



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 [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

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

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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

¹ 42 U.S.C. 2000ff–2000ff-11.

² 42 U.S.C. 12101–12117.

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

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.

⁴ The Patient Protection and Affordable Care Act, Pub. L. 111-148, and the Health Care and Education Reconciliation Act, Pub. L. 111-152, are known collectively as the Affordable Care Act. Section 1201 of the Affordable Care Act amended and moved the nondiscrimination and wellness provisions of the Public Health Service (PHS) Act from section 2702 to section 2705 and extended the nondiscrimination provisions to the individual 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

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 entities covered by GINA⁸ from requesting, requiring, or purchasing genetic information, unless one or more of six narrow exceptions applies, and strictly limits the disclosure of genetic information by GINA-covered entities.⁹ The statute and the 2010 Title II final rule define “genetic information” to include: information about an individual’s genetic tests; information about the genetic tests of a family member; information about the manifestation of a disease or disorder in family members of an individual (i.e., family

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).

⁸ Unless otherwise noted, the term “GINA” refers to Title II of GINA.

⁹ See 42 U.S.C. 2000ff–2000ff-11; see also 29 CFR 1635.4–1635.9.

medical history);¹⁰ requests for and receipt of genetic services by an individual or a family member; and genetic information about a fetus carried by an individual or family member or of an embryo legally held by the individual or family member using assisted reproductive technology.¹¹ Family members of an individual include someone who is a dependent of an individual through marriage, birth, adoption, or placement for adoption and any other individual who is a first-, second-, third-, or fourth-degree relative of the individual.¹²

There are only six limited circumstances in which an employer¹³ may request, require, or purchase genetic information about an applicant or employee. One exception

¹⁰ Congress recognized “that a family medical history could be used as a surrogate for genetic traits by a health plan or health insurance issuer. A consistent history of a heritable disease in a patient’s family may be viewed to indicate that the patient himself or herself is at increased risk for that disease.” For that reason, Congress believed it was important to include family medical history in the definition of “genetic information.” S. Rep. No. 110-48, at 28.

¹¹ See 42 U.S.C. 2000ff(4), 2000ff-8(b); see also 29 CFR 1635.3.

¹² See 42 U.S.C. 2000ff(3)(A) (defining family member for purposes of GINA to include a dependent within the meaning of section 701(f)(2) of ERISA); see also 29 CFR 1635.3(a). The Commission’s definition of “dependent” is solely for purposes of interpreting Title II of GINA, and is not relevant to interpreting the term “dependent” under Title I of GINA or under section 701(f)(2) of ERISA and the parallel provisions of the PHS Act and the Code. See the preamble to the EEOC’s regulations implementing Title II of GINA at 75 FR 68,914, note 5 (and the preamble to the regulations implementing Title I of GINA at 74 FR 51,664, 51,666) for additional information.

¹³ GINA applies to individuals and covered entities in addition to employees and employers, including employment agencies, unions and their members, and joint-labor management training and apprenticeship programs. See 42 U.S.C. 2000ff-1, 2000ff-2, 2000ff-3, 2000ff-4 (describing the prohibited practices of each of these entities); see also 29 CFR 1635.2(b) (defining “covered entity”), 1635.4 (describing prohibited practices). For the sake of readability, and recognizing that employers will be the covered entity most likely to offer employer-sponsored wellness programs, the preamble will refer to employers and employees throughout.

permits employers that offer health or genetic services, including such services offered as part of voluntary wellness programs,¹⁴ to request genetic information as part of these programs, as long as certain specific requirements are met.¹⁵ The regulations implementing Title II currently make clear that one of the requirements is that the employer-sponsored wellness program cannot condition inducements to employees on the provision of genetic information.¹⁶ This requirement is derived from a prohibition in

¹⁴ A wellness program, defined as a “program offered by an employer that is designed to promote health or prevent disease,” is one type of health or genetic service that an employer might offer. See Section 2705(j)(1)(A) of the PHS Act, as amended by the Affordable Care Act. A wellness program that provides medical care (including genetic counseling) may constitute a group health plan required to comply with section 9802 of the Code, 26 U.S.C. 9802, section 702 of the ERISA, 29 U.S.C. 1182, or section 2705 of the PHS Act (i.e., Title I of GINA). Regulations issued under these statutes address employer-sponsored wellness programs that collect genetic information. Moreover, employer-sponsored wellness programs that condition rewards on an individual satisfying a standard related to a health factor must meet additional requirements. See 26 CFR 54.9802-1(f); 29 CFR 2590.702(f); 45 CFR 146.121(f). As noted above, the EEOC has also issued a final rule amending the regulations and interpretive guidance implementing Title I of the ADA as they relate to employer-sponsored wellness programs. See 29 CFR 1630.14, published elsewhere in this issue of the Federal Register.

¹⁵ See 42 U.S.C. 2000ff-1(b)(2), 2000ff-2(b)(2), 2000ff-3(b)(2), 2000ff-4(b)(2); see also 29 CFR 1635.8(b)(2). Other health or genetic services include services such as an Employee Assistance Program or a health clinic that provides flu shots. Under GINA, employers may request genetic information as part of such health or genetic services, as long as the requirements of 29 CFR 1635.8(b)(2) are met.

¹⁶ See 29 CFR 1635.8(b)(2)(ii). Consistent with the requirements of paragraph (b)(2)(i) of this section, a covered entity may not offer an inducement for individuals to provide genetic information, but may offer inducements for completion of HRAs that include questions about family medical history or other genetic information, provided the covered entity makes clear, in language reasonably likely to be understood by those completing the HRA, that the inducement will be made available whether or not the participant answers questions regarding genetic information.

Title I of GINA (which applies to health plans and health insurance issuers) against adjusting premium or contribution amounts on the basis of genetic information.¹⁷

Although the EEOC received no comments prior to the publication of the Title II final rule in 2010 regarding how GINA's restriction on employers' acquiring genetic information interacts with the practice of offering employees inducements where a spouse participates in an employer-sponsored wellness program, this question arose after publication of the Title II final rule in 2010. Read one way, such a practice could be interpreted to violate the 29 CFR 1635.8(b)(2)(ii) prohibition on providing financial inducements in return for an employee's protected genetic information. This is because information an employer seeks from a spouse (who is a "family member" under GINA as set forth at 42 U.S.C. 2000ff(4)(a)(ii) and 29 CFR 1635.3(a)(1)) about his or her manifestation of disease or disorder is treated under GINA as requesting genetic information about the employee. Although the EEOC's original regulations specifically permitted employers to seek information about manifestation of diseases or disorders in employees' family members who are receiving health or genetic services from the employer, including such services offered as part of a voluntary employer-sponsored

¹⁷ Title I of GINA applies to genetic information discrimination in health coverage and not employment. The Departments responsible for enforcing Title I determined that permitting employers to condition wellness program inducements on the provision of genetic information would undermine Title I's prohibition on adjusting premium or contribution amounts on the basis of genetic information. For more on the protections provided by Title I of GINA, see DOL – Employee Benefits Security Administration, FAQs on the Genetic Information Nondiscrimination Act (2010), www.dol.gov/ebsa/pdf/faq-GINA.pdf. For a discussion of how Titles I and II of GINA allow employers and plans to use financial inducements to promote employee wellness and healthy lifestyles, see the preamble to the 2010 Title II final rule at 75 FR 68,923 (Nov. 9, 2010).

wellness program,¹⁸ the regulations did not say whether inducements could be provided in exchange for such information. The Commission now finalizes the clarification that an employer may, in certain circumstances, offer an employee limited inducements for the employee's spouse to provide information about the spouse's manifestation of disease or disorder as part of a HRA administered in connection with an employer-sponsored wellness program, provided that GINA's confidentiality requirements are observed and any information obtained is not used to discriminate against an employee.¹⁹ However, this narrow exception to the general rule that inducements may not be offered in exchange for an employee's genetic information does not extend to genetic information about a spouse or to information about manifestation of diseases or disorders in, or genetic information about, an employee's children.

Background on the Notice of Proposed Rulemaking on GINA and Employer-Sponsored 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

¹⁸ See 29 CFR 1635.8(c)(2).

¹⁹ One industry group argued that using the phrase "current or past health status" to describe the types of questions to spouses that could include inducements was confusing because not all information about a spouse's current or past health status meets the definition of genetic information. In order to clarify that the rule only applies to questions asked of the spouse that meet the definition of genetic information, the final rule will replace the phrase "current or past health status" with "manifestation of disease or disorder."

Executive Order 12067).²⁰ The NPRM was then published in the Federal Register on October 30, 2015 for a 60-day public comment period,²¹ which was extended for an additional 30 days²² and ended on January 28, 2016.

The NPRM sought comment on the proposed revisions to the GINA regulation which:

- Clarified that an employer may offer, as part of its health plan, a limited inducement (in the form of a reward or penalty) to an employee whose spouse (1) is covered under the employee's health plan; (2) receives health or genetic services offered by the employer, including as part of a wellness program; and (3) provides information about his or her current or past health status.
- Explained that the total inducement for an employee and spouse to participate in an employer-sponsored wellness program that is part of a group health plan and collects information about the spouse's current or past health status may not exceed 30 percent of the total cost of the plan in which the employee and any dependents are enrolled.
- Described how inducements must be apportioned between the employee and spouse.

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 Genetic Information Nondiscrimination Act, 80 FR 66853 (proposed October 30, 2015) (to be codified at 29 CFR part 1635).

²² Genetic Information Nondiscrimination Act, 80 FR 75956 (proposed December, 7, 2015) (to be codified at 29 CFR part 1635).

- Explained that inducements may be financial or in kind, consistent with regulations issued by DOL, HHS, and Treasury to implement the wellness program provisions in the Affordable Care Act. For that reason, the proposed rule deleted the term “financial” where it appeared as a modifier for the term “inducement” in 29 CFR 1635.8(b)(2).
- Explained that any request for current or past health status information from an employee’s spouse must comply in all other respects with 29 CFR 1635.8(b)(2) concerning requests for genetic information that are part of voluntary health or genetic services offered by an employer.
- Explained that an employer may not require employees (or employees’ spouses or dependents covered by the employees’ health plan) to agree to the sale, or waive the confidentiality, of their genetic information as a condition for receiving an inducement or participating in an employer-sponsored wellness program.
- Added an example making it clear that a request for current or past health status information from an employee’s spouse who is participating in a wellness program does not constitute an unlawful request for genetic information about the employee.
- Made several technical changes to correct a previous drafting error and to add references, where needed, to HIPAA and the Affordable Care Act.

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

- Whether employers that offer inducements to encourage the spouses of employees to disclose information about current or past health status must also offer similar inducements to persons who choose not to disclose such information but, who

instead, provide certification from a medical professional stating that the spouse is under the care of a physician and that any medical risks identified by that physician are under active treatment.

