Proposed Rule – Amendments to Regulations Under the Genetic Information Nondiscrimination Act of 2008

Equal Employment Opportunity Commission

29 CFR Part 1635

[Docket No.]

RIN 3046-AB11

Amendments to Regulations Under the Genetic Information Nondiscrimination Act of 2008

AGENCY: Equal Employment Opportunity Commission.

ACTION: Proposed rule.

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

DATES: Comments regarding this proposal must be received by the Commission on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Please see the section entitled **ADDRESSES** for additional information on submitting comments.

ADDRESSES: You may submit comments, identified by RIN number 3046-AB11, 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) (this is not a toll-free number) or 1-800-669-6820 (TTY).
- Mail: Rachel V. See, 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: Rachel V. See, 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 to 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, if the Commission's library has reopened to the public.

FOR FURTHER INFORMATION CONTACT: Kerry E. Leibig, Senior Attorney Advisor, at (202) 921-2663 (voice), or 1-800-669-6820 (TTY). Requests for this notice in an alternative format should be made to the Office of Communications and Legislative Affairs at (202) 921-3191(voice) (this is not a toll-free number) or 1-800-669-6820 (TTY).

SUPPLEMENTARY INFORMATION:

Discussion

Many employers that sponsor group health plans**[1]** also offer health promotion and disease prevention activities, known as wellness programs, to employees and family members enrolled in health plans.**[2]** Wellness programs may be part of an employer's group health plans, may themselves qualify as group health plans, or may be offered even if an employer does not offer a health plan or health insurance coverage. Many of these wellness programs include disability-related inquiries or medical examinations, such as programs that ask employees to complete a health risk assessment and/or undergo biometric health screenings that measure their risk factors for certain medical conditions.**[3]** Other employers offer wellness programs to help employees meet health goals, such as educational classes, onsite exercise facilities, and/or coaching, that do not require them to provide medical information.**[4]**

Some employers offer incentives**[5]** to encourage employees simply to participate in a wellness program, while others offer incentives for employees to complete an activity related to a health factor or to achieve health outcomes.**[6]** Incentives can be framed as rewards or penalties and often take the form of prizes, cash, a reduction or increase in health care premiums or cost sharing, or payroll deductions.**[7]** Some employers offer employees' family members the opportunity to participate in wellness programs.**[8]** When a wellness program collects medical information from an employee's family members, Title II of the Genetic Information Nondiscrimination Act of 2008 (GINA)**[9]** is implicated, as explained below, because information about the manifestation of diseases and disorders in family members is considered the "genetic information" of the employee under GINA's statutory terms. Wellness programs must also comply with other laws enforced by the EEOC (and, where applicable, other federal agencies) and with laws regulating group health plans when such programs are part of, or qualify as, group health plans.

Brief Overview of the EEOC's Attempts to Regulate Incentives Provided by Wellness Programs Under Title II of GINA

In 2016, the EEOC issued a final rule on wellness programs under Title II of GINA to accompany the agency's rule on wellness programs under the Americans with Disabilities Act (ADA). The 2016 rule was the culmination of a years-long, exhaustive process undertaken to respond to ongoing stakeholder concerns. Specifically, stakeholders questioned whether the EEOC's 2010 GINA Title II regulations, which included a general rule prohibiting incentives in return for genetic information, disallowed the practice of offering an employee an incentive if his or her spouse provides information about the spouse's manifestation of disease or disorder to a wellness program, since such information is considered genetic information of the employee under Title II of GINA's statutory definitions. Based on extensive stakeholder input through the Commission meeting and rulemaking processes, the 2016 rule interpreted GINA to allow such incentives up to the same 30 percent maximum permitted under the regulations implementing the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Affordable Care Act**[10]** that apply to certain types of wellness programs (2013 HIPAA regulations).**[11]** Soon after the EEOC's 2016 GINA rule was issued, AARP**[12]** filed a lawsuit challenging it (along with the ADA wellness regulations issued on the same day) under the Administrative Procedure Act (APA). The U.S. District Court for the District of Columbia ultimately ruled on the merits that the EEOC failed to provide a sufficient explanation for the decision to adopt a 30 percent incentive limit from another federal law, and the EEOC accordingly rescinded the incentive portion of the 2016 GINA rule.

The EEOC is now proposing a new rule that takes account of the court's decision and again seeks to provide the guidance stakeholders continue to seek on this question. This new proposed rule adopts an incentive level based on the statutory provisions of Title II of GINA and the EEOC's obligation to substantively interpret them. In light of the court's ruling and the requirements of Title II of GINA, rather than the 30 percent level previously adopted, we now propose that employer-provided wellness programs may offer no more than a de minimis incentive to an employee in return for the employee's family members providing information about the family members' manifestation of diseases or disorders to a wellness program. As described in detail below, this de minimis standard is based on two provisions under Title II of GINA: the absolute prohibition on using genetic information to make employment decisions and the restrictions on acquiring genetic information.

Title II of GINA and Other Laws Prohibiting Employment Discrimination

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. 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 noted common misconceptions that an individual's genetic predisposition for a condition necessarily leads to the individual 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.**[13]**

Congress therefore understood that, without legal protections in place, individuals might 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 could be used to deny health coverage or employment.**[14]** Consequently, GINA restricts when employers and insurers can acquire and disclose genetic information, and includes an absolute prohibition on employers using genetic information in making employment decisions.**[15]** The EEOC issued implementing regulations on November 9, 2010, to provide all entities subject to Title II of GINA additional guidance with regard to the law's requirements. *See* 75 FR 68912 (Nov. 9, 2010).

The statute and the EEOC's GINA Title II regulations provide that "genetic 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);**[16]** 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.

Under GINA, family members of an individual include someone who is a dependent of an individual through marriage (i.e., spouse), 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 ERISA); *see also* 29 CFR 1635.3(a).**[17]**

Although similar to Title I of the ADA in that both laws are concerned with limiting the use, acquisition, and disclosure of medical information in the employment setting, GINA's restrictions with respect to genetic information include more protections, consistent with GINA's specific purposes. Unlike the ADA, which allows employers to consider medical information in certain limited circumstances (such as using 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, with no exceptions.**[18]**

GINA also is stricter than the ADA with respect to the acquisition of protected information. For example, even though the ADA allows an employer to require a pre-employment medical examination of all employees to whom it has offered a particular job, GINA limits the examination's scope by prohibiting 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 to determine continued fitness for duty.

Under GINA, there are six limited circumstances in which an employer**[19]** may request, require, or purchase genetic information about an applicant or employee. One permits employers that offer health or genetic services, including such services offered as part of wellness programs,**[20]** to request genetic information as part of these programs, as long as certain specific requirements are met.**[21]** *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 Commission's 2010 regulations implementing Title II of GINA made clear that one of the requirements is that the wellness program cannot condition incentives to employees on the provision of genetic information. This requirement is consistent with Title I of GINA's explicit prohibition against adjusting premium or contribution amounts on the basis of genetic information. In fact, one of the reasons the EEOC adopted the "no incentive" rule in 2010 was the determination, made in consultation with the federal agencies responsible for enforcing Title I of GINA,**[22]** that permitting employers to condition wellness program incentives on the provision of genetic information would undermine Title I's prohibition on obtaining genetic information for underwriting purposes (which includes a prohibition on offering rewards in return for genetic information provided in connection with a wellness program). **[23]**

Thus, under the existing rule set forth at 29 CFR part 1635 employers may acquire genetic information as part of a wellness program that meets certain strict rules but may not offer any incentives in exchange for genetic information.

