EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1630

RIN 3046-AB01

Amendments to Regulations under the Americans with Disabilities Act

AGENCY: Equal Employment Opportunity Commission.

ACTION: Proposed rule.

SUMMARY: The Equal Employment Opportunity Commission ("EEOC" or "Commission") is issuing a proposed rule that would amend the regulations and interpretive guidance implementing Title I of the Americans with Disabilities Act (ADA) as they relate to employer wellness programs. The proposed rule amends the ADA regulations to provide guidance on the extent to which employers may use incentives to encourage employees to participate in wellness programs that include disability-related inquiries and/or medical examinations.

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

ADDRESSES: You may submit comments, identified by RIN number 3046-AB01, by any of the following methods:

- Federal eRulemaking Portal: 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) 663-4070 (voice) or (202) 663-4074 (TTY). (These are not toll free numbers).
- Mail: Bernadette B. Wilson, 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: Bernadette Wilson, 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, 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. 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 60 days after publication in the Federal Register] until the Commission publishes the rule in final form.

FOR FURTHER INFORMATION CONTACT: Christopher J. Kuczynski, Assistant Legal Counsel, (202) 663-4665, or Joyce Walker-Jones, Senior Attorney Advisor, at (202) 663-7031,

or (202) 663-7026 (TTY), Office of Legal Counsel, U.S. Equal Employment Opportunity Commission. (These are not toll free numbers.) Requests for this notice in an alternative format should be made to the Office of Communications and Legislative Affairs at (202) 663-4191 (voice) or (202) 663-4494 (TTY). (These are not toll free numbers.)

SUPPLEMENTARY INFORMATION:

Introduction

The Equal Employment Opportunity Commission ("EEOC" or "Commission") is issuing a proposed rule that would amend the regulations and interpretive guidance implementing Title I of the Americans with Disabilities Act (ADA) as they relate to employer wellness programs. Congress enacted the ADA in 1990 to prohibit discrimination against individuals with disabilities. The EEOC issued implementing regulations in 1991 to provide additional guidance on the law's requirements and prohibited practices with respect to employment.[1] This proposed rule provides guidance on the extent to which the ADA permits employers to offer incentives to employees to promote participation in wellness programs that are employee health programs.[2] It does not apply to similar types of programs that may be provided by entities other than those

[1] The citations in this proposed rule are to the 2011 regulations. In 2011, EEOC issued amended regulations to revise the definition of disability and other provisions to conform to changes to the ADA made by the ADA Amendments Act of 2008, but did not amend the provisions concerning disability-related inquiries and medical examinations of employees at 29 CFR 1630.14 that affect employee health programs. Some of the other revisions, however, resulted in renumbering.

[2] The ADA provides that, "[a] covered entity may conduct voluntary medical examinations and inquiries, including voluntary medical histories, which are part of an employee health program available to employees at that work site." 42 U.S.C. 12112(d)(4)(B)(emphasis added). As referenced in this proposed rule, wellness programs are "employee health programs."

subject to Title I of the ADA, such as social service agencies covered under Title II of the ADA, 42 U.S.C. 12131 et seq., or places of public accommodation subject to Title III of the ADA, 42 U.S.C. 12181 et seq., who may provide similar programs to individuals who are considered volunteers.[3]

A wellness program may be part of a group health plan or may be offered outside of a group health plan.[4] The references in the proposed rule regarding the requirement to provide a notice and the use of incentives, and changes to the corresponding section of the interpretive guidance, apply only to wellness programs that are part of or provided by a group health plan or by a health insurance issuer offering group health insurance in connection with a group health plan. [5] The term "group health plan" includes both insured and self-insured group health plans and is used interchangeably with the term "health plan" throughout the preamble. All of the other proposed changes to the regulations apply to all "health programs," which include wellness programs whether or not they are offered as part of or outside of a group health plan or group health insurance coverage. The term "incentives" includes both financial and in-kind incentives, such as time-off awards, prizes, or other items of value.

[3] This proposed rule also does not address the extent to which Title II of the Genetic Information Nondiscrimination Act (GINA) of 2008, 42 U.S.C. 2000ff, et seq., affects an employer's ability to condition incentives on a family member's participation in a wellness program. This issue will be addressed in future EEOC rulemaking.

[4] The term "group health plan" is defined in ERISA section 733(a). An employer may establish or maintain more than one group health plan.

[5] This proposed rule asks for comments on whether employers offer (or are likely to offer in the future) wellness programs outside of a group health plan or group health insurance coverage that use incentives to promote participation in such programs or to encourage employees to achieve certain health outcomes and whether EEOC should issue regulations specifically limiting incentives provided as part of such programs.

Discussion

As a means of attempting to improve employees' health and reduce health care costs, many employers that provide health coverage also offer employee health programs and activities to promote healthier lifestyles or prevent disease.[6] Commonly referred to as workplace wellness programs, these programs may include, for example: nutrition classes, onsite exercise facilities, weight loss and smoking cessation programs, and/or coaching to help employees meet health goals. Wellness programs also may incorporate health risk assessments and biometric screenings that measure an employee's health risk factors, such as body weight and cholesterol, blood glucose, and blood pressure levels.[7] Some employers offer incentives to encourage employees simply to participate in a wellness program, while others offer incentives based on whether employees achieve certain health outcomes.[8] Incentives can be framed as rewards or penalties and often take the form of prizes, cash, or a reduction or increase in health care premiums or cost sharing. Of the employers who offer incentives to complete wellness programs, the majority use incentives totaling less than $500 per year.[9]

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[6] *See* Rand Health, Workplace Wellness Programs Study Final Report (2013), sponsored by the U.S. Departments of Labor and Health and Human Services, available at http://www.rand.org/content/dam/rand/pubs/research_reports/RR200/RR254/RAND_RR254.pdf [hereinafter referred to as the RAND Final Report]; see also The Kaiser Family Foundation and Health Research & Educational Trust 2014 Employer Health Benefits Survey, available at http://kff.org/health-costs/report/2014-employer-health-benefits-survey/ [hereinafter referred to as the Kaiser Survey].

[7] Id.

[8] According to the RAND Final Report, 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 Kaiser Survey found that 36 percent of large employers with 200 or more employees and 18 percent of smaller employers offer financial incentives to participate in a wellness program.

[9] According to the Kaiser Survey, 68 percent of all large firms that offered an incentive for the completion of a wellness program used a maximum incentive below $500.

