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EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1635

RIN 3046-AB02

Genetic Information Nondiscrimination Act of 2008

AGENCY: Equal Employment Opportunity Commission.

ACTION: Proposed rule.

SUMMARY: The Equal Employment Opportunity Commission (“EEOC” or “Commission”) is issuing a proposed rule that would amend the regulations implementing Title II of the Genetic Information Nondiscrimination Act of 2008 as they relate to employer wellness programs. The proposed regulations address the extent to which an employer may offer an employee inducements for the employee’s spouse who is also a participant in the employer’s health plan to provide information about the spouse’s current or past health status as part of a health risk assessment administered in connection with the employer’s offer of health services as part of an employer-sponsored wellness program. Several technical changes to the existing regulation are also proposed.

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

ADDRESSES: You may submit comments, identified by *RIN number* 3046-AB02, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- FAX: (202) 663-4114. (There is no toll free FAX number). Only comments of six or fewer pages will be accepted via FAX transmittal, in order to assure access to the equipment. Receipt of FAX transmittals will not be acknowledged, except that the sender may request confirmation of receipt by calling the Executive Secretariat staff at (202) 663-4070 (voice) or (202) 663-4074 (TTY). (These are not toll free numbers).
- Mail: Bernadette Wilson, Acting Executive Officer, Executive Secretariat, Equal Employment Opportunity Commission, U.S. Equal Employment Opportunity Commission, 131 M Street, N.E., Washington, DC 20507.
- Hand Delivery / Courier: Bernadette Wilson, Acting Executive Officer, Executive Secretariat, Equal Employment Opportunity Commission, U.S. Equal Employment Opportunity Commission, 131 M Street, N.E., Washington, DC 20507.

Instructions: The Commission invites comments from all interested parties. All comment submissions must include the agency name and docket number or the Regulatory Information Number (RIN) for this rulemaking. Comments need be submitted in only one of the above-listed formats. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information you provide.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>. Copies of the received comments also will be available for review at the Commission's library, 131 M Street, NE, Suite 4NW08R, Washington, DC 20507, between the hours of 9:30 a.m. and 5:00 p.m., from [INSERT DATE 60 DAYS AFTER DATE

OF PUBLICATION IN FEDERAL REGISTER] until the Commission publishes the rule in final form.

FOR FURTHER INFORMATION CONTACT: Christopher J. Kuczynski, Assistant Legal Counsel, at (202) 663-4665 (voice), or Kerry E. Leibig, Senior Attorney Advisor, at (202) 663-4516 (voice), or (202) 663-7026 (TTY). Requests for this notice in an alternative format should be made to the Office of Communications and Legislative Affairs at (202) 663-4191 (voice) or (202) 663-4494 (TTY).

SUPPLEMENTARY INFORMATION:

Introduction

Congress enacted Title II of the Genetic Information Nondiscrimination Act of 2008 (“GINA”), codified at 42 U.S.C. 2000ff *et seq.*, to protect job applicants, current and former employees, labor union members, and apprentices and trainees from employment discrimination based on their genetic information. In enacting GINA, Congress noted, “New knowledge about genetics may allow for the development of better therapies that are more effective against disease or have fewer side effects than current treatments. These advances give rise to the potential misuse of genetic information to discriminate in health insurance and employment.” *See* GINA Section 2(1), 42 U.S.C. 2000ff, note. Congress also expressed concerns about common misconceptions that an individual’s genetic predisposition for a condition necessarily leads to the individuals developing the condition, explaining that

[a]n employer might use information about an employee’s genetic profile to deny employment to an individual who is healthy and able to perform the job. With these misconceptions so prevalent, employers may come to rely on genetic testing to “weed out” those employees who carry genes associated with diseases. Similarly, genetic traits may come to be used by health insurance companies to deny coverage to those who are seen as “bad genetic

risks.’’ Enabling employers, health insurers and others to base decisions about individuals on the characteristics that are assumed to be their genetic destiny would be an undesirable outcome of our national investment in genetic research, and may significantly diminish the benefits that this research offers.¹

Congress enacted GINA to address concerns prevalent at the time that individuals would not take advantage of the increasing number of genetic tests that could inform them as to whether they were at risk of developing specific diseases or disorders due to fear that genetic information would be used to deny health coverage or employment.² Consequently, GINA restricts acquisition and disclosure of genetic information, and includes an absolute prohibition on the use of genetic information in making employment decisions.³ 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. *See* 75 FR 68912 (Nov. 9, 2010).

Title II of GINA prohibits the use of genetic information in employment; restricts employers and other entities covered by GINA⁴ 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. *See* 42 U.S.C. 2000ff *et seq.*; *see also* 29 CFR 1635.4 – 1635.9. The statute and the Title II final rule say that “genetic

¹ H. Rep. 110-28, Part 1, 28 (Mar. 5, 2007).

