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Regulations Under the Americans With Disabilities Act; Genetic Information
Nondiscrimination Act

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION**29 CFR Part 1630**

RIN 3046-AB01

Regulations Under the Americans With Disabilities Act**AGENCY:** Equal Employment Opportunity Commission.**ACTION:** Final rule.

SUMMARY: The Equal Employment Opportunity Commission (EEOC or Commission) is issuing its final rule to amend the regulations and interpretive guidance implementing Title I of the Americans with Disabilities Act (ADA) to provide guidance on the extent to which employers may use incentives to encourage employees to participate in wellness programs that ask them to respond to disability-related inquiries and/or undergo medical examinations. This rule applies to all wellness programs that include disability-related inquiries and/or medical examinations whether they are offered only to employees enrolled in an employer-sponsored group health plan, offered to all employees regardless of whether they are enrolled in such a plan, or offered as a benefit of employment by employers that do not sponsor a group health plan or group health insurance. Published elsewhere in this issue of the **Federal Register**, the EEOC also issued a final rule to amend the regulations implementing Title II of the Genetic Information Nondiscrimination Act (GINA) that addresses the extent to which employers may offer incentives for an employee's spouse to participate in a wellness program.

DATES: *Effective date:* This rule is effective July 18, 2016.

Applicability date: This rule is applicable beginning on January 1, 2017.

FOR FURTHER INFORMATION CONTACT: Christopher J. Kuczynski, Assistant Legal Counsel, (202) 663-4665, or Joyce Walker-Jones, Senior Attorney Advisor, (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 rule in an alternative format should be made to the Office of Communications and Legislative Affairs, (202) 663-4191 (voice) or (202) 663-4494 (TTY). (These are not toll free numbers.)

SUPPLEMENTARY INFORMATION:**Introduction**

This rule applies to wellness programs that are considered “employee

health programs” under Title I of the 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 that may provide similar programs to individuals who are considered volunteers.

A wellness program that is an employee health program may be part of a group health plan or may be offered outside of a group health plan or group health insurance coverage.⁴ All of the provisions in this rule, including the requirement to provide a notice and limitations on incentives, apply to all employee health programs that ask employees to respond to disability-related inquiries and/or undergo medical examinations. Wellness programs that do not include disability-related inquiries or medical examinations (such as those that provide general health and educational information) are not subject to this final rule, although such programs must be available to all employees and must provide reasonable accommodations to employees with disabilities.

Discussion

Many employers that sponsor group health plans also offer health promotion and disease prevention activities, known as wellness programs, to employees enrolled in a health plan.⁵ Some employers, however, offer wellness programs that are available to

all employees whether or not they are enrolled in an employer-sponsored health plan, while other employers do not offer a group health plan or group health insurance coverage but offer some type of workplace wellness program. Many of these programs obtain medical information from employees by asking them to complete a health risk assessment (HRA) and/or undergo biometric screenings for risk factors (such as high blood pressure or cholesterol). Other wellness programs provide educational health-related information or programs that may include: nutrition classes, weight loss and smoking cessation programs, onsite exercise facilities, and/or coaching to help employees meet health goals.

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.⁶ 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.

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,⁷ and other employment discrimination laws enforced by the EEOC. 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 also must comply with the nondiscrimination provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Affordable Care Act, 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.”⁸ A wellness program

¹ 42 U.S.C. 12101–12117.

² 42 U.S.C. 12131–12134.

³ 42 U.S.C. 12181–12189.

⁴ 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 . . .”

⁵ An annual survey conducted by the Kaiser Family Foundation Health Research and Educational Trust indicated that 55 percent of large firms that offered 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), <https://kaiserfamilyfoundation.files.wordpress.com/2016/01/8742-02-workplace-wellness-programs-characteristics-and-requirements.pdf>.

⁶ 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 [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, a survey conducted by the Kaiser Foundation 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. See *Employer Health Benefits Survey*, Kaiser Family Foundation (2014), <http://kff.org/health-costs/report/2014-employer-health-benefits-survey/> [hereinafter *Kaiser Survey*].

⁷ 42 U.S.C. 2000ff–2000ff–11.

⁸ The Patient Protection and Affordable Care Act, Pub. L. 111–148, 124 Stat. 119 (2010) (codified as

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 and Other Laws Prohibiting Employment Discrimination

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."⁹ The ADA also restricts the medical information employers may obtain from employees by generally prohibiting them from making disability-related inquiries or requiring medical examinations.¹⁰ The statute, however, provides an exception to this rule for voluntary employee health programs, which include many workplace wellness programs.¹¹

amended in scattered sections of 25 U.S.C., 26 U.S.C., 29 U.S.C., and 42 U.S.C.), and the Health Care and Education Reconciliation Act of 2010, Pub. L. 111–152, 124 Stat. 1029 (codified at 42 U.S.C. 18121, 18043; 26 U.S.C. 1411, 14191; 20 U.S.C. 1087i–2), 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 health insurance 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, making them applicable to group health plans and group health insurance issuers.

⁹ 42 U.S.C. 12112(a); 29 CFR 1630.4(a)(1)(vi). Title I of the ADA applies to, in addition to employers, 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, the final rule, and the interpretive guidance frequently use the term "covered entity," as that term appears throughout EEOC's entire ADA regulation.

¹⁰ 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 an inquiry. 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> [hereafter *Guidance*].

¹¹ 42 U.S.C. 12112(d)(4)(B). A covered entity may conduct voluntary medical examinations, including

Additionally, 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.¹² Employers also must comply with other laws the EEOC enforces that prohibit discrimination based on race, color, national origin, sex (including pregnancy, gender identity, transgender status, and sexual orientation), religion, compensation, age, or genetic information.¹³

HIPAA's Nondiscrimination Provisions

HIPAA's nondiscrimination provisions, as amended by the Affordable Care Act, generally prohibit group health plans and health insurance issuers providing 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

voluntary medical histories, that are part of an employee health program available to employees at that work site.

¹² 42 U.S.C. 12112(b)(5)(A); 29 CFR 1630.9 (prohibiting 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").

¹³ 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 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 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 or the ADEA if that program discriminates on the basis of race, color, national origin, sex (including pregnancy, gender identity, transgender status, and sexual orientation), religion, or age.

¹⁴ The nondiscrimination provisions originally enacted in HIPAA set forth eight health status-related factors, which the December 13, 2006, final regulations refer to as "health factors." 71 FR 75014 (Dec. 13, 2006). Under HIPAA and the 2006 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.

coinsurance), in return for adherence to certain programs of health promotion and disease prevention.¹⁵

The 2013 final tri-Department regulations to implement HIPAA's nondiscrimination provisions discuss two types of wellness programs: "participatory" and "health contingent."¹⁶ Participatory wellness programs 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 ask employees only to complete a HRA or attend a smoking cessation program. The tri-Department regulations do not impose any incentive limits on "participatory" wellness programs and state that they are permissible as long as 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. Examples of health-contingent wellness programs include a program that requires employees to walk or do a certain amount of exercise weekly (an activity-based program) or to reduce their blood pressure or cholesterol level (an outcome-based program) in order to earn an incentive. Incentives offered in connection with health-contingent wellness programs generally must not

¹⁵ Prior to the enactment of the Affordable Care Act, HIPAA added section 9802 of the Code, section 702 of 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 are 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 cost of coverage under the plan. See PHS Act section 2705(j)(3)(A). The tri-Departments 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. Incentives for Nondiscriminatory Wellness Programs in Group Health Plans, 78 FR 33158 (June 3, 2013) (codified at 26 CFR 54.9802–1; 29 CFR 2590.702; 45 CFR 46.121). 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)."

¹⁶ See 26 CFR 54.9802–1(f); 29 CFR 2590.702(f); 45 CFR 146.121(f).

exceed 30 percent of the total cost of self-only health coverage where only an employee, not the employee's dependents, is eligible for the wellness program.¹⁷ There are five requirements for health-contingent wellness programs under PHS Act section 2705 and the 2013 final regulations. Generally, health-contingent wellness programs 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 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; (4) be reasonably designed to promote health or prevent disease and not be overly burdensome; 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.¹⁸

Finally, the 2013 final 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, and GINA.¹⁹

¹⁷ Under the tri-Department wellness regulations implementing section 2705 of the PHS Act (as amended by the Affordable Care Act), the applicable percentage is increased to 50 percent to the extent that the additional percentage is in connection with a program designed to prevent or reduce tobacco use. See 26 CFR 54.9802-1(f)(5); 29 CFR 2590.702(f)(5); 45 CFR 146.121(f)(3).

¹⁸ Although the five requirements for health-contingent programs generally are the same for activity-only wellness programs and outcome-based wellness programs under the tri-Department 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).

