamble, under the authority of [insert cite], the EEOC amends [insert cite] of title 29 of the Code of Federal Regulations as follows:

PART 1630 – REGULATIONS TO IMPLEMENT THE EQUAL EMPLOYMENT PROVISIONS OF THE AMERICANS WITH DISABILITIES ACT

1. The authority citation for Part 1630 continues to read as follows:

Authority: 42 U.S.C. 12116 and 12205a of the Americans with Disabilities Act, as amended.

Part 1630 -- [Amended]

2. In § 1630.14, revise paragraph (d) to read as follows:

*   *   *   *   *

(d) Other acceptable examinations and inquiries. A covered entity may conduct voluntary medical examinations and activities, including voluntary medical histories, which are part of an employee health program, including a wellness program, available to employees at the work site.

(1) *Types of Wellness Programs*. For purposes of this section, a wellness program is a program of health promotion or disease prevention that includes disability-related inquiries or medical examinations. Wellness programs that do not include disability-related inquiries or medical examinations, such as those that provide general health and educational information or reward employees for attending a smoking cessation or nutrition class, are not subject to the rules set forth in this section.

(i) *Participatory wellness program*. If none of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor (or if a wellness program does not provide a reward), the wellness program is a participatory wellness program.

(ii) *Health-contingent wellness program*. A health-contingent wellness program is a program that requires an individual to satisfy a standard related to a health factor to obtain a reward (or requires an individual to undertake more than a similarly situated individual based on a health factor in order to obtain the same reward). A health-contingent wellness program may be an activity-only wellness program or an outcome-based wellness program.

(2) *Voluntary*. A wellness program is voluntary as long as the covered entity:

(i) Does not require employees to participate in the wellness program;

(ii) 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 under paragraph (d)(5) of this section) for employees who do not participate; and

(iii) 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, codified at 42 U.S.C. 12203.

(iv) Does not offer more than a de minimis incentive (such as a water bottle or gift card of modest value) in exchange for an employee participating in the wellness program (unless the program is a health-contingent wellness program that falls within the safe-harbor under § 1630.16(f)(2)).

(3)(i) *Confidentiality*. Information obtained under paragraph (d) of this section regarding the medical condition or history of any employee shall be collected and maintained on separate forms and in separate medical files and be treated as a confidential medical record, except that:

(A) Supervisors and managers may be informed regarding necessary restrictions on the work or duties of the employee and necessary accommodations;

(B) First aid and safety personnel may be informed, when appropriate, if the disability might require emergency treatment; and

(C) Government officials investigating compliance with this part shall be provided relevant information on request.

(ii) Information obtained under paragraph (d) or (e) of this section regarding the medical condition or history of any employee shall not be used for any purpose inconsistent with this part.

(iii) Except as permitted under paragraph (d)(3)(i) and as is necessary to administer the group health plan, information obtained under paragraph (d) of this section 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.

(iv) A covered entity shall not require an employee to agree to the sale, exchange, sharing, transfer, or other disclosure of medical information (except to the extent permitted by this part to carry out specific activities related to the wellness program), or to waive any confidentiality protections in this part as a condition for participating in a wellness program or for earning any incentive the covered entity offers in connection with such a program.

(4) *Other federal laws*. Compliance with the requirements of paragraph (d) of this section, including the limit on incentives under the ADA, does not relieve a covered entity from the obligation to comply in all respects with the nondiscrimination provisions of Title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e *et seq*., the Equal Pay Act of 1963, 29 U.S.C. 206(d), the Age Discrimination in Employment Act of 1967, 29 U.S.C. 621 et seq., Title II of the Genetic Information Nondiscrimination Act of 2008, 42 U.S.C. 2000ff, et seq., or other sections of Title I of the ADA.

(5) *Application of insurance safe harbor to certain wellness programs.* The "safe harbor" provisions in section 1630.16(f) of this part applicable to health insurance, life insurance, and other benefit plans shall apply to incentives offered by a covered entity under a health-contingent wellness program that is part of, or that qualifies as, a covered entity's group health plan. Where this exception applies, it is limited to permitting the use of the maximum incentive level for such wellness programs permitted under HIPAA regulations, but does not otherwise excuse compliance with the other ADA requirements for voluntary participation in wellness programs that include disability-related inquiries or medical examinations. Factors that help determine whether a health-contingent wellness program is part of, or qualifies as, a covered entity's group health plan for purposes of the ADA include whether the program–

(i) is offered only to employees who are enrolled in an employer-sponsored group health plan;

(ii) ties any incentive offered to cost-sharing or premium reductions (or increases) under the group health plan;

(iii) is offered by a vendor that has contracted with the group health plan or insurer; and,

(iv) is a term of coverage under the terms of a group health plan.

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§1630.16 Specific activities permitted.

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(f) *Health insurance, life insurance, and other benefit plans* (1) An insurer, hospital, or medical service company, health maintenance organization, or any agent or entity that administers benefit plans, or similar organizations may underwrite risks, classify risks, or administer such risks that are based on or not inconsistent with State law.

(2) A covered entity may establish, sponsor, observe or administer 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.

Incentives offered by a health-contingent wellness program (as defined at § 1630.14(d)(1)(ii)) that is part of a group health plan or is itself a group health plan are permissible under this section as long as:

(i) The program meets the requirements established for health-contingent wellness programs (activity-only or outcome-based, as applicable) by the regulations implementing section 9802 of the Internal Revenue Code, section 702 of Employee Retirement Income Security Act and section 2705 of the Public Health Service Act set forth at 26 CFR 54.9802-1(f); 29 CFR 2590.702(f); and 45 CFR 146.121(f), as applicable; and

(ii) A covered entity otherwise complies with the requirements in § 1630.14(d)(2)(i)—(iii) of this part.

(3) A covered entity may establish, sponsor, observe, or administer the terms of a bona fide benefit plan that is not subject to State laws that regulate insurance. Such a bona fide benefit plan may include workplace wellness programs that meet the requirements set forth in paragraph (f)(2) of this section.

(4) The activities described in paragraphs (f) (1), (2), and (3) of this section are permitted unless these activities are being used as a subterfuge to evade the purposes of this part.

(5) *Other federal laws*. Compliance with the requirements of this paragraph (f), including the limit on incentives, does not relieve a covered entity from the obligation to comply in all respects with the nondiscrimination provisions of Title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e *et seq*., the Equal Pay Act of 1963, 29 U.S.C. 206(d), the Age Discrimination in Employment Act of 1967, 29 U.S.C. 621 *et seq*., Title II of the Genetic Information Nondiscrimination Act of 2008, 42 U.S.C. 2000ff, *et seq*., or other sections of Title I of the ADA.

