

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1635

RIN [3046—AA84]

Regulations Under the Genetic Information Nondiscrimination Act of 2008

AGENCY: Equal Employment Opportunity Commission.

ACTION: Final rule.

SUMMARY: The Equal Employment Opportunity Commission (“EEOC” or “Commission”) is issuing a final rule to implement Title II of the Genetic Information Nondiscrimination Act of 2008 (“GINA”). Congress enacted Title II of GINA to protect job applicants, current and former employees, labor union members, and apprentices and trainees from discrimination based on their genetic information. Title II of GINA requires the EEOC to issue implementing regulations. The Commission issued a proposed rule in the **Federal Register** on March 2, 2009, for a sixty-day notice and comment period that ended on May 1, 2009. After consideration of the public comments, the Commission has revised portions of both the final rule and the preamble.

DATES: Effective January 10, 2011.

FOR FURTHER INFORMATION CONTACT: Christopher J. Kuczynski, Assistant Legal Counsel, or Kerry E. Leibig, Senior Attorney Advisor, at (202) 663-4638 (voice) or (202) 663-7026 (TTY). (These are not toll free numbers.) This rule also is available in the following formats: large print, Braille, audio tape, and electronic file on computer disk. Requests for this rule in an alternative format should be made to the Publications Information Center at 1-800-669-3362 (voice) or 1-800-800-3302 (TTY).

SUPPLEMENTARY INFORMATION:

Introduction

On May 21, 2008, President George W. Bush signed the Genetic Information Nondiscrimination Act of 2008 (“GINA”), Public Law 110-233, 122 Stat. 881, codified at 42 U.S.C. 2000ff *et seq.*, into law. Congress enacted GINA in recognition of, among many achievements in the field of genetics, the decoding of the human genome and the creation and increased use of genomic medicine. As 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.” GINA Section 2(1), 42 U.S.C. 2000ff, note.

Experts predict that the twenty-first century will see tremendous strides in the new field of genomic medicine, bringing it into mainstream medical practice. The National Human Genome Research Institute (NHGRI), the institute within the National Institutes of Health responsible for the mapping of the human genome, notes that “by identifying the genetic factors associated with disease, researchers may be able to design more effective drugs; to prescribe the best treatment for each patient; to identify and monitor individuals at high risk from disease; and to avoid adverse drug reactions.” NHGRI, *The Future of Genomic Medicine: Policy Implications for Research and Medicine* (Bethesda, Md. Nov. 16, 2005), available at <http://www.genome.gov/17516574> (last visited July 7, 2010).

Many genetic tests now exist that can inform individuals whether they may be at risk for developing a specific disease or disorder. But just as the number of genetic tests increases, so do the concerns of the general public about whether they may be at risk of losing access to health coverage or employment if insurers or employers have their genetic information. Congress enacted GINA to address these concerns, by prohibiting discrimination based on genetic information and restricting acquisition and disclosure of such information, so that the general public would not fear adverse employment- or health coverage-related consequences for having a genetic test or participating in research studies that examine genetic information. Scientific advances require significant cooperation and participation from members of the general public. In the absence of such participation, geneticists and other scientists would be hampered in their research, and efforts to develop new medicines and treatments for genetic diseases and disorders would be slowed or stymied.

GINA Title I’s health coverage provisions apply to group health plans sponsored by private employers, unions, and state and local government employers; issuers in the group and individual health insurance markets; and issuers of Medicare supplemental (Medigap) insurance.¹ These Title I provisions generally prohibit

discrimination in group premiums based on genetic information and the use of genetic information as a basis for determining eligibility or setting premiums in the individual and Medigap insurance markets, and place limitations on genetic testing and the collection of genetic information in group health plan coverage, the individual insurance market, and the Medigap insurance market. Title I also requires the Secretary of Health and Human Services to revise the privacy regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HHS has published a notice of proposed rulemaking that proposes to clarify that genetic information is health information, and to prohibit group health plans, health insurance issuers (including HMOs), issuers of Medicare supplemental policies, and all other health plans covered under the HIPAA privacy regulations from using or disclosing genetic information for underwriting purposes.

Title II of GINA prohibits use of genetic information in the employment context, restricts employers and other entities covered by Title II from requesting, requiring, or purchasing genetic information, and strictly limits such entities from disclosing genetic information. The law incorporates by reference many of the familiar definitions, remedies, and procedures from Title VII of the Civil Rights Act of 1964, as amended, and other statutes protecting federal, state, and Congressional employees from discrimination.²

Background

The Commission published a proposed rule to implement Title II of GINA on March 2, 2009, and asked for public comment on the proposed rule, the discussion in the preamble, and other Title II issues not addressed in either document. *See* 74 FR 9056 (March 2, 2009). Several days earlier, on February 25, 2009, the Commission held a public meeting to announce its approval of the proposed rule at which invited panelists spoke about the impact of genetic information discrimination in the workplace (transcript available at <http://www.eeoc.gov/eeoc/meetings/2-25-09/index.cfm>). Although they had not had an opportunity to review the

¹ This regulation does not interpret the requirements of GINA Title I relating to genetic nondiscrimination in health coverage. Those requirements are administered by the Departments of Health and Human Services, Labor, and the Treasury.

² Prior to November 21, 2009, Executive Order 13145 prohibited federal executive branch agencies from discriminating against applicants and employees on the basis of genetic information and limited access to and use of genetic information. Since its effective date in November 2009, GINA has protected federal employees from genetic discrimination.

proposed rule, commenters at the public meeting did express their views on issues they believed should be addressed in EEOC's regulation to effectuate Title II's purposes.

The Commission received 43 comments from individuals, from groups representing individuals, and from organizations representing employers and professionals in response to the proposed rule. Most of those who participated in the February 25, 2009 public meeting submitted written comments after reviewing the proposed rule that were consistent with their public testimony. Further, on March 26, 2010, President Obama appointed to the Commission by way of recess appointments the Chair and two new Commissioners. These new members of the Commission (and others who were previously serving on the Commission) met with a number of stakeholders who had submitted comments to the record. Records of these meetings are included in the rulemaking docket.

In developing this regulation, the Commission closely followed the terms of the statute. The Commission's goal is to implement the various provisions of Title II consistent with Congress's intent, to provide some additional clarification of those provisions, and to explain more fully those sections where Congress incorporated by reference provisions from other statutes. For example, where GINA section 201(2)(A)(i) defines *employee* by reference to Title VII of the Civil Rights Act of 1964 and other statutes, this regulation expands on that reference by importing language from these statutes so that those using the final regulation need not refer to other sources when determining the scope of GINA's coverage.³

The Commission also recognizes that Title II of GINA includes terms that are outside the areas of its expertise. In particular, the definition of "genetic test" refers to "analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes." None of these terms is common to employment discrimination law. For this reason, Commission staff sought and obtained technical assistance from NHGRI, the institute within the National Institutes of Health responsible for decoding the human genome and for developing technologies applicable to the study of the genetic components of complex disorders.

The Commission also coordinated with the Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury, which have responsibility for issuing regulations applicable to GINA Title I. In particular, DOL (the Employee Benefits Security Administration), HHS (the Centers for Medicare & Medicaid Services), and the Treasury (the Internal Revenue Service) are responsible for issuing regulations applicable to GINA sections 101–103.⁴ These agencies issued interim final rules on sections 101 through 103 of GINA on October 7, 2009. See 74 FR 51664. The HHS Office for Civil Rights is responsible for issuing the regulations applicable to GINA section 105 and issued a proposed rule on October 7, 2009 at 74 FR 51698. Among the various Title II provisions are several that address the relationship between Title I and Title II, and the relationship between Title II and several statutes that the Departments enforce, including the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act, the Internal Revenue Code, and HIPAA.

Section-by-Section Analysis of the Regulation

Section 1635.1 Purpose

In this section, the Commission sets forth the general purposes of GINA. The language in this section of the final rule has been modified slightly in response to several comments that disagreed with the characterization of Title II as prohibiting the "deliberate acquisition" of genetic information. See Comments of the American Civil Liberties Union (ACLU), Coalition for Genetic Fairness (CGF), Genetic Alliance, and the Genetics and Public Policy Center in collaboration with Jeremy Gruber (GPPC). These organizations noted that the term "deliberate acquisition" suggested that a covered entity must have a specific intent to acquire genetic information in order to violate the law. According to these commenters, a covered entity violates GINA by engaging in acts that present a heightened risk of acquiring genetic information, even without a specific intention to do so, such as when they fail to inform an individual from whom they have requested documentation about a manifested disease or disorder not to provide genetic information or when they access sources of information (e.g., certain types of databases, Web

sites, or social networking sites) that are likely to contain genetic information about individuals.