Employee health programs offered by employers must comply with laws enforced by the EEOC, including Title I of the Americans with Disabilities Act (ADA) which restricts the medical information employers may obtain from applicants and employees and makes it illegal to discriminate against individuals based on disability.[10] They also must comply with other laws EEOC enforces that prohibit discrimination based on race, color, sex (including pregnancy), national origin, religion, compensation, age, or genetic information.[11] Additionally, wellness programs that are part of group health plans must comply with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Patient Protection and Affordable Care Act ("Affordable Care Act")[12] -- set forth in regulations jointly issued by the Department of Labor (DOL), Department of the Treasury, and Department of

[10] 42 U.S.C. 12101 et seq.

[11] See 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 (ADEA) of 1967, 29 U.S.C. 621 et seq.; and Title II of GINA. However, this proposed rule concerns only the application of the ADA's rules limiting disability-related inquiries and medical examinations of employees 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 accompanying the proposed rule explains, even if an employer's wellness program complies with the incentive limits set forth in the ADA regulations, the employer violates Title VII or the ADEA if that program discriminates on the basis of race, sex, national origin, or age.

[12] The Patient Protection and Affordable Care Act, Pub. L. 111-148, and the Health Care and Education Reconciliation Act, Pub. L. 111-152, are known collectively as the Affordable Care Act. Section 1201 of the Affordable Care Act amended and moved the nondiscrimination and wellness provisions of the Public Health Service (PHS) Act from section 2702 to section 2705, and extended the nondiscrimination provisions to the individual market. The Affordable Care Act also added section 715(a)(1) to ERISA and section 9815(a)(1) to the 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.

Health and Human Services (HHS) -- that generally prohibit discrimination in group health plans based on any health factor.[13]

The laws relevant to this proposed rule are discussed below.

HIPAA's Nondiscrimination Provisions

HIPAA's nondiscrimination provisions, as amended by the Affordable Care Act, generally prohibit group health plans and health insurance issuers offering group health insurance in connection with a group health plan from discriminating against participants and beneficiaries in premiums, benefits, or eligibility based on a health factor.[14] An exception to the general rule allows premium discounts or rebates or modification to otherwise applicable cost sharing (including copayments, deductibles, or coinsurance) in return for adherence to certain programs of health promotion and disease prevention.[15]

[13] A wellness program that is part of a group health plan also must comply with HIPAA's Privacy, Security, and Breach Notification requirements set forth at 45 CFR part 160 and part 164. These requirements are discussed later in this preamble.

[14] The HIPAA nondiscrimination provisions set forth eight health status-related factors, which the December 13, 2006 final regulations refer to as ''health factors.'' Under HIPAA and the 2006 regulations, as well as under the Public Health Service (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. 71 FR 75014 (Dec. 13, 2006). In the view of the Departments of Labor, HHS, and the Treasury, "[t]hese terms are largely overlapping and, in combination, include any factor related to an individual's health." 66 FR 1379 (January 8, 2001).

[15] Prior to the enactment of the Affordable Care Act, HIPAA added section 9802 of the Internal Revenue Code, section 702 of the Employee Retirement Income Security Act (ERISA), and section 2702 of the PHS Act. DOL, Treasury, and HHS issued joint final regulations in 2006 regarding wellness programs in connection with a group health plan or group health insurance coverage under which any of the conditions for obtaining a reward is based on satisfying a standard related to a health factor. See 26 CFR 54.9802-1(f); 29 CFR 2590.702(f); 45 CFR 146.121(f). Paragraph (f)(2) of the 2006 regulations limited the total reward for such wellness programs to 20 percent of the total cost of coverage under the plan. The Affordable Care Act amended the PHS Act to raise the limitation on incentives to 30 percent of the total

HIPAA's nondiscrimination provisions, as amended by the Affordable Care Act, and the 2013 final regulations issued by the Departments of Labor, Treasury, and HHS, discuss two types of wellness programs: participatory and health-contingent. Participatory wellness programs either do not provide a reward or do not include any conditions for obtaining a reward that are based on an individual satisfying a standard related to a health factor. Examples in the final regulations include: a program that reimburses employees for all or part of the cost for membership in a fitness center; a program that reimburses employees for the costs of participating, or that otherwise provides a reward for participating, in a smoking cessation program without regard to whether the employee quits smoking; and a program that provides a reward to employees who complete a health risk assessment (HRA) regarding current health status, without any further action (educational or otherwise) required by the employee with regard to the health issues identified as part of the assessment. The 2013 final regulations state that participatory wellness programs are permissible under the HIPAA nondiscrimination requirements provided they are made available to all similarly situated individuals.

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 based on a health factor in order to obtain the same reward). Activity-only programs require individuals to perform or complete an activity related to a health factor in order to obtain a reward, but do not

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cost of coverage under the plan. See PHS Act section 2705(j)(3)(A). The DOL, IRS, and HHS issued final regulations in June 2013 to implement PHS Act section 2705 and amend the 2006 HIPAA regulations regarding nondiscriminatory wellness programs in group health coverage. 78 FR 33158 (June 3, 2013). Under the 2013 final regulations on nondiscriminatory wellness programs, references to "a plan providing a reward include both providing 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 imposing a penalty (such as a surcharge or other financial or nonfinancial disincentive)."

require an individual to attain or maintain a specific health outcome. Outcome-based programs require individuals to attain or maintain a specific health outcome (such as not smoking or attaining certain results on biometric screenings) in order to obtain a reward.

There are five requirements for health-contingent wellness programs under the Public Health Service (PHS) Act section 2705 and the 2013 final regulations.[16] First, all individuals eligible for a health-contingent wellness program must be given the opportunity to qualify for the reward at least once per year. Second, the total reward offered to an individual under all health-contingent wellness programs with respect to a plan cannot exceed 30 percent of the total cost of employee-only coverage under the plan, including both employee and employer contributions towards the cost of coverage (or 50 percent to the extent that the additional percentage is attributed to tobacco prevention or reduction). Third, health-contingent wellness programs must be reasonably designed to promote health or prevent disease. Fourth, the full reward under a health-contingent wellness program must be available to all similarly situated individuals. For this purpose, an activity-only program must allow a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard, and for any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard. An outcome-based program must allow a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward to any individual who does not meet the initial standard based on a measurement, test, or screening. Fifth, plans and issuers must disclose the availability of a reasonable alternative

[16] 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).

standard to qualify for the reward in all plan materials describing the terms of a health-contingent wellness program and in any disclosure that an individual did not satisfy an initial outcome-based standard.