In the Appendix to Part 1630 revise Section 1630.14(d), to read as follows:

Appendix to Part 1630—Interpretive Guidance on Title I of the Americans With Disabilities Act

* * * * *

Section 1630.14 Medical Examinations and Inquiries Specifically Permitted

Section 1630.14(d)(1): Types of Employee Health Programs

Part 1630 permits voluntary medical examinations, including voluntary medical histories, as part of employee health programs. These health programs typically include two types of wellness programs: “participatory” and “health-contingent.” Participatory wellness programs either do not provide a reward or do not require participants to satisfy a standard related to a health factor in order to obtain a reward. For example, participatory wellness programs subject to the ADA may include a health risk assessment consisting of a medical questionnaire, with or without medical examinations, to determine risk factors or screening for high blood pressure, cholesterol, or glucose. Health-contingent wellness programs, which may be either activity-only or outcome-based, require individuals to satisfy a standard related to a health factor to obtain a reward (which may include avoidance of a penalty). Examples include programs that reward employees for walking, dieting, or exercising (activity-only programs) or programs that use biometric screening or a health risk assessment to identify employees with certain medical conditions or risk factors (such as high cholesterol, blood pressure, or glucose) and reward those at low risk or those who meet certain targets or reasonable alternative standards (outcome-based programs).

Many wellness programs are offered by employers as part of a group health plan in an attempt to improve overall employee health with the goal of realizing lower health care costs. Employers also may offer wellness programs that are available to all employees, regardless of whether they are enrolled in a group health plan, or offer wellness programs even if they do not sponsor a group health plan or group health insurance.

Section 1630.14(d)(2): Definition of “Voluntary”

Section 1630.14(d)(2)(i)–(iii) of this part states that all wellness programs that include disability-related inquiries and/or medical examinations must be voluntary in order to comply with the ADA. This means that covered entities may not require employees to participate in such programs, may not deny employees access to health coverage under any of their group health plans or particular benefits packages within a group health plan for non-participation, may not limit coverage under their group health plans for such employees (except to the extent the limitation, such as having to pay a higher deductible, may be the result of forgoing a financial incentive permissible under paragraph 1630.14(d)(5)), and may not take any other adverse action against employees who choose not to answer disability-related inquiries or undergo medical examinations. Additionally, covered entities may not retaliate against, interfere with, coerce, intimidate, or threaten employees within the meaning of Section 503 of the ADA, codified at 42 U.S.C. 12203. For example, an employer may not retaliate against an employee who declines to participate in a wellness program or files a charge with the EEOC concerning the program, may not coerce an employee into participating in a wellness program, and may not threaten an employee with discipline if the employee does not participate in a wellness program. *See* 42 U.S.C. 12203(a),(b); 29 CFR 1630.12. Even where the safe harbor applies to permit a more than de minimis incentive under section 1630.14(d)(5), each of these other requirements still applies.

Section 1630.14(d)(2)(iv) of this part also states that, to be considered voluntary, a wellness program may offer no more than a de minimis incentive (such as a water bottle or gift card of modest value) in exchange for the employee participating in the wellness program (unless the program is a health-contingent wellness program that falls within the safe harbor under section 1630.16(f)(2)). For example, charging an employee $50 per month more for health insurance (or a total of $600 per year) for not completing a health risk assessment as part of a participatory wellness program would not be a de minimis incentive and, therefore, would violate the ADA because the employee would be treated less favorably with respect to the cost of health insurance than employees who chose to provide their health information. Incentives such as paying for an employee’s annual gym membership or rewarding an employee with airline tickets also would not be de minimis. The one exception to this de minimis incentive limit is for health contingent wellness programs that are covered under both this rule and the HIPAA regulations setting maximum incentive limits. Under the safe harbor provision of these regulations, at section 1630.16(f), such programs are permitted to use the incentive limit permitted under the HIPAA regulations, but must otherwise comply with all other requirements for voluntary wellness programs that include disability-related inquiries or medical examinations.

Section 1630.14(d)(3)(i)–(iv): Confidentiality

Paragraphs (d)(3)(i)–(ii) state 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 this part, such as limiting insurance eligibility. *See* House Labor Report at 75; House Judiciary Report at 43–44. Further, although an exception to confidentiality that tracks the
language of the ADA itself states that information gathered in the course of providing employees with voluntary health services may be disclosed to

managers and supervisors in connection with necessary work restrictions or accommodations, such an exception would rarely, if ever, apply to medical information collected as part of a wellness program. Presumably, an employee who learns that he or she has a disability as a result of biometric screening done as part of a wellness program will request a reasonable accommodation if one is needed. In addition, as described more fully below, certain disclosures that are permitted for employee health programs generally may not be permissible under the HIPAA Privacy Rule for wellness programs that are part of a group health plan without the written authorization of the individual.

Section 1630.14(d)(3)(iii) provides that a covered entity only may receive information collected as part of an employee health program in aggregate form that does not disclose, and is not reasonably likely to disclose, the identity of specific individuals. Notably, both employers that sponsor employee health programs and the employee health programs themselves (if they are administered by the employer or qualify as the employer's agent) are responsible for ensuring compliance with this provision.

Where a wellness program is part of, or qualifies as, a group health plan, the individually identifiable health information collected from or created about participants as part of the wellness program is protected health information (PHI) under the HIPAA Privacy, Security, and Breach Notification Rules. (45 CFR parts 160 and 164.) The HIPAA Privacy, Security, and Breach Notification Rules apply to HIPAA-covered entities, which include group health plans, and generally protect identifiable health information maintained by or on behalf of such entities, by among other provisions, setting limits and conditions on the uses and disclosures that may be made of such information.

PHI is information, including demographic data that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual (including, for example, address, birth date, or social security number), and that relates to: an individual's past, present, or future physical or mental health or condition; the provision of health care to the individual; or the past, present, or future payment for the provision of health care to the individual. HIPAA covered entities may not disclose PHI to an individual's employer except in limited circumstances. For example, as discussed more fully below, an employer that sponsors a group health plan may receive PHI to administer the plan (without authorization of the individual), but only if the employer certifies to the plan that it will safeguard the information and not improperly use or share the information. *See Standards for Privacy of Individually Identifiable Health Information* ("Privacy Rule"), Pub. L. 104-191; 45 CFR Part 160 and Part 164, Subparts A and E and guidance issued by the U.S. Department of Health and Human Services.**[69]** However, there are no restrictions on the use or disclosure of health information that has been de-identified in accordance with the HIPAA Privacy Rule. Individuals may file a complaint with HHS if they believe a health plan fails to comply with privacy requirements and HHS may require corrective action or impose civil money penalties for noncompliance.