Prior to publication of the final rule in 2010, the EEOC received no comments regarding how Title II's acquisition prohibition or the health or genetic service exception to that prohibition interact with the practice of offering employees incentives where a spouse participates in a wellness program, despite the fact that information about the manifestation of disease or disorder in a spouse is genetic information about the employee. Several months after the rule was published, however, this question was raised by stakeholders. *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 (http://www.eeoc.gov/eeoc/meetings/5-8-13/moore.cfm)** (attachment to written testimony). Two panelists also raised this question during a May 2013 Commission meeting on Wellness Programs. *See* Written Testimony of Leslie Silverman available at **http://www.eeoc.gov/eeoc/meetings/5-8-13/silverman.cfm (http://www.eeoc.gov/eeoc/meetings/5-8-13/silverman.cfm)** and Written Testimony of Amy Moore available at **http://www.eeoc.gov/eeoc/meetings/5-8-13/moore.cfm (http://www.eeoc.gov/eeoc/meetings/5-8-13/moore.cfm)**. Although these interested stakeholders argued that spousal incentives are an important tool for employers who wish to promote healthy lifestyles and reduce health risks of all individuals covered by an employer's insurance plan, they did not provide any details about the average amount of these incentives or how commonly they are used.

When this issue was raised, the EEOC consulted with the tri-Departments and learned that, despite Title I's general prohibition on obtaining genetic information for underwriting purposes (including offering rewards in return for genetic information provided in connection with a wellness program), the enforcement agencies interpret Title I to allow group health plans to use information about the manifestation of a disease or disorder of any plan participant for underwriting purposes, even if that plan participant is the family member of another plan participant. In other words, under Title I, incentives are permitted in return for family members providing their health information to a wellness program if that family member also participates in the plan.**[24]** Under Title I, this is not considered giving an incentive for genetic information because the incentive is going to a plan participant for his or her own health information. By contrast, Title II regulates the employment relationship and treats health insurance as an employment benefit. Under Title II, information about a family member's manifestation of disease or disorder is statutorily the genetic information of the employee, and the fact that the family member is participating in the health plan or a wellness program does not change the fact that his or her health information is genetic information about the employee. Thus, providing the employee with an incentive in return for a family member's provision of information about the family member's manifestation of disease or disorder to a wellness program, while not an issue under Title I as interpreted by the agencies that enforce it, is problematic under Title II.

To respond to growing stakeholder concerns about whether the EEOC intended to declare unlawful the practice of providing employees incentives in exchange for spousal participation in wellness programs, the EEOC began to consider whether and how the regulations implementing Title II of GINA and, in particular, the prohibition on providing incentives in exchange for genetic information, should be amended.

This proposed rule is our second attempt to address these concerns. This proposal would make an exception to allow employers to offer incentives in return for one specific type of genetic information when that information is requested as part of a wellness program that also meets the other requirements of 29 CFR 1635.8(b)(2). Specifically, this proposed rule would allow employers to offer a de minimis incentive to an employee in return for the employee's family members providing information about the family members' manifestation of diseases or disorders to a wellness program. This proposed rule does not alter the general prohibition on offering incentives in return for any other type of genetic information or in any circumstance other than those described in this rule.

In addition, however, as discussed in detail later in this preamble, the EEOC invites comments on possible justifications under Title II of GINA for adoption of a higher than de minimis incentive level, as well as the maximum amount of such an incentive.

Wellness programs must comply with Title I of the ADA, prohibiting discrimination on the basis of disability, and other laws the EEOC enforces that prohibit discrimination based on race, color, national origin, sex, religion, compensation, or age, in addition to Title II of GINA.**[25]**

Final 2016 GINA Wellness Rule

In response to numerous inquiries received after the issuance of the regulations implementing Title II of GINA in November 2010 about whether GINA-covered entities could offer incentives to employees for their family members to provide information about the family member's manifestation of diseases or disorders as part of a wellness program, the Commission issued an amended rule on May 17, 2016, addressing this additional question. Although the Commission received numerous comments both for and against the proposal to allow spousal incentives under Title II of GINA, and many commenters argued that the permissible incentives should parallel those allowed under the 2013 HIPAA regulations (currently 30 percent of the total cost of the health plan in which the employee is enrolled**[26]**), the comments provided little detail as to how common spousal incentives were or the typical level of such incentives.

The EEOC's 2016 final rule provided that such health information is genetic information about the employee (because it is information about the manifestation of disease or disorder in a family member, *i.e.*, the employee's family medical history, which is a type of genetic information about the employee). However, the 2016 rule made an exception to the general prohibition on incentives in return for genetic information to allow covered entities to offer employees limited incentives for spouses to provide information about their manifestation of diseases or disorders.

Specifically, the 2016 rule provided, in 29 CFR 1635.8(b)(2)(iii), that: an employer may offer a limited incentive (not to exceed 30 percent of the total cost of self-only coverage) to an employee whose spouse is permitted to participate in the wellness program and, as part of that program, provides information about the spouse's manifestation of diseases or disorders (a type of genetic information of the employee, not the spouse); incentives for such information may be financial or in-kind; employers may not offer an incentive in exchange for an employee providing his or her own genetic information; employers may not offer an incentive in exchange for a spouse providing the spouse's own genetic information; and employers may not offer an incentive in exchange for information about a child's manifestation of disease or disorder or genetic information. The 2016 rule also included several other protections for employees, including enhanced confidentiality protections and a prohibition on denying health insurance or benefits to an employee whose spouse refuses to provide health information. This 2016 GINA wellness rule was issued on the same day as an ADA final rule that also addressed wellness programs. *See* 81 FR 31143 (May 17, 2016) and 81 FR 31125 (May 17, 2016).

AARP Lawsuit

On October 24, 2016, AARP filed a lawsuit against the EEOC in the U.S. District Court for the District of Columbia, challenging both the ADA and GINA wellness program regulations under the Administrative Procedure Act (APA). AARP argued that the GINA rule's 30 percent incentive limits were inconsistent with the "voluntary" requirement of GINA because employees would feel coerced to disclose genetic information to receive a reward or avoid a penalty. Although the court denied AARP's motion for a preliminary injunction, it ultimately ruled on the merits that the EEOC failed to provide a sufficient explanation for its decision to adopt the 30 percent incentive limit and remanded both the ADA and GINA rules to the Commission for reconsideration. *AARP v. EEOC*, 267 F. Supp. 3d 14, 29-34, 38 (D.D.C. 2017). Following a motion by AARP to alter or amend the court's summary judgment order, the court vacated the incentive sections of the rules, effective January 1, 2019. *AARP v. EEOC*, 292 F. Supp. 3d 238, 241 (D.D.C. 2017). The EEOC issued conforming regulations, striking the sections of both the ADA and GINA regulations that included the incentive rules – 29 CFR 1640.14(d)(3) (ADA) and 1635.8(b)(2)(iii) (for GINA). *See* 83 FR 65296 (Dec. 20, 2018).

The court in *AARP v. EEOC* found sufficient evidence to support the EEOC's conclusion that regulation was needed to clarify employer obligations with respect to the use of incentives to increase employee participation in wellness programs. However, the court found that the EEOC did not adequately explain the basis for its decision to permit the 30 percent incentive level, which the court construed as being an interpretation of GINA's "voluntary" provision (42 U.S.C. §§ 2000ff-(1)(b)(2)(A)(B), 2000ff-(2)((b)(2)(B), 2000ff-(3)(b)(2)(B), 2000ff-(4)(b)(2)(B)) , and found insufficient the EEOC's explanation that it adopted the 30 percent incentive limit to harmonize its regulations with the HIPAA statute and regulations governing wellness programs. *AARP v. EEOC*, 267 F. Supp. 3d at 29-30. In discussing the concept of voluntariness, the court concluded that there was no indication that the EEOC considered the financial and economic impact that the 30 percent incentive would have on employees and their family members or whether it would result in employees with lower incomes feeling coerced to participate in wellness programs. *Id*. at 32. Due to the court's decision, the EEOC amended the GINA regulations to remove the incentive section at 29 CFR 1635.8(b)(2)(iii), effective January 1, 2019. *See* 83 FR 65296 (Dec. 20, 2018).