² *See, e.g.*, S. REP. NO. 110-48, at 7 (2007) (noting that “a 2004 poll taken by the Genetics and Public Policy Center at Johns Hopkins University found that 92 percent of those surveyed felt that employers should not have access to genetic test results” and that “[f]ears about the possible misuse of genetic knowledge appear to influence the public’s desire to protect the privacy of genetic information”); *see also id.* at 10 (“While people fear discriminatory action based on their genes, they also fear the unauthorized disclosure or collection of genetic information. The need to protect the privacy of genetic information is important. Knowledge that a person has a particular medical condition or genetic trait may be embarrassing or damaging to that individual, or his or her family members.”).

³ S. REP. NO. 110-48, at 10 (2007); H.R. Rep. No. 110-28, pt. 3, at 29.

⁴ Unless otherwise noted, the term “GINA” refers to Title II of GINA.

information” includes: 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 medical history);⁵ 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. *See* 42 U.S.C. 2000ff(4) and 2000ff-8(b); *see also* 29 CFR 1635.3. 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. *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 the Employee Retirement Income Security Act (ERISA)); *see also* 29 CFR 1635.3(a).⁶

Although similar to Title I of the Americans with Disabilities Act (ADA) in that both laws are concerned with limiting the use, acquisition, and disclosure of medical information in the employment setting, GINA, consistent with Congressional concern about the uniquely personal nature of genetic information, provides unique protections. Unlike the ADA, which allows employers to consider medical information in certain limited circumstances (such as using

⁵ 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 (2007).

⁶ 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 Public Health Service Act (PHSA) and the Internal Revenue Code (Code). *See* the preamble to EEOC’s regulations implementing Title II of GINA at 75 FR 68914, note 5 (November 9, 2010) and the preamble to the regulations implementing Title I of GINA at 74 FR 51664, 51666 (October 7, 2009) for additional information.

information from a post-offer medical examination to determine an applicant's current ability to perform a job), GINA prohibits employers from using genetic information in employment decisions in all circumstances, with no exceptions.⁷ GINA also is stricter in its limits of the acquisition of protected information than the ADA. For example, even though the ADA allows an employer to require a medical examination of all employees to whom it has offered a particular job, GINA limits the scope of medical examinations for employees who have been offered a particular job insofar as it prohibits inquiries about family medical history or other types of genetic information. GINA likewise prohibits employers from obtaining family medical history or any other type of genetic information through any medical examination required of employees for the purpose of determining continued fitness for duty.

There are only six very limited circumstances in which an employer⁸ may request, require, or purchase genetic information about an applicant or employee. One of the six narrow exceptions to GINA's acquisition prohibition permits employers that offer health or genetic services, including such services offered as part of voluntary wellness programs,⁹ to request

⁷ Sec. 202(a) of Title II of GINA limits employer use of genetic information. Employers cannot "fail or refuse to hire, or to discharge, any employee, or otherwise discriminate against any employee with respect to the compensation, terms, conditions, or privileges of employment" or otherwise "limit, segregate, or classify the employees" in any way that would tend to deprive the employee of employment opportunities based on genetic information. Section 202(a) provides no exceptions to prohibitions on employer use.

⁸ 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 and 2000ff-4 (describing the prohibited practices of each of these entities); *see also* 29 CFR 1635.2(b) (definition of covered entity) and 29 CFR 1635.4 (description of prohibited practices). For the sake of readability, and recognizing that employers will be the covered entity most likely to offer wellness programs, the NPRM will refer to employers and employees throughout.

⁹ 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. Section 2705(j)(1)(A) of the PHSA, 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

genetic information as part of these programs, as long as certain specific requirements are met.¹⁰ 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). The regulations implementing Title II currently make clear that one of the requirements is that the wellness program cannot condition inducements to employees on the provision of genetic information. This requirement is derived from Title I of GINA's explicit prohibition against adjusting premium or contribution amounts on the basis of genetic information.¹¹

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 a wellness program, this question has arisen since publication of the final rule. The EEOC has received numerous inquiries about whether an employer will violate GINA and, in particular, 29 CFR 1635.8(b)(2), by offering an employee an inducement if the employee's spouse who is

the PHSA(i.e., Title I of GINA). Regulations issued under these statutes address wellness programs that collect genetic information. Moreover, 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), and 45 CFR 146.121(f). In addition, EEOC has issued proposed rules that would amend the regulations and interpretive guidance implementing Title I of the ADA as they relate to employer wellness programs. See 80 FR 21659 (April 20, 2015).

¹⁰Other 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.

¹¹ Title I of GINA applies to genetic information discrimination in health insurance and not employment. In the Commission's original GINA Title II regulation, the Commission, in consultation with the federal agencies 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 www.dol.gov/ebsa/faqs/faq-GINA.html. 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 GINA Title II final rule at 75 FR 68923 (November 9, 2010).

covered under the employer's group health plan¹² completes a health risk assessment (HRA) -- including those involving a medical questionnaire, a medical examination (e.g., to detect high blood pressure or high cholesterol), or both -- that seeks information about the spouse's current or past health status, in connection with the spouse's receipt of health or genetic services as part of an employer-sponsored wellness program. *See, e.g.*, Letter from the ERISA Industry Committee to EEOC (February 17, 2012) available at <http://www.eeoc.gov/eeoc/meetings/5-8-13/moore.cfm> (attachment to written testimony). Online reports have raised the same concern. *See, e.g.*, Tower Watson, Health Care Reform Bulletin (Oct. 2011) available at <http://www.towerswatson.com/en/Insights/Newsletters/Americas/health-care-reform-bulletin/2011/Providing-Financial-Incentives-for-an-Employees-Spouse-to-Complete-a-Health-Risk-Assessment>. Two panelists also raised this question during a May 2013 Commission meeting on Wellness Programs. *See* Written Testimony of Leslie Silverman available at <http://www.eeoc.gov/eeoc/meetings/5-8-13/silverman.cfm> and Written Testimony of Amy Moore available at <http://www.eeoc.gov/eeoc/meetings/5-8-13/moore.cfm>.