The 2013 final regulations recognize that compliance with HIPAA 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 (Title VII), and the Genetic Information Nondiscrimination Act (GINA).[17]

Title I of the ADA

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."[18] The ADA also requires employers to provide reasonable

[17] 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.").

[18] See 42 U.S.C. 12112(a) and 29 CFR 1630.4(a)(1)(vi). Title I of the ADA applies to individuals and covered entities other than employees and employers, including employment agencies, labor organizations, and joint-labor management committees. See 42 U.S.C. 12111(2), 12111(4), 12111(5), and 12112(b) (describing the prohibited practices of each of these entities); see also 29 CFR 1630.2(b) (definition of covered entity) and 29 CFR 1630.4(a)(1) (description of prohibited practices). Although employers generally will be the ADA covered entities that offer wellness programs, this preamble, the proposed rule, and the interpretive guidance accompanying the proposed rule frequently use the term "covered entity," as that term appears throughout EEOC's entire ADA regulation. The term "covered entity" also has a different meaning for purposes of the HIPAA Privacy, Security, and Breach Notification Rules, as explained later in this preamble. The proposed rule uses the term "HIPAA covered entity" when discussing HIPAA privacy requirements that apply to the group health plan.

accommodations (modifications or adjustments) to enable individuals with disabilities to have equal access to the fringe benefits offered to individuals without disabilities.[19] Additionally, the ADA restricts employers from obtaining medical information from employees by generally prohibiting them from making disability-related inquiries or requiring medical examinations.[20] The statute, however, provides an exception to this rule by stating that "[a] covered entity may conduct voluntary medical examinations, including voluntary medical histories, which are part of an employee health program available to employees at that work site."[21] Employee health programs include workplace wellness programs. In previous guidance on disability-related inquiries and medical examinations under the ADA, EEOC stated that: "A wellness program is 'voluntary' as long as an employer neither requires participation nor penalizes employees who do not participate."[22] However, neither the statute nor EEOC's regulations address the extent to which incentives might affect the voluntary nature of a wellness program.

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[19] 42 U.S.C. 12112(b)(5)(A) and 29 CFR 1630.9 (prohibiting covered entity from failing to provide reasonable accommodations absent undue hardship); 29 CFR 1630.2(o)(1)(iii) (reasonable accommodation includes modifications and adjustments that enable a covered entity's employees to enjoy "equal benefits and privileges of employment.")

[20] 42 U.S.C. 12112(d)(4)(A) (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."). EEOC refers to the types of inquiries prohibited by the ADA as "disability-related inquiries" and has issued guidance on what constitutes such an inquiry. See Enforcement Guidance on Disability-Related Inquiries and Medical Examinations of Employees Under the Americans with Disabilities Act, Q&A 1 (July 27, 2000), available at http://www.eeoc.gov/policy/docs/guidance-inquiries.html (hereafter "Guidance").

[21] 42 U.S.C. 12112(d)(4)(B).

[22] See Guidance, at Q&A 22.

The Interaction of Title I of the ADA and HIPAA's Nondiscrimination Provisions, as Amended by the Affordable Care Act

The Commission's interpretation of the term "voluntary" in the ADA's disability-related inquiries and medical examinations provision is central to the interaction between the ADA and HIPAA's wellness program provisions, as amended by the Affordable Care Act. A plausible reading of "voluntary" in isolation is that covered entities can only offer de minimis rewards or penalties to employees for their participation (or nonparticipation) in wellness programs that include disability-related inquiries and medical examinations. That reading, however, would make many wellness program incentives tied to the disclosure of health information or the completion of medical examinations expressly permitted by HIPAA impermissible under the ADA. Although it is clear that compliance with the standards in HIPAA is not determinative of compliance with the ADA,[23] the Commission believes that it has a responsibility to interpret the ADA in a manner that reflects both the ADA's goal of limiting employer access to medical information and HIPAA's and the Affordable Care Act's provisions promoting wellness programs.

Accordingly, the Commission concludes that allowing certain incentives related to wellness programs, while limiting them to prevent economic coercion that could render provision of medical information involuntary, is the best way to effectuate the purposes of the wellness program provisions of both laws.[24] One purpose of the ADA's provision applicable to

[23] See 78 FR at 33168 (noting that HIPAA compliance is not determinative of ADA compliance); see also PHS Act section 2705(j)(3)(A) (noting that wellness programs complying with the HIPAA requirements "shall not violate this section" of the Act).

[24] The Commission does not believe that the ADA's "safe harbor" provision applicable to insurance, as interpreted by the court in Seff v. Broward County, 778 F. Supp. 2d 1370 (S.D. Fla. 2011), affirmed, 691 F.3d 1221 (11th Cir. 2012), is the proper basis for finding wellness program incentives permissible. The

employee health programs is to allow such programs access to medical information where employees voluntarily provide that information.[25] One purpose of HIPAA's nondiscrimination provisions governing wellness programs is to ensure that wellness programs do not offer incentives so large as to have the effect of denying coverage or creating too heavy a financial penalty for individuals who do not meet certain health standards.[26] HIPAA's nondiscrimination provisions governing wellness programs, however, do not include provisions like those in the ADA that limit the kinds of medical information employers may ask employees to provide through disability-related inquiries or medical examinations.

The proposed rule explains what an employee health program is, what it means for an employee health program to be voluntary, what incentives employers may offer as part of a voluntary employee health program, and what requirements apply concerning notice and confidentiality of medical information obtained as part of voluntary employee health programs. In addition, the proposed rule explains that compliance with rules concerning voluntary employee health programs does not ensure compliance with all the antidiscrimination laws EEOC enforces.

The proposed rule clarifies that an employer may offer limited incentives up to a maximum of 30 percent of the total cost of employee-only coverage, whether in the form of a

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ADA contains a clear "safe harbor" for wellness programs – the "voluntary" provision at 42 U.S.C. 12112(d)(4)(B). See H.R. Rep. 101-485, pt. 2, at 51 ("A growing number of employers today are offering voluntary wellness programs in the workplace. These programs often include medical screening for high blood pressure, weight control, cancer detection, and the like. As long as the programs are voluntary and the medical records are maintained in a confidential manner and not used for the purpose of limiting health insurance eligibility or of preventing occupational advancement, these activities would fall within the purview of accepted activities."). Reading the insurance safe harbor as exempting these programs from coverage would render the "voluntary" provision superfluous.

[25] See id. at H.R. Rep. 101-485, pt. 2, at 51.