EEOC anticipates that a program that is part of a HIPAA-covered entity likely will be able to comply with its obligation under section 1630.14(d)(3)(iii) by complying with the HIPAA Privacy Rule. An employer that is a group health plan sponsor and receives personally identifiable health information from or on behalf of the group health plan, as permitted by HIPAA when the plan sponsor is administering aspects of the plan, may generally satisfy its requirement to comply with section 1630.14(d)(3)(iii) by certifying to the group health plan, as provided by 45 CFR 164.504(f)(2)(ii), that it will not use or disclose the information for purposes not permitted by its plan documents and the Privacy Rule, such as for employment purposes, and abiding by that certification. **[70]** Further, if an employer is not performing plan administration functions on behalf of the group health plan, it may receive aggregate information from the wellness program under section 1630.14(d)(3)(iii) only so long as the information is de-identified in accordance with the HIPAA Privacy Rule. 45 CFR 164.514. In addition, disclosures of protected health information from the wellness program may only be made in accordance with the Privacy Rule. Thus, certain disclosures that are otherwise permitted under sections 1630.14(d)(3)(i)–(ii) for employee health programs generally may not be permissible under the Privacy Rule for wellness programs that are part of a group health plan without the written authorization of the individual. For example, the ADA allows disclosures of medical information when an employee needs a reasonable accommodation or requires emergency treatment at work.

Section 1630.14(d)(3)(iv) provides that a covered entity may not require an employee to agree to the sale, exchange, sharing, transfer, or other disclosure of medical information (except to the extent permitted by this part to carry out specific activities related to the wellness program), or waive confidentiality protections available under the ADA as a condition for participating in a wellness program or receiving a wellness program incentive.

Employers and wellness program providers must take steps to protect the confidentiality of employee medical information provided as part of an employee health program. Some of the following steps may be required by law; others may be best practices. It is critical to properly train all individuals who handle medical information about the requirements of the ADA and, as applicable, HIPAA's privacy, security, and breach notification requirements and any other privacy laws. Employers and program providers should have clear privacy policies and procedures related to the collection, storage, and disclosure of medical information. On-line systems and other technology should guard against unauthorized access, such as through use of encryption for medical information stored electronically. Breaches of confidentiality should be reported to affected employees immediately and should be thoroughly investigated. Employers should make clear that individuals responsible for disclosures of confidential medical information will be disciplined and should consider discontinuing relationships with vendors responsible for breaches of confidentiality.

Individuals who handle medical information that is part of an employee health program should not be responsible for making decisions related to employment, such as hiring, termination, or discipline. Use of a third-party vendor that maintains strict confidentiality and data security procedures may reduce the risk that medical information will be disclosed to individuals who make employment decisions, particularly for employers whose organizational structure makes it difficult to provide adequate safeguards. If an employer uses a third-party vendor, it should be familiar with the vendor's privacy policies for ensuring the confidentiality of medical information and security policies that guard against inadvertent disclosure to, or access by, unauthorized parties. Employers that administer their own wellness programs need adequate firewalls in place to prevent unintended disclosure. If individuals who handle medical information obtained through a wellness program do act as decision-makers (which may be the case for a small employer that administers its own wellness program), they may not use the information for

Section 1630.14(d)(4): Compliance with Other Employment Nondiscrimination Laws

Section 1630.14(d)(4) clarifies that compliance with the requirements of paragraph (d) of this section, including the limits on incentives applicable under the ADA, does not mean that a covered entity complies with other federal employment nondiscrimination laws, such as Title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e *et seq.*, the Equal Pay Act of 1963, 29 U.S.C. 206(d), the Age Discrimination in Employment Act of 1967, 29 U.S.C. 621 *et seq.*, Title II of the Genetic Information Nondiscrimination Act of 2008, 42 U.S.C. 2000ff *et seq.*, and other sections of Title I of the ADA. Thus, even though an employer's wellness program might comply with the incentive limits set out in paragraph (d)(2), the employer would violate federal nondiscrimination statutes if that program discriminates on the basis of race, sex, color, religion, national origin, age, or genetic information.

Section 1630.14(d)(5): Application of the ADA's Safe Harbor Provision

Finally, section 1630.14(d)(5) states that the "safe harbor" provision, set forth in section 501(c) of the ADA, 42 U.S.C. 12201(c), that allows insurers and benefit plans to underwrite, classify, and administer risks, applies to incentives offered by a covered entity under a health-contingent wellness program that is part of, or that qualifies as, a covered entity's group health plan. This section lists four factors that are helpful in determining whether a wellness program is part of a covered entity's group health plan for purposes of the ADA: (i) the program only is offered to employees who are enrolled in an employer-sponsored group health plan; (ii) any incentive offered is tied to cost-sharing or premium reductions (or increases) under the group health plan; (iii) it is offered by a vendor that has contracted with the group health plan or insurer; and, (iv) it is a term of coverage under the terms of a group health plan.

A health-contingent wellness program that is part of, or that qualifies as, a group health plan is protected by the safe harbor with respect to the incentive offered when it uses information from health risk assessments and biometric screenings and requires employees to satisfy a standard related to health factor, such as achieving a certain blood pressure or cholesterol level, to receive an award or avoid a penalty. However, participatory wellness programs that simply collect employee health information through health risk assessments or biometric screenings without tracking results and requiring employees to achieve certain health goals in order to earn an award or avoid a penalty, are not underwriting, classifying, or administering risks and, therefore, are not protected by the safe harbor.

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Section 1630.16 Specific Activities Permitted

Section (f) (1): <u>Health insurance, life insurance, and other benefit plans</u>

This provision, known as the ADA safe harbor, is a limited exemption that is only applicable to those who establish, sponsor, observe, or administer benefit plans, such as health and life insurance plans. It does not apply to those who establish, sponsor, observe, or administer plans not involving benefits, such as liability insurance plans.

The purpose of this provision is to permit the development and administration of benefit plans in accordance with accepted principles of risk assessment. This provision is not intended to disrupt the current regulatory structure for self-insured employers. These employers may establish, sponsor, observe, or administer the terms of a bona fide benefit plan not subject to State laws that regulate insurance. This provision is also not intended to disrupt the current nature of insurance underwriting, or current insurance industry practices in sales, underwriting, pricing, administrative, and other services, claims and similar insurance related activities based on classification of risks as regulated by state insurance law.

The activities permitted by this provision do not violate part 1630 even if they result in limitations on individuals with disabilities, provided that these activities are not used as a subterfuge to evade the purposes of this part. Whether or not these activities are being used as a subterfuge is to be determined without regard to the date the insurance plan or employee benefit plan was adopted.