Read in one way, conditioning all or part of an inducement on the provision of the spouse's current or past health information could be read to violate the 29 CFR 1635.8(b)(2)(ii) prohibition on providing financial inducements in return for an employee's protected genetic information. When an employer seeks information from a spouse (who is a "family member" under GINA as set forth at 29 CFR 1635.3(a)(1)) about his or her current or past health status, the employer is also treated under GINA as requesting genetic information about the employee. This is because GINA defines the term "genetic information" of an employee broadly to include

¹² 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 NPRM.

information about a family member's (including a spouse's) current or past health status.¹³

However, the EEOC's regulations specifically permit employers to seek such information from a family member who is receiving health or genetic services from the employer, including such services offered as part of a voluntary wellness program, as long as each of the requirements of 29 CFR 1635.8(b)(2)(i) concerning health or genetic services provided on a voluntary basis are met. *See* 29 CFR 1635.8(c)(2).

The proposed regulations would clarify that GINA does not prohibit employers from offering limited inducements (whether in the form of rewards or penalties avoided¹⁴) for the provision by spouses (covered by the employer's group health plan) of information about their current or past health status as part of a HRA, which may include a medical questionnaire, a medical examination (e.g., to detect high blood pressure or high cholesterol), or both, as long as the requirements of 29 CFR 1635.8(b)(2)(i) are satisfied. These requirements include that the provision of genetic information be voluntary and that the individual from whom the genetic information is being obtained provides prior, knowing, voluntary, and written authorization, which may include authorization in electronic format.¹⁵

¹³ The term "genetic information" includes "the manifestation of a disease or disorder in family members of [an] individual." 42 USC 2000ff(4)(a)(ii). An individual's family members include anyone who is "a dependent (as such term is used for purposes of section 1181(f)(2) of Title 29), which includes a spouse. 42 USC 2000ff(3)(a). *See also* 29 CFR 1635.3(a)(1) (defining "family member" to include "[a] person who is a dependent . . . as the result of marriage . . .").

¹⁴ Under the PHSA, as amended by the Affordable Care Act, when a wellness program offers a reward, the term refers both to obtaining a reward (such as a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism, an additional benefit, or any financial or other incentive) and avoiding a penalty (such as the absence of a premium surcharge or other financial or nonfinancial disincentive). *See* 26 CFR 54.9802-1(f)(1)(i), 29 CFR 2590.702(f)(1)(i), and 45 CFR 146.121(f)(1)(i). We have adopted this definition.

¹⁵ 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

The Commission further proposes to add to the existing 1635.8(b)(2) requirements a requirement that any health or genetic services in connection with which an employer requests genetic information be reasonably designed to promote health or prevent disease. This addition will make the revised GINA regulations consistent with the proposed rule amending the ADA's regulations as they relate to wellness programs, which permits employers to collect medical information as part of a wellness program only if the program and the disability-related inquiries and medical examinations that are part of the program are reasonably designed to promote health or prevent disease.

These regulations further propose that inducements in exchange for current or past health status information about an employee's children (biological and non-biological¹⁶) are not

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 terms that do not disclose the identity of specific individuals. *See* 29 CFR 1635.8(b)(2)(i). When an employer requests only current or past health status information from the employee's spouse, authorization by the spouse for the acquisition of the information will suffice to meet GINA's requirement; the employee does not have to separately authorize acquisition of the spouse's current or past health status information. *See* 29 CFR 1635.8(b)(2)(i)(B).

The ADA does not have the same statutory requirement for authorization as is in GINA. In light of this statutory difference, the NPRM on the ADA and wellness programs published by the Commission on April 20, 2015 would require a notice to employees in connection with such a HRA where a wellness program is part of a group health plan. The notice must clearly explain what medical information will be obtained, how it will be used, who will receive it, and the restrictions on disclosure. *See* 80 FR 21659 (April 20, 2015). The ADA proposed rule did not include an authorization requirement, although EEOC asked in the preamble whether one should be part of the final rule. The ADA proposed rule cannot alter the statutory authorization requirements under GINA.