[26] 71 Fed. Reg. 75014, 75018 (December 13, 2006).

reward or penalty, to promote an employee's participation in a wellness program that includes disability-related inquiries or medical examinations as long as participation is voluntary. As noted below, EEOC seeks comment on whether additional protections for low-income employees are needed. Voluntary means that a covered entity: (1) does not require employees to participate; (2) does not deny coverage under any of its group health plans or particular benefits packages within a group health plan for non-participation or limit the extent of such coverage (except pursuant to allowed incentives); and (3) does not take any adverse employment action or retaliate against, interfere with, coerce, intimidate, or threaten employees within the meaning of Section 503 of the ADA, at 42 U.S.C. 12203.

Further, to ensure that participation in a wellness program that includes disability-related inquiries and/or medical examinations, and that is part of a group health plan, is truly voluntary, an employer must provide a notice that clearly explains what medical information will be obtained, who will receive the medical information, how the medical information will be used, the restrictions on its disclosure, and the methods the covered entity will employ to prevent improper disclosure of the medical information. Finally, the proposed rule allows the disclosure of medical information obtained by wellness programs to employers only in aggregate form, except as needed to administer the health plan. The proposed rule does not implicate disability-related inquiries or medical examinations outside the context of a voluntary wellness program.

Summary of Proposed Revisions

The proposed rule re-asserts the Commission's position, based on the language of the ADA, that employee health programs that include disability-related inquiries or medical examinations (including inquiries or medical examinations that are part of a HRA or medical

history) must be voluntary and clarifies the application of that rule in light of the amendments made to HIPAA by the Affordable Care Act.

Proposed section 1630.14(d)(1) says that an employee health program, including any disability-related inquiries and medical examinations that are part of such a program, must be reasonably designed to promote health or prevent disease. This standard is similar to the standard under the tri-agency regulations applicable to health-contingent wellness programs[27]. In order to meet the standard, the program must have a reasonable chance of improving the health of, or preventing disease in, participating employees, and must not be overly burdensome, a subterfuge for violating the ADA or other laws prohibiting employment discrimination, or highly suspect in the method chosen to promote health or prevent disease. The interpretive guidance offers examples of programs that would and would not meet this standard.

Section 1630.14(d)(2)(i)-(iii) explains that, for a program to be considered voluntary, a covered entity may not require an employee to participate in such a program and 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 refuse to participate in an employee health program or fail to achieve certain health outcomes. Additionally, 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).

Section 1630.14(d)(2)(iv) says that for an employee's participation in a wellness program that is part of a group health plan to be deemed voluntary, a covered entity must provide a notice

[27] See 26 CFR 54.9802-1(f)(3)(iii); 29 CFR 2590.702(f)(3)(iii); 45 CFR 146.121(f)(iii).

clearly explaining what medical information will be obtained, how the medical information will be used, who will receive the medical information, the restrictions on its disclosure, and the methods the covered entity uses to prevent improper disclosure of medical information.

Section 1630.14(d)(3) clarifies that the offer of limited incentives to participate in wellness programs that are part of a group health plan and that include disability-related inquiries and/or medical examinations, will not render the program involuntary. However, the total allowable incentive available under all programs (both participatory programs and health-contingent programs) may not exceed 30 percent of the total cost of employee-only coverage, which generally is the maximum allowable incentive available under HIPAA and the Affordable Care Act for health-contingent wellness programs.[28]

The EEOC proposes to extend the 30 percent limit set under HIPAA and the Affordable Care Act to include participatory wellness programs that ask an employee to respond to a disability-related inquiry or undergo a medical examination. HIPAA and Affordable Care Act wellness program provisions are limited to regulating what constitutes discrimination based on a health factor. As long as an incentive for a participatory wellness program is available to all similarly situated employees, regardless of any health factor, the incentive will not violate HIPAA and the Affordable Care Act. By contrast, the ADA rules concerning disability-related inquiries and medical examinations of employees limit the circumstances under which employers may obtain medical information from employees and the type of information that may be sought. For this reason, EEOC has determined that placing limits on the rewards employers may offer for employee participation (or penalties for non-participation) where participation requires

[28] The interpretive guidance accompanying the proposed rule as well as question 6 below address the application of incentives related to smoking cessation programs.

employees to answer disability-related inquiries or take medical examinations promotes the ADA's interest in ensuring that incentive limits are not so high as to make participation in the program involuntary. At the same time, these limits comport with HIPAA and the Affordable Care Act wellness program provisions.

The EEOC has not changed any of the exceptions to confidentiality set out in section 1630.14(d). The Commission, however, proposes to add a new subsection, 1630.14(d)(6), concerning the confidentiality and use of medical information gathered in the course of providing voluntary health services to employees, including information collected as part of an employee's participation in an employee health program. This subsection states that medical information collected through an employee health program only may be provided to a covered entity under the ADA 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 and except as permitted under 1630.14(d)(4). The interpretive guidance explains that both employers that sponsor wellness programs and administrators of wellness programs acting as agents of employers have obligations to ensure compliance with this provision.

Further, the interpretive guidance explains that where a wellness program is part of 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 under the HIPAA Privacy, Security, and Breach Notification Rules. *See* 45 CFR Part 160 and Part 164. The HIPAA Privacy, Security, and Breach Notification Rules apply to HIPAA covered entities, which include group health plans, and generally protect the individually identifiable health information maintained by or on behalf of such entities. Accordingly, the interpretative guidance provides that where a wellness program is part of a group health plan and required to comply

with HIPAA, its obligation to comply with section 1630.14(d)(6) generally may be satisfied by adhering to the HIPAA Privacy Rule. Thus, when an employer that is a health plan sponsor performing plan administration receives individually identifiable health information from or on behalf of the group health plan, as permitted by HIPAA, it generally satisfies its requirement to comply with section 1630.14(d)(6) 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 group health plan documents and the HIPAA Privacy Rule and abiding by that certification. If an employer is not performing plan administration on behalf of the group health plan, then the aggregate information that the employer may receive from the wellness program under section 1630.14(d)(6) must be de-identified in accordance with the HIPAA Privacy Rule. Further, other 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 1630.14(d)(4) 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.

Section 1630.14(d)(7) clarifies that compliance with paragraph (d) of this section, including the proposed limit on incentives under the ADA, does not relieve a covered entity of its obligation to comply with other employment nondiscrimination laws. Thus, for example, as the interpretive guidance accompanying the proposed rule explains, even if an employer's wellness program complies with the incentive limits set forth in the ADA regulations, the employer would violate Title VII or the Age Discrimination in Employment Act (ADEA) if that program discriminates on the basis of race, sex, national origin, or age, or any other grounds prohibited by those statutes.