However, an employer or other covered entity cannot deny an individual with a disability who is qualified equal access to insurance or subject an individual with a disability who is qualified to different terms or conditions of insurance based on disability alone, if the disability does not pose increased risks. Part 1630 requires that decisions not based on risk classification be made in conformity with non-discrimination requirements. *See* Senate Report at 84-86; House Labor Report at 136-138; House Judiciary Report at 70-71. See the discussion in this appendix at § 1630.5 Limiting, Segregating and Classifying.

Subsections (f)(2) (i)-(ii) explain that a health-contingent wellness program (as defined at 1630.14(d)(1)(ii)) that is part of a group health plan or is itself a group health plan is permissible under this section as long as it meets the requirements established for health-contingent wellness programs by the regulations implementing sections 9802 of the Internal Revenue Code, 702 of the Employee Retirement Income Security Act and 2705 of the Public Health Service Act set forth at 26 CFR 54.9802-1(f); 29 CFR 2590.702(f); and 45 CFR 146.121(f), as applicable; and otherwise complies with the requirements in § 1630.14(d)(2)(i)—(iii) of this part. Generally, this means that the program must be available to all similarly situated individuals and must: 1) give eligible individuals an opportunity to qualify for a reward at least once per year; 2) limit the size of the reward to currently no more than 30 percent of the total cost of coverage (or, 50 percent to the extent that the wellness program is designed to prevent or reduce tobacco use); 3) provide a reasonable alternative standard (or waiver) to qualify for a reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard or for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard; 4) be reasonably designed to promote health or prevent disease and not be overly burdensome, a subterfuge for discriminating based on a health factor, or highly suspect in the method chosen to promote health or prevent disease; and 5) disclose the availability of a reasonable alternative standard to qualify for the reward in plan materials that provide details regarding the wellness program, and in the case of an outcome-based program, in any disclosure that an individual did not satisfy an initial outcome-based standard. *Id.* Under the ADA,

covered entities also may not require employees to participate in such programs, may not deny employees access to health coverage under any of their group health plans or particular benefits packages within a group health plan for non-participation, may not limit coverage under their health plans for such employees (except to the extent the limitation, such as having to pay a higher deductible, may be the result of forgoing a financial incentive permissible under paragraph 1630.14(d)(5)), and may not take any other adverse action against employees who choose not to answer disability-related inquiries or undergo medical examinations. Additionally, covered entities may not retaliate against, interfere with, coerce, intimidate, or threaten employees within the meaning of Section 503 of the ADA, codified at 42 U.S.C. 12203. For example, an employer may not retaliate against an employee who declines to participate in a health program or files a charge with the EEOC concerning the program, may not coerce an employee into participating in a health program, and may not threaten an employee with discipline if the employee does not participate in a health program. *See* 42 U.S.C. 12203(a),(b); 29 CFR 1630.12.

The maximum amount of the incentive an employer may provide an employee who answers disability-related inquiries and/or undergoes medical examinations in connection with a health-contingent wellness program that is part of a group health plan is calculated based on the total cost of coverage, including employer and employee contributions. It also depends on whether family members are given an opportunity to participate in the wellness program and to earn an incentive. If only the employee is allowed to participate, the incentive is equal to 30 percent of the total cost of self-only coverage (50 percent if the program is designed to prevent or reduce tobacco use), regardless of the type of health plan in which the employee is enrolled. Suppose, for example, that an employer offers self-only coverage at a total cost (employer plus employee contributions) of $6,000 annually and allows only employees to participate in its health-contingent wellness program that asks for employee medical information. The maximum incentive the employer may offer is $1,800 annually, even if the employee is enrolled in self-and-family coverage that costs $16,000. If the program is designed to prevent or reduce tobacco use, the incentive may be as much as $3,000.

See 26 CFR 54.9802-1(f)(3)(ii), (f)(4)(ii) and (f)(5); 29 CFR 2590.702(f)(3)(ii), (f)(4)(ii) and (f)(5); and 45 CFR 146.121(f)(3)(ii), (f)(4)(ii) and (f)(5).

Section 1630.16(f)(5): *Compliance with Other Employment Nondiscrimination Laws*

This section clarifies that compliance with the requirements of paragraphs (f)(1) and (2) of this section, including the incentives permitted by HIPAA, does not mean that a covered entity complies with other federal employment nondiscrimination laws, such as Title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e *et seq.*, the Equal Pay Act of 1963, 29 U.S.C. 206(d), the Age Discrimination in Employment Act of 1967, 29 U.S.C. 621 et seq., Title II of the Genetic Information Nondiscrimination Act of 2008, 42 U.S.C. 2000ff et seq., and other sections of Title I of the ADA. Thus, an employer would violate federal nondiscrimination statutes if a health-contingent wellness program discriminates on the basis of race, sex, color, religion, national origin, or age.

Finally, section 1630.16(f)(3), which allows employers to "establish, sponsor, observe, or administer the terms of a bona fide benefit plan that is not subject to State laws that regulate insurance," provides that wellness program incentives that are part of a health plan governed by ERISA and that are consistent with incentives allowed under DOL's ERISA regulations are permitted by the ADA.

Dated:

Janet Dhillon
Chair, U.S. Equal Employment Opportunity Commission

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[1] 42 U.S.C. 12112(a); 29 CFR 1630.4(a)(1)(vi). In addition to employers, Title I of the ADA applies to covered entities including employment agencies, labor organizations, and joint-labor management committees. *See* 42 U.S.C. 12111(2), (4), (5), 12112(b) (describing the prohibited practices of each of these entities); *see also* 29 CFR 1630.2(b) (giving the definition of covered entity); 1630.4(a)(1) (describing prohibited practices). Although employers generally will be the ADA-covered entities that offer wellness programs, this preamble and the interpretive guidance frequently use the term "covered entity," as that term appears throughout EEOC's entire ADA regulation.

[2] 42 U.S.C. 12131–12134.

[3] 42 U.S.C. 12181–12189.

[4] A report on the characteristics of workplace wellness programs conducted by the Kaiser Family Foundation Health Research and Educational Trust indicated that 55 percent of large firms (with 200 or more workers) that offer wellness programs said that most of their wellness benefits were provided by the group health plan. *See* Karen Pollitz & Matthew Rae, Kaiser Family Foundation, *Workplace Wellness Programs Characteristics and Requirements* 5 (2016), **http://files.kff.org/attachment/Issue-Brief-Workplace-Wellness-Programs-Characteristics-and-Requirements (http://files.kff.org/attachment/Issue-Brief-Workplace-Wellness-Programs-Characteristics-and-Requirements)** .