¹⁶ GINA defines information about the manifestation of a disease or disorder in an employee's adopted child to be genetic information about the employee. *See* 29 CFR 1635.3(c)(1)(ii) (genetic information includes information about the "manifestation of disease or disorder in family members of the

permitted, although an employer may offer health or genetic services (including participation in a wellness program) to an employee's children on a voluntary basis and may ask questions about a child's current or past health status as part of providing such services. Although information about the manifestation of disease or disorder in spouses or children is genetic information protected by GINA, adopting a very narrow exception that permits inducements only for a spouse's current or past health status strikes the appropriate balance between GINA's goal of providing strong protections against employment discrimination based on the possibility that an employee may develop a disease or disorder in the future or may face discrimination because a family member is expected to become ill in the future, and the goal of the wellness program provisions of the Health Insurance Portability and Accountability Act ("HIPAA"), as amended by the Affordable Care Act, of promoting participation in employer-sponsored wellness programs. There is minimal, if any, chance of eliciting information about an employee's own genetic make-up or predisposition for disease from the information about current or past health status of the employee's spouse. By contrast, there is a significantly higher likelihood of eliciting information about an employee's own genetic make-up or predisposition for disease from information about the current or past health status of the employee's children, which is why the proposed revision does not permit inducements in exchange for such information. Further, the legislative history makes clear that Congress was particularly concerned about allowing

individual") and 1635.3(a)(1) (a family member includes anyone who is a dependent "as the result of marriage, birth, adoption or placement for adoption). Family members also include first- through fourth-degree relatives of an individual or of the individual's dependents. 29 CFR 1635.3(a)(2). Thus, information about the manifested disease or disorder of a stepchild – the first-degree relative of an employee's spouse – is genetic information about the employee.

employers access to information revealing the possible genetic conditions of employees' children.¹⁷

Furthermore, while the proposal allows inducements in return for a spouse's current and past health status, it does not allow inducements in return for the spouse providing his or her own genetic information, including the results of his or her genetic tests. Limiting inducements in this way not only promotes consistency with Title I of GINA, which prohibits inducements in return for the genetic information of a spouse who is a plan participant, but also ensures that the exception to the prohibition on inducements in return for genetic information is drawn narrowly.¹⁸ See 42 U.S.C. 300gg-4(b)(3)(A). Additionally, this approach has the advantage of reducing administrative burdens on employers by allowing them to use the same HRA – with questions about family medical history and other genetic information clearly identified and a statement that these questions need not be answered in order to receive an inducement – for employees and their spouses.

¹⁷ GINA's legislative history recognized "that a family medical history could be used as a surrogate for [an employee's] genetic traits, [and that] 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." S. Rep. No. 110-48, at 28 (2007). See, e.g., Statement of Sen. Edward M. Kennedy, GINA's principal sponsor in the Senate, 154 CONG. REC. S3363, S337 (Apr. 28, 2008) (noting concerns of mother who paid out of pocket for anonymous genetic testing because she feared that the results would be used to discriminate against her daughters); Statement of Senator Christopher Dodd, 154 CONG. REC. S3363, S3369-70 (Apr. 28, 2008) ("Many people are also afraid of affecting their children's ability to get jobs or obtain insurance. So without adequate protections against discrimination, people may forgo genetic testing, even in cases where the results have the potential to save their lives or the lives of their family."); Statement of Sen. Brownback, *id.* ("Genetic discrimination against anyone is unacceptable, particularly those who are next generation, our children."); Statement of Sen. Olympia Snowe (noting constituent's fears that having the BRAC test "would ruin her daughter's ability to obtain insurance in the future.") *id.* at S3367.

¹⁸ See *John Hancock Mut. Life Ins. Co. v. Harris Trust & Sav. Bank*, 510 U.S. 86, 97 (1993) ("[W]e [are] inclined, generally, to tight reading of exemptions from comprehensive [statutory] schemes.") *citing* *Commissioner v. Clark*, 489 U.S. 726, 739-40 (1989) (when a general policy is qualified by an exception, the Court "usually read[s] the exception narrowly in order to the preserve the primary operation of the [policy]"), and *A.H. Phillips, Inc. v. Walling*, 324 U.S. 490, 493 (1945).

This proposal would not alter the absolute prohibition against the use of genetic information in making employment decisions. Were an employer to use information about a spouse's current or past health status to make an employment decision about an employee, it would violate GINA's prohibition on using genetic information.¹⁹ Nor would the proposal permit inducements in return for genetic information of an employee in any circumstance other than where an employee's spouse who is enrolled in the employer's group health plan provides information about his or her current or past health as part of a HRA. Inducements in return for information about the current or past health of an employee's children, or in exchange for inquiries directed to an employee about the employee's family medical history or other genetic information, for example, are still prohibited.

The revisions also prohibit conditioning participation in a wellness program or any inducement on an individual, or an individual's spouse or family member, waiving GINA's confidentiality provisions.

Summary of the Proposed Regulation

Revisions to the Wellness Program Exception

The EEOC proposes to make six substantive changes to its GINA regulations. First, we propose to add a new subsection to 29 CFR 1635.8(b)(2), to be numbered 1635.8(b)(2)(i)(A). It would explain 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. In order to meet this standard, the program must have a reasonable chance of improving

¹⁹ If the information about the spouse disclosed a disability, the employer would also violate the ADA's prohibition on discrimination based on association with someone with a disability. *See* 42 U.S.C. 12112(b)(4).