¹⁹ See *Incentives for Nondiscriminatory Wellness Programs in Group Health Plans*, 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 jointly 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

Background on the Notice of Proposed Rulemaking on the ADA and Wellness Programs

The Commission drafted a Notice of Proposed Rulemaking (NPRM) that was circulated to the Office of Management and Budget for review (pursuant to Executive Order 12866) and to federal executive branch agencies for comment (pursuant to Executive Order 12067).²⁰ The NPRM was then published in the **Federal Register** on April 20, 2015, for a 60-day public comment period.²¹

The NPRM re-asserted the Commission's position that, as required by the ADA, 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 defined what that term meant in light of the amendments made to HIPAA by the Affordable Care Act. The NPRM sought comment on wellness programs in general and on any of the proposed revisions to the ADA regulations and interpretative guidance at § 1630.14, which:

- Explained that an "employee health program" must be "reasonably designed to promote health or prevent disease" 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";
- Defined the term "voluntary" and explained that in order for participation in an employee health program to be voluntary, a covered entity may not require employees to participate, deny access to health coverage for nonparticipation, generally limit coverage under its health plans, take any other adverse action, or retaliate, interfere with, coerce, intimidate, or threaten an employee who does not participate or

fails to achieve certain health outcomes, and must provide a notice clearly explaining what medical information will be obtained, how it will be used, who will receive it, and the restrictions on disclosure;

- Clarified that an employer may offer incentives up to a maximum of 30 percent of the total cost of self-only coverage to promote an employee's participation in a wellness program that includes disability-related inquiries or medical examinations (including a blood test to detect the presence of nicotine as part of a smoking cessation program), and that this limit applies whether the program is participatory only, health contingent, or a program that includes both participatory and health-contingent components;
- Explained the requirements concerning the confidentiality of medical information obtained as part of voluntary employee health programs and added a new paragraph that provided that a covered entity only may receive information collected by a wellness program in aggregate form that does not disclose, and is not reasonably likely to disclose, the identity of specific individuals except as necessary to administer the plan; and
- Clarified that compliance with the rules governing voluntary employee health programs, including the limits on financial incentives applicable under the ADA, does not ensure compliance with all of the antidiscrimination laws the EEOC enforces.

The NPRM also explained that the references to the requirement to provide a notice and the limitations on incentives in the proposed rule, and the 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 health insurance in connection with a group health plan. The proposed rule asked for comments on whether employers offer or are likely to offer wellness programs outside of a group health plan or group health insurance coverage and whether the Commission should issue regulations specifically limiting incentives provided as part of such programs.

Additionally, the Commission specifically sought comments on several other issues, including:

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

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>.

²⁰ While there are differences between the definitions and requirements for wellness programs set forth in the Affordable Care Act, PHS Act, ERISA, the Code, and Title II of GINA, this final rule is being issued after review by and consultation with the tri-Departments.

²¹ Amendments to Regulations Under the Americans With Disabilities Act, 80 FR 21659 (proposed April 20, 2015)(to be codified at 29 CFR part 1630).

- similar 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;
- 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 Act²² and, therefore, in effect coercive for an employee;
 - Whether employees participating in wellness programs that include disability-related inquiries and/or medical examinations, and that are part of a group health plan, should be required to provide prior, written, and knowing authorization that their participation is voluntary and whether there are existing forms that could provide adequate protection;
 - Whether the proposed notice requirement should apply only to wellness programs that offer more than de minimis rewards or penalties to employees who participate (or decline to participate) in wellness programs that ask them to respond to disability-related inquiries and/or undergo medical examinations; and
 - Whether the proposed rule’s 30 percent limit on incentives offered with respect to wellness programs that ask employees to respond to disability-related inquiries and/or undergo medical examinations would have any impact on programs intended to prevent or reduce tobacco use.

Summary of Revisions and Response to Comments

During the 60-day comment period, the Commission received nearly 2,750 public comments on the NPRM from a

²² Specifically, the Commission sought input on whether it would be appropriate 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), under which an offer of health insurance coverage is affordable if the employee’s required contribution for self-only coverage is no more than a specified percentage (9.5 percent as adjusted) of household income (or based on one of three affordability safe harbors set forth in 26 CFR 54.4980H–5(e)). For purposes of sections 36B and 4980H of the Code, the affordability of eligible employer-sponsored coverage is determined by assuming that each employee fails to satisfy the requirements of a wellness program, except for the requirements of a nondiscriminatory wellness program related to tobacco use. See 26 CFR 1.36B–2(c)(3)(v)(A)(4).

wide spectrum of stakeholders, including, among others: Individuals, including individuals with disabilities and those who are considered overweight or have eating disorders; disability rights and other advocacy organizations and their members; civil rights groups; federal and state government employees and representatives, including a joint letter from members of Congress; employer associations and industry groups and law firms on their behalf; and health insurance issuers and associations representing them, third party administrators, and wellness vendors (referred to as “health care groups”). The comments from individuals included 2,410 similar, but not uniform, letters—almost all of which were submitted by a national organization that supports women and families—urging the Commission to address HRAs that ask women whether they are pregnant or plan on becoming pregnant. Most of the comments (2,723) were submitted through the United States Government’s electronic docket system, *Regulations.gov*. The remaining 25 comments (a few of which also were submitted through *Regulations.gov*) were mailed or faxed to the Executive Secretariat. Additionally, members of the Commission met or had telephone conversations with several stakeholder groups, a number of which also submitted written comments.

The Commission has reviewed and considered each of the comments in preparing this final rule. The first section of this preamble addresses general comments concerning the Commission’s interpretation of the interaction between the ADA and HIPAA’s wellness program provisions, the final rule’s applicability date, and the ADA’s “safe harbor” provision.

The second section discusses comments submitted in response to questions the NPRM asked about several issues, as noted above.

Finally, because three of the questions asked in the NPRM directly relate to the provisions regarding the notice requirement and the limitations on incentives, the preamble addresses those comments in the last section that discusses comments regarding specific provisions.

General Comments

Interaction Between the ADA and HIPAA’s Wellness Program Provisions

The Commission received a number of comments expressing support for, and concerns about, wellness programs. For example, while many commenters stated that properly designed wellness

programs have the potential to help employees become healthier and bring down health care costs, they believe that these programs also carry serious potential to discriminate in ways long prohibited by the civil rights laws by allowing employers to coerce employees into providing medical information. Disability rights and advocacy groups expressed concerns that the EEOC was abandoning its prior position that a voluntary wellness program that includes disability-related inquiries and/or medical examinations cannot involve penalties, while employer and industry groups commented that the proposed rule’s limitation on incentives is inconsistent with the tri-Department rules.

Although the Commission recognizes that compliance with the standards in HIPAA, as amended by the Affordable Care Act, is not determinative of compliance with the ADA, we believe that the final rule interprets the ADA in a manner that reflects the ADA’s goal of limiting employer access to medical information and is consistent with HIPAA’s provisions promoting wellness programs. Accordingly, after consideration of all of the comments, the Commission reaffirms its conclusion 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.

Applicability Date

Employer associations and industry groups also submitted comments regarding the effective date of the final rule, recommending that it allow enough time for employers to bring their wellness programs into compliance, that it be issued jointly with the GINA wellness rule, and that it not be applied retroactively. The Commission agrees and concludes that the provisions of this rule set forth at § 1630.14(d)(2)(iv) (concerning notice) and § 1630.14(d)(3) (concerning incentives) will apply only prospectively to employer wellness programs as of the first day of the first plan year that begins on or after January 1, 2017, for the health plan used to determine the level of incentive permitted under this regulation. So, for example, if the plan year for the health plan used to calculate the permissible incentive limit begins on January 1, 2017, that is the date on which the provisions of this rule governing incentives apply to the wellness program. If the plan year of the plan used to calculate the level of incentives

begins on March 1, 2017, the provisions on incentives and notice requirements will apply to the wellness program as of that date. For this purpose, the second lowest cost Silver Plan is treated as having a calendar year plan year.

All other provisions of this final rule are clarifications of existing obligations that apply at, and prior to, issuance of this final rule.²³

ADA's "Safe Harbor" Provision

A number of stakeholders commented on a footnote in the NPRM, which noted that the ADA's safe harbor provision applicable to insurance²⁴ does not apply to wellness programs that include disability-related questions or medical examinations. The safe harbor provision 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."

Employer associations and industry groups that commented on the footnote thought that the safe harbor provision applies to wellness programs that ask disability-related questions or require medical examinations. Several members of Congress asserted that the EEOC was inappropriately seeking to rewrite the statute and vacate court decisions through regulation. A few commenters distinguished between wellness programs that are part of a group health plan, to which the commenters said the safe harbor should apply, and those that are not part of a group health plan, to which it should not apply. Several noted that information obtained through wellness programs could provide employers with valuable insight that would help them develop and administer present and future plans. Two comments expressed the view that the EEOC has no authority to interpret the meaning of the safe harbor provision because it is in Title V of the ADA, not Title I, and these commenters urged deletion of the entire footnote.

The Commission has authority to interpret the safe harbor provision because, by its express terms, this

provision applies to Titles I through IV of the ADA. Moreover, as stated in § 1630.14(d)(6) of this rule, we reaffirm our position that the safe harbor provision does not apply to an employer's decision to offer rewards or impose penalties in connection with wellness programs that include disability-related inquiries or medical examinations.

First, as we observed in the preamble to our proposed rule, the ADA, codified at 42 U.S.C. 12112(d)(4)(B), specifically provides an exception that allows employers to make disability-related inquiries or conduct medical examinations as part of an employee health program as long as employee participation is voluntary. To read the insurance safe harbor provision as applicable to wellness programs—and thus to permit incentives in excess of what this rule allows and even to permit practices such as requiring employees to participate in wellness programs in order to maintain their health insurance—would render 42 U.S.C. 12112(d)(4)(B) superfluous.²⁵

One commenter disagreed, arguing that application of the insurance safe harbor provision to wellness programs that are part of a group health plan would not render 42 U.S.C. 12112(d)(4)(B) superfluous, as that section could still apply to wellness programs that are not part of a group health plan. We, however, discern no Congressional intent—either in the plain language of 42 U.S.C. 12112(d)(4)(B) or in the legislative history on that section of the ADA—to restrict the section's reach only to health programs that are not part of a group health plan.