For reasons more fully set forth in the preamble's discussion of 1635.8(a), (b)(1) and (4), the Commission agrees that a covered entity may violate GINA without a specific intent to acquire genetic information. For that reason, the Commission has removed the reference to "deliberate acquisition" of genetic information in 1635.1. We likewise recognize that not every acquisition of genetic information violates GINA. Accordingly, the section now simply indicates that Title II of GINA restricts requesting, requiring, or purchasing genetic information. The rest of the language of 1635.1 concerning GINA's prohibition on the use of genetic information in employment decision-making, the requirement that genetic information be kept confidential (which includes maintaining written genetic information that exists in paper or electronic form as a confidential medical record), and the limitations on disclosure of genetic information is the same as the language in the proposed rule.

We have also modified this section to include a point made only in the preamble to the proposed rule. A new subparagraph, 1635.1(b), clarifies that the final rule does not apply to actions of a covered entity that do not pertain to an individual's status as an employee, member of a labor organization, or participant in an apprenticeship program. The final rule offers two examples to illustrate this point. Title II of GINA would not apply to a medical examination of an individual conducted for the purpose of diagnosis and treatment unrelated to employment, which is conducted by a health care professional in the hospital or other health care facility where the individual is an employee. Similarly, Title II would not govern the actions of a covered entity carried out in its capacity as a law enforcement agency investigating criminal conduct, even where the subject of the investigation is also an employee of the covered entity.

Section 1635.2 Definitions—General

The Commission reiterates the definitions set forth in GINA section 201, many of which come from Title VII of the Civil Rights Act of 1964. However, where the statute merely incorporates by reference different categories of covered employees, the regulation describes more fully the employees GINA protects. We have retained without change language from the proposed rule which said that the term "employee" also includes former

³ Unless otherwise noted, use of the term "GINA" means "Title II of GINA." When needed for clarity, the preamble will refer to Title I of GINA or Title II of GINA.

⁴ The National Association of Insurance Commissioners issued conforming model regulations relating to section 104 on September 24, 2008, published in the *Federal Register* on April 24, 2009 at 74 FR 18808.

employees. We received two comments raising concerns with this inclusion. The Illinois Credit Union League (ICUL) suggested that there should be a temporal qualifier on the term “former employee,” while a comment jointly submitted by the U.S. Chamber of Commerce, the Society for Human Resource Management and a number of other employer representatives (Chamber/SHRM) objected that our citation to *Robinson v. Shell Oil Co.*, 519 U.S. 337, 346 (1997), did not support the proposition that the term “employee” also includes former employees. Chamber/SHRM contends that *Robinson* decided only that the term “employee” as used in Title VII’s anti-retaliation provision, 42 U.S.C. 2000e-3(a), applied to former employees, not whether “employee” as used in section 701(f) of Title VII applied to former employees. In *Robinson*, the Supreme Court observed that the definition of “employee” in section 701(f), which is the basis for the term “employee” in GINA, “lacks any temporal qualifier and is consistent with either current or past employment.” *Robinson*, 519 U.S. at 342. The Commission has read *Robinson* as supporting its well-established position that “[f]ormer employees are protected by the EEO statutes when they are subjected to discrimination arising from the former employment relationship.” See EEOC’s Compliance Manual Section 2 on *Threshold Issues* at § 2-III.A.2. & n. 79 (available at <http://www.eeoc.gov/policy/docs/threshold.html#2-III-A-2>) (citing to *Robinson*). An example under GINA would be a situation in which a former employer disclosed to a prospective employer an individual’s genetic information. Accordingly, the final regulation makes clear that the term “employee” includes an applicant and a former employee.

The final regulation provides a concise explanation of the employers covered by GINA, rather than following the statute’s example of providing citations to definitions of “employer” provided by other laws. For example, the final regulation explains that Indian tribes, as well as bona fide private clubs (other than labor organizations) that are exempt from taxation under section 501(c) of the Internal Revenue Code of 1986, are not employers, rather than merely referring to Title VII’s exclusion of these groups from the definition of “employer.” See 42 U.S.C. 2000e(b)(1) and (2).

One commenter asked that the final regulation state that there is no individual liability for violations of GINA. See Comment of TOC Management Services (TOC). As the

statute makes clear, GINA’s definition of “employer” includes employers as defined by Title VII at 42 U.S.C. 2000(e)b. Numerous courts have held that this definition was not intended to permit individual liability. See *Lane v. Lucent Tech., Inc.*, 388 F. Supp. 2d 590 (M.D.N.C. 2005) (citing cases from every circuit except the First Circuit rejecting individual liability); see also, e.g., *Mandell v. County of Suffolk*, 316 F.3d 368 (2d Cir. 2003); *Wathen v. General Elec. Co.*, 115 F.3d 400 (6th Cir. 1997); *Cross v. Alabama*, 49 F.3d 1490 (11th Cir. 1995); *Grant v. Lone Star Co.*, 21 F.3d 649 (5th Cir. 1994). Therefore, it is not necessary to make this point in the regulation.

The final regulation includes a definition of “covered entity.” It uses the term to refer to all entities subject to Title II of GINA: The different categories of GINA-covered employers (private sector, state and local government, Congressional employers, executive branch, federal/civil service), as well as employment agencies, labor organizations, and joint labor-management training and apprenticeship programs. By using the term “covered entity” to describe the requirements or prohibited practices applicable to all entities subject to Title II of GINA, the final regulation avoids some of the repetition found in sections 202–205 of the statute. This use of the term “covered entity” as a simplifying shorthand to aid in the readability of the final regulation is similar to EEOC’s use of “covered entity” in the regulation implementing Title I of the Americans with Disabilities Act, 42 U.S.C. 12111 (ADA). One comment urged the Commission not to use the term “covered entity” because of possible confusion with the same term in HIPAA. See Comment of American Medical Association (AMA). We do not believe that use of the term “covered entity” in this regulation will cause confusion, as most of the entities subject to Title II are not HIPAA covered entities and those that are should be able to distinguish between their roles as HIPAA covered entities and as covered entities subject to Title II of GINA. We note that HIPAA covered entities do not appear to have experienced confusion from use of the term “covered entities” in Title I of the ADA, even though the ADA, like HIPAA, places limitations on the acquisition and disclosure of medical information.

The final regulation says that the term “covered entity” includes an “employing office.” The term “employing office,” referenced in sections 201 and 207 of GINA, is used in the Congressional

Accountability Act, which protects employees in the legislative branch. See 2 U.S.C. 1301(9). Although the EEOC has no enforcement authority under the Congressional Accountability Act, as the only agency with authority to issue regulations under Title II of GINA, we believe that referencing that law in this final regulation appropriately puts employees in the legislative branch and covered employing offices on notice of their rights and responsibilities under GINA.

Section 1635.3 Definitions Specific to GINA

GINA includes six terms not found in any of the other employment discrimination statutes that the Commission enforces. This final regulation provides some additional guidance regarding these terms. One comment said that many of the definitions in the NPRM were too difficult to understand without scientific knowledge. See Comment of Federal Deposit Insurance Corporation (FDIC). As noted above, in developing these definitions, EEOC coordinated closely with NHGRI. We also were careful to track closely the language of Title II itself where possible to avoid any unintended consequences that might result from attempting to paraphrase or simplify scientifically technical language. However, we have added a number of examples to the regulation itself that will further clarify the meanings of some of these terms.