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. Collecting information on a health questionnaire without providing follow-up information or advice would not be reasonably designed to promote health or prevent disease. Additionally, a program is not reasonably designed to promote health or prevent disease if it imposes, as a condition 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. A program is also not reasonably designed if it exists merely to shift costs from the covered entity to targeted employees based on their health.

Second, we propose to add a subsection to 29 CFR 1635.8(b)(2), to be numbered 1635.8(b)(2)(iii). It would explain that, consistent with the requirements of paragraphs (b)(2)(i) and (b)(2)(ii), a covered entity may offer, as part of its health plan, an inducement 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 as part of a HRA.

No inducement may be offered, however, in return for the spouse providing his or her own genetic information, including results of his or her genetic tests.²⁰

²⁰ 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 a group health plan or for underwriting purposes. *See* 26 CFR 54.9802-3T(b) and (d); 29 CFR 2590.702-1(b) and (d)); 45 CFR 146.122(b) and (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

The HRA, 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) 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,²¹ 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 past or current health status, though a separate authorization for the acquisition of this information from the employee is not necessary.

The total inducement to the employee and spouse may not exceed 30 percent of the total annual cost of coverage for the plan in which the employee and any dependents are enrolled. The 30 percent limit includes any inducement for a spouse's current or past health status information and any other inducements to the employee, as permitted under Title I of the ADA, for the employee's participation in a wellness program that asks disability-related questions or includes medical examinations. Thus, for example, if an employer offers health insurance

146.122(d)(1)(ii). . Consequently, 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 an HRA as long as the request is not in connection with enrollment and no rewards are provided.

²¹ 42 U.S.C. 2000ff-1(b)(2)(B) states that the "employee" must provide prior, knowing, voluntary, and written authorization. EEOC regulations implementing Title II of GINA, by contrast, use the broader term "individual" when describing the prior, knowing, voluntary and written authorization requirement. *See* 29 CFR 1635.8(b)(2)(i)(B). 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.

coverage at a total cost (taking into account both employer and employee contributions towards the cost of coverage for the benefit package) of \$14,000 to cover an employee and the employee's spouse and/or spouse and other dependents, and provides the option of participating in a wellness program to the employee and spouse covered by the plan, it may not offer a total inducement greater than 30 percent of \$14,000, or \$4,200.

This type of inducement limit generally parallels the limitations set forth in section 1201 of the Affordable Care Act,²² which explains that when dependents of employees, such as spouses, are permitted to fully participate in a health-contingent wellness program, the reward offered must not exceed the applicable percentage of the total cost of the coverage in which an employee and dependents are enrolled. *See* 26 CFR 54.9802-1(f)(3)(ii) and (4)(ii); 29 CFR 2590.702(f)(3)(ii) and (4)(ii); 45 CFR 146.121(f)(3)(ii) and (f)(4)(ii). The limited exception that the Commission proposes to make under Title II of GINA thus allows a practice that is in line with Title I of GINA and the Affordable Care Act. *See* 26 CFR 54.9802-1(f)(3)(ii) and (4)(ii); 29 CFR 2590.702(f)(3)(ii) and (4)(ii); 45 CFR 146.121(f)(3)(ii) and (f)(4)(ii) for the references to the implementing Affordable Care Act regulations; *see* section 702(b)(3)(B) of ERISA (29 U.S.C. 1182(b)(3)(B)); section 2705(b)(3)(B) of the PHS (42 U.S.C. 300gg-4(b)(3)(B)); and section 9802(b)(3)(B) of the Code (26 U.S.C. 9802(b)(3)(B)) for references to Title I of GINA. The EEOC has determined that extending the 30 percent limit established by the Affordable Care Act for health-contingent wellness program inducements in return for information about the health status (but not the genetic information) of spouses promotes GINA's interest in limiting access to genetic information and ensuring that inducements are not so high as to be coercive,

²² Section 1201 of the Affordable Care Act added PHS section 2705(j) and Section 1563 of the Affordable Care Act incorporated by reference such provision into section 715(a)(1) to the ERISA, and section 9815(a)(1) to the Code. *See* 29 U.S.C. 1182(j)(3)(A); 42 U.S.C. 300gg-4(j)(3)(A); 26 U.S.C. 9802(j)(3)(A).

and thus prohibited. The EEOC consulted with the Departments of Health and Human Services, Labor, and the Treasury, which share interpretive jurisdiction over the wellness program provisions under HIPAA and the Affordable Care Act, and while the proposed revisions may differ in some respects from the wellness program standards set forth by the Affordable Care Act and its implementing regulations,²³ the EEOC believes that employers will be able to comply with both the wellness requirements under the Affordable Care Act and these regulations.²⁴

Third, in addition to limiting the total inducement to 30 percent of the total cost of coverage for the plan in which the employee and any dependents are enrolled, the proposed rule, at new section 1635.8(b)(2)(iv), describes the manner in which inducements for employees and spouses are to be apportioned. The EEOC proposes that the maximum share of the inducement attributable to the employee's participation in an employer wellness program (or multiple employer wellness programs that request such information) be equal to 30 percent of the cost of self-only coverage, which is the maximum amount the Commission has proposed may be offered under the ADA for an employee to answer disability-related inquiries or take medical examinations in connection with a wellness program that is part of a group health plan. *See* 80 FR 21659, 21663 (April 20, 2015). The remainder of the inducement – equal to 30 percent of