[5] The term "group health plan," which includes both insured and self-insured group health plans, as defined in the Employee Retirement Income Security Act (ERISA) section 733(a), is an "employee welfare benefit plan" to the extent that the plan provides medical care to employees and their dependents directly or through insurance, reimbursement, or otherwise. An employer may establish or maintain more than one group health plan. ERISA section 3(1) defines an "employee welfare benefit plan" as "any plan, fund, or program . . . established or maintained by an employer or by an employee organization, or by both, to the extent that such plan, fund, or program was established or is maintained for the purpose of providing for its participants or their beneficiaries . . . medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability, death or unemployment . . . ."

[6] Among employers offering health benefits, 42 percent of small employers and 60 percent of large employers offer employees the opportunity to complete a health risk assessment, while 33 percent of small employers and 50 percent of large employers offer employees the opportunity to complete a biometric screening. *See Employer Health Benefits Survey*, Kaiser Family Foundation (2020),**https://www.kff.org/report-section/ehbs-2020-section-12-health-screening-and-health-promotion-and-wellness-programs/ (https://www.kff.org/report-section/ehbs-2020-section-12-health-screening-and-health-promotion-and-wellness-programs/)** [hereinafter 2020 Kaiser Survey].

[7] *See EEOC Enforcement Guidance on Disability-Related Inquiries and Medical Examinations of Employees Under the Americans with Disabilities Act*, Question 1 (2000), **http://www.eeoc.gov/policy/docs/guidance-inquiries.html (http://www.eeoc.gov/policy/docs/guidance-inquiries.html)** [hereinafter *Guidance*].

[8] *Id.* at Question 2. For a discussion of pertinent ADA provisions, *see* text accompanying nn.16-20, *infra*.

[9] Most employers that offer health benefits offer programs to help employees identify health risks and unhealthy behaviors. Fifty three percent of small employers and 81 percent of large employers offer at least one program in smoking cessation, weight management, or behavioral or lifestyle coaching. *See* 2020 Kaiser Survey.

[10] *See* RAND Health, *Workplace Programs Study: Final Report* xx (2013), **http://www.rand.org/content/dam/rand/pubs/research_reports/RR200/RR254/RAND_RR254.pdf (http://www.rand.org/content/dam/rand/pubs/research_reports/RR200/RR254/RAND_RR254.pdf)** [hereinafter *RAND Final Report*]. The study found that 69 percent of employers with at least 50 employees offer financial incentives to encourage employee participation, while 10 percent offer incentives tied to health outcomes. By contrast, the most recent Kaiser Survey found that 52 percent of large employers offering health benefits that ask employees to complete a health risk assessment offer an incentive, while 65 percent offer an incentive to employees complete biometric screening. Additionally, 18 percent reward or penalize employees based on achieving (or failing to achieve) specified outcomes (such as a targeted body mass index). Among large employers offering health benefits that offer any type of incentive for meeting biometric outcomes, 12 percent offer a maximum incentive of $150 or less; 32 percent offer between $151 and $500; 17 percent offer between $501 and $1,000; 29 percent offer more than $1,000; and 4 percent offer more than $2,000. *See* 2020 Kaiser Survey.

[11] The terms "incentive" and "reward" as used in this preamble and proposed rule are intended to be consistent. In regulations issued under the Public Health Service Act (PHS Act), as amended by the Affordable Care Act, "reward" is defined as "obtaining a reward (such as a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism, an additional benefit, or any financial or other incentive) and avoiding a penalty (such as the absence of a premium surcharge or other financial or nonfinancial disincentive"). *See* 26 CFR 54.9802-1(f)(1)(i), 29 CFR 2590.702(f)(1)(i), and 45 CFR 146.121(f)(1)(i).

[12] The Commission interprets the ADA as requiring employers to maintain the confidentiality of health information, such as records and data pertaining to patient histories, lab results, and diagnostic tests, as well as information about an employee's medical history, including symptoms, diagnoses, procedures, and outcomes.

[13] AARP is a nonprofit, nonpartisan membership organization for people age 50 and over. *See* **https://www.aarp.org/ (https://www.aarp.org/)** .

[14] 42 U.S.C. 2000ff–2000ff-11.

[15] The Patient Protection and Affordable Care Act (Pub. L. 111-148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this proposed rule, the two statutes are collectively referred to as the "Affordable Care Act".

[16] Section 1201 of the Affordable Care Act amended and moved the nondiscrimination and wellness provisions of the PHS Act from section 2702 to section 2705, and extended the nondiscrimination provisions (but generally not the wellness program provisions) to the individual market. The Affordable Care Act also added section 715(a)(1) to ERISA and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act, including PHS Act section 2705, into ERISA and the Code and make them applicable to group health plans and group health insurance issuers.

[17] 42 U.S.C. 12112(d)(4)(A) (stating that a covered entity "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"). The EEOC refers to the types of inquiries prohibited by the ADA as "disability-related inquiries" and has issued guidance on what constitutes such inquiries. *See* n.7, *supra.*

[18] 42 U.S.C. 12112(d)(4)(B). A covered entity may conduct voluntary medical examinations, including voluntary medical histories, that are part of an employee health program available to employees at that work site.

[19] 42 U.S.C. 12201(c); 29 CFR 1630.16(f). The safe harbor provision states, in pertinent part, that insurers and other entities that administer benefit plans are not prohibited from "establishing, sponsoring, observing, or administering the terms of a bona fide benefit plan based on underwriting risks, classifying risks, or administering risks that are based on or not inconsistent with state law." A separate subsection permits a covered entity to "establish, sponsor, observe, or administer the terms of a bona fide benefit plan that is not subject to State laws that regulate insurance." 42 U.S.C. 12201(c)(3); 29 CFR 1630.16(f)(3).

[20] 42 U.S.C. 12112(b)(5)(A); 29 CFR 1630.9 (prohibiting a covered entity from failing to provide reasonable accommodations absent undue hardship); 29 CFR 1630.2(o)(1)(iii) (providing that reasonable accommodation includes modifications and adjustments that enable a covered

entity's employees to enjoy "equal benefits and privileges of employment").

[21] *See* Title VII of the Civil Rights Act of 1964 (Title VII), 42 U.S.C. 2000e–2000e-17; the Equal Pay Act of 1963, 29 U.S.C. 206(d); the Age Discrimination in Employment Act of 1967 (ADEA), 29 U.S.C. 621–634; and Title II of GINA. However, this proposed rule concerns the regulations and interpretive guidance implementing Title I of the ADA as they relate to employer-sponsored wellness programs. Compliance with the limits on incentives in this proposed rule does not necessarily result in compliance with other nondiscrimination laws or other parts of the ADA. For example, as the interpretive guidance explains, even if an employer's wellness program complies with the incentive limits set forth in the ADA regulations, the employer violates Title VII, the ADEA, or GINA if that program discriminates on the basis of race, color, national origin, sex, religion, age, or genetic information.