This Proposed Rule

The EEOC is now proposing this new rule on incentive levels based solely on the EEOC's obligation to interpret the substantive provisions of Title II of GINA. The proposed rule addresses the concerns identified by the court in its ruling that the 2016 GINA rule was lacking under the APA and proposes other adjustments to the GINA regulations for clarity and consistency. Addressing the same questions discussed in the 2016 GINA rule, this proposed rule addresses the extent to which an employer may offer incentives to an employee in exchange for the employee's spouse (or other family member who may also participate in the employer's wellness program) **[27]** providing information about that family member's manifestation of disease or disorder and/or for that family member to achieve health outcomes as part of an employer-sponsored wellness program. Information about a family member's manifestation of disease or disorder is one type of genetic information *about the employee* (also known as "family medical history") but is *not* genetic information about the family member for purposes of Title II of GINA.

In proposing this new rule, the Commission is mindful of the court's observation in *AARP v. EEOC* that, in the EEOC's 2016 wellness rule, the agency neither adopted standards identical to the HIPAA incentive provisions**[28]** nor considered whether a 30 percent incentive level would result in employees with lower incomes feeling coerced to participate in wellness programs. The Commission also is mindful in making this proposal that another existing federal law (namely the nondiscrimination rules adopted under HIPAA, as amended by the Affordable Care Act), applies to these same practices (offering incentives) for health-contingent wellness programs that are part of or qualify as group health plans.**[29]**

In addition, later in this proposal we ask a number of questions about actual practices and evidence about customary incentive levels to encourage the use of wellness progress as Congress intended.**[30]** Such evidence and comment will inform final decisions about incentive levels going forward.

Under the proposed rule, the general prohibition on providing incentives in return for genetic information adopted in the 2010 rule would remain, but the exception first created in the 2016 rule allowing the offering of limited incentives to spouses who provide information about their manifestation of diseases or disorders to wellness programs would be altered considerably. Specifically, the proposed rule would limit wellness programs to offer a de minimis incentive to all family members, not just spouses, in exchange for family members providing information about their manifestation of diseases or disorders. **[31]**

Finally, the proposed rule does not alter the prohibition on providing incentives in return for genetic information of an employee in any circumstance other than where an employee's family member provides information about his or her manifestation of diseases or disorders and/or achieves health outcomes as part of an employer-sponsored wellness program. For example, the Title II GINA regulations will continue to prohibit any incentives in exchange for inquiries directed to an employee about the employee's family medical history or other genetic information.

Compliance with GINA's Health and Genetic Services Exception: Proposed Section 1635.8(b)(2)(i)

First, all wellness programs that collect genetic information must comply with the requirements of the statute's health and genetic services exception to the general prohibition on acquiring genetic information. This exception allows employers and other covered entities to acquire genetic information where the employer offers health or genetic services, including such services offered as part of a wellness program if: the employee**[32]** provides prior, knowing, voluntary, and written authorization**[33]**; only the employee (or family member if the family member is receiving genetic services) and the licensed health care professional or board certified genetic counselor involved in providing such services receive the individually identifiable information concerning the results of such services; and any individually identifiable genetic information provided in connection with the services is only available for purposes of such services and may be disclosed to the employer only in aggregate terms that do not disclose the identity of specific employees or family members. *See* 42 U.S.C. 2000ff-1(b)(2); 2000ff-2(b)(2); 2000ff-3(b)(2), 2000ff-4(b)(2).

The EEOC made additions to this statutory health and genetic services exception in the 2010 regulations implementing Title II of GINA, providing (within section 1635.8(b)(2)) that the exception for health and genetic services applied to "voluntary" wellness programs (the statute refers only to "wellness programs"). Specifically, section 1635.8(b)(2)(i)(B) stated that the provision of genetic information by the individual must be voluntary, meaning the covered entity neither requires the individual to provide genetic information nor penalizes those who choose not to provide it. These additions were included to make the rules under Title II of GINA consistent with subregulatory guidance under Title I of the ADA. This subregulatory ADA guidance stated that employers are allowed to request medical information as part of employee health plans only if participation in those health plans is voluntary (meaning that participation is not required and refusal to participate is not penalized), but did not address whether incentives are permissible under this definition.**[34]** In other words, neither (1) the requirement that the health and genetic services exception in Title II of GINA apply only to "voluntary" wellness programs nor (2) the regulatory definition of "voluntary" provided in the 2010 GINA regulations are statutory requirements under GINA. The statute itself speaks to the concept of "voluntary" only as it relates to individuals providing "prior, knowing, voluntary, and written authorization" when giving their genetic information to an employer-provided health or genetic service.**[35]** Moreover, although the 2009 proposed rule that first suggested making these additions requested comments on the scope of the term "voluntary," and we received a variety of comments linking the concept to incentive levels, the statute itself does not tie the concept of "voluntary authorization" to incentives nor does Title II of the statute mention incentives at all.

Given these considerations, along with the fact that the EEOC had not yet made a policy determination as to whether the ADA's subregulatory definition of "voluntary" permitted incentives, it was determined in 2010 that within the regulations implementing Title II of GINA, the concept of "voluntary" and the issue of incentives levels should be kept separate. The 2010 final rule therefore adopted a general prohibition on incentives in return for genetic information as a requirement separate from both voluntariness and voluntary authorization.**[36]**

We now propose to remove these extra-statutory requirements pertaining to voluntariness. The existing language that we propose to retain in the GINA regulation – that genetic information obtained through employer-provided health or genetic services be provided only if *prior, knowing, voluntary, and written authorization* is obtained, along with GINA's regulatory requirements for satisfying that standard**[37]** – is sufficient to ensure that participation in a wellness program that collects genetic information is lawful only when prior, knowing, voluntary, and written authorization is obtained.

In addition to better aligning the health and services exception to the statutory text, we further propose to eliminate the requirement that wellness programs be reasonably designed, adopted in the 2016 regulation. The proposed de minimis incentive standard that would apply under GINA to all employer-provided wellness programs requesting that employees' family members provide information about the manifestation of disease or disorder in these family members suggests that, unless the family member believes the wellness program has some value in promoting health or preventing disease, the family member will not participate.**[38]** Therefore, we believe that a separate "reasonably designed" standard under Title II of GINA would invite confusion and possible inconsistency. For these reasons, the proposed rule would delete the requirement, currently at section 1635.8(b)(2)(i)(A), that the health or genetic service must be "reasonably designed to promote health or prevent disease" as unnecessary.

De Minimis Incentives for Health Information from Family Members Participating in Wellness Programs: Proposed Section 1635.8(b)(2)(iii)

The Commission proposes allowing an employer to offer no more than a de minimis incentive to an employee in exchange for his or her family members' participation in a wellness program that includes inquiries about their manifestation of diseases or disorders (one form of genetic information about the employee). For example, a water bottle or a gift card of modest value for each participating family member would clearly be de minimis.

The Commission bases the proposed de minimis standard on two clear prohibitions in Title II of GINA. First, Title II of GINA prohibits the use of genetic information – or the refusal to provide it – as the basis for any employment practice affecting an employee's "terms, conditions, or privileges of employment . . ."**[39]** A practice like imposing a substantial surcharge on any employee whose family member does not provide information about their manifested diseases or disorders (i.e., genetic information about the employee) or withholding a reward from an employee whose family members do not provide genetic information about the employee would constitute actions that discriminate in an employee's terms, conditions, or privileges of employment, insofar as such an employee would receive less compensation than similarly situated employees whose family members provided their health information.