- Whether the proposed authorization requirements apply only to employer-sponsored wellness programs that offer more than de minimis rewards or penalties to employees whose spouses provide information about current or past health status as part of a HRA.
- Which best practices or procedural safeguards ensure that employer-sponsored wellness programs are designed to promote health or prevent disease and do not operate to shift costs to employees with spouses who have health impairments or stigmatized conditions.
- Whether the rule should include more specific guidance to employers regarding how to implement the requirements of 29 CFR 1635.9(a) for electronically stored records. If so, what procedures are needed to achieve GINA's goal of ensuring the confidentiality of genetic information with respect to electronic records stored by employers.
- Whether there are best practices or procedural safeguards to ensure that information about spouses' current health status is protected from disclosure.
- Whether the regulation should restrict the collection of any genetic information by an employer-sponsored wellness program to only the minimum necessary to directly support the specific wellness activities, interventions, and advice provided through the program – namely information collected through the program's HRA and

- biometric screening. Should programs be prohibited from accessing genetic information from other sources, such as patient claims data and medical records data.
- Whether employers offer (or are likely to offer in the future) wellness programs outside of a group health plan or group health insurance coverage that use inducements to encourage employees' spouses to provide information about current or past health status as part of a HRA, and the extent to which the GINA regulations should allow inducements provided as part of such programs.

Summary of Revisions and Response to Comments

During the 60-day comment period, which was extended by 30 days, the Commission received 3,003²³ comments on the NPRM from a wide spectrum of stakeholders, including, among others: individuals, including individuals with disabilities; disability rights and other advocacy organizations and their members; members of Congress; employer associations and industry groups; and health insurance issuers, third party administrators, and wellness vendors. The comments from individuals included 2,911 similar, but not uniform, letters – almost all of which were submitted by a national organization that supports women and families. Most of the comments (3,000) were submitted through the United States Government's electronic docket system, Regulations.gov, under EEOC-2015-0009. The remaining three comments were mailed or faxed to the Executive Secretariat.

The Commission has reviewed and considered each of the comments in preparing this final rule. The first section of this preamble begins by clarifying the purpose of this

²³ One of these comments was withdrawn when the commenter submitted a "corrected" version of the comment.

rule. It goes on to address general comments about the interaction between GINA and the wellness program provisions of HIPAA, as amended by the Affordable Care Act; interaction between GINA and the ADA; the final rule's applicability date; the rule's treatment of inducements for information from the children of employees; the confidentiality protections of the rule; tobacco cessation programs; and the Commission's burden calculations.

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

The third section addresses comments regarding specific provisions of the rule.

General Comments

Purpose of the Rule

Many comments submitted by individuals objected to a rule that would allow employers to charge employees more for benefits based on the illness of family members, impose stiff penalties on people that do not measure up to certain health guidelines, allow employers to fire or otherwise adversely treat employees based on medical information collected through employer-sponsored wellness programs, and/or allow "metrics" that would harm millions of people with disabilities. This rule, however, is more limited in scope. Instead, it addresses the very limited question of the extent to which an employer may offer inducements to an employee for the employee's spouse to provide information about the spouse's manifestation of disease or disorder as part of a HRA administered in connection with an employer-sponsored wellness program. The absolute prohibition on the use of genetic information to make employment decisions enshrined in Title II of

GINA remains intact, as do the existing protections of Title I of the ADA, which prohibits discrimination on the basis of disability.

Interaction Between GINA and HIPAA's Wellness Program Provisions

The Commission received comments expressing support for and/or concerns about employer-sponsored wellness programs. For example, many commenters stated that although properly designed employer-sponsored 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 for discrimination in ways already prohibited by GINA and other civil rights laws, by allowing employers to coerce employees into providing genetic information (as well as other health information). Disability rights and health advocacy groups expressed concern that the EEOC was abandoning its prior position that GINA prohibits financial inducements in return for all genetic information, while employer and industry groups commented that the proposed rule's limitation on inducements was inconsistent with the wellness program rules under section 2705(j) of the PHS Act. Disability rights groups further noted that there was no need to alter Title II of GINA's prohibition on financial incentives in order to conform to laws that regulate insurance discrimination, given that Title II of GINA is about employment discrimination, and pointed out that the tri-Department wellness regulations explicitly state that GINA imposes separate and additional restrictions.

Although the Commission recognizes that compliance with the standards in HIPAA, as amended by the Affordable Care Act, is not determinative of compliance with

Title II of GINA,²⁴ we believe that the final rule interprets GINA in a manner that reflects both GINA's goal of providing strong protections against employment discrimination based on the possibility that an employee or the employee's family member may develop a disease or disorder in the future and HIPAA's provisions promoting wellness programs. Additionally, as we pointed out in the preamble to the proposed rule, allowing limited inducements for spouses to provide information about manifested diseases or disorders (but not their own genetic information) as part of a HRA administered in connection with an employer-sponsored wellness program is consistent with HIPAA, as amended by the Affordable Care Act, and Title I of GINA.²⁵ Accordingly, after consideration of all of the comments, the Commission reaffirms its conclusion that allowing inducements in return for a spouse providing information about his or her manifestation of disease and disorder, while limiting inducements to prevent economic coercion, is the best way to effectuate the purposes of the wellness provisions of GINA and HIPAA.

²⁴ As the tri-Department wellness regulations acknowledge, the Affordable Care Act did not amend or overturn GINA, and compliance with the Affordable Care Act and its implementing regulations is not determinative of compliance with GINA. See *Incentives for Nondiscriminatory Wellness Programs in Group Health Plans*, 78 FR 33158, 33168 (June 3, 2013). A publication issued jointly by the tri-Departments further explains that a wellness program that complies with the tri-Departments' wellness program regulations does not necessarily comply with any other provision of the PHS Act, the Code, ERISA, (including the Consolidated Omnibus Budget Reconciliation Act (COBRA) continuation provisions), or any other state or federal law, such as the ADA, or the privacy and security obligations of HIPAA, where applicable. Similarly, the fact that an employer-sponsored 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 the Affordable Care Act Implementation (part XXV)*, Question 2 (2015), <http://www.dol.gov/ebsa/pdf/faq-aca25.pdf> and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Tri-agency-Wellness-FAQS-4-16-15pdf-AdobeAcrobat-Pro.pdf>.

²⁵ See 80 FR at 66857, *supra* note 20.

Interaction with the ADA and Other Equal Employment Opportunity (EEO) Laws

The Commission received a number of comments requesting that the final rule be issued jointly with the final ADA wellness rule, a suggestion that has been adopted.

Comments raising more substantive concerns about the interaction between the ADA and GINA focused on the desire for alignment of the inducement limits available under the statutes, suggesting that the incentive limit under the ADA, which is based on the total cost of self-only coverage, be revised to correspond with the inducement limit proposed in the GINA NPRM, which is based on the total cost of coverage for the plan in which the employee and any dependents are enrolled. The Commission declines to adopt this recommendation, however, because the ADA does not apply to the inducements employer-sponsored wellness programs offer in connection with spousal participation. As discussed in more detail below, this final GINA rule will, consistent with the ADA final rule, limit the maximum share of the inducement attributable to the employee's participation in an employer-sponsored wellness program (or multiple employer-sponsored wellness programs that request such information) to up to 30 percent of the cost of self-only coverage. Furthermore, the maximum total inducement for a spouse to provide information about his or her manifestation of disease or disorder will also be 30 percent of the total cost of (employee) self-only coverage, so that the combined total inducement will be no more than twice the cost of 30 percent of self-only coverage.

An advocacy group representing older individuals commented that protections similar to those proposed in the ADA wellness NPRM against conditioning access to employer-provided health insurance on the provision of medical information to an employer-sponsored wellness program and on retaliation against those who do not

participate should be included in the GINA final rule. Protections in the statute and the existing GINA regulations make clear that an employer may not use genetic information to make employment decisions, including decisions about benefits.²⁶ Both the statute and the existing regulations also provide that it is unlawful for an employer to discriminate against any individual because that individual has opposed any act or practice made unlawful by Title II of GINA.²⁷ We agree, however, that it would improve the final rule specifically to provide that it is a violation of Title II of GINA for an employer to deny access to health insurance or any package of health insurance benefits to an employee and/or his or her family members, or to retaliate against an employee, based on a spouse's refusal to provide information about his or her manifestation of disease or disorder to an employer-sponsored wellness program. We have added clarification to the final rule at §1635.8(b)(2)(v).

Another advocacy group whose mission is to protect the rights of women and girls asked that the final rule include language making clear that in addition to complying with the requirements of the final rule, employers must abide by other nondiscrimination provisions, including, for example, Title VII of the Civil Rights Act of 1964. We have not added any language to the final rule on this topic because the existing regulations already state that nothing contained in §1635.8(b)(2) limits the rights or protections of an individual under the ADA, or other applicable civil rights laws, or under HIPAA, as amended by GINA. We have made technical revisions to this provision due to the changes made to the renumbering of other provisions.

²⁶ See 42 U.S.C. 2000ff-1(a), 2000ff-2(a), 2000ff-3(a), 2000ff-4(a); 29 CFR 1635.4.

²⁷ See 42 U.S.C. 2000ff-8(c); 29 CFR 1635.7.

Applicability Date

Employer associations and industry groups 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 ADA wellness rule, and that it not be applied retroactively. The Commission agrees and concludes that the provisions of §1635.8(b)(2)(iii) related to wellness program inducements will apply only prospectively to employer-sponsored 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 inducement permitted under this regulation. So, for example, if the plan year for the health plan used to calculate the permissible inducement limit begins on January 1, 2017, that is the date on which the provisions of this rule governing inducements apply to the employer-sponsored wellness program. If the plan year of the plan used to calculate the level of inducements begins on March 1, 2017, the provisions on inducements will apply to the employer-sponsored 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.²⁸

²⁸ Prior EEOC interpretations set forth in the 2010 final rule implementing Title II of GINA, Regulations Under the Genetic Information Nondiscrimination Act of 2007, 75 FR 68912 (Nov. 9, 2010) (codified at 29 CFR part 1635), and the proposed rule on GINA and employer-sponsored wellness programs, Genetic Information Nondiscrimination Act, 80 FR 66853 (proposed Oct. 30, 2015) (to be codified at 29 CFR part 1635), may be considered in determining whether inducements provided prior to this applicability date for an employee's spouse or other dependents to provide information about their

Prohibition on Inducements for Information from Children of Employees

A number of advocacy groups, employer groups, and industry groups, in addition to members of Congress, submitted comments concerning the Commission's proposal that no inducement be permitted in return for the current or past health status information or the genetic information of employees' children. Two commenters, pointing to the fact that Title II of GINA defines "family members" to include both spouses and children, argued that there was no basis for making a distinction between spouses and children and that, therefore, no inducements should be permitted in return for current or past health information of either. Others argued that prohibiting inducements in return for past or current health information of children conflicts with the Affordable Care Act's requirement that employers who offer health insurance coverage to dependents of employees must offer coverage to dependents up to age 26 and that, therefore, inducements should be permitted in return for current or past health information from both spouses and children. Although some commenters agreed with the Commission's argument that health information about a child is more likely to reveal genetic information about an employee, one commenter noted that this does not support the distinction made in the proposed rule because the same cannot be said of health information about a spouse and adopted children. Commenters also asked for clarification of whether the prohibition applied to the current or past health status information of all children, including children up to the age of 26 who are permitted to remain on their parents' health plans, or just minor children, with some urging the

manifested diseases or disorders as part of an employer-sponsored wellness program comply with GINA.