Employee health programs that do not include disability-related inquiries or medical examinations, such as those that provide employees with general health information and education programs are not subject to the incentive rules discussed here. Like other benefit programs offered by covered entities, however, these programs must not discriminate against employees with disabilities. This nondiscrimination requirement includes providing reasonable accommodations that enable employees with disabilities to fully participate in employee health programs and earn any reward or avoid any penalty offered as part of those programs.[29]

This revision will require renumbering 29 CFR 1630.14(d).

The Commission invites written comments from members of the public on any issues related to this proposed rule, including general comments about wellness programs or about particular practices that might violate the ADA or other laws enforced by the EEOC. In addition, the Commission specifically requests comments on several issues:

(1) Whether the way in which the Commission reconciles the ADA's "voluntary" requirement with the wellness program provisions in the Affordable Care Act is appropriate given the intent behind both provisions. Specifically, the Commission seeks comment on:

(a) Whether to be "voluntary" under the ADA, entities that offer incentives to encourage employees to disclose medical information must also offer similar

[29] Additionally, as discussed earlier in this preamble, the regulations under HIPAA and the Affordable Care Act require that an activity-only program allow a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the 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 it is medically inadvisable to attempt to satisfy the otherwise applicable standard. Similarly, an outcome-based program must allow a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward to any individual who does not meet the initial standard based on a measurement, test, or screening.

incentives to persons who choose not to disclose such information, but who instead provide certification from a medical professional stating that the employee is under the care of a physician and that any medical risks identified by that physician are under active treatment.

(b) Whether to be considered "voluntary" under the ADA, the incentives provided in a wellness program that asks employees to respond to disability-related inquiries and/or undergo medical examinations may not be so large as to render health insurance coverage unaffordable under the Affordable Care Act and therefore in effect coercive for an employee. Specifically, the Commission seeks input on whether it would be appropriate for the Commission to provide that the incentives employers offer to employees to promote participation in wellness programs must not render the cost of health insurance unaffordable to employees within the meaning of 26 U.S.C. 36B (c)(2)(C) as implemented by 26 CFR 54.4980H-5(e). Generally, the cost of health insurance is affordable within the meaning of 26 U.S.C. 36B(c)(2)(C) if the portion an employee would have to pay for employee-only coverage would not exceed a specified percent of household income (9.56 percent in 2015). Where such incentives would render a plan unaffordable for an individual, it would be deemed coercive and involuntary to require that individual to answer disability-related inquiries and/or submit to medical examinations connected with the wellness program at issue.

(c) Whether there are any methods other than those mentioned in the proposed regulation and the questions above by which the Commission can effectuate

the intent of both the "voluntary" requirement in the ADA and the provisions in the Affordable Care Act intended to encourage workplace health promotion and disease prevention.

(2) Should the proposed notice requirements of this rule, at section 1630.14(d)(2)(iv), also include a requirement that employees participating in wellness programs that include disability-related inquiries and/or medical examinations, and that are part of a group health plan, provide prior, written, and knowing confirmation that their participation is voluntary? If so, what form should such an authorization take? Are principles of informed consent in the medical context helpful in fashioning an appropriate authorization? Are there existing forms that could provide adequate protections, such as forms developed under HIPAA, forms employers already use in connection with wellness programs, or forms employers use to comply with Title II of GINA? What costs would be associated with developing an appropriate authorization form and/or collecting and maintaining authorization forms for employees who decide to participate in wellness programs?

(3) Should the proposed notice requirement apply only to wellness programs that offer more than de minimis rewards or penalties to employees who participate (or decline to participate) in wellness programs that ask them to respond to disability-related inquiries and/or undergo medical examinations? If so, how should the Commission define “de minimis”?

(4) Which best practices ensure that wellness programs are designed to promote health and do not operate to shift costs to employees with health impairments or stigmatized conditions?

(5) Whether employers offer (or are likely to offer in the future) wellness programs outside of a group health plan or group health insurance coverage that use incentives to promote participation in such programs or to encourage employees to achieve certain health outcomes and the extent to which the ADA regulations should limit incentives provided as part of such programs.

(6) What will be the practical effect of adopting the specific incentive limit set forth in the proposed rule (rather than expressly referencing and incorporating the wellness-program incentive limits as they are defined by the Secretaries of Labor, Treasury, and Health and Human Services pursuant to the Affordable Care Act)? Specifically, what, if any, will be the impact of the proposed rule's 30-percent limit on incentives offered with respect to wellness programs intended to prevent or reduce tobacco use where such programs ask employees to respond to disability-related inquiries and/or undergo medical examinations?

Regulatory Procedures

Executive Order 12866

Pursuant to Executive Order 12866, EEOC has coordinated this proposed rule with the Office of Management and Budget. Under section 3(f)(1) of Executive Order 12866, 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 cost-benefit analysis of the proposed regulation is not required, the Commission recognizes that providing some information on potential costs and benefits of the rule may be helpful in assisting members of the public in better understanding the potential impact of the proposed rule. The Commission notes that the rule will significantly aid compliance with the ADA and with HIPAA, as amended by the Affordable Care Act, by employers and group health plans that offer wellness programs. 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 the ADA does permit employers to offer incentives to promote participation in wellness programs that include disability-related inquiries and/or medical examinations. We believe that a potential benefit of this rule is that it will enable employers to adopt wellness programs that include incentives with certainty about their obligations under the ADA. The Commission does not believe the costs associated with the rule are significant. Employers covered by the ADA are already required to comply with wellness program incentive limits for health-contingent wellness programs. EEOC's proposed rule differs from HIPAA's wellness program incentives only in that it extends the 30 percent limit on incentives under health-contingent wellness programs to participatory wellness programs. HIPAA, as amended by the Affordable Care Act, places no limits on incentives for participatory wellness programs. As the incentives offered by the vast majority of employers currently fall below the limit of 30 percent of the cost of self-only coverage, the Commission does not believe the rule will negatively affect the ability of employers to offer incentives sufficient to promote meaningful participation in wellness programs.