Section 1635.3(a) Family Member

The statute defines an individual’s “family member” both by reference to ERISA section 701(f)(2) and as extending to the individual’s fourth degree relatives. First, section 201(3)(a) of GINA states that family member is defined as “a dependent (as that term is used for purposes of section [701(f)(2) of ERISA])” of the individual.⁵ For purposes of Title II, the Commission has determined that the dependents covered by Title II are limited to persons who are or become related to an individual

⁵ The Commission’s definition of “dependent” is solely for purposes of interpreting Title II of GINA, and is not relevant to interpreting the term “dependent” under Title I of GINA or under section 701(f)(2) of ERISA and the parallel provisions of the Public Health Service Act and the Internal Revenue Code. The Commission believes its interpretation of the term “family member,” particularly the way in which GINA’s reference to section 701(f)(2) of ERISA relates to that term, is consistent with the plain language of both section 701(f)(2) and Title II of GINA, furthers Congress’s intent to prohibit genetic discrimination in the employment context, and provides covered entities with clear standards governing compliance with the law.

through marriage, birth, adoption, or placement for adoption.⁶

Groups who represent employers thought that persons who become dependents by adoption or placement for adoption should not be considered family members, because genetic information about them would not indicate whether an individual protected by GINA might acquire a disease or disorder. See Comments of Illinois Chamber of Commerce (ICC) and Chamber/SHRM. However, GINA's express reference to section 701(f)(2) of ERISA and section 701(f)(2)'s explicit reference to dependents by adoption or placement for adoption makes it absolutely clear that Congress intended to include such persons in GINA's definition of "family member." Moreover, the acquisition of information about the occurrence of a disease or disorder in an applicant's or employee's adopted child could certainly result in the type of discrimination GINA was intended to prohibit. For example, an employer might use information it obtains about the current health status of an adopted child to discriminate against an employee because of concerns over potential health care costs, including increased health insurance rates, associated with the family member's medical condition. See S. Rep. No. 110–48 at 28 (indicating that spouses and adopted children were included in the definition of family member for this exact reason).

Second, GINA includes as family members persons related from the first to the fourth degree of an individual. The degree of relationship reflects the average proportion of genes in common between two individuals. The GINA provisions thus include the individual's children, siblings, and parents (first degree), grandparents, grandchildren, uncles, aunts, nephews, nieces, and half-siblings (second degree), great-grandparents, great grandchildren, great uncles, great aunts, and first cousins (third degree), and great-great grandparents and first cousins once removed (the children of a first cousin) (fourth degree). The inclusion of half-siblings among second-degree relatives responds to a comment we received to the proposed rule which said that we had incorrectly listed half-siblings

among first-degree relatives.⁷ See Comment of GPPC.

The Commission declines, however, to expand the degree of relationship of family members beyond the fourth degree as one comment suggested we should do. See Comment of Members of the Personal Genetics Education Project (PGE). Whether or not genetic information about an individual's relatives beyond the fourth degree of relationship has predictive value with respect to the individual, the language of the statute on which the regulation is patterned does not permit such an expansion of the definition of "family member." In fact, GINA's definition of "family member" is already broader than that term is understood in the practice of medicine. As discussed in the following section, a typical family medical history used for the purposes of diagnosis and treatment includes information about an individual's first-degree, second-degree, and third-degree relatives.

Section 1635.3(b) Family Medical History

The final regulation includes a definition of "family medical history" because it is a term used in the statute's discussion of prohibited employment practices, but it is not specifically defined by the statute. In the legislative history of GINA, Congress stated that the term "family medical history [should] be understood as it is used by medical professionals when treating or examining patients." S. Rep. No. 110–48, at 16. In particular, the Senate Report notes as follows:

[T]he American Medical Association (AMA) has developed an adult family history form as a tool to aid the physician and patient to rule out a condition that may have developed later in life, which may or may not have been inherited. This form requests information about the patient's brothers, sisters, and their children, biological mother, the mother's brothers, sisters, and their children, maternal grandfather, maternal grandmother, biological father, the father's brothers, sisters, and their children, paternal grandfather and paternal grandmother. The committee expects that the use of "family history" in this bill will evolve with the medical profession and the tools it develops in this area.

Id. The Report further notes that "a family medical history could be used as a surrogate for a genetic trait," *id.*, and that the definition of "genetic information" had to include "family

medical history" to prevent a covered entity from making decisions about an individual's health based on the existence of an inheritable disease of a family member. See also *id.* at 28 (reiterating the Title I discussion of family medical history in the Report section addressing Title II).⁸

Citing this legislative history, some employer groups urged that we include the word "inheritable" before the words "disease or disorder" in the regulation's definition of "family medical history," arguing that Congress did not intend that GINA apply to conditions such as the common cold or the flu. See Comments of Chamber/SHRM and ICC. For three reasons, the Commission has decided not to make this change in the final rule. First, the regulation's language is consistent with the plain language of the statute, which also does not include the word "inheritable." Second, given the rapidly-developing field of genetics, we believe that requiring Title II covered entities or EEOC investigators to determine whether a disease or disorder in family members of an individual is "inheritable" or has a genetic basis would present significant compliance and enforcement problems. Finally, the Commission doubts that questions about whether a family member has a cold, the flu, or similar conditions will often result in charges being filed under GINA.

One commenter also suggested that we clarify that medical information obtained from one employee will not be considered family medical history of a family member who also works for the employer. See Comment of Chamber/SHRM. This commenter is apparently concerned that an employer will be liable for a violation of GINA if it requests information about a manifested disease or disorder of an employee whose family member also works for the employer. The Commission recognizes the problem that this commenter is trying to avoid, but does not agree with the proposed solution. We disagree that the first employee's medical information is not family medical history as to the second employee. An employer who learns that one employee has a manifested disease or disorder would be in possession of family medical history about a second employee who is a

⁸ Since 2004 the U.S. Surgeon General's Family History Initiative has actively promoted the collection and use of family history information in clinical settings, including featuring a bilingual Web-based tool through which the user creates and organizes his/her family health history (<http://www.hhs.gov/familyhistory/>). GINA is not intended to limit the collection of family medical history by health care professionals for diagnostic or treatment purposes.

⁶ "Placement for adoption" or being placed for adoption means the assumption and retention of a legal obligation for total or partial support of a child by a person with whom the child has been placed in anticipation of the child's adoption. The child's placement for adoption with such person ends upon the termination of such legal obligation. See 29 CFR 2590.701–2 (the definitions for part 7 of ERISA)

⁷ This approach is different from the approach taken in regulations implementing Title I of GINA. See GINA Title I regulations at 26 CFR 54.9802–3T(a)(2)(ii), 29 CFR 2590.702–1(a)(2)(ii) and 45 CFR 146.122(a)(2)(ii), which were published in the **Federal Register** on October 7, 2009 at 74 FR 51664.

family member as defined by GINA. Likewise, an employer who learns the results of one employee's genetic test or learns that the employee has sought or received genetic services would possess genetic information about the employee who is a family member. (See discussion of the definition of "genetic information," below.) We do not think Congress could have intended that an employee not be protected from the discriminatory use or the disclosure of his or her genetic information just because the employer obtained it from a family member who was also an employee.

However, we do agree with the comment to the extent it seeks to limit liability under GINA for the acquisition of information about an employee's manifested condition. Although acquisition of information about manifested conditions is limited under other laws such as the ADA, it is permissible under GINA, even where an employee's family member works for the same employer. We have added a new subsection to § 1635.8 to clarify this point, and to make the related point that an employer will not violate GINA's provisions prohibiting the acquisition of an employee's genetic information when it requests genetic information or information about a manifested disease or disorder from an employee's family member to whom health or genetic services are being provided on a voluntary basis. (See discussion of § 1635.8(c), below.)

Section 1635.3(c) Genetic Information

GINA section 201(4) and the regulation define genetic information to include information from genetic tests, the genetic tests of family members, and family medical history. Genetic information also includes information about an individual's or family member's request for or receipt of genetic services. GINA section 209(b) and the regulation add that the term genetic information includes genetic information of a fetus carried by an individual or an individual's family member or an embryo lawfully held by an individual or family member receiving assistive reproductive services. See Comment of FDIC (noting that the preamble to the proposed rule cited to the wrong section of GINA when discussing the genetic information of a fetus or embryo). The statute and regulation exclude from coverage information about an individual's or family member's age or gender. In response to a comment, and mindful that many employers routinely request such information on a voluntary basis to comply with their EEO obligations, the

final rule also says that information about race and ethnicity that is not derived from a genetic test is not genetic information. See Comment of ACLU.

Section 1635.3(d) Genetic Monitoring

Genetic monitoring is defined in GINA section 201(5) as the "periodic examination of employees to evaluate acquired modifications to their genetic material * * * caused by the toxic substances they use or are exposed to in performing their jobs." The final regulation uses language similar to that found in the statute in defining the term. As more fully described in 1635.8(b)(5) and its accompanying preamble discussion, a covered entity may acquire genetic information as part of genetic monitoring that is either required by law or voluntarily undertaken, provided the entity complies strictly with certain conditions.

Section 1635.3(e) Genetic Services

The term "genetic services" is defined in GINA section 201(6). It includes genetic tests, genetic counseling, and genetic education. Making an employment decision based on knowledge that an individual has received genetic services violates GINA, even if the covered entity is unaware of the specific nature of the genetic services received or the specific information exchanged in the course of providing them.