Commission to extend the prohibition and others arguing that children between the ages of 18 and 26 were not in need of this additional protection and would benefit from participation in an employer-sponsored wellness program.

The Commission maintains its conclusion that the information about the manifestation of a disease or disorder in an employee's child can more easily lead to genetic discrimination against an employee than information about an employee's spouse. Even where the information provided concerns an adopted child, it is unlikely that a wellness program will know whether the child is biological or adopted, and the information may therefore be used to make predictions about an employee's health. Consequently, the final rule provides that no inducements are permitted in return for information about the manifestation of disease or disorder of an employee's children and makes no distinction between adult and minor children or between biological and adopted children.

The fact that the final rule treats health information about spouses and children differently with respect to wellness program inducements, however, does not alter the statutory definition of family member, which includes both spouses and children. Nor does the distinction, as suggested by some commenters, mean that employers are prohibited from offering health or genetic services (including participation in an employer-sponsored wellness program) to an employee's children on a voluntary basis. They may do so, but may not offer any inducement in exchange for information about the manifestation of any disease or disorder in the child.²⁹

²⁹ See 29 CFR 1635.8(b)(2)(A)(iii).

The Commission agrees with commenters who suggested that the final rule should clarify that the prohibition on inducements applies to adult children. The possibility that information about a child could be used to discriminate against an employee on the basis of genetic information is not diminished by the age of the child whose information is provided. Therefore, the rule does not distinguish between minor children and those 18 years of age and older, and makes explicit that the prohibition extends to adult children. This clarification is being made to 29 CFR 1635.8(b)(2)(A)(iii).

Confidentiality Protections

The Commission received numerous comments from individuals and advocacy groups asking that we strengthen the confidentiality protections of the rule, especially given that the availability of inducements in return for certain genetic information would likely mean that more genetic information will end up in the hands of employer-sponsored wellness programs. Commenters questioned how employer-sponsored wellness programs would use the information, to whom they would disclose and/or sell it, and how they would ensure that it remained confidential. One commenter further noted that many people erroneously assume that the privacy protections of HIPAA apply to all employer-sponsored wellness programs and therefore “may let their privacy guard down.” Some of these commenters provided specific examples of ways in which employer-sponsored wellness programs were not maintaining, or might not maintain in the future, the confidentiality of genetic information in their possession – pointing to, for example, advances in technology that allow for the re-identification and de-aggregation of unidentifiable and aggregate data that some employer-sponsored wellness programs

are taking or might take advantage of – and/or made specific suggestions on how GINA’s confidentiality protections could be improved. These suggestions included, among other ideas: adding a requirement that individuals have the right to receive copies of all personal information collected about them as part of an employer-sponsored wellness program, to challenge the accuracy and completeness of that information, and to obtain a list of parties with whom that information was shared and a description of the compensation or consideration received for that disclosure; providing that covered entities are strictly liable for any confidentiality breaches and are not permitted to disclaim liability for harms that result from sharing data; requiring wellness programs to delete all genetic information obtained about an individual participating in the employer-sponsored wellness program if that individual stops participating and requests that his or her genetic information be deleted; and prohibiting the storage of individually identifiable information obtained by the wellness program on work computers, servers, or paper files. Another commenter noted that the rule should include confidentiality protections for health information provided by spouses who do not want that information to fall into the hands of the employee, due, for example, to domestic violence.

In response, the Commission notes that Title II of GINA and the existing regulations implementing it include specific confidentiality provisions which require employers and other covered entities that possess genetic information to maintain it in medical files (including where the information exists in electronic forms or files) that are separate from personnel files and treat such information as a confidential medical record. These provisions prohibit the disclosure of genetic information except in six very limited

circumstances.³⁰ The provision which allows employers to acquire genetic information as part of health or genetic services such as employer-sponsored wellness programs further requires that the authorization an individual must sign explain the restrictions on the disclosure of that information; that individually identifiable genetic information is provided only to the individual receiving the services and the licensed health care professionals or board certified genetic counselors involved in providing those services; and that any individually identifiable genetic information is only available for purposes of the health or genetic services and is not disclosed to the employer except in aggregate terms.³¹ The Commission intends to continue its vigorous enforcement of these requirements and believes that they already provide strong protections against unlawful disclosure of genetic information provided as part of employer-sponsored wellness programs.³² Some of the ideas offered by advocacy groups as best practices, such as giving individuals the right to receive copies of genetic information collected about them, are already requirements of the regulation.³³ Although others may make sense as best practices, such as allowing an individual to challenge the accuracy of genetic information within the employer's possession, the Commission does not believe it is necessary to add to the already stringent confidentiality requirements that exist in the regulations.

Tobacco Cessation

³⁰ See 42 U.S.C. 2000ff-5; 29 CFR 1635.9.

³¹ See 42 U.S.C. 2000ff-1(b)(2), 2000ff-2(b)(2), 2000ff-3(b)(2), 2000ff-4(b)(2); 29 CFR 1635.8(b)(2)(i).

³² 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 164.512(d).

³³ See 29 CFR 1635.9(b)(1).

Several commenters asked that the Commission clarify its position on GINA’s application to tobacco-related employer-sponsored wellness programs, such as smoking cessation programs. In response, we reaffirm that the inducement rules in §1635.8(b)(2) apply only to health and genetic services that request genetic information. An employer-sponsored wellness program does not request genetic information when it asks the spouse of an employee whether he or she uses tobacco or ceased using tobacco upon completion of a wellness program or when it requires a spouse to take a blood test to determine nicotine levels, as these are not requests for information about the spouse’s manifestation of disease or disorder.

Burden

One commenter asserted that the EEOC underestimated the burden the proposed rule would impose on employers, arguing that the rule was an economically significant one that would have an annual effect on the economy of \$100 million or more. Among other things, the commenter argued that the EEOC underestimated training, compliance review, and program revision costs; failed to include “familiarization” costs; and failed to provide necessary empirical support for various conclusions. We disagree.

The proposed rule appropriately estimated the training cost by using wage data from the Bureau of Labor Statistics indicating a median \$49.41 per hour wage for human resource management professionals.³⁴ Although the commenter argues that this rate should be tripled to reflect “fully loaded” hourly rates paid by the government to private

³⁴ The EEOC estimated that a covered entity will train three human resource management professionals, for one hour each. The estimated cost was \$49.41 per person and \$148.23 per covered entity.

contractors for professional labor, actual hourly wages of human resource professionals better estimate the economic costs of training. The fully loaded hourly rate inappropriately includes coverage of the private contractor's fixed costs and, as a result, will erroneously bias the estimated economic impact. Costs such as a private contractor's office rent and marketing budget are not an economic impact of the regulation. As such, the estimate of the marginal economic impact of the regulation excludes firms' fixed costs because those costs are incurred whether or not the GINA regulation is revised. Moreover, in most cases, a covered entity's compliance effort will be conducted by its own human resource management professionals. The median wage of human resource management professionals therefore reasonably estimates the economic impact of up to three person-hours of staff time. The EEOC's estimates of three human resource professionals per covered entity and one hour per person are cautious and reflect agency experience and expertise.

In response to the commenter's argument that the projected costs should have included the hiring of a private contractor to provide training, we reiterate that human resource professionals will be able to learn what is necessary for compliance with the rule by reading the EEOC's freely provided technical assistance documents, or participating in our general or GINA-specific outreach programs, many of which are free.

Although the commenter asserts that "great effort" will be expended by entities that are not covered by Title II of GINA in reading the rule to ensure that they are not covered and that these costs should be included, the proposed regulation does not alter long established coverage requirements of Title II of GINA, and it is unlikely that entities that have never before concerned themselves with compliance with this and other

workplace nondiscrimination laws will now undergo “great effort” to ensure that the changes in this rule do not apply to them.

Finally, we note that the final rule does not require any changes to employer-sponsored wellness programs that are already in compliance with Title II of GINA and its existing implementing regulations. Instead, this rule merely clarifies that offering limited inducements to spouses is permitted in certain circumstances.

We, therefore, reiterate our conclusion that the rule 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.

Comments Responding to Questions in the NPRM

One commenter argued that the Commission could not take any action on issues described only in the portion of the NPRM that asked questions because the mere posing of a question does not provide the regulated community with sufficient information to adequately assess the impact of any eventual proposal as required by the Administrative Procedure Act (APA). We note, however, that notice is sufficient under the APA when the final rule “follow[s] logically” from the notice so that “interested parties [are allowed] a fair opportunity to comment” upon what becomes the final rule.³⁵ The NPRM described the “subjects and issues involved” as required by the APA.³⁶ The fact that the

³⁵ See Conn. Light & Power v. Nuclear Regulatory Comm’n., 673 F.2d 525, 533 (D.C. Cir. 1982).

³⁶ “The Administrative Procedure Act requires an agency engaged in informal rule-making to publish a notice of proposed rule-making in the Federal Register that includes

EEOC did receive comments on all seven of the “subjects and issues” raised in the questions demonstrates that the notice was adequate.³⁷

Certification in Lieu of Spouse Providing Information about Manifestation of Disease or Disorder

Individuals, including individuals with disabilities and their advocates, as well as one insurance company and one industry group, commented that spouses should be allowed to provide a certification from a medical professional stating that the spouse is under the care of a physician and that any medical risks identified by that physician are under active treatment, instead of being required to answer questions about manifested diseases or disorders. By contrast, most of the health insurance issuers, industry groups, and employer groups that commented argued that allowing a spouse to receive the same inducement for completing such a certification would circumvent the ability of an employer-sponsored wellness program to assess and mitigate health risks. Several industry groups also pointed out that this alternative was not necessary because the tri-Department wellness regulations already provide a waiver standard that is sufficient to ensure individuals can earn full inducements even if an impairment makes it difficult to meet the requirements of a health-contingent wellness program.