The only other potential cost is associated with the requirement that employers provide a notice to employees informing them what medical information will be obtained, how it will be

used, who will receive it, and the restrictions on disclosure. For the reasons set forth in the Paperwork Reduction Act analysis that follows, the Commission concludes that approximately 299,115 employers will need to develop such a notice. The Commission estimates the time required to develop the notice to be four hours, for a total of 1,196,460 hours. According to data from the Bureau of Labor Statistics, the average hourly compensation for employees in "management, professional, and related" occupations was $55.56 as of December 2014, and the average hourly compensation for employees working in "office and administrative support" was $23.98. See Bureau of Labor Statistics, Employer Costs for Employee Compensation – December 2014 (March 11, 2015), available at www.bls.gov/news.release/pdf/ecec.pdf. Assuming that 50 percent of the time required to develop an appropriate notice is attributable to employees working in management, professional, and related occupations and that 50 percent of the time is attributable to employees working in office and administrative support, the Commission estimates that the total cost of developing a notice that complies with the requirements of the proposed rule would be $42,583,000. We note that some employers and group health plans may already have notices that comply with these requirements, and that those that do not will incur only a one-time cost to develop an appropriate notice. The Commission seeks comments on these cost estimates.

Other requirements in the rule will result in no costs, since they simply restate basic principles of nondiscrimination under the ADA. Even in the absence of this rule, employers are prohibited from requiring employees to participate in employee health programs that include disability-related inquiries and/or medical examinations; denying employees health insurance (or any other benefit of employment) if they do not participate in wellness programs; retaliating against employees who file charges claiming that a wellness program violates the ADA; and

attempting to induce participation in employee health programs through interference with their ADA rights, coercion, intimidation, and threats. Employers are also required to provide reasonable accommodations to enable employees to enjoy equal benefits and privileges of employment, which would include participation in employee health programs. To the extent confidentiality of medical information acquired in the course of providing an employee health program is required, the proposed rule will result in no additional costs. The ADA already requires employers to keep medical information about applicants and employees confidential.

To the extent the proposed rule can be read to impose additional confidentiality obligations, the interpretive guidance to the rule makes clear that a wellness program that is part of a group health plan may generally satisfy its obligation to comply with proposed section 1630.14(d)(6) by adhering to the HIPAA Privacy Rule. *See* 45 C.F.R. Part 160 and Part 164, Subparts A and E. An employer that is a health plan sponsor and receives individually 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 comply with the proposed rule by certifying to the group health plan, also pursuant to the HIPAA Privacy Rule, 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. Further, if an employer is not performing plan administration functions on behalf of the group health plan, then the employer may receive aggregate information from the wellness program under section 1630.14(d)(6) only so long as it is de-identified in accordance with the HIPAA Privacy Rule.

Paperwork Reduction Act

These proposed additions to EEOC's regulations contain an information collection requirement subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. As required by the Paperwork Reduction Act, the EEOC is submitting to OMB a request for approval of the information collection requirement under section 3507(d) of the Act. Organizations or individuals desiring to submit comments for consideration by OMB on the information collection requirement should address them to Chad Lallemand in the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Room 10235, New Executive Office Building, Washington, DC 20503, or by e-mail to OIRA_submission@omb.eop.gov.

Copies of comments should also be sent to Bernadette Wilson, Acting Executive Officer, Executive Secretariat, Equal Employment Opportunity Commission, 131 M Street, NE, Washington, DC 20507. As a convenience to commenters, the Executive Secretariat will accept comments totaling six or fewer pages via FAX transmittal. This limitation is necessary to assure access to the equipment. The telephone number of the fax receiver is (202) 663-4114. (This is not a toll-free number.) 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) 663-4070 (voice) or (202) 663-4074 (TTY). (These are not toll-free numbers.) Instead of sending written comments to EEOC, you may submit comments and attachments electronically at http://www.regulations.gov, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments. All comments received through this portal will be posted without change, including any personal information you provide. Copies of comments submitted by the public to EEOC directly or through the Federal eRulemaking Portal will be available for

review at the Commission's library between the hours of 9:00 a.m. and 5:00 p.m. Eastern Time or can be reviewed at http://www.regulations.gov.

Overview of This Information Collection

Collection Title: Notice requirement under Title I of the ADA, 29 CFR 1630.14(d)(2)(iv)

OMB number: 3046-xxxx.

Description of affected public: Employers with 15 or more employees that are subject to Title I of the ADA and offer wellness programs as part of group health plans.

Number of respondents: 299,115

Initial one-time hour burden: 1,196,460

Annual hour burden*:* None

Number of forms*:* None

Federal cost*:* None

Abstract*:* The proposed rule says that a wellness program that includes disability-related inquiries or medical examinations and that is part of a group health plan must meet several requirements to be deemed voluntary, including providing a notice to employees informing them what medical information will be obtained, how it will be used, who will receive it, and the restrictions on disclosure.

Burden Statement*:* We estimate that there are approximately 782,000 employers with 15 or more employees subject to the ADA and, of that number, one half to two thirds (391,000 to 586,500) offer some type of wellness program.[30] Of those employers, 32 percent to 51 percent require employees to complete a health risk assessment (HRA) that likely contains disability-

[30] According to the RAND Final Report, "approximately half of U.S. employers offer wellness promotion initiatives." By contrast, the Kaiser Survey found that "[s]eventy-four percent of employers offering health benefits" offer at least one wellness program.

related questions.[31] Using the highest estimates, we assume that 299,115 (51 percent of 586,500 employers) will be covered by this requirement.

Some employers and group health plans may already use forms that comply with the proposed notice requirement; therefore, the burden only will be on employers and group health plans that will incur a one-time burden to develop an appropriate notice to ensure that employees who provide medical information pursuant to a wellness program do so voluntarily. This notice may be included on or attached to any HRA employees are asked to complete and should explain what medical information will be obtained, how it will be used, who will receive it, and the restrictions on disclosure. Assuming that creation of such a document would take four hours, and assuming that 299,115 employers would be covered by the proposed regulation, this one-time burden would be 1,196,460 hours. Because employers do not have to develop a new form unless they collect medical information for a different purpose, they will be able to annually redistribute the same notice to all relevant employees.

For those wishing to comment on the above information collection, OMB is particularly interested in comments which:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the Commission's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

[31] The Kaiser Survey reports that 51 percent of large employers versus 32 percent of small employers ask employees to complete a HRA.

(4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Regulatory Flexibility Act

Title I of the ADA applies to approximately 782,000 employers with 15 or more employees subject to the ADA, approximately 764,233 of which are small firms (entities with 15-500 employees) according to data provided by the Small Business Administration Office of Advocacy. See Firm Size Data at http://www.sba.gov/advocacy/849/12162.