Second, Title II of GINA includes a limitation on requesting, requiring, or purchasing genetic information, with six narrow exceptions.**[40]** In other words, a violation of Title II does not require that an employment practice be based on genetic information – it is enough to simply acquire genetic information outside of one of six narrow exceptions. Although GINA Title II's health and genetic services exception (42 U.S.C. 2000ff-1(b)(2)) permits the acquisition of genetic information as part of a wellness program when certain requirements are met,**[41]** the 2010 regulations implementing Title II explained that one of these requirements is that the wellness program cannot condition incentives to employees on the provision of genetic information in order to be lawful under Title II.**[42]**

Allowing de minimis incentives would not affect terms, conditions, or privileges of employment, thereby avoiding a violation of the prohibition on using genetic information. A de minimis incentive would also provide some flexibility to encourage participation in wellness programs without eliminating the general prohibition against providing incentives in return for genetic information, thereby safeguarding the limitation on acquiring genetic information.

For these reasons, the Commission proposes that an employer may offer no more than a de minimis incentive to an employee in exchange for his or her family members participating in a wellness program that includes inquiries about family members' manifested diseases or disorders. For example, a water bottle or a gift card of modest value for each participating family member would clearly be de minimis.

Proposed Incentive Level and the Voluntary Authorization Standard

Although the proposed de minimis standard is consistent with the requirement that an entity providing health and genetic services obtain prior, knowing, written, and voluntary authorization when requiring genetic information, it is not intended to be an interpretation of that requirement. As noted above, Title II of GINA does not define "voluntary authorization" and the 2010 regulations explained that this requirement is satisfied if the entity requesting genetic information 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 purposes for which it will be used; and (3) describes the restrictions on disclosure of genetic information. The general prohibition on providing incentives in return for genetic information adopted in the 2010 regulation was, as explained in detail above, adopted as a prohibition independent of the voluntary authorization requirement, given the lack of statutory guidance indicating that the requirement was intended to incorporate incentive limits. Furthermore, the general incentive prohibition was not intended to be an interpretation of the broader concept of voluntariness adopted in the 2010 regulations (and rescinded under the current proposal) given the fact that the EEOC had not yet made a policy determination as to whether the ADA's subregulatory definition of voluntary, which the GINA regulation was intended to parallel, included a prohibition on incentives. It is to the general prohibition on providing incentives in return for genetic information, and not to the requirement of voluntary authorization, that we now make an exception that allows incentives for genetic information in one circumstance – when a wellness program offers an employee an incentive in return for his or her family member providing information about the family member's manifestation of disease or disorder.

Proposed Incentive Level and HIPAA's Nondiscrimination Provisions

The Commission is aware that HIPAA, as amended by the Affordable Care Act, allows certain wellness programs within group health plans to offer incentives beyond the de minimis level proposed in this rule. Indeed, the main rationale of the 2016 GINA wellness regulation's adoption of the 30 percent incentive rule outlined above was that incentive levels under Title II of GINA should be harmonized with those described in the 2013 HIPAA regulations. **[43]** But as those very regulations explain, the tri-Departments:

> recognize that many other laws may regulate plans and issuers in their provision of benefits to participants and beneficiaries. These laws include, but are not limited to, the ADA, Title VII of the Civil Rights Act of 1694, . . . [and] the Genetic Information Nondiscrimination Act of 2008 . .

. the Departments reiterate that compliance with [the 2013 HIPAA regulations] is not determinative of compliance with any other applicable requirements.**[44]**

Moreover, as noted above, the court in *AARP v. EEOC* rejected the argument that the need to harmonize with HIPAA, as amended by the Affordable Care Act, justifies adoption of a 30 percent incentive level under Title II of GINA. As that decision correctly points out, Congress chose the 30 percent incentive level in the context of preventing insurance discrimination under HIPAA, as amended by the Affordable Care Act, a wholly different purpose than that which underlies Title II of GINA. Any interpretation of the prohibitions and restrictions imposed by Title II of GINA should be based on Title II of GINA, not on a different statute.

An example of this principle can be seen in the proposed rule, published elsewhere in this issue of the Federal Register, addressing allowable incentives under the ADA. That rule, while proposing that all wellness programs that include disability-related inquiries and/or require medical exams provide no more than a de minimis incentive, recognizes an exception based on the safe harbor provision of the ADA. 42 U.S.C. 12201(c)(2); 29 CFR 1630.16(f)(2). As explained in detail in the ADA proposed rule, the EEOC proposes that the ADA's safe harbor for insurance practices involving underwriting, administering, and classifying risks allows covered entities under the ADA to provide incentives up to the maximum permitted for health-contingent wellness programs that are part of, or qualify as, group health plans as permitted under HIPAA, as amended by the Affordable Care Act, provided certain other conditions are met. The ADA's safe harbor provision thus provides a statutory justification under the ADA for allowing covered entities, as part of administering and classifying risks, to adopt an incentive for certain wellness programs as permitted under HIPAA, as amended by the Affordable Care Act, where HIPAA also applies to such programs. Title II of GINA, however, contains no such statutory safe harbor provision.

The Commission recognizes that the issue of what level of incentives should be permitted under Title II of GINA can be viewed differently. Some may argue, for example, that the Commission should adopt the maximum incentive level for health-contingent programs that are part of, or qualify as, group health plans permitted under the 2013 HIPAA regulations because such an incentive level would be consistent with practices permitted under Title I of GINA and HIPAA, as amended by the Affordable Care Act. As noted above, despite the general prohibition on obtaining genetic information for underwriting purposes (including offering discounts, rebates, and other rewards in return for participating in wellness programs), Title I allows incentives in return for family members' provision of information about their manifestations of diseases or disorders to a wellness program if that family member also participates in the plan. This is not considered giving an incentive for genetic information under Title I because the incentive is going to a plan participant for his or her own health information.

The fact that Title I of GINA allows this type of incentive is consistent with the already-existing practice at the time GINA was enacted of allowing incentives as part of wellness programs. For several years prior to GINA's enactment, the 2006 HIPAA regulations allowed health-contingent wellness programs that are part of group health plans or qualify as group health plans to offer incentives to family members who provide information about manifested diseases or disorders. These 2006 HIPAA regulations permitted rewards or penalties of up to 20 percent of the total cost of coverage under the health plan an employee enrolled in if the employee's dependents, including family members, were given an opportunity to fully participate in a health-contingent wellness program. The 2006 HIPAA regulations were essentially codified in section 2705 of the PHS Act by section 1201 of the Affordable Care Act, which, in 2010, re-affirmed that rewards or penalties could be offered in connection with family member participation in health-contingent wellness programs, and raised the amount to 30 percent of the total cost of coverage under the employee's plan (with an option for the tri-Departments to raise the level as high as 50 percent). The final 2013 tri-Department regulations implementing section 2705 of the PHS Act reflect the current allowable rewards or penalties, including for health-contingent wellness programs in which employees' dependents are allowed to fully participate. *See* 26 CFR 54.9802-1(f)(3)(ii), (4)(ii) and (5); 29 CFR 2590.702(f)(3)(ii), (4)(ii) and (5); 45 CFR 146.121(f)(3)(ii), (f)(4)(ii) and (5).

Thus, under both Title I of GINA and under HIPAA, as amended by the Affordable Care Act, if family members are permitted to participate in a health-contingent wellness program that is part of a group health plan or qualifies as a group health plan, the wellness program may offer incentives up to 30 percent of the total cost of coverage in which the employee and any dependents are enrolled (50 percent to the extent the wellness program is designed to prevent or reduce tobacco use). From this, one might argue that adopting an exception to the general de minimis standard proposed above for health-contingent wellness programs that are part of, or qualify as, group health plans, justifiably recognizes the statutory and regulatory landscape created by Congress and the tri-Departments under Title I of GINA and HIPAA, as amended by the Affordable Care Act.

This rationale, which relies on statutes not enforced by the EEOC to direct the EEOC's interpretation of its own laws, was criticized roundly by the court in *AARP v. EEOC*, which urged the EEOC to base any incentive level adopted on the legal requirements of Title II of GINA itself, not statutes enforced and interpreted by other federal agencies. Therefore, despite the existence of a different incentive rule under Title I and HIPAA, as amended by the Affordable Care Act, we now propose a de minimis incentive standard based on Title II of GINA's prohibition on the use of genetic information and restrictions on the acquisition of genetic information.