‘either the terms or substance of the proposed rule or a description of the subjects and issues involved.’” See id. at 530 (quoting the APA, 5 U.S.C. 553(b)(3)).

³⁷ “The purpose of the comment period is to allow interested members of the public to communicate information, concerns, and criticisms to the agency during the rule-making process.” Id.; see also City of Stoughton v. EPA, 858 F.2d 747, 753 (D.C. Cir. 1988) (holding that petitioner could not challenge sufficiency of notice when petitioner had submitted comments on the issue that petitioner claimed was inadequately noticed).

The Commission has decided that although some spouses may already 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 employer-sponsored wellness programs that the Affordable Care Act intended to promote. For example, employers may use aggregate information from HRAs to determine the prevalence of certain conditions in their workforce and in the families of their workforce for the purpose of designing specific programs aimed at improving the health of employees and spouses with those conditions.³⁸ The Commission concludes that protections in the final rule – such as the requirement that employer-sponsored wellness programs that collect genetic information be reasonably designed to promote health and prevent disease and the existing confidentiality requirements – provide spouses with significant protections without adopting a medical certification as an alternative to providing information about the manifestation of disease or disorder.

Applying Authorization Requirements Only to Employer-Sponsored Wellness Programs that Offer More than De Minimis Inducements for Information about Spouses'

Manifestation of Disease or Disorder

Most of the individuals and advocacy groups who commented on this issue argued that the authorization requirements should apply to all employer-sponsored wellness programs, regardless of the level of inducement offered, in order to provide appropriate protections for genetic information. Some of these commenters noted that

³⁸ See, e.g., RAND Health, Workplace Wellness Programs Study Final Report, 101 (2013), http://www.rand.org/content/dam/rand/pubs/research_reports/RR200/RR254/RAND_RR254.pdf [hereinafter RAND Final Report].

employers have ways to pressure employees to participate in wellness programs that have nothing to do with inducements, and others noted that any ambiguity in the definition of “de minimis” could lead to failure to obtain authorization even when significant inducements are offered. Although one health insurance company asserted that the authorization rule should apply to all employer-sponsored wellness programs due to the administrative complications that different standards would cause, most health insurance companies, as well as the employer associations and industry groups that commented on this issue, went beyond asserting that there should be a de minimis exception to the authorization rules and argued for more significant revisions to the proposed rule. For example, some argued that the EEOC has no statutory authority to impose a requirement that employers obtain authorization from spouses, others argued that asking a spouse about his or her own health was not genetic information and, therefore, not subject to GINA at all, others argued that a de minimis exception should apply to all of the requirements of the proposed rule, and still others argued that the EEOC should consider whether the authorization requirement in general serves any purpose, given that a family’s decision to participate in an employer-sponsored wellness program should be sufficient confirmation of voluntariness.

We decline to exclude programs that offer de minimis inducements from the authorization requirement of the rule. Although commenters gave examples of some inducements that might be considered de minimis, no commenters offered a workable principle that could be used as the basis for defining which inducements 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 threshold for the de minimis value. We

have responded to arguments that the authorization requirement of the rule be eliminated for various reasons in the in-depth discussion of the authorization provision, below. (See Comments Regarding Specific Provisions: Authorization for Collection of Genetic Information).

Best Practices or Procedural Safeguards to Ensure Employer-Sponsored Wellness Programs Are Designed to Promote Health or Prevent Disease and Do Not Operate to Shift Costs

Individuals and advocacy groups responded to this question with the same suggestions they made for strengthening the definition of employer-sponsored wellness programs that are “reasonably designed to promote health or prevent disease,” discussed below, raising ideas such as requiring that employer-sponsored wellness programs be based on scientifically valid evidence or that they include due process protections for individuals who claim rules are unfairly applied to them. Health insurance issuers, employer associations, and industry groups similarly reasserted the objections they raised in response to the proposed rule’s suggestion that a “reasonably designed” standard be adopted, arguing that existing HIPAA, Affordable Care Act, and GINA protections are sufficient to protect against discrimination and unlawful disclosures of genetic information. Some also expressed frustration with the very idea that employer-sponsored wellness programs might operate to shift costs in a discriminatory way. The final rule will not adopt additional protections to safeguard spousal information or prevent cost-shifting, because existing protections are sufficient. We will, however, discuss these issues in more detail below, given that they essentially reiterate comments received in response to the proposal to adopt a “reasonably designed” standard. (See Comments

Regarding Specific Provisions: Health or Genetic Services Must Be Reasonably Designed).

More Specific Guidance and Procedures on Confidentiality Requirements for Electronically Stored Records

Several commenters urged the EEOC to convene expert stakeholder groups or hold public meetings to determine what guidance should be offered to employers on how to protect electronically stored data. Some commented that the EEOC should require specific protocols to maximize the safety of electronically stored genetic information without providing specifics; others provided suggested restrictions or referred to security standards such as those being developed by the Precision Medicine Initiative or those that already exist under the HIPAA Privacy and Security Rules (some arguing that HIPAA's existing standard already sufficiently restricts employer-provided wellness programs and others arguing that rules identical to those under HIPAA should be specifically applied to all employer-provided wellness programs). Others argued that since it is unclear whether certain kinds of genetic information can ever be stored in a way that prevents re-identification, employers should not be permitted to store such data (e.g., molecular genetic data).

The goal of the confidentiality and disclosure rules of GINA is to protect genetic information as required by the statute whether that information is in paper or electronic format. As noted above, the regulations already have specific confidentiality provisions that require employers and other covered entities that possess genetic information to maintain it in medical files (including where the information exists in electronic forms or files) that are separate from personnel files, and treat such information as a confidential

medical record. These provisions prohibit the disclosure of genetic information except in six very limited circumstances.³⁹ The provision that allows employers to acquire genetic information as part of health or genetic services such as wellness programs further requires that the authorization form the employer must provide to an individual to sign before providing genetic information as part of health or genetic services must explain the restrictions on the disclosure of that information. Specifically, the authorization must explain that individually identifiable genetic information is provided only to the individual receiving the services and the licensed health care professionals or board certified genetic counselors involved in providing those services; and that any individually identifiable genetic information is only available for purposes of the health or genetic services and is not disclosed to the employer except in aggregate terms.⁴⁰ Although we do not believe that it is necessary to adopt additional protections for electronically stored data, we believe there are certain best practices that employers may want to consider in terms of safeguarding all genetic information in their possession.⁴¹

Best Practices or Procedural Safeguards to Ensure That Information about Spouses’
Manifested Diseases or Disorders Is Protected From Disclosure

³⁹ See 42 U.S.C. 2000ff-5(b); 29 CFR 1635.9.

⁴⁰ See 29 CFR 1635.8(b)(2)(i).

⁴¹ See, e.g., 29 CFR part 1630 app. 1630.14(d)(4)(i) through (iv): Confidentiality, which describes best practices such as ensuring that individuals who handle medical information (in this case, genetic information) that is part of an employee health program are not responsible for making decisions related to employment, and that breaches of confidentiality are reported to affected employees immediately and thoroughly investigated.

Those who commented on this question raised points quite similar to those raised about ensuring the confidentiality of electronically stored data, which are discussed above. Health insurance issuers, employer associations, and industry groups asserted that existing HIPAA privacy and security requirements, along with GINA's existing rules, were sufficient, while advocacy groups provided ideas for strengthening applicable confidentiality requirements. We reiterate that we do not believe that additional protections are needed, given GINA's requirements that genetic information be kept confidential and disclosed in only six limited circumstances, but urge employers to consider adopting best practices such as those set forth in the appendix accompanying the ADA Final Rule, issued today. Such practices include adoption and communication of strong privacy policies, training for individuals who handle confidential medical information, encryption of electronic files, and policies that require prompt notification of employees whose information is compromised if data breaches occur.

Restriction on the Collection of Genetic Information to Only the Minimum Necessary to Directly Support the Specific Wellness Activities and Prohibition on Accessing Genetic Information from Other Sources

Individuals and advocacy groups argued that the collection of genetic information by employer-sponsored wellness programs should be restricted to the minimum necessary to directly support specific wellness activities and interventions. Many of these commenters also urged the EEOC to prohibit employer-sponsored wellness programs from obtaining genetic information from sources other than voluntarily submitted health risk assessments and biometric screenings, such as patient claims data or medical records data. Taking the opposite view, health insurance issuers, employer associations, and

industry groups argued against adopting any further restrictions on employer-sponsored wellness programs. Some asserted that information from sources such as claims data and medical records assists in the development of effective employer-sponsored wellness programs and that restricting access to it would impede the design and success of the programs. These commenters also pointed out that when an employer-sponsored wellness program is offered as part of a health plan, it may work more optimally to allow that program to quickly identify people in need of services by using claims data already being received by the administrator of the health plan. These and other commenters noted that no additional restrictions were needed because the existing frameworks of the ADA and GINA adequately limit the information that may be collected as part of an employer-sponsored wellness program, while others said that existing tri-Department wellness rules requiring “reasonable design” ensure that programs are nondiscriminatory. Several of these commenters also noted that any additional restrictions would unnecessarily stifle innovation in the design and implementation of employer-sponsored wellness programs.

The final rule will not include a specific restriction on the collection of genetic information to only the minimum necessary to directly support specific employer-sponsored wellness program activities or a limitation on accessing genetic information from other sources. The Commission believes that the protections in the final rule – such as the requirement that employer-sponsored wellness programs that collect genetic information be reasonably designed to promote health and prevent disease and the existing confidentiality requirements – provide significant protections for employees and

spouses without adopting further restrictions or limitations. (See Comments Regarding Specific Provisions: Health or Genetic Services Must Be Reasonably Designed).

Employer-Sponsored Wellness Programs Offered Outside of Employer-Sponsored Group Health Plans

Numerous comments offering a broad range of opinions were submitted in response to the question in the NPRM asking whether employers offer or are likely to offer wellness programs outside of a group health plan or group health insurance coverage that use inducements to encourage employees' spouses to provide information about current or past health status as part of a HRA, and the extent to which the GINA regulations should allow inducements provided as part of such programs. Some commenters stated many employers already offer wellness programs that are outside group health plans, while others pointed out that employer-sponsored wellness programs that offer medical care are group health programs in themselves. Some argued that the final rule should apply both to wellness programs that are part of an employer-sponsored health plan and to wellness programs offered by employers outside 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." Others argued against applying the final rule to programs offered by employers that operate outside group health plans (thereby either allowing these programs to impose higher inducements in return for genetic information or, in the opinion of one advocacy group, meaning that these programs would be prohibited from offering inducements for genetic information at all). One employer association asserted that many of its members offer inducements for HRAs only under employer-sponsored wellness programs that are part of a larger group health plan, but

that the breadth of the tri-Department's wellness program rules has the effect of applying at least some nondiscrimination requirements to nearly all wellness programs. That commenter concluded that it would be a better use of the EEOC's time to work on the alignment of Title II of GINA with the Affordable Care Act, rather than focusing on this issue. One industry group indicated that the proposed rule failed to provide guidance for stand-alone wellness programs and argued that anything less than the 30 percent maximum incentive standard would conflict with the Affordable Care Act.