Additionally, the plain language of the safe harbor provision, and an abundance of legislative history explaining it, make its narrow purpose clear. At the time the ADA was enacted, health plans were allowed to engage in some practices that are no longer permitted today. For example, before HIPAA made the practice illegal in 1996, group health plans were allowed to charge individuals in the plan higher rates based on increased risks associated with their medical conditions.²⁶ The ADA's safe harbor provision was intended to protect this now unlawful practice, provided that such decisions to treat people differently because of their medical conditions were based on real

risks and costs associated with those conditions.

In commenting on the safe harbor provision, the report of the House Committee on Education and Labor accompanying the ADA noted:

Under the ADA, a person with a disability cannot be denied insurance or be subject to different terms or conditions of insurance based on disability alone, if the disability does not impose increased risks.

* * *

Moreover, while a plan which limits certain kinds of coverage based on classification of risk would be allowed under this section [codified at 42 U.S.C. 12201(c)], the plan may not refuse to insure, or refuse to continue to insure, or limit the amount, extent, or kind of coverage available to an individual, or charge a different rate for the same coverage solely because of a physical or mental impairment, except where the refusal, limitation, or rate differential is based on sound actuarial principles or is related to actual or reasonably anticipated experience.²⁷

For example, a blind person may not be denied coverage based on blindness independent of [f] actuarial risk classification.²⁸

The same report summarized the safe harbor's purpose as follows:

[S]ection 501 is intended to afford insurers and employers the same opportunities they would enjoy in the absence of this legislation to design and administer insurance products and benefit plans in a manner that is consistent with basic insurance risk classification. . . . Without such a clarification, the legislation could arguably find violative of its provisions any action taken by an insurer or employer which treats disabled persons differently under an insurance or benefit plan because they represent an increased hazard of illness or death.²⁹

The safe harbor provision, then, allows the insurance industry and sponsors of insurance plans, such as employers, to treat individuals differently based on disability (normally a prohibited

²⁷ See H.R. Rep. No. 101-485, pt. 2, at 136-37 (1990). The report further states that the "safe harbor" provision "ensures that decisions concerning the insurance of persons with disabilities which are not based on bona fide risk classification be made in conformity with non-discrimination requirements" and that benefit plans "need to be able to continue business practices in the way they underwrite, classify, and administer risks, so long as they carry out those functions in accordance with accepted principles of insurance risk classification." *Id.*; see also H.R. Rep. No. 101-485, pt. 3, at 71 (the "ADA requires that underwriting and classification of risks be based on sound actuarial principles or be related to actual or reasonably anticipated experience"); S. Rep. No. 101-116, at 84 (1989) ("The Committee does not intend that any provisions of this legislation should affect the way the insurance industry does business [under] State laws.").

²⁸ H.R. Rep. No. 101-485, pt. 2, at 137.

²⁹ *Id.* at 137-38; see also S. Rep. No. 101-116, at 85-86.

²³ Prior EEOC interpretations, including those set forth in the 1991 final rule implementing Title I of the ADA, Equal Employment Opportunities for Individuals With Disabilities, 56 FR 35726 (July 26, 1991), and in Commission guidance, *Guidance*, *supra* note 10, may be considered in determining whether wellness programs that began prior to this rule's applicability date and that ask employees disability-related questions or require them to undergo medical examinations comply with the ADA.

²⁴ 42 U.S.C. 12201(c).

²⁵ See Amendments to Regulations Under the Americans With Disabilities Act, 80 FR at 21662 n.24.

²⁶ See 29 U.S.C. 1182(b).

practice under the ADA), but only if the differences can be justified by increased risks and costs “based on sound actuarial data and not on speculation.”³⁰

Nowhere does the ADA’s legislative history refer to wellness programs in connection with the safe harbor provision. The evidence, in fact, is to the contrary. The only reference to wellness programs is in a committee report discussing the ADA provision governing voluntary health programs.³¹

Consistent with this legislative history, EEOC’s ADA regulations, the interpretive guidance accompanying them, and interim enforcement guidance that the Commission issued in 1993 and that is still in effect, confirm that the safe harbor provision applies to the practices of the insurance industry with respect to the use of sound actuarial data to make determinations about insurability and the establishment of rates. Section 1630.16(f) of the regulations incorporates the language of section 501(c) of the ADA. The interpretive guidance provides that the safe harbor provision “is a limited exception that is only applicable to those who establish, sponsor, observe, or administer benefit plans, such as health and 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.”³² EEOC’s interim guidance on insurance further states:

Risk classification refers to the identification of risk factors and the grouping of those factors that pose similar risks. Risk factors may include characterizations such as age, occupation, personal habits (e.g., smoking), and medical history. Underwriting refers to the application of the various risk factors or risk classes to a particular individual or group (usually only if the group is small) for the purpose of determining whether to provide insurance.³³

³⁰ H.R. Rep. No. 101–485, pt. 3, at 70. The safe harbor provision also permitted practices such as excluding or limiting coverage for individuals with pre-existing conditions (now prohibited as a result of the Affordable Care Act), even though they adversely affect people with disabilities, as long as they were not a subterfuge to evade the purposes of the ADA. See S. Rep. No. 101–116, at 29; H.R. Rep. No. 101–485, pt. 2, at 59.

³¹ See H.R. Rep. No. 101–485, pt. 2, at 75 (noting that “[a] growing number of employers . . . are offering voluntary wellness programs” and that “[a]s 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 preventing occupational advancement, these activities would fall within the purview of accepted activities”).

³² 29 CFR part 1630, app. 1630.16(f).

³³ EEOC, *Interim Enforcement Guidance: Application of the ADA to Health Insurance* 13, n.15 (1993), <http://eEOC.gov/policy/docs/guidance.pdf>.

Although employers claim that they use wellness programs to make their employees healthier and thus ultimately to reduce their health care costs, such use of wellness programs does not constitute underwriting or risk classification protected by the insurance safe harbor.

The Commission disagrees with the result in the two district court decisions that have applied the safe harbor provision far more expansively to support employers’ imposition of penalties on employees who do not answer disability-related questions or undergo medical examinations in connection with wellness programs, *Seff v. Broward County*³⁴ and *EEOC v. Flambeau, Inc.*³⁵ However, neither court ruled that the language of the statute was unambiguous. Hence, the agency has the authority and responsibility to provide its own considered analysis of the statutory provision, which is provided above.³⁶

The Commission also believes both cases were wrongly decided. The employers in *Seff* and *Flambeau* did not use wellness programs in a manner consistent with the application of the safe harbor provision. In neither *Seff* nor *Flambeau* did the employer or its health plan use wellness program data 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. Moreover, there is no evidence in either *Seff* or *Flambeau* that the decision to impose a surcharge or to exclude an employee from coverage under a health plan was based on actual risks that non-participating employees posed.

Seff, in particular, seems to endorse an almost limitless application of the safe harbor provision. The court thought

³⁴ *Seff v. Broward Cty.*, 778 F. Supp. 2d 1370 (S.D. Fla. 2011), *aff’d*, 691 F.3d 1221 (11th Cir. 2012) (involving an employer that charged employees who did not complete a health risk assessment 20 dollars every two weeks).

³⁵ *EEOC v. Flambeau, Inc.*, No. 14–cv–638–bbc, 2015 WL 9593632 (W.D. Wis. Dec. 30, 2015) (involving an employer that terminated insurance coverage of employee who did not undergo biometric screening).

³⁶ As the Supreme Court explained in *National Cable and Telecommunications Ass’n v. Brand X Internet Services*, 545 U.S. 967, 972 (2005), a judicial decision determining the meaning of a statutory provision is controlling only if it “holds that its construction follows from the unambiguous terms of the statute and thus leaves no room for agency discretion.” This follows from the deference accorded agencies under *Chevron U.S.A. Inc. v. National Resources Defense Council*, 467 U.S. 837, XX (1984). See also *id.* at 985 (“Before a judicial construction of a statute, whether contained in a precedent or not, may trump an agency’s, the court must hold that the statute unambiguously requires the court’s construction.”)

the safe harbor applied because the wellness program was “designed to mitigate” risks and was “based on the theory” that getting employees to be involved in their own health care leads to a healthier workforce.³⁷ If this were a sufficient justification for the safe harbor, then any medical inquiry directed at an employee as part of a health plan is permissible if there is some possibility—real or theoretical—that the information might be used to reduce risks. Thus, the requirement in 42 U.S.C. 12112(d)(4)(B) that disability-related inquiries and medical examinations conducted as part of a health program must be voluntary would be meaningless for anyone who receives employer-provided health insurance, because any inquiry or medical examination could be defended on the ground that it might result in reduced health risks.

Comments Responding to Questions in the NPRM

Certification in Lieu of Answering Disability-Related Inquiries or Undergoing Medical Examinations

Individuals, including individuals with disabilities and their advocates, commented that employees should be allowed to provide a certification from a medical professional that any medical risks they have are under active treatment instead of being required to complete a HRA or undergo a medical examination. By contrast, health insurance issuers and employer groups generally commented that allowing an employee to submit such a certification instead of completing a HRA would circumvent the ability of a wellness program to assess and mitigate health risks.

The Commission has decided that although some employees already may be aware of their particular risk factors, a general certification or attestation that they are receiving medical care for those risks would limit the effectiveness of wellness programs that the Affordable Care Act clearly intends to promote. For example, employers may use aggregate information from HRAs to determine the prevalence of certain conditions in their workforce to design specific programs aimed at improving the health of employees with those conditions. The Commission concludes that protections in the final rule—such as the requirement that wellness programs be reasonably designed to promote health or prevent disease, and confidentiality requirements that have been further strengthened over those in the proposed

³⁷ *Seff*, 778 F. Supp. 2d at 1374.

rule—provide employees with significant protections without adopting a medical certification as an alternative to completion of a HRA or biometric screening.