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 clarifies that, in most respects, employers who offer wellness programs that are part of their health plans may offer incentives to employees consistent with HIPAA and the Affordable Care Act without violating the ADA. The amount of an incentive offered for participation (alone or in combination with incentives offered for health-contingent wellness programs) in a wellness program will not render a program involuntary under the ADA as long as the incentive does not exceed 30 percent of the total cost of employee-only coverage.

To the extent that employers will expend resources to train human resources staff and others on the revised rule, we note 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 2013, the agency's outreach programs reached more than 280,000 persons through participation in more than 3,800 no-cost educational,

training, and outreach events. We estimate that the typical human resources professional will need to dedicate, at most, 90 minutes to gain a satisfactory understanding of the revised regulations. We further estimate that the median hourly pay rate of a human resources professional is approximately $48.50. *See* Bureau of Labor Statistics, Occupational Employment and Wages, May 2013 at 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 $72.75 and $363.75.

EEOC does not believe that this cost will be significant for the impacted small entities. We urge small entities to submit comments concerning 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.

List of Subjects in 29 CFR Part 1630

Equal employment opportunity, Individuals with disabilities.

For the Commission,

Dated: April 13, 2015.

Bernadette B. Wilson,
Acting Executive Officer.

For the reasons set forth in the preamble, the EEOC proposes to amend 29 CFR Part 1630 to read as follows:

PART 1630 – [AMENDED]

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

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

2. Amend § 1630.14 by:

a. Redesignating paragraph (d)(1) as paragraph (d)(4);

b. Redesignating paragraph (d)(2) as paragraph (d)(5);

c. Adding new paragraphs (d)(1), (d)(2), (d)(3), (d)(6), and (d)(7).

The revisions and additions read as follows:

§ 1630.14 Medical examinations and inquiries specifically permitted.

* * * * *

(d) * * *

(1) Employee health program. An employee health program, including any disability-related inquiries or medical examinations that are part of such program, must be reasonably designed to promote health or prevent disease. A program satisfies this standard if it has a reasonable chance of improving the health of, or preventing disease in, participating employees, and it is not overly burdensome, is not a subterfuge for violating

the ADA or other laws prohibiting employment discrimination, and is not highly suspect in the method chosen to promote health or prevent disease.

(2) Voluntary. An employee health program that includes disability-related inquiries or medical examinations (including disability-related inquiries or medical examinations that are part of a health risk assessment) is voluntary as long as a covered entity:

(i) Does not require employees to participate;

(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)(3) of this section) for employees who do not participate;

(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, at 42 U.S.C. 12203; and

(iv) Where a health program is a wellness program that is part of a group health plan, provides employees with a notice that:

(A) Is written so that the employee from whom medical information is being obtained is reasonably likely to understand it;

(B) Describes the type of medical information that will be obtained and the specific purposes for which the medical information will be used; and

(C) Describes the restrictions on the disclosure of the employee's medical information, the employer representatives or other parties with whom the information will be shared, and the methods that the covered entity will use to ensure that medical

information is not improperly disclosed (including whether it complies with the measures set forth in the HIPAA regulations codified at 45 CFR parts 160 and 164).

(3) Incentives offered for employee wellness programs that are part of a group health plan. The use of incentives (financial or in-kind) in an employee wellness program, whether in the form of a reward or penalty, together with the reward for any other wellness program that is offered as part of a group health plan (as defined in 29 USC 1191b(a)), will not render the program involuntary if the maximum allowable incentive available under the program (whether the program is a participatory program or a health-contingent program, or some combination of the two, as those terms are defined in regulations at 26 CFR 54.9802-1(f)(1)(ii) and (iii), 29 CFR 2590.702(f)(1)(ii) and (iii), and 45 CFR 146.121(f)(1)(ii) and (iii), respectively) does not exceed 30 percent of the total cost of employee-only coverage.

* * * * *

(6) Except as permitted under paragraph (d)(4) and as is necessary to administer the 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.

(7) 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.

3. 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): Health Program

Part 1630 permits voluntary medical examinations and inquiries, including voluntary medical histories, as part of employee health programs. These health programs include wellness programs, which often incorporate, for example: a health risk assessment (HRA) (consisting of a medical questionnaire, with or without medical examinations, to determine risk factors); medical screening for high blood pressure, cholesterol, or glucose; classes to help employees stop smoking or lose weight; physical activities in which employees can engage (such as walking or exercising daily); coaching to help employees meet health goals; and/or the administration of prescription drugs (like insulin). Many employers offer wellness programs as part of a group health plan as a means of improving overall employee health with the goal of realizing lower health care costs.

It is not sufficient for a covered entity merely to claim that its collection of medical information is part of a wellness program; the program, including any disability-related inquiries and medical examinations that are part of such program, must be reasonably designed to promote

health or prevent disease. In order to meet this standard, the program must have a reasonable chance of improving the health of, or preventing disease in, participating employees, and must not be overly burdensome, a subterfuge for violating the ADA or other laws prohibiting employment discrimination, or highly suspect in the method chosen to promote health or prevent disease. Conducting a HRA and/or a biometric screening of employees for the purpose of alerting them to health risks of which they may have been unaware would meet this standard, as would the use of aggregate information from employee HRAs by an employer to design and offer health programs aimed at specific conditions that are prevalent in the workplace. An employer might conclude from aggregate information, for example, that a significant number of its employees have diabetes or high blood pressure and might design specific programs that would enable employees to treat or manage these conditions. On the other hand, collecting medical information on a health questionnaire without providing employees follow-up information or advice, such as providing feedback about risk factors or using aggregate information to design programs or treat any specific conditions, would not be reasonably designed to promote health. Additionally, a program is not reasonably designed to promote health or prevent disease if it imposes, as a condition to obtaining a reward, an overly burdensome amount of time for participation, requires unreasonably intrusive procedures, or places significant costs related to medical examinations on employees. A program also is not reasonably designed if it exists mainly to shift costs from the covered entity to targeted employees based on their health.

Section 1630.14(d)(2): Definition of "Voluntary"

Section 1630.14(d)(2)(i)-(iii) of this part says that participation in employee health programs that include disability-related inquiries or medical examinations (such as disability-related inquiries or medical examinations that are part of a HRA) 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 its 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 (e.g., having to pay a higher deductible) may be the result of forgoing a financial incentive permissible under paragraph (d)(3), and may not take any other adverse action against employees who choose not to answer disability-related inquiries or submit to 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, at 42 U.S.C. 12203. For example, an employer may not retaliate against an employee who refused to participate in a health program or filed a charge with the EEOC concerning the program, may not coerce an employee into participating in a health program or into giving the employer access to medical information collected as part of the 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) and (b); 29 CFR 1630.12.