Rather than listing factors for determining whether an employer-sponsored 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 apply to all employer-sponsored wellness programs that request genetic information. This means that this rule applies to employer-sponsored wellness programs that are: offered only to spouses of employees enrolled in an employer-sponsored group health plan; offered to spouses of all employees regardless of whether the employee or spouse is enrolled in such a plan; or offered as a benefit of employment to spouses of employees of employers who do not sponsor a group health plan or group health insurance.

We considered taking the position that employer-sponsored wellness programs that are not offered through a group health plan and that request information about the manifestation of disease or disorder from spouses could not offer any inducements. However, having concluded that some level of inducement is consistent with other requirements of 29 CFR 1635.8(b)(2), including the requirement that the employer-sponsored wellness program be "voluntary," where the wellness program is part of a group health plan, there seemed to be no basis for reaching a contrary conclusion with

respect to employer-sponsored wellness programs that are outside of a group health plan. At the same time, allowing unlimited inducements where an employer-sponsored wellness program is not offered through a group health plan would be inconsistent with our position that limitations on spousal inducements are necessary to promote GINA's interest in limiting access to genetic information and ensuring that inducements are not so high as to be coercive. Accordingly, as noted below, this rule explains how to calculate the permissible inducement level for employer-sponsored wellness programs regardless of whether they are related to a group health plan.

Comments Regarding Specific Provisions

Section 1635.8(b)(2)(i)(A) Health or Genetic Services Must Be Reasonably Designed

The NPRM proposed that employers may request, require, or purchase genetic information as part of health or genetic services only when those services, including any acquisition of genetic information that is part of those services, are reasonably designed to promote health or prevent disease. Many commenters, including health insurance issuers, employer associations, industry groups, and a Congressional committee, urged the EEOC to strike this requirement, noting that it was beyond the EEOC's authority under GINA to impose a reasonable design requirement on health and genetic services and that the EEOC should leave it to the tri-Departments to determine what constitutes a reasonably designed employer-sponsored wellness program. Some of these commenters further noted that the proposed requirement was confusing because even though it sounded very similar, or even identical, to the corresponding requirement in the Affordable Care Act, it seemed to mean something different. They urged the Commission to delete the examples in the preamble and instead make clear that, as with

the Affordable Care Act, satisfaction of the reasonable design standard is based on all facts and circumstances. Several of these commenters made specific mention of the preamble’s example of a HRA that would not meet the “reasonably designed” standard – one that collected information without providing follow-up information or advice – arguing that this conclusion did not conform to the Affordable Care Act’s definition and that it is not always appropriate to provide follow-up information. Some further argued that if the Commission was going to rely on examples to explain the standard, it should put the examples in the regulation itself and make them more detailed.

Individuals and advocacy groups, on the other hand, argued that the new standard was not sufficiently rigorous and that it should be based on clinical guidelines or national standards, or that there should be a stronger connection between the content of a HRA and the development of specific disease management programs. Some argued, for example, for a requirement that employer-sponsored wellness programs collect no more than the minimum necessary information from spouses directly linked to specific program services in order to meet the “reasonably designed” standard and/or that employer-sponsored wellness programs be required to provide scientific evidence that demonstrates that the program improves health or prevents disease. Others noted that the standard as described has virtually no meaning and will allow employers to decide for themselves what is “reasonable.”

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 requirement in the NPRM that employers may request, require, or purchase genetic information as part of health or genetic services only when those

services, including any acquisition of genetic information that is part of those services, are reasonably designed to promote health or prevent disease. As noted in the NPRM, in order to meet this standard, the program must have a reasonable chance of improving the health of, or preventing disease in, participating individuals, and must not be overly burdensome, a subterfuge for violating Title II of GINA or other laws prohibiting employment discrimination, or highly suspect in the method chosen to promote health or prevent disease. The examples in the preamble to the proposed rule were intended simply to illustrate how this standard works. We now clarify, in agreement with several comments about one of these examples, that 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 participant's health 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. Additionally, we would consider a program to not be reasonably designed to promote health or prevent disease if it imposes, as a condition of obtaining a reward, an overly burdensome amount of time for participation, requires unreasonably intrusive procedures, or places significant costs related to medical examinations on employees. We also would not consider a program to be reasonably designed to promote health or prevent disease if it exists merely to shift costs from the covered entity to targeted employees based on their health or if the employer is only using the program for data collection or to try to determine its future health costs. Additionally, under these rules, an employer-sponsored wellness program is not reasonably designed if it penalizes an employee because a spouse's manifestation of disease or disorder prevents or inhibits

the spouse from participating or from achieving a certain health outcome. For example, an employer may not deny an employee an inducement for participation of either the employee or the spouse in an employer-sponsored wellness program because the employee's spouse has blood pressure, a cholesterol level, or a blood glucose level that the employer considers too high.

The Commission believes that because the requirement that an employer-sponsored wellness program be "reasonably designed to promote health or prevent disease" is a standard with which health plans are now sufficiently familiar, it is reasonable to apply that standard under GINA to employers that sponsor wellness programs. For consistency, this same requirement, with the same examples, has recently been adopted under the ADA.⁴² 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 genetic information while providing a degree of flexibility in designing wellness programs.

Section 1635.8(b)(2)(iii)

When an Inducement May Be Offered

As noted in the general comments section, above, numerous individuals and advocacy groups urged the Commission to abandon the position set forth in the proposed rule that employers may offer limited inducements when a spouse who receives genetic services offered by an employer provides information about his or her current or past health status information as part of a HRA. These commenters, as well as some members

⁴² See 29 CFR 1630.14(d)(1); published elsewhere in this issue of the Federal Register.

of Congress, argued that the absolute prohibition on financial inducements set forth in the existing GINA regulations should be reaffirmed, arguing that allowing employer-sponsored wellness programs to offer inducements in exchange for spouses to provide information about their current or past health status would be coercive and would substantially weaken GINA's protections. Several industry and employer groups, on the other hand, expressed support for the proposed rule's clarification that GINA does not preclude inducements for spouses for completion of HRAs when the requirements of § 1635.8(b)(2)(i) were met, while expressing deep dissatisfaction with the limitations on those inducements. As noted above, one industry group argued that use of the phrase "current or past health status" in describing the types of questions to spouses that could include inducements was confusing because not all information about a spouse's current or past health status meets the definition of genetic information. For example, some might consider questions about height, weight, and exercise regimes to be questions about "current health status," although such questions asked of an employee's spouse are not requests for genetic information under GINA.

The Commission retains the NPRM's requirements that, consistent with the requirements of §1635.8(b)(2)(i) and (ii), a covered entity may offer an inducement to an employee whose spouse provides information about the spouse's own current or past health status as part of a HRA. In order to clarify that the rule only applies to questions asked of the spouse that meet the definition of genetic information, the final rule will replace the phrase "current or past health status" with "manifestation of disease or disorder." Moreover, as discussed in detail above, because the final rule will apply not only to employer-sponsored wellness programs that are part of group health plans, but to

all wellness programs offered by employers, the language of the final rule at §1635.8(b)(2)(iii) will be revised to eliminate references to the employer's health plan. (See Comments Responding to Questions: Wellness Programs Offered Outside of Employer-Sponsored Group Health Plans.) The final rule will also explain how inducement limits are to be calculated in situations where participation in an employer-sponsored wellness program does not depend on enrollment in a particular group health plan, and in situations where an employer does not offer a group health plan but still wants to offer inducements for employees and their spouses to participate in wellness programs. Finally, the final rule retains the requirement that no inducement may be offered in return for the spouse providing his or her own genetic information, including results of his or her genetic tests, as well as the prohibition on providing inducements in return for health information about an employee's children.⁴³ (See General Comments: Prohibition on Inducements for Information from Children of Employees.)

⁴³ 29 CFR 1635.8(b)(2)(i)(B). Title I of GINA specifically prohibits a group health plan and a health insurance issuer in the group or individual market from collecting (including requesting, requiring or purchasing) genetic information prior to or in connection with enrollment in health coverage or for underwriting purposes. See 26 CFR 54.9802-3T(b), (d); 29 CFR 2590.702-1(b), (d); 45 CFR 146.122(b), (d); 45 CFR 147.110; 45 CFR 148.180(b), (d). "Underwriting purposes" includes rules for eligibility for benefits and the computation of premium or contribution amounts under the plan or coverage including any discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a HRA or participating in a wellness program. See 26 CFR 54.9802-3T(d)(1)(ii); 29 CFR 2590.702-1(d)(1)(ii); 45 CFR 146.122(d)(1)(ii); 45 CFR 148.180(f)(1)(ii). Consequently, employer-sponsored wellness programs that provide rewards for completing HRAs that request a plan participant's genetic information, including family medical history, violate the prohibition against requesting genetic information for underwriting purposes, regardless of whether the plan participant provides authorization. Under Title I of GINA, a group health plan and a health insurance issuer in the group or individual market may request genetic information through a HRA as long as the request is not in connection with enrollment and no rewards are provided.

Level of Inducement That May Be Offered

The Commission received numerous comments on this provision of the proposed rule. As stated in the general comments section of this preamble, individuals and health advocacy groups said that the proposed rule was based on the erroneous assumption that the GINA rule must be “conformed” to provisions of the Affordable Care Act concerning employer-sponsored wellness programs. These and other commenters, including some members of Congress, commented that allowing employer-sponsored wellness programs to offer inducements up to 30 percent in exchange for spouses to provide information about their current or past health status would be coercive and would substantially weaken GINA’s protection and urged the Commission to strike this proposal and reaffirm that inducements are not permitted in return for genetic information. Other advocacy groups argued that allowing inducements for spousal information would lead to conflict within families, worsening the mental and physical health of family members when, for example, an employee and spouse disagree about whether the spouse will provide the information needed to obtain a reward or avoid a penalty. One commenter noted that a rule that permits employers to increase the amount an employee pays for health insurance by as much as 30 percent of the total cost of coverage if the employee or the employee’s spouse fails to provide certain health information would lead some to forego employer-provided health insurance and thus increase the pool of families without “good” health insurance coverage. Employer and industry groups, however, commented that the EEOC should align the inducement limits for employer-sponsored wellness programs with the

inducement limits established in the tri-Department wellness regulations. One industry group asserted that requests to an individual for information about his or her own past or current health status is not genetic information (except for genetic test results) and that the EEOC therefore did not have authority under GINA to adopt requirements with respect to inducements for this information. Another industry group, after expressing strong disapproval of the proposed rule's inducement limitation, went on to provide suggestions for improving the description of that limitation if the Commission were to adopt it, suggesting, for example, that certain provisions in the regulatory language be moved. Although some of these commenters appreciated that the proposed rule based the inducement limit on the total cost of coverage for the plan in which the employee and any dependents are enrolled, employer associations and industry groups generally asserted that the inducement limits should conform to those established by the tri-Department wellness regulations, particularly the lack of incentive limits on participatory programs.