Whether To Incorporate an “Affordability Standard” To Determine Whether a Wellness Program Is “Voluntary”

One individual commented that if the EEOC feels constrained to adopt the rule that 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, it should at least do so based on the cost of the family premium for individuals who have family coverage.³⁸ Several disability advocacy groups commented that if the Commission retains its proposed “30 percent rule,” it should include protection for low-income employees and employees with disabilities, such that the incentives may not be so large as to render health insurance coverage unaffordable using a threshold far lower than the applicable percentage used to determine whether coverage is affordable under the Affordable Care Act (9.5 percent as adjusted). By contrast, a health insurance issuer commented that it is unclear how “low income” would be defined, or how an employer would be aware of an employee’s household financial circumstances in order to determine which employees would be considered low income. Other industry groups commented that current Treasury regulations already provide that the affordability of eligible employer-sponsored coverage is determined by assuming that each employee fails to satisfy the requirements of a wellness program (except for the requirements of a nondiscriminatory wellness program related to tobacco use).³⁹

The Commission has decided that by extending 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, this rule promotes the ADA’s interest in ensuring that incentive limits are not so high as to make participation in a wellness program involuntary. We also agree that the Treasury regulations that provide that the affordability of eligible

employer-sponsored coverage is determined by assuming that each employee fails to satisfy the requirements of a wellness program (except for the requirements of a nondiscriminatory wellness program related to tobacco use) already serves as a constraint on the level of incentives an employer may offer, since affordability generally is calculated based on the employee’s cost of coverage relative to his or her income without considering the value of any wellness program incentive. Accordingly, the Commission declines to incorporate an affordability standard into the final rule.

Wellness Programs Offered Outside of Employer-Sponsored Group Health Plans

Several comments were submitted in response to the question in the NPRM asking whether employers offer or are likely to offer wellness programs not in connection with a group health plan or group health insurance coverage (outside of a group health plan), and whether the final rule should specifically limit incentives provided as part of such programs. One advocacy group commented that more employers are sending employees to Exchanges for health care coverage but are offering wellness programs in an effort to improve employees’ health and increase job productivity. Some commenters stated that the final rule should apply both to wellness programs that are part of an employer-sponsored health plan as well as to wellness programs offered outside of such plans, while others asked the EEOC to clarify what it means for a wellness program “to be part of, or provided by, a group health plan.” One group said that an example of a wellness program offered outside of a group health plan is one that is available to all employees whether or not they participate in an employer-sponsored group health plan. Another group suggested criteria for determining whether a wellness program is part of or outside of a group health plan, such as: (1) Whether the program is offered by a vendor that has contracted with the group health plan or insurer; (2) whether it only is offered to employees enrolled in a group health plan; and (3) whether the wellness program is described as a covered benefit under the terms of the group health plan.

Rather than listing factors for determining whether a wellness program is part of, or outside of, an employer-sponsored group health plan, the Commission has decided that all of the provisions in this rule, including the requirement to provide a notice and the limitations on incentives, apply to all

wellness programs that include disability-related inquiries and/or medical examinations. This means that this rule applies to wellness programs that are: offered only to employees enrolled in an employer-sponsored group health plan; offered to all employees regardless of whether they are enrolled in such a plan; or offered as a benefit of employment by employers that do not sponsor a group health plan or group health insurance.

We considered taking the position that wellness programs that are not offered through a group health plan that require employees to provide medical information could not offer any incentives. However, such an approach would be inconsistent with our conclusion, with respect to wellness programs that are part of a group health plan, that the offer of limited incentives will not render the program involuntary. Similarly, allowing unlimited incentives where a wellness program is not offered through a group health plan would be inconsistent with our position that limitations on incentives are necessary to ensure voluntariness. Accordingly, as noted below, this rule explains how to calculate the permissible incentive level for wellness programs regardless of whether they are related or unrelated to a group health plan.

Comments Regarding Specific Provisions

Section 1630.14(d)(1): Explanation of What Constitutes a “Health Program”

Some commenters suggested that the EEOC leave it to the tri-Departments to determine what constitutes a health or wellness program, while others commented that wellness programs should be required to be based on clinical guidelines or national standards or have a stronger connection between the content of a HRA and the development of specific disease management programs.

The final rule acknowledges that satisfaction of the “reasonably designed” standard must be determined by examining all of the relevant facts and circumstances and otherwise retains the NPRM’s requirement 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-Department regulations applicable to health-contingent wellness programs.⁴⁰ In order to meet this

³⁸ See 26 U.S.C. 36B(c)(2)(C); 26 CFR 54.4980H–5(e).

³⁹ See 26 CFR 1.36B–2(c)(3)(v)(A)(4).

⁴⁰ This rule applies the “reasonably designed” standard to both participatory and health-contingent wellness programs, while the tri-

standard, a program—including a wellness program that is unrelated to a group health plan—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. Programs consisting of a measurement, test, screening, or collection of health-related information without providing results, follow-up information, or advice designed to improve the health of participating employees would not be reasonably designed to promote health or prevent disease, unless the collected information actually is used to design a program that addresses at least a subset of conditions identified. Further, imposing a penalty solely on an employee's failure to achieve a particular health outcome (such as failing to attain a certain weight or cholesterol level) would, in many instances, discriminate against individuals based on disability.⁴¹ The interpretive guidance offers examples of programs that would and would not meet this standard.

Finally, because the ADA generally restricts the medical information employers may obtain from employees, the Commission believes that requiring wellness programs that include disability-related inquiries and/or medical examinations to be “reasonably designed to promote health or prevent disease” is necessary to give meaning to

the exception for inquiries and examinations that are part of voluntary employee health programs. In addition, this is a standard with which health plans are now sufficiently familiar, and, thus, it is reasonable to apply that standard under the ADA to employers that sponsor wellness programs. Although the standard is less stringent than some commenters would prefer, the Commission believes it provides a sufficient level of protection against the misuse of employee medical information.

Section 1630.14(d)(2)(i) Through (iv): Definition of the Term “Voluntary”

(i) Does Not Require Employees To Participate

Individuals with disabilities and their advocates commented that participation in wellness programs is not voluntary when an employee has no choice or when financial penalties are the cost of opting out. By contrast, health insurance and employer groups commented that if an employee has a choice whether to participate, even if that choice may result in a penalty, participation should be considered voluntary.

To give meaning to the ADA's requirement that an employee's participation in a wellness program must be voluntary, the incentives for participation cannot be so substantial as to be coercive. We, therefore, reject the suggestion that merely offering employees a choice whether or not to participate renders participation voluntary, regardless of the consequences associated with that choice. Nonetheless, although substantial, the Commission concludes that, given current insurance rates, offering an incentive of up to 30 percent of the total cost of self-only coverage does not, without more, render a wellness program coercive. Accordingly, the final rule does not make any changes to the requirement that, in order for a wellness program to be considered voluntary, an employer may not require employees to participate in the program.

(ii) Does Not Deny Coverage Under Any Group Health Plan to Employees for Non-Participation

Some employer and health care groups commented that a number of employers have begun experimenting with tiered health plan benefit and cost-sharing structures (sometimes called “gateway plans”) that base eligibility for a particular health plan on completing a HRA or undergoing biometric screenings and asked the Commission to allow for such plans. For example, a

health insurance issuer commented that a current trend is to allow employees who participate in a wellness program to enroll in a comprehensive health plan, while offering non-participants a less comprehensive plan or one that requires higher premiums or cost-sharing.

The Commission concludes that the ADA does not prohibit an employer from denying an incentive that is within the limits set out in this final rule to an employee who does not participate in a wellness program that includes disability-related inquiries or medical examinations; nor does it prohibit requiring an employee to pay more for insurance that is more comprehensive. The ADA, however, does prohibit the outright denial of access to a benefit available by virtue of employment. When an employer denies access to a health plan because the employee does not answer disability-related inquiries or undergo medical examinations, it discriminates against the employee within the meaning of 42 U.S.C. 12112(d)(4) by requiring the employee to answer questions or undergo medical examinations that are not job related and consistent with business necessity and cannot be considered voluntary. Consequently, we decline to change this provision in the final rule to allow for the kind of tiered health plans described by commenters. However, an employer still may offer incentives up to 30 percent of the total cost of self-only coverage based on participation in a wellness program. Thus, an employee who chooses a more comprehensive health plan but declines to participate in a wellness program could pay more for the same comprehensive health plan than an employee who participates in a wellness program.

(iii) Does Not Take Any Adverse Action, Retaliate Against, or Coerce Employees Who Choose Not To Participate

Individuals, including individuals with disabilities and their advocates, and civil rights groups generally commented that because financial incentives can be significant enough to become coercive for many employees, the proposed rule did not offer enough protection and was inconsistent with the plain language of the ADA. Health insurance and employer groups, however, supported the provision.