²³ There are differences between the inducement limit provided in this proposal under GINA and the inducement limits under the wellness regulations implementing HIPAA, as amended by the Affordable Care Act, including that under those wellness regulations: (1) the inducement limit does not apply to “participatory wellness programs,” which include HRAs that all participants may answer, regardless of their health status (but only to “health-contingent wellness programs”); and (2) the inducement limit on health-contingent wellness programs does not contain specific rules apportioning the inducement between the spouse and the employee. *See* 26 CFR 54.9802-1(f); 29 CFR 2590.702(f); 45 CFR 146.121(f).

²⁴ Regulations implementing the wellness provisions in HIPAA, as amended by the Affordable Care Act, permit covered entities to offer financial incentives as high as 50 percent of the total cost of employee coverage for tobacco-related wellness programs, such as smoking cessation programs. *See* 26 CFR 54.9802-1(f)(5); 29 CFR 2590.702(f)(5); 45 CFR 146.121(f)(5). The inducement rules in 1635.8(b)(2) apply only to health and genetic services that request genetic information. A smoking cessation program that asks employees whether they use tobacco (or whether they ceased using tobacco upon completion of the program) or requires blood tests to determine nicotine levels is not a wellness program that requests genetic information and is therefore not covered by this proposed rule.

the total cost of coverage for the plan in which the employee and any dependents are enrolled minus 30 percent of the total cost of self-only coverage – may be provided in exchange for the spouse providing information to an employer wellness program (or multiple employer wellness programs that request such information) about his or her current or past health status. These limitations would be set forth at 29 CFR 1635.8(b)(2)(iv)(a) and (b)

Thus, for example, if an employee is enrolled in a health plan that covers the employee and any class of dependents for which the total cost of coverage is \$14,000, the maximum inducement the employer can offer for the employee and the employee's spouse to provide information about their current or past health status is 30 percent of \$14,000, or \$4,200. If the employer's self-only coverage costs \$6,000, the maximum allowable incentive the employer may offer for the employee's participation is 30 percent of \$6,000, or \$1,800. The rest of the inducement, \$4,200 minus \$1,800, or \$2,400, may be offered for the spouse to provide current or past health status information. However, an employer would be free to offer all or part of the \$2,400 inducement in other ways as well, such as for the employee, the spouse, and/or another of the employee's dependents to undertake activities that would qualify as participatory or health-contingent programs but do not include requests for genetic information, disability-related inquiries, or medical examinations. Thus, in the example above, an employer could offer \$1,800 for the employee to answer disability-related questions and/or to take medical examinations as part of a health risk assessment, could offer the same amount for the employee's spouse to answer the same questions and to take the same medical examinations, and could offer the remaining \$600 for the employee, the spouse, or both to undertake an activity-based health-contingent program, such as a program that requires participants to walk a certain amount each week. Additionally, a wellness program may offer inducements in accordance with HIPAA and

the Affordable Care Act without regard to the limits on apportionment set forth in this proposed rule if neither the employee nor the employee's spouse are required to provide current or past health status information, so long as the wellness program otherwise complies with the requirements of the ADA and GINA.

Fourth, proposed section 1635.8(b)(2)(vi) would prohibit a covered entity from conditioning participation in a wellness program or an inducement on an employee, or the employee's spouse or other covered dependent, agreeing to the sale of genetic information or waiving protections provided under section 1635.9. Section 1635.9 prohibits the disclosure of genetic information, except in six narrowly defined circumstances.

Fifth, we propose to add another example to 29 CFR 1635.8(c)(2) to make clear that an employer is permitted to seek information -- through medical questionnaires, medical examinations (e.g., to detect high blood pressure or high cholesterol), or both -- about the current or past health status of an employee's spouse who is covered by the employer's group health plan and is completing a HRA on a voluntary basis in compliance with 29 CFR 1635.8(b)(2). This provision of the regulations describes two circumstances under which the employer is permitted to request, require, or purchase genetic information or information about the past or current health status of an employee's family members who are receiving health or genetic services on a voluntary basis. The provision cross-references 29 CFR 1635.8(b)(2) to make clear that such acquisitions are only permitted if 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.

Finally, the revisions would remove the term "financial" as a modifier of the type of inducements discussed in the regulation 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.²⁵ Since promulgation of the original Title II regulations in 2010, the EEOC has become aware that inducements other than those that might be called purely financial are used with some frequency and intends that the regulations apply to all such inducements.

These revisions would require renumbering throughout 29 CFR 1635.8(b)(2), as well as the addition of a reference to the new subsections within 29 CFR 1635.8(b)(2)(ii).