Most individuals and advocacy groups that submitted comments did not comment on the proposed rule's discussion of how inducements should be apportioned. Two groups that did comment indicated their support for the idea, assuming that the EEOC was going to move forward with the proposal to allow inducements. In contrast, numerous health insurance issuers, employer associations, industry groups, as well as a Congressional committee and various United States Senators, commented that the apportionment rule should be eliminated, arguing that it was administratively complicated and/or that it conflicts with the tri-Departments' wellness regulations, which does not require apportionment. Many of these commenters also pointed out that the apportionment rule conflicts with the general practice of providing an equal inducement

to an employee and a spouse when both participate in an employer-sponsored wellness program and that encouraging a larger inducement for spouses was arbitrary, implied that the spouse's achievement of a health goal is more valuable than the employee's equal accomplishment, and/or conflicted with the idea of a reasonably designed wellness program. One group requested that, if the EEOC were to move forward with apportionment rules, the rule clarify that the amount of the inducement attributable to the spouse does not have to be paid directly to the spouse but, instead, could be paid as part of a premium reduction or in any other way that the other portion of the inducement was being paid.

The Commission agrees that the proposed rule's apportionment standards, which would have permitted a larger inducement to the spouse for providing similar information to that which the employee provided, is overly complicated and sends the wrong message about the value of employer-sponsored wellness programs for each participating individual. Moreover, we determined, in developing the final ADA rule on employer-sponsored wellness programs, that incentives in excess of 30 percent of the cost of self-only coverage offered in exchange for an employee answering disability-related questions or taking medical examinations as part of a wellness program would be coercive. We see no reason for adopting a different threshold where the employee's spouse is the individual whose health information is being sought. Consequently, this final rule states that when an employee and the employee's spouse are given the opportunity to enroll in an employer-sponsored wellness program, the inducement to each may not exceed 30 percent of the total cost of (1) self-only coverage under the group health plan in which the employee is enrolled (including both employee and employer cost), if enrollment in the

plan is a condition for participation in the wellness program; (2) self-only coverage under the group health plan offered by the employer (including both employee and employer cost), where the employer offers a single group health plan, but participation in a wellness program does not depend on the employee's or spouse's enrollment in that plan; (3) the lowest cost self-only coverage under a major medical group health plan offered by the employer (including both employee and employer cost), where the employer has more than one group health plan, but enrollment in a particular plan is not a condition for participating in the wellness program; or (4) the second lowest cost Silver Plan⁴⁴ available on the Exchange in the location that the employer identifies as its principal place of business if the employer offers no group health plan. In this last instance, the maximum inducement to the employee and the spouse is equal to 30 percent of the cost of covering an individual who is a 40-year-old non-smoker. Thus, the amount of the inducement available to the spouse cannot exceed the amount an employer may offer to an employee, under the ADA, to participate in a wellness program that includes disability-related questions or a medical examination.

The final rule includes examples explaining how the inducement limits are to be calculated. For example, if an employee is enrolled in a group health plan through the employer at a total cost (taking into account both employer and employee contributions towards the cost of coverage) of \$14,000 for family coverage, that plan has a self-only

⁴⁴ 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).

option for a total cost of \$6,000, and the employer provides the option of participating in a wellness program to the employee and spouse if they participate in the plan, the employer may not offer more than \$1,800 to the employee and \$1,800 to the spouse. If participation in a particular group health plan is not required for the employee and spouse to earn an inducement and the employer has only one group health plan under which self-only coverage costs \$7,000, the employee and the spouse can each get an inducement of up to \$2,100. If participation in a particular group health plan is not required for the employee and the spouse to earn an inducement and the employer has more than one group health plan and self-only coverage under the major medical group health plans range in cost from \$5,000 to \$8,000, the employee and spouse can each get an inducement of up to \$1,500. Finally, if the employer offers no group health plan at all and the second lowest-cost Silver Plan 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 would cost a 40-year-old non-smoker \$4,000, the maximum inducement the employer could offer the employee and the spouse would be no more than \$1,200 each to answer questions about their current health or to take a medical examination as part of a wellness program.

As noted in the ADA final rule, the Commission has concluded that the employer's lowest total cost self-only coverage under a major medical group health plan is an appropriate benchmark for establishing the inducement limit where an employer has more than one group health plan and participation in an employer-sponsored 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 inducements in return for a spouse providing information about his or her manifestation of disease or disorder are not coercive.

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 Exchange.⁴⁵ 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.⁴⁶ Additionally, because the Silver Plan typically is neither the least nor the most expensive plan available on the Exchanges, inducement limits that are tied to its costs may promote participation in wellness programs while not being so high as to be coercive.

Revisions will be made to §1635.8(b)(2)(iii) to correspond to these changes. We also clarify that the portion of the inducement attributable to the spouse's provision of information about his or her manifestation of disease or disorder need not be paid directly to the spouse, but may be paid in whatever way the remaining portion of the inducement is made such as, for example, as part of a reduction in premium.

Authorization for Collection of Genetic Information

⁴⁵ See 26 U.S.C. 36B(b)(2).

⁴⁶ 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 (HHS report covering marketplace enrollment from November 15, 2014 through February 15, 2015, indicating that, based on enrollment through all marketplaces, 67 percent of people who selected a marketplace plan selected Silver.)

Although numerous health and other advocacy groups agreed that authorization is a much needed component of employer-sponsored wellness programs that collect genetic information, they went on to argue that the authorization requirements of GINA should be strengthened. Some noted that the authorization forms currently in use by wellness vendors tend to use arcane language, are insufficiently understood, and/or on occasion are hidden in obscure links that few people read. Others suggested that in order to truly ensure that participation in an employer-sponsored wellness program that collects genetic information is voluntary, authorization requirements should allow a participant who indicates that his or her participation is not voluntary to obtain the reward or avoid the penalty even if his or her spouse does not provide the requested information. Several advocacy groups suggested that the Commission provide model authorization forms and notices. While some health insurance issuers and industry groups agreed that the Commission should provide model language that would satisfy the authorization requirements, these commenters, as well as employer groups, generally urged the Commission to strike or limit the authorization requirement. Some argued that the Commission did not have the authority to require spouses to provide authorization because the statutory language requires that prior, knowing, written, and voluntary authorization be provided by the employee, not by other individuals. Others noted that requiring multiple authorization forms would unduly complicate the operation of employer-sponsored wellness programs and that a single authorization completed by the employee should be sufficient.

This final rule adds no new notice or authorization requirements. It reaffirms that when an employer offers an employee an inducement in return for his or her spouse's

providing information about the spouse's manifestation of disease or disorder as part of a HRA, the HRA (which may include a medical questionnaire, a medical examination, or both), must otherwise comply with § 1635.8(b)(2)(i) in the same manner as if completed by the employee, including the requirement that the spouse provide prior knowing, voluntary, and written authorization when the spouse is providing his or her own genetic information, and the requirement that the authorization form describe the confidentiality protections and restrictions on the disclosure of genetic information. The employer also must obtain authorization from the spouse when collecting information about the spouse's manifestation of disease or disorder, although a separate authorization for the acquisition of this information from the employee is not necessary.

The Commission believes that GINA's existing authorization requirements prohibit many of the practices about which advocacy groups expressed concern. For example, these requirements already prohibit an employer-sponsored wellness program that collects genetic information from using an authorization notice that uses arcane legal language or is otherwise difficult to understand.⁴⁷ Moreover, although it is true that

⁴⁷ The GINA notice and authorization requirement, which was included in the EEOC's regulations pursuant to a specific statutory requirement, see 42 U.S.C. 2000ff-1(b)(2)(B), is only met if the covered entity uses an authorization form that (1) is written so that the individual from whom the genetic information is being obtained is reasonably likely to understand it; (2) describes the type of genetic information that will be obtained and the general purpose for which it will be used; and (3) describes the restrictions on disclosure of genetic information. The GINA notice and authorization rule also requires that individually identifiable genetic information is provided only to the individual (or family member if the family member is receiving genetic services) and the licensed health care professionals or board certified genetic counselors involved in providing such services, and is not accessible to managers, supervisors, or others who make employment decisions, or to anyone else in the workplace; and, finally, that any individually identifiable genetic information provided under 29 CFR 1635.8(b)(2) is only available for purposes of such services and is not disclosed to the covered entity except in aggregate

GINA’s statutory language, at 42 U.S.C. 2000ff-1(b)(2)(B), states that the “employee” must provide prior, knowing, voluntary, and written authorization, the EEOC’s original implementing regulations use the broader term “individual” when describing the prior, knowing, voluntary, and written authorization requirement.⁴⁸ As noted in the preamble to the proposed rule, the Commission believes that “individual” best reflects the intent of Congress, especially when considering the provisions in 42 U.S.C. 2000ff-1(b), which prohibit employers from requesting, requiring, or purchasing genetic information about both employees and their family members with limited exceptions, and the general purpose of the statute.

Section 1635.8(b)(2)(vi) Prohibition on Conditioning Participation in an Employer-Sponsored Wellness Program on Agreeing to Sale of Genetic Information or Waiving Confidentiality

Individuals and advocacy groups that commented on this portion of the proposed rule supported it but requested that it be strengthened. They argued, for example, that the provision should be expanded to not only prohibit conditioning participation in an employer-sponsored wellness program on agreeing to the sale of genetic information, but also other forms of sharing genetic information such as exchanges and transfers. Others argued that the provision should state that harm will be presumed from unauthorized disclosure of genetic information and that, if sharing does occur, employers should be required to reveal the identity of those with whom they shared the genetic information.

terms that do not disclose the identity of specific individuals. See 29 CFR 1635.8(b)(2)(i).

⁴⁸ See 29 CFR 1635.8(b)(2)(i)(B).

One industry group expressed support for the notion that genetic information, as one type of protected health information, should not be sold, but noted that this did not necessarily apply to de-identified or aggregate data.