A number of comments asked that the final rule offer additional examples of genetic services that emphasize the term's breadth, including genetic education before and after testing and preventive therapies that an individual might undergo in response to a genetic test to reduce or eliminate the risk of acquiring a condition in the future. See Comments of AMA, CGF, Genetic Alliance, and GPPC. We have not made any additions to the definition in the final regulation. The definition of genetic services provided in the proposed rule encompasses genetic education, whether it is offered before, after, or unrelated to genetic testing. Moreover, we have determined that the statutory definition of genetic services was not intended to encompass the types of clinical services mentioned by these commenters.

Section 1635.3(f) Genetic Test

GINA section 201(7) defines "genetic test" to mean the "analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes." Genetic tests are used to detect gene variants associated with a specific

disease or condition. For example, tests to determine whether an individual carries the genetic variant evidencing a predisposition to breast cancer—whether the individual has the BRCA1 or BRCA2 variant—or to determine whether an individual has a genetic variant associated with hereditary nonpolyposis colorectal cancer are genetic tests. It is important to note, however, that the presence of a genetic variant relating to a predisposition to disease is not evidence of, and does not equate to, disease. Similarly, a positive test for a genetic variant as strongly penetrant as Huntington's Disease does not equate to the presence of the disease, even though development of the disease is almost inevitable.

The Commission invited comments on the scope of the term "genetic test." In response, we received comments generally agreeing with how the Commission characterized certain kinds of tests in the preamble and text of the proposed rule. Several comments asked that we place examples from the preamble to the proposed rule in the text of the regulation itself, and we have done so. See Comments of the Equal Employment Advisory Council (EEAC), CGF, Genetic Alliance, GPPC and TOC. Thus, the regulation says that tests for infectious and communicable diseases that may be transmitted through food handling, complete blood counts, cholesterol tests, and liver-function tests are not genetic tests. To the proposed rule's examples of genetic tests, we have added a number of others suggested by several commenters, including carrier screenings of adults to determine the risk of conditions such as cystic fibrosis, sickle cell anemia, spinal muscular atrophy, and fragile X syndrome in future offspring; amniocentesis and other evaluations used to determine the presence of genetic abnormalities in a fetus; newborn screening tests for conditions such as PKU, which may allow preventive treatment to begin before the disease manifests; DNA testing that reveals family relationships (e.g., paternity tests); and DNA testing that determines the presence of genetic markers associated with ancestry. See Comments of CGF, Genetic Alliance, and GPPC.

Two commenters requested that the preamble and regulation refrain from listing specific tests that are excluded from the definition of genetic test. One argued that the science of genetics is constantly developing and that it is therefore shortsighted to specify tests that are not genetic in nature. See Comment of National Counsel of EEOC Locals no. 216, American Federation of Government Employees, AFL-CIO

(AFGE). Although we acknowledge this concern, excluding illustrative examples of what does not meet this definition would only serve to confuse those attempting to understand the bounds of the law.

Another comment argued that while the excluded tests are not genetic tests, it is still important that the results of tests that are not genetic tests be kept confidential and not be used as a basis for discrimination. *See* Comment of Disability Rights Legal Center (DRLC). Concerns about the discriminatory use of medical tests that are not genetic are addressed by the ADA, which limits the use of medical examinations and prohibits the use of medical and non-medical tests that screen out or tend to screen out an individual with a disability or a class of individuals with disabilities from employment, unless the test is shown to be job-related for the position in question and consistent with business necessity. *See* 29 CFR 1630.10. Section 1635.11(a) of the final rule and the accompanying preamble discussion make it clear that Title II of GINA does not limit other laws, including the ADA, that protect individuals on the basis of disability.

The Title II definition of “genetic test” differs from the definition of this term in Title I. Specifically, the Title II definition does not have the express exclusion that Title I does for “an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.” GINA 101(d), 29 U.S.C. 1191b–(d)(7)(B). However, as explained below, the Commission borrowed from Title I’s use of the term “manifest” in the definition of “genetic test” in formulating a definition of “manifested or manifestation.”

Section 1635.3(g) Manifestation or Manifested

The final rule includes a definition of the term “manifestation or manifested” because sections 201(4)(A)(iii) and 210 use the terms. Specifically, GINA section 201(4)(A)(iii), defining “genetic information,” refers to the “manifestation of a disease or disorder in family members” of an individual, and section 210, entitled “Medical information that is not genetic information,” refers to a “manifested disease, disorder, or pathological condition.”

The definition of “manifestation or manifested” was developed with the assistance of NHGRI. The proposed rule

defined “manifestation or manifested” to mean, with respect to a disease, disorder, or pathological condition:

that an individual has been or could reasonably be diagnosed with the disease, disorder, or pathological condition by a health care professional with appropriate training and expertise in the field of medicine involved. For purposes of this part, a disease, disorder, or pathological condition is not manifested if the diagnosis is based principally on genetic information or on the results of one or more genetic tests.

The final rule deletes the words “or on the results of one or more genetic tests,” which are unnecessary, given that the term “genetic information” already includes the results of genetic tests. The definition of the term “manifested” is consistent both with the definition of genetic test found in Title I, which permits use of certain diagnostic tests in order to determine whether an individual has a current—or manifest—disease, disorder, or condition. *see* S. Rep. No. 110–48, at 16, and with the notion, discussed above in conjunction with the definition of genetic test (§ 1635.3(f)), that the mere presence of a genetic variant does not mean that an individual has an associated condition, disease, or disorder. The presence of a genetic variant alone does not constitute a diagnosis; other signs or symptoms must be present. This interpretation is consistent with current ERISA regulations which prohibit a group health plan, and a health insurance issuer offering group health insurance coverage, from imposing a preexisting condition exclusion relating to a condition based solely on genetic information. Thus, for example, a woman who has group health plan coverage and has the BRCA1 gene variant may not be subject to a preexisting condition exclusion merely because she has the variant. *Id.* Example at 29 CFR 2590.701–3(b)(6)(ii). However, if an individual is diagnosed with a condition, even if the condition relates to genetic information—for example, breast cancer stemming from the BRCA1 gene variant—the plan may impose a preexisting condition exclusion with respect to the condition as of the date the disease was diagnosed, subject to other HIPAA portability requirements. *See* 29 CFR 2590.701–3(b)(6)(i).

Similarly, Huntington’s Disease (HD) is an example of a genetic disease that is not diagnosed solely through use of a genetic test; other signs and symptoms must be present. The presence of the genetic variant virtually guarantees the later development of disease, but the disease does not usually manifest until adulthood. Therefore, even when a

genetic variant is 100 percent predictive for development of disease, the presence of the variant does not by itself equal diagnosis of the disease.

Two comments asked the Commission to delete from § 1635.3(g) the concept that a disease, disorder, or pathological condition is not manifested if it is based “principally on genetic information or on the results of one or more genetic tests.” *See* Comments of America’s Health Insurance Plans (AHIP) and Chamber/SHRM; *see also* Comments of EEAC and SBA (raising similar concern). Although the Commission has deleted reference to “the results of one or more genetic tests” as explained above, the final rule still includes the basic concept that a condition is not manifest if it is based principally on genetic information. We agree, however, that a clarification is needed to address what we believe to be the central concern of these commenters, i.e., that the language at issue extends the protections of GINA to people with manifested conditions when genetic information played a role in diagnosing them. We therefore note that where diagnosis of a disease, disorder, or pathological conditions depends on both the presence of signs and symptoms and genetic information, the disease, disorder, or pathological condition will be considered manifested. The fact that an individual has the diagnosed disease, disorder, or pathological condition will not be considered genetic information about the individual; nor will information about the signs or symptoms the individual has. Such information, however, is still subject to other laws regulating the acquisition and use of medical information, including Title I of the ADA. *See* 42 U.S.C. 12112(d). Moreover, information about any genetic test or family medical history used as part of the diagnosis of the disease, disorder, or pathological condition is genetic information subject to Title II of GINA and this regulation.

Several commenters requested that the final regulation clarify that the genetic information of an individual with a manifested disease is still protected under GINA, citing the example of an individual with breast cancer who undergoes a genetic test and learns that she tests positive for a BRCA mutation, which increases one’s risk for developing ovarian cancer as well as breast cancer. *See* Comments of CGF, Genetic Alliance, and GPPC. These commenters requested that we make clear that discriminating against this individual due to the presence of the genetic variant is a violation of GINA despite the fact that she also has a

manifested disease caused by the variant. We note that § 1635.12(b) makes it clear that genetic information of an individual with a manifested disease is protected genetic information under GINA and that discriminating against someone based on this information is prohibited.