[22] *See* n.15, *supra.*

[23] HIPAA and its implementing regulations issued by the tri-Departments on December 13, 2006 (2006 HIPAA regulations) set forth eight health status-related factors.). 71 FR 75014 (Dec. 13, 2006). Under HIPAA and the 2006 HIPAA regulations, as well as under PHS Act section 2705 (as added by the Affordable Care Act), the eight health factors are: health status, medical condition (including both physical and mental illnesses), claims experience, receipt of health care, medical history, genetic information, evidence of insurability (including conditions arising out of acts of domestic violence), and disability.

[24] Under the 2006 HIPAA regulations issued by the tri-Departments, the total incentive available under a wellness program that conditioned a reward on satisfying a standard related to a health factor could not exceed 20 percent of the total cost of coverage. Under the 2013 tri-Department regulations, which reflect amendments made by the Affordable Care Act that raised the limit, the total incentive available under a wellness program that conditions a reward on satisfying a standard related to a health factor cannot exceed 30 percent of the total cost of coverage (50 percent for programs designed to prevent or reduce tobacco use). *See* 2006 HIPAA regulations; *see also* 26 CFR 54.9802-1(f); 29 CFR 2590.702(f); 45 CFR 146.121(f).

[25] *See* 78 FR 33158 (June 3, 2013) (codified at 26 CFR 54.9802-1; 29 CFR 2590.702; 45 CFR 146.121 and 147.110).

[26] *See* 26 CFR 54.9802-1(f); 29 CFR 2590.702(f); 45 CFR 146.121(f).

[27] *See* n.11, *supra*.

[28] The preamble to the 2013 HIPAA regulations states: "Availability regardless of health status ensures that the general prohibition against discrimination based on a health factor is not implicated." Accordingly, where "there is no discrimination based on a health factor under HIPAA, the wellness exception [to that prohibition] is not relevant." 78 FR 33161 (June 3, 2013). Note that participatory wellness programs, but generally not health-contingent wellness programs, are permitted in the individual health insurance market.

[29] If, in addition to the employee, any class of dependents (such as spouses, or spouses and dependent children) may participate in the health-contingent wellness program, the reward cannot exceed 30 percent of the total cost of the coverage in which the employee and any dependents are enrolled (such as family coverage or employee-plus one coverage).

[30] As defined by the tri-Departments, for activity-only programs, a reasonable alternative standard (or waiver of the otherwise applicable standard) must be offered to any individual for whom it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard, or for whom it is medically inadvisable to attempt to satisfy the otherwise applicable standard. For outcome-based programs, the reasonable alternative standard (or waiver of the otherwise applicable standard) must be offered to any individual who does not meet the initial standard based on the measurement, test or screening. Examples of "reasonable alternative standards" include completion of an educational course, participation in a diet program, or meeting a standard that accommodates the recommendations of the individual's personal physician with regard to medical appropriateness. *See* HIPAA and the Affordable Care Act Wellness Requirements at: **https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/publications/caghipaaandaca.pdf (https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/publications/caghipaaandaca.pdf)** .

[31] Although the five requirements for health-contingent programs generally are the same for activity-only wellness programs and outcome-based wellness programs under the 2013 HIPAA regulations, there are some differences. For the requirements applicable to activity-only programs, see 26 CFR 54.9802-1(f)(3), 29 CFR 2590.702(f)(3), and 45 CFR 146.121(f)(3). For requirements applicable to outcome-based programs, see 26 CFR 54.9802-1(f)(4), 29 CFR 2590.702(f)(4), and 45 CFR 146.121(f)(4).

[32] *See* 78 FR at 33168. ("The Departments recognize that many other laws may regulate plans and issuers in their provision of benefits to participants and beneficiaries. These laws include, but are not limited to, the ADA, Title VII of the Civil Rights Act of 1964, Code section 105(h) and PHS Act section 2716 (prohibiting discrimination in favor of highly compensated individuals), the Genetic Information Nondiscrimination Act of 2008, the Family and Medical Leave Act, ERISA's fiduciary provisions, and State law."). A publication issued by the tri-Departments also explains that the fact that a wellness program complies with the tri-Department wellness program regulations does not necessarily mean it complies with any other provision of the PHS Act, the Code, ERISA (including the Consolidated Omnibus Budget Reconciliation Act (COBRA) continuation provisions), or any other state or federal law, such as the ADA or the privacy and security obligations of HIPAA. Similarly, the fact that a wellness program meets the requirements of the ADA is not determinative of compliance with the PHS Act, ERISA, or the Code. *See* DOL – Employee Benefits Security Administration, FAQs About Affordable Care Act Implementation (Part XXV), **http://www.dol.gov/ebsa/faqs/faq-aca25.html (http://www.dol.gov/ebsa/faqs/faq-aca25.html)** and HHS – Centers for Medicare & Medicaid Services, FAQs About Affordable Care Act Implementation (Part XXV), **https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Tri-agency-Wellness-FAQS-4-16-15pdf-**

AdobeAcrobat-Pro.pdf (https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Tri-agency-Wellness-FAQS-4-16-15pdf-AdobeAcrobat-Pro.pdf) .

[33] *See* Pub. L. 104-191. HIPAA amended the Code, ERISA, and PHS Act to provide improved portability and continuity of health coverage and states that: "[T]he HIPAA nondiscrimination provisions do not prevent a plan or issuer from establishing discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention." *Id.* at sec. 702(b)(2)(B). The interim rule issued by the tri-Departments in 1997 included an example illustrating a wellness program that rewarded plan participants for achieving certain health outcomes. In the example, the program offered an unspecified premium discount to participants who, after six weeks, achieved a cholesterol level of under 200. The rule stated that, in this example, giving a discount only to participants who achieved the target level would discriminate against participants who otherwise complied with the program but were unable to meet the target due to a health-related status factor. *See* Interim Rules for Health Insurance Portability, 62 FR 16894 (Apr. 8, 1997) at 16939.

[34] *See* Notice of Proposed Rulemaking for Bona Fide Wellness Programs at *https://www.federalregister.gov/documents/2001/01/08/01-107/notice-of-proposed-rulemaking-for-bona-fide-wellness-programs*.

[35] *See* Guidance, n.7, *supra.*

[36] *Id.* at Q&A 22.

[37] Although AARP does not dispute that some level of incentives may be permissible under the ADA and GINA, it argued that "the EEOC did not adequately justify reversal of its longstanding policy [stated in the inquiries and examinations guidance] that prohibited the use of incentives." *AARP v. EEOC*, 267 F. Supp. 3d 14, 29 (D.D.C. 2017). *See also* n.45, *infra.*

[38] *See* n.24, *supra.*

[39] *See* n.18, *supra.*

[40] That correspondence, which was issued in response to a letter from a stakeholder, was rescinded at the beginning of the new administration in 2009.