Section 1630.14(d)(2)(iv) of this part also states that for a wellness program that is part of a group health plan to be voluntary, an employer must provide employees with a notice clearly explaining what medical information will be obtained, how the medical information will be used, who will receive the medical information, the restrictions on its disclosure, and the methods the covered entity uses to prevent improper disclosure of medical information.

Section 1630.14(d)(3): Limitations on Incentives

The ADA, interpreted in light of the Health Insurance Portability and Accountability Act (HIPAA), as amended by the Affordable Care Act, does not prohibit the use of incentives to encourage participation in employee health programs, but it does place limits on them. In general, the use of limited incentives (which include both financial and in-kind incentives, such as time-off awards, prizes, or other items of value) in a wellness program that is part of a group health plan or group health insurance coverage will not render a wellness program involuntary. However, the maximum allowable incentive for a participatory program that involves asking disability-related questions or conducting medical examinations (such as having employees complete a HRA) or for a health-contingent program that requires participants to satisfy a standard related to a health factor may not exceed 30 percent of the total cost of employee-only coverage. Thus, for example, for purposes of compliance with these provisions under the ADA, suppose a group health plan under which an employee is enrolled has a total annual premium for employee-only coverage of $5,000 (which includes both the employer's and employee's contributions toward coverage). The plan provides a $250 reward to employees who complete a HRA (this reward is given to any participant who completes the HRA, without regard to the health issues identified as part of the assessment). The plan also offers a health-contingent wellness program to promote cardiovascular health, with an opportunity to earn a $1,500 reward. An employee who satisfies both components of the program could earn a total reward of $1,750. Such a reward would violate the ADA because the total reward available exceeds 30 percent of

the total cost of coverage. However, if the employer offered no reward for completing the HRA and a $1,500 reward for achieving health outcomes under the wellness program (or offered $750 for completing the HRA and $750 for achieving health outcomes in the wellness program), the incentives would comply with the ADA. Not all wellness programs require disability-related inquiries or medical examinations in order to earn an incentive. Examples may include attending nutrition, weight loss, or smoking cessation classes. These types of programs are not subject to the ADA incentive rules discussed here, although programs that qualify as health- contingent programs are subject to HIPAA incentive limits.

Under the ADA, regardless of whether a wellness program includes disability-related inquiries or medical examinations, reasonable accommodations must be provided, absent undue hardship, to enable employees with disabilities to earn whatever financial incentive an employer or other covered entity offers. Providing a reasonable alternative standard and notice to the employee of the availability of a reasonable alternative under HIPAA and the Affordable Care Act as part of a health-contingent program would likely fulfill a covered entity's obligation to provide a reasonable accommodation under the ADA. However, under the ADA, a covered entity would have to provide a reasonable accommodation for a participatory program even though HIPAA and the Affordable Care Act do not require such programs to offer a reasonable alternative standard.

For example, an employer that offers employees a financial incentive to attend a nutrition class, regardless of whether they reach a healthy weight as a result, would have to provide a sign language interpreter so that an employee who is deaf and who needs an interpreter to understand the information communicated in the class could earn the incentive, as long as providing the interpreter would not result in undue hardship to the employer. Similarly, an employer would,

absent undue hardship, have to provide written materials that are part of a wellness program in an alternate format, such as in large print or on computer disk, for someone with a vision impairment. An individual with a disability also may need a reasonable accommodation to participate in a wellness program that includes disability-related inquiries or medical examinations, including waiver of a generally applicable requirement. For example, an employer that offers a reward for completing a biometric screening that includes a blood draw would have to provide an alternative test (or certification requirement) so that an employee with a disability that makes drawing blood dangerous can participate and earn the incentive.

Application of Section 1630.14(d)(3) to Smoking Cessation Programs

Regulations implementing the wellness provisions in HIPAA, as amended by the Affordable Care Act, permit covered entities to offer incentives as high as 50 percent of the total cost of employee coverage for tobacco-related wellness programs, such as smoking cessation programs. As noted above, the incentive rules in Section 1630.14(d)(3) apply only to employee health programs that include disability-related inquiries or medical examinations. A smoking cessation program that merely asks employees whether or not they use tobacco (or whether or not they ceased using tobacco upon completion of the program) is not an employee health program that includes disability-related inquiries or medical examinations. The incentive rules in Section 1630.14(d)(3) would not apply to incentives a covered entity could offer in connection with such a program. Therefore, a covered entity would be permitted to offer incentives as high as 50 percent of the cost of employee coverage for that smoking cessation program, pursuant to the regulations implementing HIPAA, as amended by the Affordable Care Act, without implicating the disability-related inquiries or medical examinations provision of the ADA. The

ADA nondiscrimination requirements, such as the need to provide reasonable accommodations that provide employees with disabilities equal access to benefits, would still apply.

By contrast, a biometric screening or other medical examination that tests for the presence of nicotine or tobacco is a medical examination. The ADA financial incentive rules discussed supra would therefore apply to a wellness program that included such a screening.

Section 1630.14(d)(4) - (6): Confidentiality

Paragraphs (d)(4) and (d)(5) say 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. 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)(6) says 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 except as is necessary to administer the plan or as permitted by section 1630.14(d)(4). 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 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. 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 a health plan fails to comply with privacy requirements and HHS may impose civil money penalties for noncompliance.

A wellness program that is part of a HIPAA covered entity likely will be able to comply with its obligation under section 1630.14(d)(6) by complying with the HIPAA Privacy Rule. An employer that is a health plan sponsor and receives individually 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)(6) 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. 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)(6) only so long as the information is de-identified in accordance with the HIPAA Privacy Rule. 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 section 1630.14(d)(4) 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.

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. Proper training of individuals who handle medical information in the requirements of the HIPAA Rules, the ADA,

and any other applicable privacy laws is critical. 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.

As a best practice, 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 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. 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 also 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 to discriminate on the basis of disability in violation of the ADA.

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.

Section 1630.14(d)(7): Compliance with Other Employment Nondiscrimination Laws

Finally, section 1630.14(d)(7) 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)(3), the employer would violate federal nondiscrimination statutes if that program discriminates on the basis of race, sex, national origin, or age.

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