Section 1635.4 Prohibited Practices—In General

In describing the prohibited practices under GINA Title II, Congress adopted language similar to that used in Title VII and other equal employment statutes, evincing its intent to prohibit discrimination with respect to a wide range of covered entity practices, including hiring, promotion and demotion, seniority, discipline, termination, compensation, and the terms, conditions, and privileges of employment. In response to a comment, we further note that the broad language Congress adopted in describing the practices prohibited by Title II makes clear that claims of harassment on the basis of genetic information are cognizable. *See* Comment of Disability Rights Legal Center (DLRC). In separate GINA sections 203–205, the statute notes additional covered actions of employment agencies (failing or refusing to refer for employment), labor unions (excluding or expelling from membership), and training, retraining, and apprenticeship programs (denying admission to or employment in such programs).

Section 1635.5 Limiting, Segregating, and Classifying

The final regulation reiterates the statutory language barring actions by covered entities that may limit, segregate, or classify employees because of genetic information. For example, an employer could not reassign someone whom it learned had a family medical history of heart disease from a job it believed would be too stressful and might eventually lead to heart-related problems for the employee. This section also makes clear that although the language of the statute specifically prohibits actions that have the “purpose or effect” of limiting, segregating, or classifying individuals on the basis of genetic information, neither the statute nor the final regulation creates a cause of action for disparate impact. Section 208 of GINA specifically prohibits such actions, and establishes the Genetic Nondiscrimination Study Commission, to examine “the developing science of genetics” and recommend to Congress “whether to provide a disparate impact cause of action under this Act.” The final regulation does not address the

establishment of this Commission, which is scheduled to begin its work on May 21, 2014.

In response to a comment, we clarify that a covered entity will not be deemed to have violated § 1635.5 if it limits or restricts an employee’s job duties based on genetic information because it was required to do so by a law or regulation mandating genetic monitoring such as regulations administered by the Occupational and Safety Health Administration (OSHA). *See* Comment of EEAC (requesting clarification of this point); *see also* 1635.8(b)(5) (concerning voluntary genetic monitoring and monitoring pursuant to state or federal law) and 1635.11(a) below (GINA does not limit the statutory or regulatory authority of OSHA, the Mine Safety and Health Administration or other workplace health and safety laws and regulations.)

Section 1635.6 Causing a Covered Entity To Discriminate

GINA sections 203(a)(3), 204(a)(3), and 205(a)(3) expressly bar employment agencies, labor organizations, and apprenticeship or other training programs from causing an employer to discriminate on the basis of genetic information. These sections recognize that employers engage in most of the employment-related activities that the Act reaches. Other covered entities, however, might engage in conduct that could cause an employer to discriminate. For example, an employment agency or union might share or attempt to share genetic information it obtained (whether legally or not) about a client or member with an employer. Such conduct would violate sections 203(a)(3) and 204(a)(3), regardless of the intent of the employment agency or union in sharing the information. *See* Comment of DLRC (requesting clarification on this point).

Although section 202 does not include a similar provision explicitly prohibiting an employer from causing another covered entity to discriminate, it is well settled under Title VII that the definition of employer includes employers’ agents under common law agency principles. *See Vinson v. Meritor Savings Bank*, 477 U.S. 57, 72 (1986). Because GINA incorporates Title VII’s definition of employer, including the application of common law agency principles, GINA would bar an employer from engaging in actions that would cause another covered entity acting as its agent to discriminate. For example, an employer that directed an employment agency to ask applicants for genetic information or told the employment agency not to send it

candidates with a family medical history for certain conditions would violate GINA. An employment agency that acted pursuant to the employer’s direction would be liable for violating GINA either directly, because the law applies to employment agencies, or as an agent of the employer. Similarly, an employer would violate GINA if it used a labor organization’s hiring hall to obtain genetic information in making job referrals, and the labor union would be liable under GINA either directly or as the employer’s agent. The final rule modifies the language of § 1635.6 of the proposed rule slightly so that it leaves no doubt that no GINA covered entity may cause another covered entity to discriminate on the basis of genetic information.

Section 1635.7 Retaliation

The final regulation reiterates the statutory prohibition against retaliation where an individual opposes any act made unlawful by GINA, files a charge of discrimination or assists another in doing so, or gives testimony in connection with a charge. Because Congress adopted in GINA the language of the anti-retaliation provision in Title VII of the Civil Rights Act of 1964, the Commission believes that Congress intended the standard for determining what constitutes retaliatory conduct under GINA to be the same as the standard under Title VII, as announced by the Supreme Court in *Burlington Northern & Santa Fe Ry. v. White*, 548 U.S. 53 (2006). In that case, the Court held that Title VII’s anti-retaliation provision protects an individual from conduct, whether related to employment or not, that a reasonable person would have found “materially adverse,” meaning that the action “well might have ‘dissuaded a reasonable worker from making or supporting a charge of discrimination.’” *Id.* at 57–58 (citations omitted).

Section 1635.8 Acquisition of Genetic Information

Each of the discrete GINA sections addressing the conduct of employers, employment agencies, labor organizations, and apprenticeship or other training programs includes a section prohibiting covered entities from requesting genetic information from applicants, employees, or other individuals; from requiring that applicants or employees provide genetic information; or from purchasing genetic information about an applicant or employee. Each section also includes the same five exceptions. Sections 202, covering employers, and 205, covering joint labor-management training and

apprenticeship programs, include a sixth exception. The proposed regulation addressed each of the exceptions, as does the final regulation. Covered entities are cautioned, however, that the use of genetic information to discriminate, no matter how that information may have been acquired, is prohibited.

Concerning the general prohibition on acquiring genetic information, two commenters noted that the regulatory language of 1635.8(a) did not track the statutory language in that it failed to indicate that the prohibition applies to the genetic information of family members of individuals, as well as to that of the individuals themselves. *See* Comment of the American Psychological Association (APA) and FDIC. Although we believe the substance of the regulatory language is correct, in that the genetic information of an individual includes the genetic information of that individual's family members, we agree that it would be best to follow the statutory language of this prohibition and have altered 1635.8(a) accordingly.

Another comment argued that a covered entity violates GINA's provisions prohibiting the acquisition of genetic information only when it undertakes the purposeful act of requesting, requiring, or purchasing genetic information. *See* Comment of Chamber/SHRM. It was improper, this comment reasoned, for the Commission to have included examples of "passive acquisition" in 1635.8(b)(1) (governing inadvertent acquisition of genetic information) and 1635.8(b)(4) (concerning acquisition of genetic information through sources that are commercially and publicly available).

However, other commenters read the prohibition on acquisition more broadly, noting their view that GINA restricts "deliberate acts that result in the acquisition of genetic information," not just purposefully requesting, requiring, or purchasing genetic information. *See* Comments of ACLU, CGF, Genetic Alliance, and GPPC. A similar construction of the acquisition prohibition underlay suggestions for changes to the portion of the rule concerning inadvertent acquisition of genetic information. Several commenters said that covered entities that make inquiries or engage in actions reasonably likely to result in the acquisition of genetic information should not be able to avail themselves of the exceptions in 1635.8(b)(1) or 1635.8(b)(4). Thus, for example, as discussed below, commenters asked that the Commission require that covered entities requesting information about an

individual's current health status (e.g., for the purpose of making a reasonable accommodation) affirmatively warn the person providing the information not to include genetic information, since acquisition of genetic information in the form of family medical history would be likely in the absence of a warning. *See* Comments of ACLU, the American Medical Association (AMA), CGF, Genetic Alliance, GPPC, and the Leadership Conference on Civil Rights (LCCR). Similarly, most of these commenters said that the exception for acquisition of genetic information from sources that are commercially and publicly available should not apply to sources that are likely to, or present a "heightened risk" of, containing genetic information, and one commenter specifically asked that the final rule prohibit Internet searches that include an individual's name and a particular genetic marker. *See* Comments of LCCR.

The Commission acknowledges all these concerns and, for purposes of GINA Title II, has added language to 1635.8(a) as follows: "Request" includes conducting an Internet search on an individual in a way that is likely to result in a covered entity obtaining genetic information; actively listening to third-party conversations or searching an individual's personal effects for the purpose of obtaining genetic information; and making requests for information about an individual's current health status in a way that is likely to result in a covered entity obtaining genetic information."