[41] *See, e.g.,* Letter from the ERISA Industry Committee to the EEOC (February 17, 2012) available at **http://www.eeoc.gov/eeoc/meetings/5-8-13/moore.cfm (http://www.eeoc.gov/eeoc/meetings/5-8-13/moore.cfm)** (attachment to written testimony). Online reports have raised the same concern. *See, e.g.*, Tower Watson, Health Care Reform Bulletin (Oct. 2011). Two panelists also raised this question during a May 2013 Commission meeting on Wellness Programs. *See* Written Testimony of Leslie Silverman available at **http://www.eeoc.gov/eeoc/meetings/5-8-13/silverman.cfm (http://www.eeoc.gov/eeoc/meetings/5-8-13/silverman.cfm)** and Written Testimony of Amy Moore available at **http://www.eeoc.gov/eeoc/meetings/5-8-13/moore.cfm (http://www.eeoc.gov/eeoc/meetings/5-8-13/moore.cfm)** .

[42] *See* n.32, *supra.*

[43] The safe harbor is part of 42 U.S.C. 12201 and 29 CFR 1630.16, which carve out a range of exceptions to otherwise applicable ADA rules to permit certain specified activities. The safe harbor allows certain insurance-related practices such as underwriting, administering, and classifying risks where not inconsistent with state law and not used as a subterfuge to evade the purposes of the ADA. 42 U.S.C. 12201(c); 29 CFR 1630.16(f).

[44] In the third case, EEOC sought a temporary restraining order to enjoin a company from continuing a wellness program that required participants in the group health plan and their covered spouses to undergo biometric screenings and refrain from tobacco use (or complete a tobacco cessation program) to avoid a surcharge. *See EEOC v. Honeywell Int'l, Inc.*, 2014 WL 5795481 (D.Minn. Nov. 6, 2014) (denying EEOC's request on the grounds that it had not shown a threat of irreparable harm). This case later was voluntarily dismissed.

[45] Citing to dictionary definitions, the court in AARP similarly reasoned that because "[t]he exact meaning of the term 'voluntary' in the [ADA and GINA] statues is ambiguous: voluntary could mean something along the lines of 'free from coercion,' or it could mean 'without valuable consideration.'" The court concluded that, in defining "voluntary" to permit a 30 percent incentive, the EEOC "has clearly chosen an interpretation consistent with the former, rather than the latter, understanding of the term." *AARP v. EEOC*, 267 F. Supp. 3d 14, 28 (D.D.C. 2017).

[46] Not everyone who testified at, or submitted comments following, the meeting was in favor of incentives. For example, the Director of Programs for the Bazelon Center for Mental Health testified that: "If a wellness program imposes financial penalties for not participating in the program, the program is not voluntary. Similarly, the program is not voluntary if individuals who choose not to participate are denied financial rewards." *See* ***https://www1.eeoc.gov//eeoc/meetings/5-8-13/mathis.cfm?renderforprint=1*** **(https://www1.eeoc.gov/eeoc/meetings/5-8-13/mathis.cfm?renderforprint=1)** .

In its statement submitted to the official record following the meeting, AARP stated:

> It is one thing if an employer gives out *de minim[i]s* rewards, such as a $10 gift card to everyone attending a health fair, or an iPod prize to employees who participate in a workplace fitness program and meet their weight loss goals. However, when it comes to an employer imposing higher premiums/copays/deductibles for health coverage, or denying discounts on those costs, based on nonparticipation or lack of achievement of particular health outcomes, the EEOC should make it clear that the program crosses the line into significant differences in employee compensation and benefits and other terms, conditions, and privileges of employment. This would be the case whether those differences amount to 5%, 10%, up to 20% as before under HIPAA, or up to 30% and even 50% as now permitted under

prima facie evidence of unlawful discrimination and should be scrutinized. In this vein, it would be extremely helpful if the Commission's guidance could elaborate upon the **definition of what constitutes "voluntary" participation.**

Statement by AARP dated May 8, 2013, Official Record of May 2013 Commission Meeting.

[47] For example, when it filed its own public comments on the EEOC's proposed rule, AARP stated that it had no objection to wellness programs that offer de minimis rewards such as gift cards or small electronics as an incentive to encourage employees to participate in health risk assessments, screenings, or other wellness program components but objected to rewards or penalties tied to the cost of health insurance and services.

[48] *See* discussion under *Lawsuits Challenging Wellness Programs, supra* at IV.B.

[49] The final ADA rule was issued on the same day as a final rule under GINA that described the incentives an employer could offer to an employee whose spouse provided information about the spouse's manifestation of disease or disorder as part of a wellness program. *See* 81 FR 31143 (May 17, 2016).

[50] A report by the Kaiser Family Foundation found that "building a better [wellness] program is almost as effective" at increasing participation in wellness programs as offering financial incentives. Pollitz and Rae, Kaiser Report, *supra* n.4. Thus, it is reasonable to assume that a wellness program that offers only a de minimis incentive will only draw significant participation if those to whom it is offered believe it will provide something of value.

[51] The Commission also received several comments on the 2015 proposed rule indicating that the ADA notice requirement was duplicative of existing law, while others asked the Commission to provide model language that would meet the necessary requirements. Thus, the Commission clarified in the 2016 rule that employers that already use written notifications that satisfied the notice requirement did not have to provide a separate ADA notice. *See* Questions and Answers: Sample Notice for Employees Regarding Employer Wellness Programs, Question 1, **https://www.eeoc.gov/laws/regulations/qanda-ada-wellness-notice.cfm (https://www.eeoc.gov/laws/regulations/qanda-ada-wellness-notice.cfm)** .

[52] 42 U.S.C. § 2000ff-1(a) & (b).

[53] 42 U.S.C. § 12112(d)(4)(B).

[54] Two commenters on the 2015 proposed rule stated that the EEOC lacks authority to interpret the ADA's safe harbor provision because it is in Title V of the ADA. In the final rule, the Commission noted that it does have such authority because the express terms of the safe harbor provision reference Title I through IV of the ADA. *See* 81 FR at 31130.

[55] Some of these factors are similar to those the court considered in *Seff v. Broward County*, 778 F. Supp. 2d 1370, 1373 (M.D. Fla. 2011), *aff'd*, 691 F.3d 1221 (11th Cir. 2012), when it determined that a wellness program that included a surcharge for non-participating employees was a "term" of the employer's health plan. The court found that the insurer administered the wellness program under its contract with the county; only plan enrollees were eligible to participate in the wellness program; and the program was communicated to enrollees in plan materials. In the preamble to the 2016 rule, the Commission discussed *Seff* at some length, criticizing its rationale for applying the ADA's safe harbor provision to a wellness program that imposed a $20 surcharge every two weeks on employees who did not provide health information as part of a participatory wellness program. *See* 81 FR at 31131. We continue to believe that the safe harbor is inapplicable to the type of wellness program at issue in that case because it was a participatory program but agree that the factors the court considered are helpful in determining when a wellness program is part of a health plan for ADA purposes.