Request for Comments on Current Practices and the Rationale for De Minimis Incentives

The Commission invites written comments from members of the public on any issues related to this proposed rule. Furthermore, the Commission specifically requests comments on the following issues:

The Commission requests comments on the current practices of employer-provided wellness programs that offer incentives to employees in return for their family members' provision of information about the family members' manifestation of disease or disorder, including: (1) whether employers are offering the maximum allowable incentive established by the 2013 HIPAA regulations for health-contingent wellness programs that are part of or qualify as group health plans in return for family members' provision of information about their manifestations of diseases or disorders to wellness programs;**[45]** (2) whether there are research-based articles, studies, or surveys about the frequency with which employer-provided wellness programs are giving incentives to employees

in return for their family members providing information about the family members' manifestation of disease or disorder, as well as the specific level of those incentives; (3) the impact, if any, that the adoption of a de minimis incentive level under Title II of GINA would have on employer-provided wellness programs that currently use a higher incentive and the relevance of such impact; and (4) whether additional examples of incentives beyond the examples of a water bottle and a gift card of modest value should be provided to illustrate what would or would not be considered de minimis.

The Commission further invites comments on the rationale outlined above for interpreting Title II of GINA to limit employers to providing no more than a de minimis incentive to an employee in return for the employee's family member providing information about the family member's manifestation of disease or disorder to a wellness program. Specifically, given the determination by the court in *AARP v. EEOC* that the need to harmonize the incentive levels adopted under Title II of GINA with those allowed under the 2013 HIPAA regulations alone is insufficient to justify the adoption of an incentive level as high as that currently allowed under the 2013 HIPAA regulations, we invite comments on (1) possible justifications under Title II of GINA for adoption of a higher than de minimis incentive level for health-contingent wellness programs that are part of or qualify as a group health plan and (2) the maximum amount of such an incentive.

Employment Discrimination Based on Family Member's Refusal to Provide Information: Proposed Section 1635.8(b)(2)(v)

This proposal would prohibit covered entities from requiring family members to provide information about their manifestation of disease or disorder to an employer-provided wellness program. Covered entities would also be prohibited from terminating or taking other adverse action (such as demoting or reprimanding), retaliating against, or harassing an employee because his or her family member refuses to provide information about the family member's manifestation of diseases or disorders to the wellness program or because the information provided reveals that a family member failed to meet a wellness program health goal. It would also be unlawful for covered entities to deny coverage under any of their group health plans or particular benefits packages within a group health plan or limit the extent of benefits provided to the employee due to a family member's refusal to provide information about the family member's manifestation of diseases or disorders to a wellness program or because information about a family member's manifestation of diseases or disorders shows that the family member failed to meet a health goal. Covered entities may, however, lawfully deny an employee an incentive based on a family member's refusal to provide this information, as set forth in proposed section 1635.8(b)(2)(iii), or if the information provided shows that the family member failed to meet a health goal (or reasonable alternative standard) on which an incentive was conditioned.

Prohibited Incentives and Actions

The proposed rule does not allow incentives in return for family members providing their own genetic information, including the results of genetic tests. Such incentives are considered prohibited "underwriting" based on genetic information under Title I of GINA. *See* 42 U.S.C. 300gg-4(b)(3)(A) and -91(19). **[46]** Under this proposal, the Commission declines to interpret Title II of GINA to allow practices clearly prohibited under Title I.

This proposal would also not alter the absolute prohibition against the use of genetic information in making employment decisions. Using information about a family member's manifestation of diseases or disorders (genetic information about the employee) to make an employment decision would violate GINA's prohibition on using genetic information.**[47]** Nor would the proposed rule permit incentives in return for genetic information of an employee in any circumstance other than where an employee's family member provides information about the family member's manifestation of diseases or disorders and/or that information shows that the family member has achieved health outcomes as part of a wellness program. Incentives in exchange for inquiries directed to an employee about the employee's family medical history or other genetic information, for example, are still prohibited.

Existing Rule on Incentives Offered for Participation in Disease Management and Other Programs, Section 1635.8(b)(2)(iv)

The EEOC is not proposing any major substantive changes to the separate rule in the existing GINA regulation that permits incentives for participation in disease management and other programs. The paragraph will be moved from section 1635.8(b)(2)(vi) to (b)(2)(iv) and the reference to "voluntarily" providing genetic information will be replaced with wording indicating that the provision of genetic information must be consistent with all the requirements of paragraphs (b)(2)(i), (ii) and (iii) of section 1635.8. Under paragraph (b)(2)(iv) of section 1635.8, a covered entity may offer incentives to encourage individuals who have provided their own genetic information indicating that they are at increased risk of acquiring a health condition in the future, in compliance with the requirements of paragraphs (b)(2)(i), (ii) and (iii), to participate in disease management programs or other programs that promote healthy lifestyles, and/or to meet particular health goals as part of a health or genetic service. However, to comply with Title II of GINA, these programs must also be offered to individuals with current health conditions and/or to individuals whose lifestyle choices put them at increased risk of developing a condition. Under such a program, the incentive is not offered in return for genetic information but, rather, may be obtained through a number of different routes, one of which involves providing genetic information, for example, in response to a health risk assessment that fits within the requirements of section 1635.8(b)(2)(ii) (a health risk assessment that offers a $150 incentive for completion and includes questions about genetic information but makes clear that the incentive will be provided whether or not the questions about genetic information are answered). Individuals who do not wish to provide genetic information but may benefit from the program may obtain the incentive and gain entrance to the program in other ways.

The regulation gives two examples of permissible incentives: (1) Employees who disclose a family medical history of diabetes, heart disease, or high blood pressure on a health risk assessment that meets the requirements of paragraphs (b)(2)(i), (ii) and (iii) of this section and employees who have a current diagnosis of one or more of these conditions are offered $150 to participate in a wellness program designed to encourage weight loss and a healthy lifestyle and (2) the same program offers an additional incentive to individuals who achieve certain health outcomes. Participants may earn points toward "prizes" totaling $150 in a single year for lowering their blood pressure, glucose, or cholesterol levels, or for losing weight.

Under the proposed rule, these incentives may be offered along with a de minimis incentive to an employee for a family member to provide information about the manifestation of disease or disorder to a wellness program. For example, if an employer offers family members the opportunity to participate in a

health risk assessment that collects information about the manifestation of disease or disorder for a de minimis incentive, it may also offer incentives to an employee and his or her family members that provide their own genetic information, in compliance with section 1635.8(b)(2)(i), (ii) and (iii), that indicates an increased risk for acquiring a health condition in the future to participate in a disease management program, as long as the requirements of section 1635.8(b)(2)(iv) are met.

Minor Revisions for Readability

In order to improve the readability of the regulations, the EEOC proposes to add headings to various sections of the rule: "Requests for Genetic Information from Individuals and their Family Members" will be added to section 1635.8(b)(2)(ii); "Requests for, and Use of, Information about the Manifestation of Diseases or Disorders from Family Members as Part of Wellness Programs" will be added to section 1635.8(b)(2)(iii); "Incentives Offered for Participation in Disease Management and Other Programs" will be added to section 1635.8(b)(2)(iv); "Sale, Exchange, or Other Disclosure of Genetic Information" will be added to section 1635.8(b)(2)(v); "Adverse Action for Non-Participation Prohibited" will be added to section 1635.8(b)(2)(vi); and "Applicability of Other Laws" will be added to section 1635.8(b)(2)(vii). Some of these sections will also be moved within section 1635.8(b)(2) for readability. Finally, the Commission proposes to correct a typographical error in the authority citation.