We think it is equally clear that Congress intended certain "passive acquisitions" of genetic information to be exceptions to the rule prohibiting acquisition, rather than being wholly outside the prohibition. The examples, particularly those in § 1635.8(b)(1) and (4), are similar to the so-called "water cooler" example that Congress thought should be an exception to the general prohibition against requesting, requiring, or purchasing genetic information. *See* S. Rep. No. 110-48, at 29 ("[t]he committee recognizes that conversations among coworkers about the health of a family member are common and intends to prevent such normal interaction from becoming the basis of litigation"). We therefore retain the examples offered in the preamble to the proposed rule, as we believe that they provide useful guidance. *See* Comment of TOC (encouraging EEOC to retain examples).

We now turn to a discussion of the specific exceptions described in 1635.8(b). We received a number of comments concerning these exceptions,

particularly in response to 1635.8(b)(1), (2) and (4).

Inadvertently Requesting or Requiring Genetic Information: First, as noted in the proposed rule, a covered entity that "inadvertently requests or requires family medical history" from an individual does not violate GINA. Congress intended this exception to address what it called the "water cooler problem" in which an employer unwittingly receives otherwise prohibited genetic information in the form of family medical history through casual conversations with an employee" or by overhearing conversations among co-workers. S. Rep. No. 110-48, at 29; *see also* H.R. Comm. on Education and Labor, Genetic Information Nondiscrimination Act of 2007, H.R. Rep. No. 110-28 part I, 37-38 (2008) (H.R. Rep. No. 110-28, part I). Congress did not want casual conversation among co-workers regarding health to trigger federal litigation whenever someone mentioned something that might constitute protected family medical history. The Commission's proposed regulation therefore noted that a covered entity inadvertently acquires family medical history where a manager or supervisor overhears a conversation among co-workers that includes information about family medical history (e.g., a conversation in which one employee tells another that her father has Alzheimer's disease).

Although the language of this exception in GINA specifically refers to family medical history, the Commission believes that it is consistent with Congress's intent to extend the exception to any genetic information that an employer inadvertently acquires. The Commission does not believe, for example, that Congress intended that an employer would be liable for the acquisition of genetic information because it overhears a conversation in which one employee tells another that her mother had a genetic test to determine whether she was at increased risk of getting breast cancer. If the exception were read to cover only family medical history, this would violate GINA, even though it occurred inadvertently, because information that a family member has had a genetic test, while genetic information, is not information about the occurrence of a disease or disorder in a family member. Although we received numerous comments in regard to 1635.8(b)(1), no commenter expressed disagreement with the decision to extend the exception to all genetic information that a covered entity inadvertently acquires. *See, e.g.,* Comment of GPPC (discussing the need for a restrictive view of this

exception, but expressing agreement that it was intended to extend to all genetic information and not just family medical history).

The Commission also understands this exception to apply in any situation in which an employer might inadvertently acquire genetic information, not just to situations involving conversations between co-workers that are overheard. The proposed regulation provided an illustrative list of examples, reiterated here, where we believe Congress intended the exception to apply. Thus, for example, the exception applies when the covered entity, acting through a supervisor or other official, receives family medical history directly from an individual following a general inquiry about the individual's health (e.g., "How are you?" or "Did they catch it early?" asked of an employee who was just diagnosed with cancer) or a question as to whether the individual has a manifested condition.⁹ Similarly, a casual question between colleagues, or between a supervisor and subordinate, concerning the general well-being of a family member would not violate GINA (e.g., "How's your son feeling today?", "Did they catch it early?" asked of an employee whose family member was just diagnosed with cancer, or "Will your daughter be OK?"), nor would the receipt of genetic information that was not solicited or sought by the employer (e.g., where a manager or supervisor receives an unsolicited email from a co-worker about the health of an employee's family member).

A number of commenters raised concerns about the exact parameters of this exception. Civil rights groups and organizations promoting genetic research asked that the EEOC clarify that pointed questions or other attempts to gather genetic information by, for example, intentionally eavesdropping on private conversations or asking highly specific follow-up questions when an employee mentions that a family member is ill, do not fall within the bounds of this exception. See Comments of ACLU, CGF, the Genetic Alliance, GPPC, and LCCR. The Illinois Chamber of Commerce (ICC) requested that the regulation specifically state that there is no violation of the prohibition against acquisition unless the employer purposefully acquires genetic information and both ICC and Chamber/SHRM requested that it be made clear that the examples provided are not

exhaustive. See Comments of ICC and Chamber/SHRM. The FDIC made a similar point when it requested that the rule state that this exception applies to questions by an employer "not likely to elicit genetic information" but does not apply to questions "likely to elicit genetic information." See Comment of FDIC.

These comments make apparent the need for greater clarity concerning this exception. We include in the final regulation itself the examples from the preamble to the proposed rule that illustrate how this exception applies and provide an additional example both here and in the final regulation at 1635.8(b)(1)(ii)(B). The additional example is as follows: A covered entity that inadvertently acquires genetic information about someone's family member in response to a general question about the family member's health may not then ask follow-up questions that are probing in nature, such as whether other family members also have the condition, or whether the individual has been tested for the condition.

We also include an additional example here and in the final regulation at 1635.8(b)(1)(ii)(D) to clarify that the inadvertent acquisition exception applies not only to interactions within the workplace during which a covered entity unwittingly receives genetic information, but also to interactions that take place in the "virtual" world, *i.e.*, through a social media platform from which a covered entity unwittingly receives genetic information. In other words, this exception applies where a manager, supervisor, union representative, or employment agency representative inadvertently learns genetic information from a social media platform which he or she was given permission to access by the creator of the profile at issue (e.g., where a supervisor and employee are connected on a social networking site and the employee provides family medical history on his page).

We further note that the examples provided in this preamble and the regulation are non-exhaustive and that other situations in which a covered entity inadvertently acquires genetic information are covered by this exception as long as the requirements provided in the regulation are met.

We received a significant number of comments expressing concern about GINA's application to a covered entity's request for medical information that results in the receipt of genetic information that was not requested. Civil rights groups, groups promoting genetic research, and others argued that

covered entities will obtain a great deal of genetic information through general requests for medical information if they are not required to affirmatively indicate that genetic information should not be provided. See Comments of the ACLU, AMA, CGF, Genetic Alliance, GPPC, and LCCR. See also Comments of Burton Blatt Institute (noting that the exception's application to acquisition through legitimate medical information requests should be limited because doctors will not know to exclude genetic information) and World Privacy Forum (requesting further limitations on this exception). Employer groups raised the related point that human resource offices do not have control over what is received from health care providers in response to requests for medical information and that covered entities should not be subjected to liability if health care providers provide genetic information that was not requested. See Comments of Chamber/SHRM, EEAC and the International Public Management Association for Human Resources, the League of Minnesota Cities and the International Municipal Lawyers Association (IPMA/IMLA).

In response to these comments and to facilitate compliance with the law, we have added language to the final rule indicating that when a covered entity warns anyone from whom it requests health-related information not to provide genetic information, the covered entity may take advantage of the exception in 1635.8(b)(1) if it nevertheless receives genetic information. This "safe harbor" in 1635.8(b)(1)(i)(B) provides that any receipt of genetic information in response to a lawful request for medical information will be deemed inadvertent and not in violation of GINA if the request contained such a warning.

The final rule includes the following language that a covered entity may use to provide such notice: "The Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits employers and other entities covered by GINA Title II from requesting or requiring genetic information of employees or their family members. In order to comply with this law, we are asking that you not provide any genetic information when responding to this request for medical information. 'Genetic information,' as defined by GINA, includes an individual's family medical history, the results of an individual's or family member's genetic tests, the fact that an individual or an individual's family member sought or received genetic services, and genetic information of a fetus carried by an individual or an individual's family member or an

⁹ When asking questions likely to elicit information about a disability, covered entities must, of course, also abide by the requirements of the ADA.

embryo lawfully held by an individual or family member receiving assistive reproductive services.” Alternative language may also be used, as long as individuals and health care providers are informed that genetic information should not be provided.

Although one commenter expressed concern that giving notice would impose an unnecessary burden on small businesses, we note that the warning may be conveyed verbally if the request for medical information itself is also verbal. See Comment of the National Federation of Independent Business (NFIB). We are aware that many businesses, especially small businesses, do not use forms when requesting medical information, and we do not intend this regulation to change the practice of making such requests verbally.

If a covered entity does not give such a written or verbal notice, it may nonetheless establish that a particular receipt of genetic information in response to a request for medical information was an inadvertent acquisition because the covered entity’s request was not made in a way that was “likely to result in the covered entity’s obtaining genetic information” (for example where an overly broad response is received in response to a tailored request for medical information). We note, however, that a warning is mandatory in all cases where a covered entity requests a health care professional to conduct an employment-related medical examination on the covered entity’s behalf, since in that situation, the covered entity should know that the acquisition of genetic information (e.g., family medical history) would be likely in the absence of the warning. (See discussion of 1635.8(d), below.)