The Commission agrees that this prohibition should be expanded. The final rule therefore prohibits a covered entity from conditioning participation in an employer-sponsored wellness program or an inducement on an employee, an employee's spouse, or other covered dependent agreeing to the sale, exchange, sharing, transfer, or other disclosure of genetic information (except to the extent permitted by paragraph 1635.8(b)(2)(i)(D)), or waiving protections provided under §1635.9. As explained above, however, the Commission does not believe that any further changes are needed because the confidentiality protections of §1635.9, as well as the specific disclosure rules that apply to health and genetic services set forth at §1635.8(b)(2), provide strong protections against disclosure of genetic information. (See General Comments: Confidentiality Provisions.)

Section 1635.8(c)(2) Employer Permitted to Seek Medical Information

Few people commented on the new example the EEOC added to this section of the rule. Two industry groups that did comment supported the EEOC's acknowledgement that employers may ask for information about the manifestation of disease, disorder, or pathological condition of a family member if that individual is receiving genetic services on a voluntary basis. However, comments indicated that clarification is needed for this example to be understood. As noted in the preamble to the proposed rule, this provision cross-references 29 CFR 1635.8(b)(2) to make clear that an employer may request information about the manifestation of disease, disorder, or

pathological condition of a family member who is participating in voluntary genetic services only when all of the requirements for seeking genetic information as part of a voluntary health or genetic service, including the rules on authorization and inducements, are met. In other words, this example does not create an exception to the general rule that inducements in return for genetic information are only permitted in one specific circumstance – when an employee’s spouse is asked to provide information about his or her manifestation of disease, disorder, or pathological condition as part of a HRA. We have revised the regulatory language so that it emphasizes the requirements of §1635.8(b)(2), including the rules on authorization and inducements.

Removal of Term “Financial” from Definition of “Inducement”

Industry groups, employer associations, and several United States Senators urged the Commission to alter this proposal so that the final rule applies only to financial incentives. These groups argued that an expansion of the definition of inducement would be inconsistent with the Affordable Care Act and Congressional intent and would increase administrative burden by requiring employers to calculate the value of in-kind inducements, such as gift cards, raffle tickets, and key chains. Many argued that applying the inducement rule to in-kind inducements would cause employers to eliminate them altogether.

The final rule reaffirms the Commission’s proposal to remove the term “financial” as a modifier of the type of inducements discussed in the regulations and make clear that the term “inducements” includes both financial and in-kind inducements, such as time-off awards, prizes, or other items of value, in the form of either rewards or penalties. Contrary to several comments received, this clarification is consistent with the

tri-Department wellness program provisions, which generally define a reward 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.”⁴⁹ Thus, because the incentive limits in the Affordable Care Act apply to in-kind incentives when they are offered within health-contingent programs, Congress and the tri-Departments clearly considered that these amounts would have to be calculated. Employers have flexibility to determine the value of in-kind incentives, as long as the method is reasonable.

Technical Amendments

We received no comments concerning the proposed technical amendments to the rule and they are therefore adopted without change.

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 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.⁵⁰

⁴⁹ 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 DOL – Employee Benefits Security Administration, FAQs on Affordable Care Act Implementation (Part XXIX) and Mental Health Parity Implementation, Question 11 (2015), <http://www.dol.gov/ebsa/pdf/faq-aca29.pdf>.

⁵⁰ See General Comments: Burden for our response to the commenter who expressed disagreement with our burden calculations.

Although a detailed cost-benefit assessment of the regulation is not required, the Commission notes that the rule will aid compliance with Title II of GINA by employers. Currently, employers face uncertainty as to whether providing an employee with an inducement if his or her spouse provides information about the spouse's manifestation of disease or disorder on a HRA will subject them to liability under Title II of GINA. This rule will clarify that offering limited inducements in these circumstances is permitted by Title II of GINA if the requirements of section 202(b)(2)(A) of GINA otherwise have been met. We believe that a potential benefit of this rule is that it will provide employers that adopt wellness programs that include spousal inducements with clarity about their obligations under GINA.

The Commission does not believe the costs to employers associated with the rule are significant. Under HIPAA, as amended by the Affordable Care Act, inducements of up to 30 percent of the total cost of coverage in which an employee is enrolled are permitted where the employee and the employee's dependents are given the opportunity to fully participate in a health-contingent wellness program. This final rule simply clarifies that a similar inducement is permissible under Title II of GINA where an employer offers inducements for an employee's spouse enrolled in the group health plan to provide information about his or her manifestation of disease or disorder. Where participation in the employer-sponsored wellness program does not depend on enrollment in a particular group health plan, employers will be able to calculate the amount of the permissible inducement by reference to easily verifiable sources, such as the cost of the group health plans they provide or by reference to the second lowest cost Silver Plan

available on the Exchange in the location that the Employer identifies as its principal place of business.

The Commission further believes that employers will face initial start-up costs to train human resources staff and others on the revised rule. The EEOC conducts extensive outreach and technical assistance programs, many of them at no cost to employers, to assist in the training of relevant personnel on EEO-related issues. For example, in FY 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 the rule has become final, we will include information about the revisions to the GINA regulations in our outreach programs in general and continue to offer GINA-specific outreach programs which will, of course, include information about the revisions. As is our practice when issuing new regulations and policy guidances, we have posted two technical assistance documents on our website explaining the revisions to the GINA regulations.⁵¹

We estimate that there are approximately 782,000 employers with 15 or more employees subject to Title II of GINA⁵² and, of that number, one half to two thirds

⁵¹ See Qs and As: The Equal Employment Opportunity Commission's Final Rule on the Genetic Information Nondiscrimination Act and Employer Wellness Programs, EEOC, <https://www.eeoc.gov/laws/types/genetic.cfm> (last visited April 14, 2016); Small Business Fact Sheet: Final Rule on Title II of the Genetic Information Nondiscrimination Act and Employer Wellness Programs, EEOC, <https://www.eeoc.gov/laws/types/genetic.cfm> (last visited April 14, 2016).

⁵² See Firm Size Data, Small Business Administration, <http://www.sba.gov/advocacy/849/12162> (last visited March 28, 2016).

(391,000 to 521,333) offer some type of employer-sponsored wellness program.⁵³ In the proposed rule, we assumed that nearly half of employer-sponsored wellness programs are open for participation by the spouses or dependents of workers, and used the highest estimates, to conclude that approximately 260,667 employers will be covered by this requirement.⁵⁴ Because the final rule now applies to a broader set of wellness programs offered by employers, we will increase these estimates and assume that 347,556 employers (two thirds of those who offer some type of wellness program) offer spouses an opportunity to participate in, at the very least, an employer-sponsored wellness program that is outside or not part of a group health plan. We further estimate that the typical human resource professional will need to dedicate, at most, 60 minutes to gain a satisfactory understanding of the revised regulations and that the median hourly pay rate

⁵³ See RAND Final Report, supra note 36, xiv, http://www.rand.org/content/dam/rand/pubs/research_reports/RR200/RR254/RAND_RR254.pdf; see also Employer Health Benefits Survey, 6 (2014), <http://files.kff.org/attachment/2014-employer-health-benefits-survey-full-report> [hereinafter the Kaiser Survey]. According to the RAND Final Report, “approximately half of U.S. employers offer wellness promotion initiatives.” By contrast, the Kaiser Survey found that “[s]eventy-four percent of employers offering health benefits” offer at least one wellness program.

⁵⁴ Although the Kaiser Survey reports that 51 percent of large employers versus 32 percent of small employers ask employees to complete a HRA, see Kaiser Survey, supra note 50, we are not aware of any data indicating what percentage of those employers provide spouses with the opportunity to participate in the HRA. We therefore have substituted a more general statistic to allow an estimate of the number of employers who will be covered by the requirements of this proposed rule. See Karen Pollitz & Matthew Roe, Kaiser Family Foundation, Workplace Wellness Programs Characteristics and Requirements 5 (2016), <http://kff.org/private-insurance/issue-brief/workplace-wellness-programs-characteristics-and-requirements/> (noting that nearly half (48 percent) of employer wellness programs are open for participation by the spouses or dependents of workers, as well as workers).

of a human resource professional is approximately \$49.41.⁵⁵ Assuming that an employer will train up to three human resource professionals/managers on the requirements of this rule, we estimate that initial training costs will be approximately \$51,518,230.⁵⁶ The Commission sought comments on these cost estimates and responded to the one comment received above. (See the discussion in General Comments: Burden.)

Finally, GINA's plain language (at 42 U.S.C. 2000ff-(1)(b)(2)) and the EEOC's regulations (at 29 CFR 1635.8(b)(2) and (c)(2)) make clear that an employer must obtain authorization for the collection of genetic information as part of providing health or genetic services to employees and their family members on a voluntary basis. Consequently, this rule imposes no new obligations with respect to authorization for the collection of genetic information.

Paperwork Reduction Act

This rule contains no new information collection requirements subject to review by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

Regulatory Flexibility Act

⁵⁵ See Occupational Employment and Wages, Bureau of Labor Statistics, <http://www.bls.gov/oes/current/oes113121.htm> (last visited March 28, 2016).

⁵⁶ A study published in 2009 by the Society for Human Resource Management (SHRM) found that the median number of full-time equivalents for a HR department was three. See SHRM, Human Capital Benchmarking Study 2009 Executive Summary, 6 (2009), https://www.shrm.org/Research/SurveyFindings/Articles/Documents/090620_Human_Cap_Benchmark_FULL_FNL.pdf. Because we are not aware of any more specific data on the average number of human resources professionals per covered employer, we have based our estimates on this figure.

Title II of GINA applies to all 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 final rule will not have a significant economic impact on a substantial number of small entities because it imposes no reporting burdens and only minimal costs on such firms. The rule simply clarifies that employers that offer wellness programs are free to adopt a certain type of inducement without violating GINA. It also corrects an internal citation and provides citations to the Affordable Care Act. It does not require any action on the part of covered entities, except to the extent that those entities created documentation or forms which cite to GINA for the proposition that the entity is unable to offer inducements to employees in return for a spouse's completion of HRAs that request information about the spouse's manifestation of disease or disorder. We do not have data on the number or size of businesses that may need to alter documents relating to their employer-sponsored wellness programs. However, our experience with enforcing the ADA, which required all employers with 15 or more employees to remove medical inquiries from application forms, suggests that revising questionnaires to eliminate or alter an instruction would not impose significant costs.

To the extent that employers will expend resources to train human resources staff and others on the revised rule, we reiterate that the EEOC conducts extensive outreach and technical assistance programs, many of them at no cost to employers, to assist in the

⁵⁷ See Firm Size Data, Small Business Administration, <http://www.sba.gov/advocacy/849/12162> (last visited March 28, 2016).

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. We will put information about the revisions to the GINA regulations in our outreach programs in general and continue to offer GINA-specific outreach programs which will, of course, include information about the revisions now that the rule is final. We will also post technical assistance documents on our website explaining the revisions to the GINA regulations, as we do with all of our new regulations and policy documents.