Executive Order 13563[48] and Executive Order 12866[49]

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

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

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

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

Although a detailed benefit-cost assessment of the proposed regulation is not required, the Commission recognizes that providing some information on potential benefits and costs of the rule may be helpful in assisting members of the public in better understanding the potential impact of the proposed rule. In this regard, the Commission notes that the rule will significantly aid compliance with Title II of GINA by employers. Currently, employers face uncertainty as to whether providing an employee with an incentive if his or her family members provides information about the family member's manifestation of disease or disorder and/or achieves health outcomes as part of an employer-sponsored wellness program will subject them to liability under Title II of GINA. This rule will clarify that offering a de minimis incentive 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 family member incentives with clarity about their obligations under GINA.

The Commission does not believe the costs to employers associated with the rule are significant. This rule simply clarifies that although Title II of GINA generally prohibits incentives in exchange for genetic information, there is an exception which allows employers to provide a de minimis incentive to an employee in one circumstance - when family members provide information about the manifestation of disease or disorder to a wellness program.

Although employers will face initial start-up costs to train human resources (HR) staff and others on the revised rule, the Commission notes that it conducts extensive outreach and technical assistance programs, many of them at no cost to employers, to assist in the training of relevant personnel on EEO-related issues. For example, in FY 2019, the agency's outreach programs reached more than 295,600 workers, employers, their representatives and advocacy groups at more than 3,800 no-cost education, training, and outreach events conducted by the EEOC. 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.**[50]**

We estimate that there are approximately 1,275,000 employers with 15 or more employees subject to Title II of GINA**[51]** and, of that number, one half to two thirds (637,500 to 850,000) offer some type of wellness program.**[52]** Assuming that nearly half of employer wellness programs are open for participation by the dependents of workers, and using the highest estimates, we assume that approximately 425,000 employers will be covered by the requirement set forth at proposed 29 CFR 1635.8(b)(2).**[53]** We further estimate that the typical HR professional will need to dedicate, at most, 30 minutes to gain a satisfactory understanding of the revised regulations, which simply state that all employer-provided wellness programs may offer a de minimis incentive to an employee in return for a family member providing information about the family member's manifestation of disease or disorder. We also estimate that the median hourly pay rate of an HR professional is approximately $54.47. *See* Bureau of Labor Statistics, Occupational Employment and

Wages, May 2018 at **http://www.bls.gov/oes/current/oes113121.htm (http://www.bls.gov/oes/current/oes113121.htm)** . Assuming that an employer will train up to three HR professionals/managers on the requirements of this rule, we estimate that initial training costs will be approximately $34,731,000. **[54]**

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 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. 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. 35).

Regulatory Flexibility Act

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

The Commission certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small entities because it imposes no reporting burdens and only minimal costs on such firms. The proposed rule simply clarifies that employers that offer wellness programs are free to adopt a certain type of incentive without violating GINA. It does not require any action on the part of covered entities, except to the extent that those entities created documents or forms related to their wellness programs that either indicate that GINA prohibits incentives to employees in return for a family member's participation in a wellness program that requests information about the family member's manifestation of disease or disorder, or provide for incentives that are inconsistent with this rule and now will have to change those forms to indicate what levels of incentives are permissible. We do not have data on the number or size of businesses that may need to alter documents relating to their wellness programs. However, our experience with enforcing the ADA, which required all employers with 15 or more employees to remove medical inquiries from application forms, suggests that revising questionnaires to eliminate or alter an instruction would not impose significant costs.

To the extent that employers will expend resources to train HR staff and others on the revised rule, we reiterate that the EEOC conducts extensive outreach and technical assistance programs, many of them at no cost to employers, to assist in the training of relevant personnel on EEO-related issues. For example, in FY 2019, the agency's outreach programs reached more than 295,600 workers, employers, their representatives and advocacy groups at more than 3,800 no-cost education, training, and outreach events conducted by the EEOC. 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, and will respond to inquiries from individual members of the public to the maximum extent possible.

We further estimate that the typical HR professional will need to dedicate, at most, 30 minutes to gain a satisfactory understanding of the revised regulations, which simply state that all employer-provided wellness programs may offer a de minimis incentive to an employee in return for a family member providing information about the family member's manifestation of disease or disorder. We further estimate that the median hourly pay rate of an HR professional is approximately $54.47. *See* Bureau of Labor Statistics, Occupational Employment and Wages, May 2018 at **http://www.bls.gov/oes/current/oes113121.htm (http://www.bls.gov/oes/current/oes113121.htm)** . Assuming that small entities have between one and five HR professionals/managers, we estimate that the cost per entity of providing appropriate training will be between approximately $27.24 and $136.18. The EEOC does not believe that this cost will be significant for the impacted small entities. We urge small entities to submit comments concerning the EEOC's estimates of the number of small entities affected, as well as the cost to those entities.

Unfunded Mandates Reform Act of 1995

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

Congressional Review Act

The Congressional Review Act (5 U.S.C. 801 et seq.) generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. A major rule cannot take effect until 60 days after it is published in the Federal Register. The CRA defines a major rule as one that has resulted in or is likely to result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, or innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. 5 U.S.C. § 804(2). The EEOC has determined

that this rule is not a major rule. The EEOC will submit a copy of the final rule to each House of the Congress and to the Comptroller General of the United States, as required.

List of Subjects in 29 CFR Part 1635

Administrative practice and procedure, Equal employment opportunity.

For the reasons set forth in the preamble, under the authority of 42 U.S.C. 2000ff-2000ff-11, the EEOC amends chapter XIV of title 29 of the Code of Federal Regulations as follows:

PART 1635—GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008

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

Authority: 42 U.S.C. 2000ff.

§ 1635.8 [Amended]

2. In § 1635.8, revise paragraph (b)(2) to read as follows:

(2) Where a covered entity offers health or genetic services, including such services offered as part of a wellness program.

(i) This exception applies only where—

(A) The individual provides prior knowing, voluntary, and written authorization, which may include authorization in electronic format. This requirement 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 purposes for which it will be used; and

(*3*) describes the restrictions on disclosure of genetic information;

(B) 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

(C) Any individually identifiable genetic information provided under paragraph (b)(2) of this section 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 (a covered entity will not violate the requirement that it receive information only in aggregate terms if it receives information that, for reasons outside the control of the provider or the covered entity (such as the small number of participants), makes the genetic information of a particular individual readily identifiable with no effort on the covered entity's part).

(ii) Requests for Genetic Information from Individuals and their Family Members. Consistent with, and in addition to, the requirements of paragraph (b)(2)(i) of this section, a covered entity may not offer an incentive (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 incentives 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 incentive will be made available whether or not the participant answers questions regarding genetic information. For example:

(A) A covered entity offers $150 to employees who complete a health risk assessment with 100 questions, the last 20 of them concerning family medical history and other genetic information. The instructions for completing the health risk assessment make clear that the incentive will be provided to all employees who respond to the first 80 questions, whether or not the remaining 20 questions concerning family medical history and other genetic information are answered. This health risk assessment does not violate Title II of GINA.

(B) Same facts as the previous example, except that the instructions do not indicate which questions request genetic information; nor does the assessment otherwise make clear which questions must be answered in order to obtain the incentive. This health risk assessment violates Title II of GINA.

(iii) Requests for, and Use of, Information about the Manifestation of Diseases or Disorders from Family Members as Part of Wellness Programs. Consistent with, and in addition to, the requirements of paragraphs (b)(2)(i) and (ii) of this section, a covered entity may offer a de minimis incentive (such as a water bottle or a gift card of modest value for each participating family member) to an employee whose family member provides information about the family member's manifestation of disease or disorder to a wellness program.

(iv) Incentive Offered for Participation in Disease Management and Other Programs. A covered entity may offer incentives to encourage individuals who have provided genetic information (e.g., family medical history) in compliance with the requirements of paragraphs (b)(2)(i), (ii), and (iii) of this section that indicates that they are at increased risk of acquiring a health condition in the future to participate in disease management programs or other programs

that promote healthy lifestyles, and/or to meet particular health goals as part of a health or genetic service. However, to comply with Title II of GINA, these programs must also be offered to individuals with current health conditions and/or to individuals whose lifestyle choices put them at increased risk of developing a condition. For example:

(A) Employees who disclose a family medical history of diabetes, heart disease, or high blood pressure on a health risk assessment that meets the requirements of paragraphs (b)(2)(i), (ii) and (iii) of this section and employees who have a current diagnosis of one or more of these conditions are offered $150 to participate in a wellness program designed to encourage weight loss and a healthy lifestyle. This does not violate Title II of GINA.