The proposed regulation noted that when a covered entity seeks information from an individual who requests a reasonable accommodation under the ADA or state or local law, the acquisition of genetic information as part of the documentation that the individual provides in support of the request is considered inadvertent, as long as the request for documentation was lawful. We received numerous comments asking us to describe in the regulation itself what it means for a request for documentation supporting a request for reasonable accommodation to be considered lawful. See Comments of APA, Disability Rights Legal Center (DRLC), the Epilepsy Foundation, and ICC. In response, we explain in the final rule that in order to be considered a lawful request for documentation made in response to an individual seeking a

reasonable accommodation under the ADA or state or local law, the request for medical documentation can be made only when the disability and/or the need for accommodation is not obvious. In this situation, the employer may ask the individual for reasonable documentation about his/her disability and/or need for accommodation. Reasonable documentation means that the employer may require only the documentation that is needed to establish that a person has a disability within the meaning of the ADA and that the disability necessitates a reasonable accommodation. For example, an employer cannot request a person’s complete medical records because they are likely to contain information unrelated to the disability at issue and the need for accommodation. If an individual has more than one disability, an employer can request information pertaining only to the disability that requires a reasonable accommodation. See EEOC’s *Enforcement Guidance on Reasonable Accommodation and Undue Hardship Under the Americans With Disabilities Act*, EEOC Notice No. 915.002 (Oct. 17, 2002), available at <http://www.eeoc.gov/policy/docs/accommodation.html>. Like any request for medical documentation, the request for documentation as part of the reasonable accommodation process should generally inform the individual or entity from whom the documentation is sought, using language like that noted above, that genetic information should not be provided.

We note that GINA’s prohibition on requesting, requiring, or purchasing genetic information would control during the interactive process used to determine an appropriate reasonable accommodation. The Commission knows of no reason why a covered entity would need to request genetic information to determine an individual’s current physical or mental limitations and whether those limitations can be accommodated.

The Commission further recognizes that other federal, state, or local laws may allow covered entities to obtain medical information about employees. A covered entity that inadvertently receives genetic information in response to a lawful request for medical information under such a law would not violate GINA. For example, a covered entity might receive genetic information in connection with an employee’s request for FMLA leave to attend to the employee’s own serious health condition or in connection with the FMLA’s employee return to work certification requirements, even though an employee is not required to provide

genetic information in either of these situations.¹⁰ Acquisition of genetic information in these circumstances will be considered inadvertent if the covered entity affirmatively warns individuals and health care providers from whom they are seeking medical documentation not to provide genetic information, or, in the absence of such a warning, where the request for medical information was not likely to result in the acquisition of genetic information.¹¹ In response to two comments concerning the need for additional clarity with regard to how the exceptions to the prohibition against acquiring genetic information apply to information received pursuant to the FMLA, we have added the above examples to 1635.8(b)(1)(ii)(D)(2) (which was 1635.8(b)(1)(iv) in the proposed rule), as well as additional detail to the preamble’s discussion of the FMLA exception (1635.8(b)(3)), discussed below. See Comments of APA and Anil Chaudhry.

The Commission believes that the first exception to the general prohibition of requesting, requiring, or purchasing genetic information should also apply when an individual requests leave pursuant to a leave policy independent of a federal, state, or local leave or disability law. Acquisition of genetic information in these circumstances, like the acquisition of genetic information where leave is requested pursuant to the FMLA or a state or local leave law, will be considered inadvertent if the covered entity affirmatively warns individuals and health care providers from whom they are seeking medical documentation not to provide genetic information, using language like that noted above, or, in the absence of such a warning, where the request for medical information was not made in a way that was likely to result in the covered entity’s obtaining genetic information. Covered entities should also be aware that overbroad requests for documentation to support

¹⁰ There is a separate exception for the acquisition of family medical history received from individuals requesting leave under the FMLA or similar state or local laws to care for a family member. This exception is discussed in detail below.

¹¹ One commenter expressed concern that adding any language to the FMLA certification form would result in a statutory violation of the FMLA. See Comment of Illinois Credit Union League. The EEOC does not enforce the Family and Medical Leave Act and therefore has no authority to interpret it. We know of no reason, however, that informing a health care provider that genetic information should not be provided when certifying an employee’s own serious health condition would lead to a violation of the FMLA. Moreover, the notice informing applicants/employees and health care providers that they must not provide genetic information, including family medical history, to covered entities need not be made on the FMLA certification form itself, as long as it is provided in writing along with the form.

an employee's use of leave may violate the ADA. For information on the appropriate scope of inquiries in response to requests for leave (other than as a reasonable accommodation), see EEOC's *Enforcement Guidance on Disability-Related Inquiries and Medical Examinations of Employees Under the Americans With Disabilities Act*, 8 Fair Empl. Prac. Man. (BNA) 405:7701, (Enforcement Guidance) Questions 15–17 (July 27, 2000) available at <http://www.eeoc.gov/policy/docs/guidance-inquiries.html>.

One commenter raised a concern about proposed 1635.8(b)(1)(vi), which extended the inadvertent acquisition exception to a covered entity that learns genetic information about an individual in response to an inquiry about the individual's general health, an inquiry about whether the individual has any current disease, disorder, or pathological condition, or an inquiry about the general health of an individual's family member. See Comment of APA. APA asked that this exception be limited to requests "permitted by Federal, State or local law." Rather than add any limiting language, we have decided to eliminate this subsection altogether, as it merely reiterates the examples spelled out in 1635.8(b)(1)(ii)(B) (formerly 1635.8(b)(1)(ii) in the proposed rule).

Finally, one commenter asked that the inadvertent acquisition exception be extended to acquisition of genetic information by a self-insured employer making health insurance billing determinations in its capacity as an insurer. See Comment of Navigenics. It is not necessary to extend the exception to cover these circumstances because, when a self-insured employer is acting in its capacity as an insurer, its actions are regulated by Title I of GINA, not Title II. Title I of GINA has specific rules about acquiring genetic information for insurance payment purposes. See 42 U.S.C. 1182(c)(3); 42 U.S.C. 300gg–1(c)(3); 26 U.S.C. 9802(c)(3).

Health or Genetic Services: GINA permits covered entities to acquire genetic information where health or genetic services are offered by the employer, including such services offered as part of a wellness program, if the covered entity meets specific requirements. The proposed regulation listed the specific requirements in the statute as prerequisites to the acquisition of genetic information when offering health or genetic services: the individual provides prior knowing, voluntary, and written authorization, meaning that the covered entity uses an authorization form that is written in

language reasonably likely to be understood by the individual from whom the information is sought; describes the information being requested; and describes the safeguards in place to protect against unlawful disclosure. Additionally, the proposed rule said that a wellness program or other health or genetic services that a covered entity offers must be voluntary. The preamble to the proposed rule noted that, under the ADA, a wellness program that requires employees to answer disability-related inquiries and/or to submit to a medical examination is voluntary if the program neither requires participation, nor penalizes employees for non-participation.

We received two comments asking whether the written request and authorization to participate in a wellness program could be provided electronically. See Comments of AHIP and Kelly Hart & Hallman (KHH). We think this is permissible and have revised the final rule accordingly. We do not think it is necessary to provide in the final rule specific standards for an electronic consent and authorization. The particular format chosen, however, must be functionally equivalent to what would be required in a written authorization, in terms of content and form. For example, because written authorization is a prerequisite to the acquisition of genetic information as part of health or genetic services offered by a covered entity, such as a voluntary wellness program, a covered entity could not utilize an on-line form that first requires an individual to input family medical history and then asks the individual to indicate his or her acceptance of the terms of an authorization. Instead, a potential participant in the health or genetic services being offered must first be presented with an electronic authorization that describes the request in terms reasonably likely to be understood by the individual, the purposes for which it will be used, and the safeguards in place for assuring its confidentiality, before any genetic information (such as family medical history) can be provided.

The proposed regulation stated that individually identifiable information may be provided only to the individual from whom it was obtained and that covered entities are entitled only to receive information in aggregate terms that do not disclose the identity of specific individuals. Some comments objected to a statement in the preamble to the proposed rule that a covered entity that receives "aggregate" information may still violate GINA where the small number of participants,

alone or in conjunction with other factors, makes an individual's genetic information readily identifiable, noting that this would impose burdens particularly on small businesses. See Comments Chamber/SHRM and IPMA/IMLA.