No changes have been made to this paragraph, which states that, in order to be considered voluntary, an employer may not retaliate against, interfere with, coerce, intimidate, or threaten employees in violation of Section 503 of the ADA, codified at 42 U.S.C. 12203 (e.g., by coercing an employee to

Department regulations apply the standard only to health-contingent wellness programs. The tri-Department regulations also state that, in order to be reasonably designed, a health-contingent outcome-based wellness program must provide a reasonable alternative standard (or waiver) for an individual to qualify for a reward if the individual does not meet the initial standard based on a measurement, test, or screening that is related to a health factor. Under the ADA, a covered entity is required to provide a reasonable accommodation (a modification or adjustment) for a participatory program even though HIPAA and the Affordable Care Act do not require such programs to offer a reasonable alternative standard (although, under the HIPAA rules, a participatory program must be made available to all similarly situated individuals, regardless of health status). Finally, unlike the tri-Department regulations, the “reasonably designed” standard applies to all employee health programs that include disability-related inquiries and/or medical examinations, even if they are not related to a group health plan. See 26 CFR 54.9802–1(f)(3)(iii), (f)(4)(iii); 29 CFR 2590.702(f)(3)(iii), (f)(4)(iii); 45 CFR 146.121(f)(3)(iii), (f)(4)(iii).

⁴¹ Changes made to the ADA by the ADA Amendments Act of 2008 adopted a broad definition of “disability” that makes it easier for an individual to show that he or she has a disability, a record of a disability, or that an employer took some adverse action because it regarded him or her as having a disability (such as imposed a penalty for not meeting a particular health outcome).

participate in an employee health program or threatening to discipline an employee who does not participate).

(iv) Notice

The Commission asked whether the requirement that employees participating in wellness programs that ask disability-related questions and/or require medical examinations be given a notice concerning the information to be collected, how it will be used, with whom it will be shared, and how it will be kept confidential should apply to all wellness programs and not just to wellness programs that are part of a group health plan. We also asked whether a notice should be required where a covered entity offers only “de minimis” incentives. (See the discussion of de minimis incentives under “Types of Incentives” below.)

Some disability advocacy groups commented that rather than trying to define what constitutes de minimis rewards or penalties, the notice requirements should apply to all programs that include disability-related inquiries or medical examinations, regardless of whether they are part of a group health plan or offer incentives. However, an employer group commented that any notice requirements should be waived where incentives are only de minimis.

Because the importance of the information the notice communicates does not depend on whether a wellness program is part of a group health plan or whether incentives are offered in connection with the program, this provision of the final rule clarifies that the requirement to provide a notice applies to all wellness programs that ask employees to respond to disability-related inquiries and/or undergo medical examinations. For these wellness programs to be deemed voluntary, a covered entity must provide a notice—in language reasonably likely to be understood by the employee from whom medical information is being obtained—that clearly explains what medical information will be obtained, how the medical information will be used, who will receive the medical information, the restrictions on its disclosure, and the methods the covered entity uses to prevent improper disclosure of medical information.

Commenters representing employer and health care groups said that the notice requirement is duplicative of existing law, while others asked the Commission to provide model language for a notice that would meet the necessary requirements. Where an employer’s current written notifications

to employees regarding wellness programs include the required information, the employer can continue to use those notifications for all of its wellness programs that ask employees to respond to disability-related inquiries and/or undergo medical examinations. However, where current notifications do not include the detailed information required by this provision, even if the employer claims to meet requirements under another law, it must revise existing notifications or develop a new notice to comply with this final rule. Within 30 days of the final rule’s publication, the Commission will provide on its Web site an example of a notice that complies with this rule.

The Commission also asked whether the proposed notice provision should include a requirement that employees participating in wellness programs that include disability-related inquiries and/or medical examinations provide prior, written, and knowing confirmation that their participation is voluntary. Disability groups expressed concerns about employees who may unwittingly “waive” their privacy rights, particularly when completing online HRAs. For example, one group commented that some HRA Web sites include a provision, buried in an obscure link, stating that using the wellness program Web site constitutes a waiver of the person’s privacy rights. Other groups commented that employees should have the option to actively opt in to a privacy notification agreement and that they should be fully informed of everything that the vendor or third party might do with personal health data, including: Marketing products and services to the employee; disclosing personal information to third party vendors that help provide services on the vendor’s site; or authorizing the third party vendor to collect the employee’s health information directly or indirectly from interaction with the services and/or from the employee’s health care provider or health insurer.

Health insurance issuers and employer groups commented that requiring employers to collect signatures from non-participants would create an administrative burden and introduce additional costs and barriers to employers’ willingness to offer wellness programs and to employees’ participation. Another stakeholder said that if the point of the proposed regulation is to minimize confusion between the ADA and Affordable Care Act rules, requiring a written authorization would undermine that point and make the determination of a “voluntary” wellness program an employee-by-employee process rather

than a determination made at the program level.

Although the Commission has decided not to include a requirement that employees must provide prior, written, and knowing authorization, we are concerned that the completion of a HRA or disclosure of health information in connection with a wellness program, particularly when online resources are used, would cause employees to waive critical confidentiality protections of their health information. We have addressed this concern in the final rule’s provisions on confidentiality of medical information. (See the discussion of § 1630.14(d)(4)(v) below.)

Section 1630.14(d)(3): ADA’s 30 Percent Limit on Financial Incentives Generally

The Commission received numerous comments on this provision of the proposed rule. As stated in the general comments section of this preamble, disability advocacy groups and individuals with disabilities said that the proposed rule was based on the erroneous assumption that the ADA must be “conformed” to provisions of the Affordable Care Act concerning wellness programs. They also commented that allowing wellness programs to offer incentives of up to 30 percent of the total cost of self-only coverage in exchange for employees responding to disability-related inquiries or undergoing medical examinations would be coercive and would substantially weaken the ADA’s protections. While some individuals with disabilities did not categorically object to allowing employers to offer incentives to employees who provide health information, they stated that employees should not have to answer questions about their disabilities in order to receive whatever reward is offered. Employer and industry groups, however, commented that the EEOC should align the incentive limits for wellness programs with the incentive limits established in the tri-Department regulations.

The final rule reaffirms that an employer may offer incentives up to a maximum of 30 percent of the total cost of self-only coverage (including both the employee’s and employer’s contribution), whether in the form of a reward or penalty, to promote an employee’s participation in a wellness program that includes disability-related inquiries and/or or medical examinations as long as participation is voluntary. The 30 percent limit applies to all workplace wellness programs whether they are: Offered only to employees enrolled in an employer-sponsored group health plan; offered to

all employees whether or not they are enrolled in such a plan; or offered as a benefit of employment where an employer does not sponsor a group health plan or group health insurance coverage.

Calculation of Incentive Limit Based on Whether Employee Is Enrolled in a Health Plan

The final rule explains how to calculate the permissible incentive limit in four situations. First, where participation in a wellness program depends on enrollment in a particular group health plan, the employer may offer an incentive up to 30 percent of the total cost of self-only coverage (including both employer and employee contributions) under that plan. Second, where an employer offers a single group health plan, but participation in a wellness program does not depend on the employee's enrollment in that plan, an employer may offer an incentive of up to 30 percent of the total cost of self-only coverage under that plan. Third, where an employer has more than one group health plan, but participation in a wellness program does not depend on the employee's enrollment in any plan, the employer may offer an incentive up to 30 percent of the total cost of the lowest cost self-only coverage under a major medical group health plan offered by the employer. Finally, where an employer does not offer a group health plan or group health insurance coverage, the rule uses the cost of the second lowest cost Silver Plan⁴² available through the state or federal health care Exchange established under the Affordable Care Act in the location that the employer identifies as its principal place of business as a benchmark for setting the incentive limit. Thus, an employer may offer incentives up to a maximum of 30 percent of the cost that would be charged for self-only coverage under such a plan if purchased by a 40-year-old non-smoker.

The Commission has concluded that the employer's lowest cost self-only coverage under a major medical group health plan is an appropriate benchmark for establishing the incentive limit where an employer has more than one group health plan and participation in a wellness program does not depend on enrollment in any particular plan for two reasons. First, it offers employers

predictability and administrative efficiency in complying with the rule. Second, the rule is consistent with the Commission's objective of ensuring that incentives for answering disability-related questions or undergoing medical examinations do not become so high as to render the employee's participation involuntary.

The second lowest cost Silver Plan available on the Exchange in the location that the employer identifies as its principal place of business is used as a benchmark for determining the amount of an eligible individual's premium tax credit for purchasing health insurance on the Exchanges.⁴³ This is the most popular plan on the Exchanges, and information about its costs for individuals who are 40 years old and non-smokers is available to the public.⁴⁴ Additionally, because the Silver Plan typically is neither the least nor most expensive plan available on the Exchanges, incentive limits that are tied to its cost may promote participation in wellness programs while not being so high as to be coercive.

Types of Incentives

Some groups also commented that non-financial incentives should not be counted toward the cap. According to these commenters, determining the value of in-kind incentives, such as employee recognition, use of a parking spot, or easing of a dress code for a wellness participant are difficult, if not impossible, to determine and that including such non-financial incentives will add an additional administrative burden and possibly discourage the use of these kinds of incentives. Others commented that if the provision is adopted, the EEOC should avoid requiring plans to calculate the value of de minimis rewards when demonstrating compliance with applicable limits.

The final rule reaffirms that the offer of limited incentives (whether financial or in-kind) to encourage employees to participate in wellness programs 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 and health-contingent programs),

whether part of, or outside of, a group health plan, may not exceed 30 percent of the total cost of self-only coverage, which generally is the maximum allowable incentive available under HIPAA and the Affordable Care Act for health-contingent wellness programs.⁴⁵ The Commission sees no reason to exclude in-kind incentives based on the difficulty of valuing them when the tri-Department regulations clearly state that the term "incentives" means "any financial or other incentive."⁴⁶ Employers have flexibility to determine the value of in-kind incentives as long as the method is reasonable.