[56] *See* International Risk Management Institute, Inc., **https://www.irmi.com/term/insurance-definitions/underwriting (https://www.irmi.com/term/insurance-definitions/underwriting)** (defining "underwriting" as "the process of determining whether to accept a risk and, if so, what amount of insurance the company will write on the accepted risk, and at what rate").

[57] *See also* American Academy of Actuaries Statement of Principles, **http://www.actuarialstandardsboard.org/wp-content/uploads/2014/07/riskclassificationSOP.pdf (http://www.actuarialstandardsboard.org/wp-content/uploads/2014/07/riskclassificationSOP.pdf)**

(defining "risk classification" as "[t]he grouping of risks with similar risk characteristics for the purpose of setting prices").

[58] *See* 78 FR 33160 (June 3, 2013). The Commission notes that, under the Affordable Care Act, when an individual's physician states that such a program standard is not medically appropriate, the plan or issuer must provide a reasonable alternative standard that accommodates the physician's recommendations with regard to medical appropriateness. The reasonable alternative standard requirement ensures that a program is reasonably designed to improve health and is not a subterfuge for discriminating against an individual based on a health factor.

[59] *See* The Shift Away from Health Risk Assessments, **https://www.fbabenefits.com/1515-2/ (https://www.fbabenefits.com/1515-2/)** (Nov. 30, 2016).

[60] In a year and a half study of employee wellness programs at a wholesale retailer, program participants reported significantly better health behaviors (*e.g.*, routine exercise and weight management), but the study found no significant improvement in employer health care savings, employee health outcomes, or health care utilization. The study also found that participation in wellness programs had no significant impact on

employee absenteeism, work performance, or tenure. *See* Zirui Song & Katherine Baicker*, Effect of a Workplace Wellness Program on Employee Health and Economic Outcomes: A Randomized Clinical Trial*, 321(15) JAMA 1491, 1497-1499 (2019).

[61] An "insured" group health plan is a health plan where the benefits are provided through insurance policies or contracts that are purchased from an insurance company or other organization, such as a health maintenance organization. By contrast, a "self-insured" group health plan is a health plan where the employer directly assumes the liability for employees' health claims costs. Private employment-based group health plans that are insured are regulated by both ERISA (the plan) and state law (the health insurance issuer). Self-insured group health plans, however, typically are subject to ERISA but are not subject to state laws that regulate insurance.

[62] Executive Order No. 13563, 3 CFR 215 (2011), available at **https://www.govinfo.gov/content/pkg/CFR-2012-title3-vol1/pdf/CFR-2012-title3-vol1-eo13563.pdf (https://www.govinfo.gov/content/pkg/CFR-2012-title3-vol1/pdf/CFR-2012-title3-vol1-eo13563.pdf)**

[63] Executive Order No. 12866, 3 CFR 638 (1993), available at available at **https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf (https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf)**

[64] *See*, *e.g.*, **https://www.eeoc.gov/laws/types/disability.cfm (https://www.eeoc.gov/laws/types/disability.cfm)** for documents explaining Title I of the ADA.

[65]*See* Data by Enterprise Employment Size, US and states, totals at **https://www.census.gov/data/tables/2016/econ/susb/2016-susb-annual.html (https://www.census.gov/data/tables/2016/econ/susb/2016-susb-annual.html)** (Year 2016, total number of firms minus those with fewer than 10 employees, equals 1,275,624 firms. No figure is available for employers with 11-15 employees, so we have used approximate figures).

[66] *See* Rand Final Report, *supra* note 10. *See also* 2019 Kaiser Survey, **https://www.kff.org/report-section/ehbs-2019-section-12-health-and-wellness-programs/ (https://www.kff.org/report-section/ehbs-2019-section-12-health-and-wellness-programs/)** . According to the RAND Final Report, "approximately half of U.S. employers offer wellness promotion initiatives." By contrast, the Kaiser Survey indicates that 50 percent of small employers and 84 percent of large employers offer at least one program in smoking cessation, weight management, or behavioral or lifestyle coaching.

[67] *See* 2019 Kaiser Survey, **https://www.kff.org/report-section/ehbs-2019-section-12-health-and-wellness-programs/ (https://www.kff.org/report-section/ehbs-2019-section-12-health-and-wellness-programs/)** . Among employers offering health benefits, 50 percent of large employers that ask employees to complete a health risk assessment offer an incentive, while 58 percent offer an incentive to employees to complete biometric screening.

[68] There are numerous reports detailing the typical ratio of full-time human resources (HR) employees to employees in an organization. Known as the HR-to-employee ratio, this number compares HR staffing levels between organizations by showing the number of HR full time employees supporting 100 full time employees in an organization. *See*, *e.g*., SHRM, How Organizational Staff Size Influences HR Metrics available at **https://www.shrm.org/ResourcesAndTools/business-solutions/Documents/Organizational%20Staff%20Size.pdf (https://www.shrm.org/ResourcesAndTools/business-solutions/Documents/Organizational%20Staff%20Size.pdf)** . According to SHRM, in 2014 the average HR-to-employee ratio was 2.57. We are not, however, aware of any recent specific data on the average number of HR professionals per covered employer and have therefore based our estimate on a SHRM report from 2009 which found that the median number of full-time equivalents for a HR department was three. *See* SHRM Human Capital Benchmarking Study, 2009 Executive Summary available at **https://www.shrm.org/Research/SurveyFindings/Articles/Documents/09-0620_Human_Cap_Benchmark_FULL_FNL.pdf (https://www.shrm.org/Research/SurveyFindings/Articles/Documents/09-0620_Human_Cap_Benchmark_FULL_FNL.pdf)** .

[69] HIPAA Privacy and Security and Workplace Wellness Programs, available at **https://www.hhs.gov/hipaa/for-professionals/privacy/workplace-wellness/index.html (https://www.hhs.gov/hipaa/for-professionals/privacy/workplace-wellness/index.html)** .

[70] This approach includes adequately separating the activities of employees who administer plan functions and those who do not, and where electronic PHI is involved, implementing reasonable and appropriate administrative, technical, and physical safeguards to protect the information, including by ensuring that there are firewalls or other security measures in place to support the required separation between plan administration and employment functions; and reporting to the group health plan any unauthorized use or disclosure, or other security incident, of which it becomes aware.