(B) The program in the previous example offers an additional incentive to individuals who achieve certain health outcomes. Participate may earn points toward "prizes" totaling $150 in a single year for lowering their blood pressure, glucose, or cholesterol levels, or for losing weight. This incentive would not violate Title II of GINA.

(v) Sale, Exchange, or Other Disclosure of Genetic Information. A covered entity may not, however, condition participation in an employer-sponsored wellness program or provide any incentive to an employee, 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)(B) of this section), or otherwise waiving the requirements of section 1635.9.

(vi) Adverse Action for Non-Participation Prohibited. A covered entity may not:

(A) require family members of employees to provide information about their manifestation of disease or disorder to an employer-provided wellness program;

(B) terminate or take other adverse action (including denying access to health insurance or any package of health insurance benefits to an employee, or the spouse or other covered dependent of the employee), retaliate against, or harass, an employee because of a family member's refusal to provide information about his or her manifestation of disease or disorder to the employer-sponsored wellness program or because information about the manifestation of disease or disorder that a family member provides reveals that a family member failed to meet a wellness program health goal except that if a family member refuses to provide this information or if the information shows that the family member failed to meet a health goal (or a reasonable alternative standard) a covered entity may deny an employee the de minimis incentive otherwise provided in return for the family member's information or satisfaction of the health goal.

(vii) Applicability of Other Laws. Nothing contained in paragraphs (b)(2)(i) 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 incentive 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 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 standard (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 and its implementing regulations (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) and its implementing regulations (29 U.S.C. 1182, 29 CFR 2590.702 and 2590.702-1), and section 2705 of the Public Health Service (PHS) Act and its implementing regulations (42 U.S.C. 300gg-4, 45 CFR 146.121, 146.122, and 147.110), as amended by section 1201 of the Affordable Care Act. Compliance with the requirements of this section does not relieve a covered entity from the obligation to comply in all respects with the nondiscrimination provisions of Title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e *et seq.*, the Equal Pay Act of 1963, 29 U.S.C. 206(d), the Age Discrimination in Employment Act of 1967, 29 U.S.C. 621 *et seq.*, Title I of the Americans with Disabilities Act, 42 U.S.C. 12101 *et seq*., or other sections of Title II of GINA.

Dated:

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

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

[2] A report on the characteristics of workplace wellness programs conducted by the Kaiser Family Foundation Health Research and Educational Trust indicated that 55 percent of large firms that offer wellness programs said that most of their wellness benefits were provided by the group health plan. *See* Karen Pollitz & Matthew Rae, Kaiser Family Foundation, *Workplace Wellness Programs Characteristics and Requirements* 5 (2016), **https://www.kff.org/private-insurance/issue-brief/workplace-wellness-programs-characteristics-and-requirements/ (https://www.kff.org/private-insurance/issue-brief/workplace-wellness-programs-characteristics-and-requirements/)** (hereinafter Pollitz and Rae, Kaiser Report).

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

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

[5] In previous regulations implementing Title II of GINA, the term "inducement" was used instead of "incentive," although the terms were intended to have the same meaning. To be consistent with terminology used in regulations issued under Title I of the ADA, this proposed rule will replace the term "inducement" with "incentive." A corresponding change will be made in the existing regulations implementing Title II of GINA.

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

[7] The terms "incentives" and "rewards" as used in this preamble and the proposed rule are intended to be consistent. In regulations issued under the Public Health Service Act (PHS Act), as amended by the Affordable Care Act, "rewards" is defined to mean 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).

[8] "Among large firms with incentives for a screening or wellness or health promotion program, 39% make dependent spouses eligible for incentives or penalties under at least one of their programs." *See Employer Health Benefits Survey*, Kaiser Family Foundation (2018), **https://www.kff.org/report-section/2018-employer-health-benefits-survey-section-12-health-and-wellness-programs/ (https://www.kff.org/report-section/2018-employer-health-benefits-survey-section-12-health-and-wellness-programs/)** (The 2020 Kaiser Survey cited elsewhere does not include information about spousal participation in wellness programs).

[9] 42 U.S.C. 2000ff *et seq.*

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

[11] *See* Incentives for Nondiscriminatory Wellness Programs in Group Health Plans, 78 Federal Register 33158 (June 3, 2013) (codified at 26 CFR 54.9802-1(f); 29 CFR 2590.702(f); 45 CFR 146.121(f) and 147.110).

[12] AARP is a nonprofit, nonpartisan membership organization for people age 50 and over.

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

[14] *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.").

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

[16] 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." S. Rep. No. 110-48, at 28 (2007). For that reason, Congress believed it was important to include family medical history in the definition of "genetic information." *Id.* However, GINA's statutory prohibitions on using, acquiring, and disclosing genetic information, including information about the manifestation of diseases and disorders in family members, is not limited to heritable conditions.

[17] The Commission's definition of "dependent" is used solely for purposes of interpreting Title II of GINA and is not relevant for purposes of interpreting the term "dependent" under Title I of GINA or under section 701(f)(2) of ERISA and the parallel provisions of PHS Act and the Internal Revenue Code (Code). *See* Preamble, Regulations Under the Genetic Information Nondiscrimination Act, 75 *Federal Register* 68914, note 5 (November 9, 2010) and Preamble, Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance Coverage and Group Health, 74 *Federal Register* 51663, 51666 (October 7, 2009) for additional information.

[18] Section 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 its prohibitions on employer use of genetic information.

[19] In addition to employers, GINA-covered entities include employment agencies, unions, 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, this NPRM will refer to employers and employees throughout.

[20] A wellness program, defined in the PHS Act 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 PHS Act, as amended by the Affordable Care Act. A wellness program may be part of a group health plan or qualify as a group health plan required to comply with section 9802 of the Code (26 U.S.C. 9802), section 702 of ERISA (29 U.S.C. 1182) or section 2705 of the PHS Act (42 U.S.C. 300gg-4) (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).

[21] 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.

[22] These agencies, referred to as the tri-Departments throughout this preamble, are the Departments of Labor, Health and Human Services, and the Treasury.

[23] Title I of GINA applies to genetic information discrimination in health coverage and not employment, and is not enforced by the Commission. For more on the protections provided by Title I of GINA, see **https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/gina.pdf (https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/gina.pdf)** . For a discussion of how Titles I and II of GINA allow employers and plans to use financial incentives to promote employee wellness and healthy lifestyles, see the preamble to the GINA Title II final rule at 75 *Federal Register* 68923 (November 9, 2010).

[24] *See* 26 CFR 54.9802-3T(b); 29 CFR 2590.702-1(b); 45 CFR 146.122(b); 45 CFR 148.180(c) and the preamble to the tri-Departments' 2008 request for information soliciting comments on the requirements of Title I of GINA which states that: "Group health plans and health insurance issuers . . . are prohibited from requesting, requiring, or purchasing genetic information for underwriting purposes [but] [p]lans and issuers are still allowed to collect . . . health information that relates to the manifestation of disease or disorder of an individual enrolled in a plan . . . and use it for permitted underwriting purposes [i.e., discounts, rebates, and other payments in return for completing a health risk assessment or participating in a wellness program] with respect to that individual." 73 FR 60208, 60210 (Oct. 10, 2008).