We also decline to exclude de minimis incentives. Although commenters gave examples of some incentives that might be considered de minimis, no commenters offered a workable principle or a dollar amount that could be used as the basis for defining which incentives are de minimis and which are not. We suspect that employers' interpretation of the term would vary, and there is no clear basis on which to establish a de minimis value threshold. Moreover, the tri-Department regulations do not distinguish between de minimis incentives and others for purposes of determining whether a plan has complied with the 30 percent incentive limit applicable to most health-contingent wellness programs, even though it is quite possible that health-contingent wellness programs utilize both de minimis and more substantial incentives. Consequently, we have not exempted the value of de minimis incentives from the 30 percent limit on incentives for wellness programs that include disability-related questions and/or medical examinations.

Calculation of Incentive Limit Based on Self-Only Coverage

Numerous commenters said that calculating the 30 percent limit on the total cost of self-only coverage does not align with the tri-Department regulations implementing HIPAA's

⁴⁵ See Incentives for Nondiscriminatory Wellness Programs in Group Health Plans, 78 FR 33158, 33,167 (June 3, 2013).

⁴⁶ See 26 CFR 54.9802-1(f)(1)(i); 29 CFR 2590.702(f)(1)(i); 45 CFR 146.121(f)(1)(i); see also FAQs About Affordable Care Act Implementation (Part XXIX) and Mental Health Parity Implementation, Q. 11, <http://www.dol.gov/ebsa/pdf/faq-aca29.pdf> (explaining that "a reward may be financial or non-financial (or in-kind). . . . [A]n individual obtaining a reward includes 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 (such as a deductible, copayment, or coinsurance), an additional benefit, or any financial or other incentive) and avoiding a penalty (such as the absence of a surcharge or other financial or nonfinancial disincentives)."

⁴² There are four "metal" categories of health plans in the Exchanges established under the Affordable Care Act: Bronze, Silver, Gold, and Platinum. See *How To Pick a Health Insurance Plan: The "Metal Categories"*, HealthCare.gov, <https://www.healthcare.gov/choose-a-plan/plans-categories/> (last visited March 29, 2016).

⁴³ See 26 U.S.C. 36B(b)(2).

⁴⁴ See, e.g., HHS, *Health Insurance Marketplaces 2015 Open Enrollment Period: March Enrollment Report* (2015), https://aspe.hhs.gov/sites/default/files/pdf/83656/ib_2015mar_enrollment.pdf (indicating that, based on marketplace enrollment from November 15, 2014 through February 15, 2015, 67 percent of people who selected a marketplace plan, selected Silver).

wellness program provisions, which provide that the incentive limit applies to the total cost of coverage in which the employee and any dependents are enrolled, when wellness programs are available to an employee's dependents or spouse. Because the ADA's prohibitions on discrimination—including its restrictions on disability-related inquiries and medical examinations—apply only to applicants and employees, not their spouses and other dependents, this rule does not address the incentives wellness programs may offer in connection with dependent or spousal participation.⁴⁷ However, because medical history about an employee's family members, including an employee's dependents and spouse, is considered genetic information about the employee, incentives offered in exchange for an employee's family member to provide such information implicates Title II of GINA.⁴⁸ The EEOC also publishes today a final rule under GINA concerning the extent to which employers may offer incentives for spouses and other family members to provide health-related information as part of a wellness program.⁴⁹

Incentives Related to Smoking Cessation Programs

The interpretive guidance accompanying the proposed rule explained the application of this provision to smoking cessation programs. Specifically, the interpretive guidance stated that because 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 30 percent incentive limit does not apply. Therefore, a covered entity may offer incentives as high as 50 percent of the cost of self-only coverage, pursuant to the regulations implementing section 2705(j) of the PHS Act, for such a

program. However, the interpretive guidance explained that because any biometric screening or other medical procedure that tests for the presence of nicotine or tobacco is a medical examination under the ADA, the 30 percent incentive limit would apply to such a screening or procedure.

Some commenters said that the distinction the proposed rule made between inquiries about tobacco use and tests to determine such use was confusing. Additionally, a national trade association representing large employers commented that the ADA's prohibition on medical examinations was intended to prohibit employers from acquiring and improperly using knowledge about an employee's or applicant's disability and was not intended to protect employees from restrictions on tobacco usage, which is not a disability. Other employer groups commented that EEOC should not reverse course on the efforts being made by wellness programs to discourage tobacco use, particularly since employees are not required to quit smoking/using tobacco but, rather, simply asked to participate in cessation programs.

The final rule retains the distinction between smoking cessation programs that require employees to be tested for nicotine use and programs that merely ask employees whether they smoke. Although the fact that someone smokes is not information about a disability, the ADA's provisions limiting disability-related inquiries and medical examinations apply to all applicants and employees, whether or not they have disabilities.⁵⁰ Moreover, whatever benefit smoking cessation programs that are part of wellness programs may have, the Commission can discern no reason for treating medical examinations to detect the use of nicotine differently from any other medical examinations when the ADA makes no such distinction.

Section 1630.14(d)(4)(i) Through (iv) (Previously 1630.14(d)(4) Through (d)(6)): Explanation of the Requirements Regarding Confidentiality of Medical Information

The NPRM had three subsections addressing the confidentiality of medical information obtained through voluntary health programs. Specifically, the Commission redesignated paragraph (d)(1) in § 1630.14, which states that information 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, as paragraph (d)(4) but did not change any of the exceptions to confidentiality set out in that section. It also redesignated paragraph (d)(2), which states that medical information regarding the medical history of any employee shall not be used for any purpose inconsistent with § 1630.14(d), as paragraph (d)(5). Finally, the Commission proposed to add a new paragraph (d)(6) to § 1630.14, 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.

Paragraph (d)(6) in § 1630.14 stated 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 explained 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.

Employer and health care groups suggested that the confidentiality provisions applicable to wellness programs should be more closely aligned with the HIPAA privacy and security standards and the Affordable Care Act. For example, an employer group commented that the EEOC's guidance implies that compliance with HIPAA's privacy and security standards may not always satisfy the ADA's requirement and that the final rule should explicitly state that compliance with the HIPAA privacy and security standards would satisfy the confidentiality requirement. By contrast, one individual commented that the Commission should strengthen employment non-discrimination protections beyond allowing disclosure of only aggregate information to the employer and recommended that individuals have the right to request that employers delete all their wellness data if they stop participating in the wellness program, or leave their employer.

In response, the Commission retains the requirements set forth in this paragraph but includes additional requirements to further protect employees' personal health information. The final rule also places all of the confidentiality requirements in a single

⁴⁷ The ADA's "association" provision that protects applicants and employees from discrimination based on their relationship or association with an individual with a disability also is not applicable here as it applies to only relationships to persons with a disability. See 42 U.S.C. 12112(b)(4).

⁴⁸ See 29 CFR 1635.3(c) (stating that genetic information includes information about "[t]he manifestation of disease or disorder in family members of [an] individual"); 29 CFR 1635.3(a)(1) (stating that a family member of an individual includes "a person who is a dependent of that individual as the result of marriage, birth, adoption, or placement for adoption").

⁴⁹ The final rule implementing Title II of GINA is published elsewhere in this issue of the **Federal Register**.

⁵⁰ See *Guidance*, *supra* note 10.

paragraph: paragraph (d)(4) in § 1630.14.⁵¹

In response to comments that participation in a wellness program, particularly completion of an online HRA, may result in employees waiving critical confidentiality protections, the final rule adds a new paragraph, (d)(4)(iv), which is similar to a provision in the final rule issued today under Title II of GINA. Section 1630.14(d)(iv) states 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 to waive confidentiality protections available under the ADA as a condition for participating in a wellness program or receiving a wellness program incentive.

The Commission declines to include a requirement that employers or wellness programs delete medical information of employees who elect not to continue participating in a wellness program. The ADA only requires that medical information of employees participating in health programs be maintained as a confidential medical record, subject to limited exceptions for its disclosure. We are mindful that other laws may require the retention of such information. Even the ADA's confidentiality provisions, codified at 42 U.S.C. 12112(d)(3)(B)(iii) and (4)(C), contemplate that otherwise confidential medical information may have to be shared with government officials investigating compliance with the ADA.

Section 1630.14(d)(5): Explanation of the Rule's Relationship to Other EEOC Nondiscrimination Laws

This paragraph of the proposed rule (previously § 1630.14(d)(7)) clarified that compliance with paragraph (d) of this section, including the limit on incentives under the ADA, does not relieve a covered entity of its obligation to comply with other employment nondiscrimination laws. Some commenters suggested that the final rule should give specific examples of wellness programs that violate other nondiscrimination laws, especially those that may have a disparate impact on a protected group.

The Commission has revised the interpretive guidance accompanying the proposed rule to further explain that 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 ADEA if that program discriminates on the basis of race, sex (including pregnancy, gender identity, transgender status, and sexual orientation), national origin, age, or any other grounds prohibited by those statutes. The interpretive guidance also explains that if a wellness program requirement (such as achieving a particular blood pressure or glucose level or body mass index) disproportionately affects individuals on the basis of some protected characteristic, an employer may be able to avoid a disparate impact claim by offering and providing a reasonable alternative standard.