Technical Amendments

The first sentence of 29 CFR 1635.8(b)(2)(iv) (which, in the proposed rule, will be renumbered as 29 CFR 1635.8(b)(2)(vii)) reads as follows: “Nothing in § 1635.8(b)(2)(iii) limits the rights or protections of an individual under the Americans with Disabilities Act (ADA), as amended, or under any other applicable civil rights law, or under the Health Insurance Portability and Accountability Act (HIPAA), as amended by GINA.” This subsection should have referred to subsection (b)(2)(ii) concerning inducements for completing HRAs, as well as subsection (b)(2)(iii) (which, in the proposed rule, will be renumbered as 29 CFR 1635.8(b)(2)(v)) concerning disease management or other programs that offer inducements for achieving certain health outcomes. We propose to revise the rule so that it references the appropriate subsections, including the newly proposed 29 CFR 1635.8(b)(2)(iii) and (iv) concerning inducements for spouses to complete HRAs. Finally, we propose to amend this and other subsections to include reference to HIPAA and the Affordable Care Act, where appropriate.

Request for Comments

²⁵ Removal of the modifier “financial” is consistent with the HIPAA and the Affordable Care Act wellness program provisions, which generally define a permissible 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.” See 26 CFR 54.9802-1(f)(1)(i); 29 CFR 2590.702(f)(1)(i); 45 CFR 146.121(f)(1)(i). See footnote 14 for additional discussion of the meaning of “inducement.”

The Commission invites written comments from members of the public on any issues related to this proposed rule about particular practices that might violate GINA. In addition, the Commission specifically requests comments on several issues:

(1) Whether employers that offer inducements to encourage the spouses of employees to disclose information about current or past health 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.

(2) Should the proposed authorization requirement apply only to 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? If so, how should the Commission define “de minimis”?

(3) 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?

(4) Given that, in contrast to the status quo when the ADA was enacted, most employers today store personnel information electronically, and in light of increasingly frequent breaches to electronically stored employment records, should the rule 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?

(5) In addition to any suggestions offered in response to the previous question, are there best practices or procedural safeguards to ensure that information about spouses' current health status is protected from disclosure?

(6) Given concerns about privacy of genetic information, should the regulation restrict the collection of any genetic information by a workplace 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?

(7) 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.

Regulatory Procedures

Executive Order 12866

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

Although a detailed cost-benefit assessment of the proposed 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 current or past health status 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 the health-contingent wellness program. This proposed 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 current or past health status information.

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 2013, the agency's outreach programs reached more than 280,000 persons through participation in more than 3,800 no-cost educational, training and outreach events. We expect to put information about the revisions to

the GINA regulations in our outreach programs in general and to continue to offer GINA-specific outreach programs which will, of course, include information about the revisions once the proposed rule becomes final. We will also post technical assistance documents on our website explaining the revisions to the GINA regulations, as we do with all of our new regulations and policy documents.²⁶

We estimate that there are approximately 782,000 employers with 15 or more employees subject to Title II of GINA²⁷ and, of that number, one half to two thirds (391,000 to 521,333) offer some type of wellness program.²⁸ Assuming that nearly half of employer wellness programs are open for participation by the spouses or dependents of workers, and using the highest estimates, we assume that approximately 260,667 employers will be covered by this requirement.²⁹ We further estimate that the typical human resources professional will need to dedicate, at most, 60 minutes to gain a satisfactory understanding of the revised regulations and

²⁶ See, e.g., <http://www.eeoc.gov/laws/types/genetic.cfm> for documents explaining Title II of GINA.

²⁷ See *Firm Size Data*, at <http://www.sba.gov/advocacy/849/12162>.

²⁸ See Rand Health, *Workplace Wellness Programs Study Final Report* (2013), sponsored by the U.S. Departments of Labor and Health and Human Services, available at http://www.rand.org/content/dam/rand/pubs/research_reports/RR200/RR254/RAND_RR254.pdf (hereinafter referred to as the RAND Final Study). See also The Kaiser Family Foundation and Health Research & Educational Trust 2014 Employer Health Benefits Survey, available at <http://kff.org/health-costs/report/2014-employer-health-benefits-survey/> [hereinafter referred to as the Kaiser Survey]. 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.

²⁹ Although the Kaiser Survey reports that 51 percent of large employers versus 32 percent of small employers ask employees to complete a HRA, 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 Kaiser Foundation, *Workplace Wellness Programs Characteristics and Requirements* (2015), available at <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).

that the median hourly pay rate of a human resources professional is approximately \$49.41. *See* Bureau of Labor Statistics, Occupational Employment and Wages, May 2014 at <http://www.bls.gov/oes/current/oes113121.htm>. Assuming that an employer will train up to three human resources professionals/managers on the requirements of this rule, we estimate that initial training costs will be approximately 38,638,670.00.³⁰

Finally, GINA's plain language (at 42 U.S.C. 2000ff-(1)(b)(2)) and EEOC's regulations (at 29 CFR 1635.8(b)(2) and (c)(2)) make it 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 proposed rule imposes no new obligations with respect to authorization for the collection of genetic information. We welcome comments on this and all of our conclusions concerning the benefits and burdens of the revisions.

Paperwork Reduction Act

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

Regulatory Flexibility Act

Title 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. *See Firm Size Data*, at <http://www.sba.gov/advocacy/849/12162>.