[25] *See* Title VII of the Civil Rights Act of 1964 (Title VII), 42 U.S.C. 2000e–2000e-17; the Equal Pay Act of 1963, 29 U.S.C. 206(d); and the Age Discrimination in Employment Act of 1967 (ADEA), 29 U.S.C. 621–634. However, this rule concerns only the application of Title II of GINA's rules limiting the provision of incentives in return for genetic information within employer-provided wellness programs. Compliance with the limits on incentives in this rule does not necessarily result in compliance with other nondiscrimination laws or other parts of the GINA. For example, even if an employer's wellness program complies with the incentive limits set forth in the GINA regulation, the employer violates Title VII, the ADEA or the ADA if that program discriminates on the basis of race, color, national origin, sex, religion, age, or disability.

[26] Under the 2013 HIPAA regulations, this amount can be raised to 50 percent when tobacco cessation programs are involved. A tobacco cessation program does not request genetic information when it asks family members whether they use tobacco or ceased using tobacco upon completion of a wellness program or when it requires family members to take a blood test to determine nicotine levels, as these are not requests for information about the family member's manifestation of disease or disorder or any other type of genetic information. Therefore, this proposed GINA rule does not apply to tobacco cessation programs that include such requests or requirements.

[27] Although the GINA wellness regulation issued in 2016 allowed incentives in exchange for only a spouse providing health information, this proposed rule allows limited incentives, when certain requirements are met, in exchange for a spouse or other family member providing health information. This parallels the HIPAA Nondiscriminatory Incentive Rule, which allows all dependents who participate in wellness programs to earn incentives and does not distinguish

between spouses and children. *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 (4)(ii) ("However, if, in addition to employees, any class of dependents (such as spouses, or spouses and dependent children) may participate in the wellness program, the reward must not exceed the applicable percentage of the total cost of the coverage in which an employee and any dependents are enrolled.) Throughout the preamble of this proposed rule, "family member" refers to spouses and other family members.

[28] The incentive provisions adopted in the 2016 GINA rule differed from the HIPAA incentive provisions in a number of ways, including by allowing incentives only for information provided by spouses, and not by other dependents, and by basing the incentive limit on the total cost of self-only coverage, as opposed to the total cost of coverage under the plan in which the employee and any dependents were enrolled.

[29] HIPAA's nondiscrimination provisions are different than those enforced by the EEOC and generally prohibit group health plans and group health insurance issuers from discriminating against individuals on the basis of health factors, either with respect to eligibility or in determining premium contributions.

[30] At the request of the court in *AARP v. EEOC*, the EEOC provided and certified the rulemaking record from the 2015-2016 GINA rulemaking, including numerous public comments arguing that the EEOC should adopt incentive levels under GINA parallel to those permitted under HIPAA, as amended by the Affordable Care Act. The court nonetheless found the EEOC failed to provide a reasoned explanation for the decision to adopt an across the board 30 percent incentive limit.

[31] Although the proposed de minimis standard is consistent with the statutory requirement that employers providing health and genetic services must obtain prior, knowing, written, and voluntary authorization when the services require genetic information (part of the statute's health and genetic services exception to the general prohibition on acquiring genetic information), it is not intended to be an interpretation of that requirement. The statutory requirement of voluntary authorization is discussed in detail below.

[32] The 2010 implementing regulations changed "employee" to "individual" because the protections of Title II of GINA apply not only to employees, but also to individuals who seek work through employment agencies, labor unions, and training programs. The Commission received no comments objecting to this alteration.

[33] *See* 29 CFR 1635.8(b)(2)(i)(C) explaining that the requirement of prior, knowing, written, and voluntary authorization is satisfied if the entity requesting genetic information uses an authorization form that: (1) [i]s written so that the individual from whom the genetic information is being obtained is reasonably likely to understand it; (2) [d]escribes the type of genetic information that will be obtained and the general purposes for which it will be used; and (3) [d]escribes the restrictions on disclosure of genetic information.

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

[35] In this way, GINA's statutory restrictions are different from the ADA's statutory restrictions. While GINA incorporates the concept of voluntariness only as it relates to "prior, knowing, voluntary, and written authorization" when providing genetic information to employer-provided health or genetic services, the ADA limits the medical information employers may obtain from employees by generally prohibiting them from making disability-related inquiries or requiring medical examinations and providing an exception that allows employers to obtain medical information as part of employee health programs, as long as any disability-related inquiries and medical examinations that are part of these programs are voluntary. *See* 42 U.S.C. 12112(d)(4)(A) and (B).

[36] *See* Preamble, Regulations Under the Genetic Information Nondiscrimination Act, 74 *Federal Register* 9056, 9062 (March 2, 2009) and Preamble, Regulations Under the Genetic Information Nondiscrimination Act, 75 Federal Register 68912, 68935 (November 10, 2010).

[37] *See* supra, note 35.

[38] A report by the Kaiser Family Foundation found that "building a better [wellness] program is almost as effective" at increasing participation in wellness programs as offering financial incentives. Pollitz and Rae, Kaiser Report, *supra* note 2. Thus, it is reasonable to assume that a wellness program that offers only a de minimis incentive will only draw significant participation if those to whom it is offered believe it will provide something of value.

[39] 42 U.S.C. 2000ff-1(a) ("It shall be an unlawful employment practice for an employer - (1) to fail or refuse to hire, or to discharge, any employee, or otherwise to discriminate against any employee with respect to the compensation, terms, conditions, or privileges of employment of the employee, because of genetic information with respect to the employee"); 29 CFR 1635.4(a) ("It is unlawful for an employer to discriminate against an individual on the basis of the genetic information of the individual in regard to hiring, discharge, compensation, terms, conditions, or privileges of employment.")

[40] 42 U.S.C. 2000ff-1(b)(1) – (6) ("It shall be an unlawful employment practice for an employer to request, require, or purchase genetic information with respect to an employee or a family member of an employee except [in these six circumstances].").

[41] *See* the detailed discussion on the requirements of this exception in the section titled Compliance with GINA's Health and Genetic Services Exception: Proposed Section 1635.8(b)(2)(i), *supra*.

[42] 29 CFR 1635.8(b)(2)(ii) (". . . 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 other paragraphs of this section] . . .").

[43]*See* Incentives for Nondiscriminatory Wellness Programs in Group Health Plans, 78 *Federal Register* 33158 (June 3, 2013) (codified at 26 CFR 54.9802-1; 29 CFR 2590.702; 45 CFR 46.121).

[44] *Id.* at 33168.

[45] *See* 26 CFR 54.9802-1(f)(3) and (f)(4); 29 CFR 2590.702(f)(3) and (f)(4); and 45 CFR 146.121(f)(3) and (f)(4). Currently, that incentive limit is 30 percent of the total cost of the health plan in which the employee is enrolled and can be raised to 50 percent when tobacco cessation programs are involved.

[46] Title I of GINA also prohibits the collection of genetic information by a group health plan or health insurance issuer offering group coverage prior to or in connection with enrollment. *See* 26 CFR 54.9802-3T(d)(2); 29 CFR 2590.702-2(d)(2); and 45 CFR 146.122(d)(2) (prohibiting the collection of genetic information prior to enrollment or in connection with the rules for eligibility and providing an incidental collection exception).

[47] If the information about the family member 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).

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

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

[50] *See*, *e.g.*, **http://www.eeoc.gov/laws/types/genetic.cfm (http://www.eeoc.gov/laws/types/genetic.cfm)** for documents explaining Title II of GINA.

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

[52] *See* Rand Final Report, *supra* note 6. *See also* 2019 Kaiser Survey, **https://www.kff.org/report-section/ehbs-2019-section-12-health-and-wellness-programs/ (https://www.kff.org/report-section/ehbs-2019-section-12-health-and-wellness-programs/)** . According to the RAND Final Report, "approximately half of U.S. employers offer wellness promotion initiatives." By contrast, the 2019 Kaiser Survey indicates that fifty percent of small employers and eighty-four percent of large employers offer at least one program in smoking cessation, weight management, or behavioral or lifestyle coaching.

[53] *See* Pollitz and Rae Kaiser Report, *supra* note 2 (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).

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