Regulatory Procedures

Executive Order 12866

Pursuant to Executive Order 12866, the EEOC has coordinated this final rule with the Office of Management and Budget. Under section 3(f)(1) of Executive Order 12866, the EEOC has determined that the amended 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 final rule 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 rule's potential impact. The Commission notes that by providing standards applicable to wellness program incentives and clarity about other ADA provisions (including the insurance safe harbor provision), the rule will significantly aid compliance with the ADA and with HIPAA's nondiscrimination provisions, as amended by the Affordable Care Act, by employers and group health plans that offer wellness programs. Currently, employers that offer wellness programs as part of group health plans face uncertainty as to whether providing incentives permitted by HIPAA will subject them to liability under the ADA. Additionally, employers that do not offer health plans and so are not subject to the wellness program provisions of HIPAA, as amended by the Affordable Care Act, have no way to determine what, if any, incentives they may want to offer are permissible under the ADA. This rule clarifies that the ADA does permit employers to offer incentives to promote participation in wellness

programs that include disability-related inquiries and/or medical examinations and sets out the limits on such incentives. The rule also removes uncertainty about whether practices that have been the subject of litigation, such as conditioning enrollment in an employer's health plan on participation in a wellness program that asks disability-related questions or requires medical examinations, are prohibited.

The Commission does not believe the costs associated with the rule are significant. Employers covered by the ADA that offer wellness programs as part of their group health plans are already required to comply with wellness program incentive limits for health-contingent wellness programs. EEOC's final rule differs from HIPAA's wellness program incentives 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 that are part of group health plans. Employers that offer wellness programs that do not require employees to participate in a particular group health plan can determine incentive limits by reference to readily available information about the cost of their own group health plan or, in the case of employers that do not offer group health insurance, the cost of the second lowest Silver Plan available under the state or federal Exchanges under the Affordable Care Act.

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 265,880 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 1,063,520 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

⁵¹ Nothing in this rule is intended to affect the ability of a health oversight agency to receive data under HIPAA. See 45 CFR 164.501 and 512(d).

December 2014, and the average hourly compensation for employees working in “office and administrative support” was \$23.98.⁵² 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 \$42,296,190. 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 sought but did not receive 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 or by coercion, intimidation, and threats. Employers are also required to provide reasonable accommodations to enable employees to enjoy the equal benefits and privileges of employment, including 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 final rule will result in no additional costs as the ADA already requires employers to keep medical information about applicants and employees confidential.

To the extent this 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 satisfy its obligation to comply with § 1630.14(d)(4)(iii) by adhering to

the HIPAA Privacy Rule.⁵³ 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 this 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 § 1630.14(d)(4)(iii) only so long as it is de-identified in accordance with the HIPAA Privacy Rule.

Paperwork Reduction Act

The final rule contains 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.

Overview of This Information Collection

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

OMB number: 3046–0047.

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, or outside of, group health plans.

Number of respondents: 265,880.

Initial one-time hour burden: 1,063,520.

Annual hour burden: None.

Number of forms: None.

Federal cost: None.

Abstract: The final rule says that a wellness program that includes disability-related inquiries or medical examinations—whether it is part of, or outside 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.

The NPRM asked for comments on whether the proposed notice

requirement was necessary and on the accuracy of its burden estimate. Although none of the comments specifically addressed the burden estimate, some commenters said that the notice requirement was duplicative of existing law, while others asked the Commission to provide model language for a notice that would meet necessary requirements. *Burden Statement:* We estimate that there are approximately 782,000 employers with 15 or more employees subject to the ADA⁵⁴ and, of that number, one half to two thirds (391,000 to 521,333) offer some type of wellness program as part of, or outside of, a group health plan.⁵⁵ Of those employers, 32 percent to 51 percent require employees to complete a HRA that likely contains disability-related questions.⁵⁶ Using the highest estimates, we assume that 265,880 employers (51 percent of 521,333 employers) will be covered by this requirement.

The final rule states that, to the extent that employers already use forms that provide the requisite information in an applicable document that complies with disclosures required under ERISA and HIPAA, they do not have to create a new notice to satisfy the requirements of this provision and can use the same notice for all of its wellness programs that ask employees to respond to disability-related inquiries and/or undergo medical examinations. Therefore, the burden only will be on employers 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.

Within 30 days of the final rule’s publication, the Commission will provide on its Web site an example of a notice that complies with the rule. Thus, the Commission anticipates that the sample notice will reduce an employer’s burden by making it easier to satisfy this requirement. Because we

⁵⁴ See *Firm Size Data*, Small Business Administration, <http://www.sba.gov/advocacy/849/12162> (last visited March 28, 2016).

⁵⁵ According to a RAND report, “approximately half of U.S. employers offer wellness promotion initiatives.” *RAND Final Report*, *supra* note X, at xiv. By contrast, a survey by the Kaiser Family Foundation found that “[s]eventy-four percent of employers offering health benefits” offer at least one wellness program. See *Kaiser Survey*, *supra* note 6, at 6.

⁵⁶ The *Kaiser Survey* reports that 51 percent of large employers versus 32 percent of small employers ask employees to complete a HRA.

⁵² See Bureau of Labor Statistics, *Employer Costs for Employee Compensation—December 2014* (2015), www.bls.gov/news.release/pdf/eccec.pdf.

⁵³ See 45 CFR parts 160 and 164, subparts A and E, respectively.

do not have data on which to base an estimate of time saved, we likely overstate the burden by assuming that creation of such a document will take four hours, and assuming that 265,880 employers will be covered by rule, this one-time burden would be 1,063,520 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.

Regulatory Flexibility Act

Title I of the ADA applies to approximately 782,000 employers with 15 or more employees, 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.⁵⁷

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. The final rule clarifies that, in most respects, employers that offer wellness programs that are part of, or outside of, their health plans may offer incentives to employees consistent with HIPAA and the Affordable Care Act without violating the ADA. The rule also clarifies that employers that offer wellness programs to all employees, regardless of whether they are enrolled in a group health plan, and employers that offer wellness programs but do not provide group health insurance, also may provide incentives for participation in such programs consistent with the limits set forth in this rule.

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 fiscal year 2014, the agency's outreach programs reached more than 236,000 persons through participation in more than 3,500 no-cost educational, training, and outreach events. Now that this rule is final, we will include information about the revisions to the regulations in our general outreach programs and continue to offer ADA-specific outreach programs that will include this information. On the date this rule is published, we also will post technical assistance documents on our Web site

explaining the revisions to these 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, 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 \$49.41.⁵⁸ 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 \$74.12 and \$370.60.

The EEOC does not believe that this cost will be significant for the impacted small entities.

Unfunded Mandates Reform Act of 1995

This 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 reasons set forth in the preamble, the EEOC amends 29 CFR part 1630 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. In § 1630.14:

- a. Redesignate paragraph (d)(1) introductory text as paragraph (d)(4)(i) with the subject heading *Confidentiality*;
- b. Add new paragraph (d)(1) introductory text;
- c. Redesignate paragraphs (d)(1)(i), (ii), and (iii) as (d)(4)(i)(A), (B), and (C);
- d. Redesignate paragraph (d)(2) as paragraph (d)(4)(ii);
- e. Add new paragraph (d)(2) and paragraph (d)(3);
- f. Add paragraphs (d)(4)(iii) and (d)(4)(iv); and
- g. Add paragraphs (d)(5) and (6);

The revisions and additions read as follows:

⁵⁸ See *Occupational Employment and Wages*, Bureau of Labor Statistics, <http://www.bls.gov/oes/current/oes113121.htm> (last visited March 28, 2016).

§ 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. A program consisting of a measurement, test, screening, or collection of health-related information without providing results, follow-up information, or advice designed to improve the health of participating employees is not reasonably designed to promote health or prevent disease, unless the collected information actually is used to design a program that addresses at least a subset of the conditions identified. 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 or simply to give an employer information to estimate future health care costs. Whether an employee health program is reasonably designed to promote health or prevent disease is evaluated in light of all the relevant facts and circumstances.

(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, codified at 42 U.S.C. 12203; and
- (iv) 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;

⁵⁷ See *Firm Size Data*, *supra* note 54.

(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.* The use of incentives (financial or in-kind) in an employee wellness program, whether in the form of a reward or penalty, 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:

(i) Thirty percent of the total cost of self-only coverage (including both the employee's and employer's contribution) of the group health plan in which the employee is enrolled when participation in the wellness program is limited to employees enrolled in the plan;

(ii) Thirty percent of the total cost of self-only coverage under the covered entity's group health plan, where the covered entity offers only one group health plan and participation in a wellness program is offered to all employees regardless of whether they are enrolled in the plan;

(iii) Thirty percent of the total cost of the lowest cost self-only coverage under a major medical group health plan where the covered entity offers more than one group health plan but participation in the wellness program is offered to employees whether or not they are enrolled in a particular plan; and

(iv) Thirty percent of the cost of self-only coverage under the second lowest cost Silver Plan for a 40-year-old non-smoker on the state or federal health care Exchange in the location that the covered entity identifies as its principal place of business if the covered entity does not offer a group health plan or group health insurance coverage.

(4) * * *

(iii) Except as permitted under paragraph (d)(4)(i) of this section and as

is necessary to administer the health plan, information obtained under this paragraph (d) 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.

(5) Compliance with the requirements of this paragraph (d), 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.

(6) The "safe harbor" provisions in § 1630.16(f) of this part applicable to health insurance, life insurance, and other benefit plans do not apply to wellness programs, even if such plans are part of a covered entity's health plan.

■ 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 many 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 flu shots.

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. Other employers offer wellness programs that are available to all employees, regardless of whether they are in enrolled in a group health plan, while some employers offer wellness programs but do not sponsor a group health plan or group health insurance.