³⁰ 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 available at https://www.shrm.org/Research/SurveyFindings/Articles/Documents/09-0620_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.

The Commission certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small entities because it imposes no reporting burdens and only minimal costs on such firms. The proposed rule simply clarifies that employers that offer wellness programs are free to adopt 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 current or past health. We do not have data on the number or size of businesses that may need to alter documents relating to their wellness programs. However, our experience with enforcing the ADA, which required all employers with 15 or more employees to remove medical inquiries from application forms, suggests that revising questionnaires to eliminate or alter an instruction would not impose significant costs.

To the extent that employers will expend resources to train human resources staff and others on the revised rule, we reiterate that the EEOC conducts extensive outreach and technical assistance programs, many of them at no cost to employers, to assist in the training of relevant personnel on EEO-related issues. For example, in FY 2013, the agency's outreach programs reached more than 280,000 persons through participation in more than 3,800 no-cost educational, training and outreach events. We expect to put information about the revisions to the GINA regulations in our outreach programs in general and to continue to offer GINA-specific outreach programs which will, of course, include information about the revisions once the proposed rule becomes final. We will also post technical assistance documents on our website explaining the

revisions to the 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 resources professional is approximately \$49.41. *See* Bureau of Labor Statistics, Occupational Employment and Wages, May 2014 at <http://www.bls.gov/oes/current/oes113121.htm>. Assuming that small entities have between one and five human resources professionals/managers, we estimate that the cost per entity of providing appropriate training will be between approximately \$49.41 and \$247.05. The EEOC does not believe that this cost will be significant for the impacted small entities. We urge small entities to submit comments concerning the EEOC's estimates of the number of small entities affected, as well as the cost to those entities.

Unfunded Mandates Reform Act of 1995

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

List of Subjects in 29 CFR Part 1635

Administrative practice and procedure, Equal employment opportunity

Dated: October 27, 2015

For the Commission:

Jenny R. Yang

Chair

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

PART 1635 – [AMENDED]

1. The authority citation for 29 CFR 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)(v) and (vii);
- e. Add new paragraphs (b)(2)(iii), (b)(2)(iv), and (b)(2)(vi);
- f. Revise newly redesignated paragraph (b)(2)(vii).
- 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.

* * * * *

(ii) Consistent with 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 the requirements of paragraphs (b)(2)(i) and (ii) of this section, a covered entity may offer, as part of its health plan, an inducement to an employee whose spouse provides information about the spouse's own current or past health status as part of a health risk assessment when the employee has elected coverage for any class of dependents under the health plan, and the spouse is included in such coverage. 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, for the current or past health status information of an employee's children, or for the genetic information of an employee's child. 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 a wellness program. This inducement, when combined with any other inducement permitted under Title I of the Americans with Disabilities Act (ADA), for an employee's participation in a wellness program that asks disability-related questions or requires medical examinations, may not exceed 30 percent of the total cost of the coverage under the plan in which an employee and the spouse are enrolled. For example, if an employer offers health insurance coverage at a total cost of \$14,000 for employees and their dependents (including spouses) and provides the option of participating in a wellness program to employees and spouses who are covered by the plan, the employer may not offer an inducement greater than 30 percent of \$14,000, or \$4,200.

(iv) When an employer offers an inducement for an employee and the employee's spouse to participate in a wellness program that requests information about the spouse's current or past health status:

(A) The maximum amount of the inducement for an employee's spouse to provide information about current or past health status may not exceed 30 percent of the total cost of coverage for the plan in which the employee is enrolled less 30 percent of the total cost of self-only coverage. For example, if an employer offers health insurance coverage at a total

cost of \$14,000 for employees and their dependents and \$6,000 for self-only coverage, the maximum inducement the employer can offer for the employee and the employee's spouse to provide information about their current or past health status is 30 percent of \$14,000, or \$4,200. The maximum amount of the \$4,200 inducement that could be offered for the employee's spouse to provide current or past health status information is \$4,200 minus \$1,800 (30 percent of the cost of self-only coverage), or \$2,400

(B) The maximum amount of the inducement the employer may offer to the employee for participation is 30 percent of the cost of self-only coverage. For example, if an employer offers health insurance coverage at a total cost of \$14,000 for employees and their dependents and \$6,000 for self-only coverage, the maximum inducement that may be offered for the employee to respond to disability-related inquiries or take medical examinations is \$1,800.

* * * * *

(vi) A covered entity may not, however, condition participation in a 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 of genetic information, including information about the current

health status of an employee's family member, or otherwise waiving the protections of § 1635.9.

(vii) Nothing contained in paragraphs (b)(2)(ii) through (vi) 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." 29 CFR 1630.2(o)(1)(iii); 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 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 PHSA (45 CFR 146.121 and 146.122), as amended by section 1201 of the Affordable Care Act.

* * * * *

(c) * * *

(2) A covered entity does not violate this section when, consistent with paragraph (b)(2) of this section, 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. 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 current or past health status of the employee’s family member who is covered by the employer’s group health plan and 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 a 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 Public Health Service Act (PHSA), 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 PHSA, 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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