We estimate that the typical human resources professional will need to dedicate, at most, 60 minutes to gain a satisfactory understanding of the revised regulations. We further estimate that the median hourly pay rate of a human resource professional is approximately \$49.41.⁵⁸ Assuming that small entities have between one and five human resource professionals/managers, we estimate that the cost per entity of providing appropriate training will be between approximately \$49.41 and \$247.05. The EEOC does not believe that this cost will be significant for the impacted small entities.

Unfunded Mandates Reform Act of 1995

⁵⁸ See Occupational Employment and Wages, *supra* note 53.

This final 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 1635

Administrative practice and procedure, Equal employment opportunity

For the reasons set forth in the preamble, the EEOC amends chapter XIV of title 29 of the Code of Federal Regulations as follows:

PART 1635 – [AMENDED]

1. The authority citation for part 1635 is revised to read as follows:

Authority: 29 U.S.C. 2000ff.

2. In § 1635.8(b):

- a. Redesignate paragraphs (b)(2)(i)(A) through (D) as paragraphs (b)(2)(i)(B) through (E);
- b. Add new paragraph (b)(2)(i)(A);
- c. Revise paragraph (b)(2)(ii) introductory text;
- d. Redesignate paragraphs (b)(2)(iii) and (iv) as paragraphs (b)(2)(vi) and (vii);
- e. Add new paragraphs (b)(2)(iii) through (v);
- f. Revise newly redesignated paragraph (b)(2)(vii); and

g. Revise paragraph (c)(2).

The revisions and additions read as follows:

§ 1635.8 Acquisition of genetic information.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(A) The health or genetic services, including any acquisition of genetic information that is part of those services, are reasonably designed to promote health or prevent disease. A program satisfies this standard if it has a reasonable chance of improving the health of, or preventing disease in, participating individuals, and it is not overly burdensome, is not a subterfuge for violating Title II of GINA or other laws prohibiting employment discrimination, and is not highly suspect in the method chosen to promote health or prevent disease. A program is not reasonably designed to promote health or prevent disease if it imposes a penalty or disadvantage on an individual because a spouse's manifestation of disease or disorder prevents or inhibits the spouse from participating or from achieving a certain health outcome. For example, an employer may not deny an employee an inducement for participation of either the employee or the spouse in an employer-sponsored wellness program because the employee's spouse has blood pressure, a cholesterol level, or a blood glucose level that the employer considers too high. In addition, a program consisting of a measurement, test, screening, or collection of health-related information without providing participants with results,

follow-up information, or advice designed to improve the participant's health 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 conditions identified. Whether health or genetic services are reasonably designed to promote health or prevent disease is evaluated in light of all the relevant facts and circumstances.

* * * * *

(ii) Consistent with, and in addition to, the requirements of paragraph (b)(2)(i) of this section, a covered entity may not offer an inducement (financial or in-kind), whether in the form of a reward or penalty, for individuals to provide genetic information, except as described in paragraphs (b)(2)(iii) and (iv) of this section, but may offer inducements for completion of health risk assessments that include questions about family medical history or other genetic information, provided the covered entity makes clear, in language reasonably likely to be understood by those completing the health risk assessment, that the inducement will be made available whether or not the participant answers questions regarding genetic information.

* * * * *

(iii) Consistent with, and in addition to, the requirements of paragraphs (b)(2)(i) and (ii) of this section, a covered entity may offer an inducement to an employee whose spouse provides information about the spouse's manifestation of disease or disorder as part of a health risk assessment. No inducement may be offered, however, in return for the spouse's providing his or her own genetic information, including results of his or her genetic tests, or for information about the manifestation of disease or disorder

in an employee's children or for genetic information about an employee's children, including adult children. The health risk assessment, which may include a medical questionnaire, a medical examination (e.g., to detect high blood pressure or high cholesterol), or both, must otherwise comply with paragraph (b)(2)(i) of this section in the same manner as if completed by the employee, including the requirement that the spouse provide prior, knowing, voluntary, and written authorization, and the requirement that the authorization form describe the confidentiality protections and restrictions on the disclosure of genetic information. The health risk assessment must also be administered in connection with the spouse's receipt of health or genetic services offered by the employer, including such services offered as part of an employer-sponsored wellness program. When an employee and spouse are given the opportunity to participate in an employer-sponsored wellness program, the inducement to each may not exceed:

(A) Thirty percent of the total cost of self-only coverage under the group health plan in which the employee is enrolled, if enrollment in the plan is a condition for participation in the employer-sponsored wellness program. For example, if an employee is enrolled in health insurance through the employer at a total cost (taking into account both employer and employee contributions toward the cost of coverage) of \$14,000 for family coverage, that plan has a self-only option for \$6,000, and the employer provides the option of participating in a wellness program to the employee and spouse because they are enrolled in the plan, the employer may not offer more than \$1,800 to the employee and \$1,800 to the spouse.

(B) Thirty percent of the total cost of self-only coverage under the group health plan offered by the employer where the employer offers a single group health plan,

but participation in a wellness program does not depend on the employee's or spouse's enrollment in that plan. For example, if the employer offers one group health plan and self-only coverage under that plan costs \$7,000, and the employer provides the option of participation in a wellness program to the employee and the spouse, the employer may not offer more than \$2,100 to the employee and \$2,100 to the spouse.

(C) Thirty percent of the total cost of the lowest cost self-only coverage under a major medical group health plan offered by the employer, if the employer offers more than one group health plan but enrollment in a particular plan is not a condition for participation in the wellness program. For example, if the employer has more than one major medical group health plan under which self-only coverage ranges in cost from \$5,000 to \$8,000, and the employer provides the option of participation in a wellness program to the employee and the spouse, the employer may not offer more than \$1,500 to the employee and \$1,500 to the spouse.

(D) Thirty percent of the cost of self-only coverage available to an individual who is 40 years old and a non-smoker under the second lowest cost Silver Plan available through the Exchange in the location that the employer identifies as its principal place of business is located, where the employer has no group health plan. For example, if the cost of insuring a 40-year-old non-smoker is \$4,000 annually, the maximum inducement the employer could offer the employee and the spouse would be no more than \$1,200 each.

(iv) A covered entity may not, however, condition participation in an employer-sponsored wellness program or provide any inducement to an employee, or the spouse or other covered dependent of the employee, in exchange for an agreement

permitting the sale, exchange, sharing, transfer, or other disclosure of genetic information, including information about the manifestation of disease or disorder of an employee's family member (except to the extent permitted by paragraph (b)(2)(i)(D)) of this section, or otherwise waiving the protections of § 1635.9.

(v) A covered entity may not deny access to health insurance or any package of health insurance benefits to an employee, or the spouse or other covered dependent of the employee, or retaliate against an employee, due to a spouse's refusal to provide information about his or her manifestation of disease or disorder to an employer-sponsored wellness program.

* * * * *

(vii) Nothing contained in paragraphs (b)(2)(ii) through (v) of this section limits the rights or protections of an individual under the Americans with Disabilities Act (ADA), as amended, or other applicable civil rights laws, or under the Health Insurance Portability and Accountability Act (HIPAA), as amended by GINA. For example, if an employer offers an inducement for participation in disease management programs or other programs that promote healthy lifestyles and/or require individuals to meet particular health goals, the employer must make reasonable accommodations to the extent required by the ADA; that is, the employer must make modifications or adjustments that enable a covered entity's employee with a disability to enjoy equal benefits and privileges of employment as are enjoyed by its other similarly situated employees without disabilities unless such covered entity can demonstrate that the accommodation would impose an undue hardship on the operation of its business. See 29 CFR 1630.2(o)(1)(iii) and 29 CFR 1630.9(a). In addition, if the employer's wellness program provides

(directly, through reimbursement, or otherwise) medical care (including genetic counseling), the program may constitute a group health plan and must comply with the special requirements for employer-sponsored wellness programs that condition rewards on an individual satisfying a standard related to a health factor, including the requirement to provide an individual with a reasonable alternative (or waiver of the otherwise applicable standard) under HIPAA, when it is unreasonably difficult due to a medical condition to satisfy or medically inadvisable to attempt to satisfy the otherwise applicable standard. See section 9802 of the Internal Revenue Code (26 U.S.C. 9802, 26 CFR 54.9802-1 and 54.9802-3T), section 702 of the Employee Retirement Income Security Act of 1974 (ERISA) (29 U.S.C. 1182, 29 CFR 2590.702 and 2590.702-1), and section 2705 of the Public Health Service (PHS) Act (45 CFR 146.121, 146.122, and 147.110), as amended by section 1201 of the Affordable Care Act.

* * * * *

(c) * * *

(2) A covered entity does not violate this section when it requests, requires, or purchases genetic information or information about the manifestation of a disease, disorder, or pathological condition of an individual's family member who is receiving health or genetic services on a voluntary basis, as long as the requirements of paragraph (b)(2) of this section, including those concerning authorization and inducements, are met. For example, an employer does not unlawfully acquire genetic information about an employee when it asks the employee's family member who is receiving health services from the employer if her diabetes is under control. Nor does an employer unlawfully acquire genetic information about an employee when it seeks information – through a

medical questionnaire, a medical examination, or both – about the manifestation of disease, disorder, or pathological condition of the employee’s family member who is completing a health risk assessment on a voluntary basis in connection with the family member’s receipt of health or genetic services (including health or genetic services provided as part of an employer-sponsored wellness program) offered by the employer in compliance with paragraph (b)(2) of this section.

* * * * *

3. In § 1635.11, revise paragraphs (b)(1)(iii) and (iv) to read as follows:

§ 1635.11 Construction.

* * * * *

(b) * * *

(1) * * *

(iii) Section 702(a)(1)(F) of ERISA (29 U.S.C. 1182(a)(1)(F)), section 2705(a)(6) of the PHS Act, as amended by section 1201 of the Affordable Care Act and section 9802(a)(1)(F) of the Internal Revenue Code (26 U.S.C. 9802(a)(1)(F)), which prohibit a group health plan or a health insurance issuer in the group or individual market from discriminating against individuals in eligibility and continued eligibility for benefits based on genetic information; or

(iv) Section 702(b)(1) of ERISA (29 U.S.C. 1182(b)(1)), section 2705(b)(1) of the PHS Act, as amended by section 1201 of the Affordable Care Act and section 9802(b)(1) of the Internal Revenue Code (26 U.S.C. 9802(b)(1)), as such sections apply with respect to genetic information as a health status-related factor, which prohibit a group health plan or a health insurance issuer in the group or individual market from

discriminating against individuals in premium or contribution rates under the plan or coverage based on genetic information.

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Dated: May 11, 2016

For the Commission:

Jenny R. Yang,

Chair

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