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. Asking employees to complete a HRA and/or undergo a biometric screening 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 HRAs by an employer to design and offer health programs aimed at specific conditions identified by the information collected. 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 meaningful follow-up information or advice, such as providing feedback about specific risk factors or using aggregate information to design programs or treat any specific conditions, would not be reasonably designed to promote health or prevent disease. 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 or simply to give an employer information to estimate future health care costs.

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

Section 1630.14(d)(2)(i) through (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 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 (e.g., having to pay a higher deductible) may be the result of forgoing a financial incentive permissible under § 1630.14(d)(3), 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 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),(b); 29 CFR 1630.12.

Section 1630.14(d)(2)(iv) of this part also states that for a wellness program that includes disability-related inquiries or medical examinations 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 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: (i) 30 Percent of the total cost of self-only coverage (including both the employee's and employer's contribution) where participation in a wellness program depends on enrollment in a particular health plan; (ii) 30 percent of the total cost of self-only coverage when the covered entity offers only one group health plan and participation in a wellness program is offered to all employees regardless of whether they are enrolled in the plan; (iii) 30 percent of the total cost of the lowest cost self-only coverage under a major medical group health plan where the covered entity offers more than one group health plan but participation in the wellness program is

offered to employees whether or not they are enrolled in a particular plan; or (iv) 30 percent of the cost to a 40-year-old non-smoker of the second lowest cost Silver Plan (available under the Affordable Care Act) in the location that the employer identifies as its principal place of business, where the covered entity does not offer a group health plan or group health insurance coverage. The following examples illustrate how to calculate the permissible incentive limits in each of these situations.

Where an employee participates in a wellness program that is only offered to employees enrolled in a group health plan and the total cost of self-only coverage under that plan is \$6,000 annually, the maximum allowable incentive is \$1,800 (30 percent of \$6,000). The same incentive would be available if this employer offers only one group health plan and allowed employees to participate in the wellness program regardless of whether they are enrolled in the health plan. Suppose, however, an employer offers three different group health plans with the total cost of self-only coverage under its major medical group health plans ranging in cost from \$5,000 to \$8,000 annually and wants to offer employees incentives for participating in a wellness program that includes a HRA and medical examination regardless of whether they are enrolled in a particular health plan. In that case, the maximum allowable incentive is \$1,500 (30 percent of the total cost of the lowest cost self-only coverage under a major medical group health plan). Finally, if the employer does not offer health insurance but wants to offer an incentive for employees to participate in a wellness program that includes disability-related inquiries or medical examinations, the maximum allowable incentive is 30 percent of what it would cost a 40-year-old non-smoker to purchase the second lowest cost Silver Plan on the federal or state health care Exchange in the location that the employer identifies as its principal place of business. Thus, if such a plan would cost \$4,000, the maximum allowable incentive would be \$1,200.

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 (such as an activity-based program that requires employees to exercise or walk) and that are part of a group health plan 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 generally 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, and reasonable alternative standards are not required at all if the program is not part of a group health plan.

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 a 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 self-only coverage for tobacco-related wellness programs, such as smoking cessation programs. As noted above, the incentive rules in paragraph 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 § 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 self-only 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)(i) Through (v): Confidentiality

Paragraphs (d)(4)(i) and (ii) 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, and sharing such information could be inconsistent with the definition of an employee health 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)(4)(iii) 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 § 1630.14(d)(4)(i). 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"), Public Law 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 they believe a health plan fails to comply with privacy requirements and HHS may require corrective action or 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 § 1630.14(d)(4)(iii) 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 § 1630.14(d)(4)(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. 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 § 1630.14(d)(4)(iii) 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 § 1630.14(d)(4)(i) and (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)(4)(iv) says 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 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. 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 to discriminate on the basis of disability in violation of the ADA.

Section 1630.14(d)(5): Compliance With Other Employment Nondiscrimination Laws

Section 1630.14(d)(5) 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 (including pregnancy, gender identity,

transgender status, and sexual orientation), color, religion, national origin, or age. Additionally, if a wellness program requirement (such as a particular blood pressure or glucose level or body mass index) disproportionately affects individuals on the basis of some protected characteristic, an employer may be able to avoid a disparate impact claim by offering and providing a reasonable alternative standard.

Section 1630.14(d)(6): Inapplicability of the ADA's Safe Harbor Provision

Finally, section 1630.14(d)(6) 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 classify, underwrite, and administer risks, does not apply to wellness programs, even if such programs are part of a covered entity's health plan. The safe harbor permits insurers and employers (as sponsors of health or other insurance benefits) to treat individuals differently based on disability, but only where justified according to accepted principles of risk classification (some of which became unlawful subsequent to passage of the ADA). *See* Senate Report at 85–86; House Education and Labor Report at 137–38. It does not apply simply because a covered entity asserts that it used information collected as part of a wellness program to estimate, or to try to reduce, its risks or health care costs.

Dated: May 11, 2016.

For the Commission:

Jenny R. Yang,
Chair.

[FR Doc. 2016–11558 Filed 5–16–16; 8:45 am]

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EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1635

RIN 3046–AB02

Genetic Information Nondiscrimination Act

AGENCY: Equal Employment Opportunity Commission.

ACTION: Final rule.

SUMMARY: The Equal Employment Opportunity Commission (EEOC or Commission) is issuing a final rule to amend the regulations implementing Title II of the Genetic Information Nondiscrimination Act of 2008 as they relate to employer-sponsored wellness programs. This rule addresses the extent to which an employer may offer an inducement to an employee for the employee's spouse to provide information about the spouse's manifestation of disease or disorder as part of a health risk assessment (HRA) administered in connection with an employer-sponsored wellness program. Several technical changes to the existing

regulations are included. Published elsewhere in this issue of the **Federal Register**, the EEOC also issued a final rule to amend the regulations and interpretive guidance implementing Title I of the Americans with Disabilities Act (ADA) that addresses the extent to which employers may use incentives to encourage employees to participate in wellness programs that ask them to respond to disability-related inquiries and/or undergo medical examinations.

DATES: *Effective date:* This rule is effective July 18, 2016.

Applicability date: This rule is applicable beginning on January 1, 2017.

FOR FURTHER INFORMATION CONTACT:

Christopher J. Kuczynski, Assistant Legal Counsel, at (202) 663–4665 (voice), or Kerry E. Leibig, Senior Attorney Advisor, at (202) 663–4516 (voice), or (202) 663–7026 (TTY). (These are not toll free numbers.) Requests for this rule 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: The Commission issued a proposed rule in the **Federal Register** on October 30, 2015, for a 60-day notice and comment period, which was extended for an additional 30 days and ended on January 28, 2016. After consideration of the public comments, the Commission has revised portions of both the final rule and the preamble.

Introduction

Several federal laws govern wellness programs offered by employers. Employer-sponsored wellness programs must comply with Title II of the Genetic Information Nondiscrimination Act of 2008 (GINA),¹ Title I of the ADA,² and other employment discrimination laws enforced by the EEOC. Employer-sponsored wellness programs that are part of, or provided by, a group health plan³, or that are provided by a health insurance issuer offering group health insurance in connection with a group health plan, must also comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) nondiscrimination provisions, as amended by the Affordable Care Act, 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).⁴ This final rule relates specifically to the requirements of Title II of GINA as they apply to employer-sponsored wellness programs, though other applicable laws are discussed in some detail.

Congress enacted Title II of GINA to protect job applicants, current and former employees, labor union members, and apprentices and trainees from employment discrimination based on their genetic information.⁵ GINA generally restricts the acquisition and disclosure of genetic information and prohibits the use of genetic information in making employment decisions.⁶ The EEOC issued implementing regulations on November 9, 2010, to provide all persons subject to Title II of GINA additional guidance with regard to the law's requirements.⁷

Discussion

Title II of GINA prohibits the use of genetic information in making employment decisions in all circumstances, with no exceptions. It also restricts employers and other

⁴ The Patient Protection and Affordable Care Act, Public Law 111–148, and the Health Care and Education Reconciliation Act, Public Law 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 health insurance market. The Affordable Care Act also added section 715(a)(1) to the Employee Retirement Income Security Act (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.

⁵ Title I of GINA applies to genetic information discrimination in health coverage (not employment), is applicable to group health plans and health insurance issuers, and is administered by the tri-Departments. Under Title I, group health plans may include, as part of a HRA, questions regarding the manifestation of a disease or disorder of individuals covered under the plan, but not genetic information (defined to include genetic test information about the individual or of family members of the individual or the manifestation of disease or disorder in family members of the individual not covered under the plan). *See* 42 U.S.C. 300gg–91(d)(16); *see also* 26 CFR 54.9802–3T(b)(2); 29 CFR 2590.702–1(b)(2); 45 CFR 146.122(a)(3). This final rule, however, which is specific to Title II, provides that all health information provided by a spouse to an employer as part of a HRA is genetic information with respect to the employee, even where both the employee and spouse are covered by the plan.

⁶ S. Rep. No. 110–48, at 10 (2007); H.R. Rep. No. 110–28, pt. 3, at 29 (2007).

⁷ *See* Regulations Under the Genetic Information Nondiscrimination Act of 2007, 75 FR 68,912 (Nov. 9, 2010) (codified at 29 CFR pt. 1635).

¹ 42 U.S.C. 2000ff–2000ff–11.

² 42 U.S.C. 12101–12117.

³ The term "group health plan" includes both insured and self-insured group health plans, and is used interchangeably with the terms "health plan" and "the plan" in this Final Rule.