In the final rule, we have retained the language in the NPRM, which tracked the statutory language. GINA says that a covered entity may only receive genetic information related to a wellness program "in aggregate terms that do not disclose the identity of specific [individuals]," see 42 U.S.C. 2000ff–1(b)(2)(D); 2000ff–2(b)(2)(D); 2000ff–3(b)(2)(D); and 2000ff–4(b)(2)(D). However, we have reconsidered the position taken in the preamble to the NPRM that a covered entity offering health or genetic services will not comply with 1635.8(b)(2) if aggregate information disclosed to the covered entity makes the genetic information of individuals readily identifiable. A provider of health or genetic services will likely be unaware of facts known to a covered entity that would make identification of specific individuals readily identifiable from aggregate information. Likewise, a covered entity may not know that the identity of specific individuals from aggregate information will be readily identifiable until after it receives the information. We do not believe that Congress intended to impose liability on covered entities who receive aggregate information about health or genetic services under such circumstances. Therefore, the Commission here clarifies that GINA is not violated if the provider of health or genetic services gives information to a covered entity in aggregate terms 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. On the other hand, efforts undertaken by a covered entity to link genetic information provided in the aggregate to a particular employee will violate GINA.

We received numerous comments in response to a question we asked in the preamble to the proposed rule concerning when a wellness program that includes a request for genetic information should be considered voluntary. Specifically, we wanted to know the level of inducement, if any, that a covered entity could offer to promote participation in a wellness program. See 74 FR 9056, 9062 (March 2, 2009). From the many comments we received emphasizing the potential cost savings and benefits for employee

health that could be brought about through wellness programs, four approaches to voluntariness emerged. One approach suggested that we use regulations promulgated pursuant to HIPAA, which define maximum levels of inducements employers may offer to employees who participate in, or achieve certain health outcomes as a result of participating in, wellness programs. See Comments of American Benefits Council (ABC), Chamber/SHRM, DMAA: The Care Continuum Alliance (DMAA), Dorsey and Whitney, LLP, Healthways, National Business Group on Health (NBGH), and United Healthcare. Under the HIPAA regulations, employers may offer financial inducements of any size to encourage participation in wellness programs, and may offer inducements of up to a specified percentage of the cost of group health insurance coverage for an individual or an individual and family to participants who achieve specific health outcomes. See 26 CFR 54.9802-1(f)(1), 29 CFR 2590.702(f)(1), and 45 CFR 146.121(f)(1) (explaining that a wellness program does not violate HIPAA's nondiscrimination requirements if none of the conditions for obtaining a reward are based on an individual satisfying a certain health standard, as long as participation in the program is offered to all similarly situated individuals). See also 26 CFR 54.9802-1(f)(2), 29 CFR 2590.702(f)(2), and 45 CFR 146.121(f)(2) (providing limits on financial inducements when rewards are conditioned on achieving certain health outcomes).¹²

Other comments appeared to suggest a combination of the approach taken in the HIPAA regulations and the rule under the ADA as articulated by EEOC in its *Enforcement Guidance on Disability-Related Inquiries and Medical Examinations of Employees Under the Americans with Disabilities Act* (July 27, 2000) (“*Enforcement Guidance*”). As we understand this suggestion, the standard for determining whether a wellness program is voluntary under the ADA—that a covered entity neither requires participation nor penalizes individuals for non-participation—should apply to GINA as well. See *Enforcement Guidance* at Question 22. Any inducement that complied with the HIPAA “twenty percent rule” should be deemed neither a penalty for non-participation nor a requirement to participate. Inducements greater than

those allowed under the “twenty percent rule” would violate the standard for voluntariness under the ADA and GINA. See Comments of AHIP, IPMA/IMLA, KHH, NFIB, and Staywell Health Management.

A third approach merely asked that we allow employers to offer inducements to promote employee participation in wellness programs, but did not indicate whether inducements should be limited in any way. See Comments of EEAC and Navigenics. Finally, several comments urged that covered entities not be allowed to offer any monetary inducements to promote participation in wellness programs that include the collection of genetic information, including family medical history. See Comments of ACLU, AMA, GPPC and World Privacy Forum.

Balancing the potential benefits of health and genetic services offered to employees on a voluntary basis, including wellness programs, with the need to construe exceptions to the prohibition of acquisition of genetic information in a manner appropriately tailored to their specific purposes, we have concluded that covered entities may offer certain kinds of financial inducements to encourage participation in health or genetic services under certain circumstances, but they may not offer an inducement for individuals to provide genetic information. As a result, the Commission concludes that it would not violate Title II of GINA for a covered entity to offer individuals an inducement for completing a health risk assessment that includes questions about family medical history or other genetic information, as long as the covered entity specifically identifies those questions and makes clear, in language reasonably likely to be understood by those completing the health risk assessment, that the individual need not answer the questions that request genetic information in order to receive the inducement. The regulation provides two examples to illustrate this approach to health risk assessments.

We also believe that Title II allows covered entities to offer financial inducements for participation in disease management programs or other programs that encourage healthy lifestyles, such as programs that provide coaching to employees attempting to meet particular health goals (e.g., achieving a certain weight, cholesterol level, or blood pressure).¹³ To avoid a

violation of Title II of GINA, however, covered entities who offer such programs and inducements to individuals based on their voluntarily provided genetic information must also offer the programs and inducements to individuals with current health conditions and/or to individuals whose lifestyle choices put them at risk of acquiring a condition.

Recognizing that employers that sponsor group health plans (including self-insured group health plans) are required to comply with Title II of GINA when operating as employers, and that their plans are required to comply with Title I of GINA, the Commission wishes to provide examples of how Titles I and II allow employers and plans to use financial incentives to promote employee wellness and healthy lifestyles.¹⁴ The Commission notes that providing financial incentives in compliance with these GINA Title II regulations does not relieve covered entities of their responsibility to comply with other GINA requirements under Title I, with other civil rights laws, such as the ADA, and with other applicable laws and regulations. See 1635.8(b)(2)(iv) (indicating that the ADA requires “reasonable accommodations” to enable individuals with disabilities to participate fully in wellness programs, and that the HIPAA nondiscrimination rules require plans and issuers to provide an individual with a “reasonable alternative” (or waiver of the otherwise applicable standard), when it is unreasonably difficult due to a medical condition to satisfy or medically inadvisable to attempt to satisfy the otherwise applicable standard, 26 CFR 54.9802-1(f)(2), 29 CFR 2590.702(f)(2), and 45 CFR 146.121(f)(2) and 1635.8(b)(2)(v) (noting that wellness programs that constitute group health plans may have to comply with Title I of GINA, among

9802 of the Internal Revenue Code of 1986, 26 U.S.C. 9802, section 702 of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1182, or section 2705 of the Public Health Service Act (i.e., Title I of GINA). Regulations issued under these statutes impose special requirements on 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).

¹⁴ Whether an employer or other covered entity that sponsors a group health plan chooses to provide benefits through self-insurance or through a policy, certificate, or contract of insurance does not affect the applicability of GINA Titles I and II. See 29 CFR 1635.11(b)(2) (discussing the relationship of GINA Titles I and II). The above examples of actions permissible under both titles are therefore helpful to all employers who offer health coverage to employees, whether through self-insured or insured plans.

¹² The 20 percent threshold described in the HIPAA nondiscrimination rules will increase to 30 percent beginning in 2014 under statutory changes made under the Patient Protection and Affordable Care Act, Public Law 111-148.

¹³ A wellness program that provides (directly, through reimbursement, or otherwise) medical care (including genetic counseling) may constitute a group health plan required to comply with section

other laws). While the GINA Title II regulations and the interim rules issued on October 7, 2009 to implement Title I (29 CFR 2590.702–1; 45 CFR 146.122, 26 CFR 54.9802–3T) each prohibit the use of financial inducements to collect genetic information, they both permit covered entities or group health plans (including self-insured plans) to:

- Provide bifurcated health risk assessments (HRAs), under which financial incentives permitted under the applicable title may be used to encourage individuals to complete the HRA, if the section of the questionnaire seeking genetic information (e.g. family medical history) includes a notice that completing that portion is optional and that the reward will be provided whether that portion is completed or not;

- Use information collected through such bifurcated HRAs, including voluntarily provided genetic information indicating that an individual may be at risk for a disease, to target advertising materials or otherwise solicit voluntary participation in a disease management or prevention program, provided that such a program is also available to individuals who do not provide genetic information as part of the HRA (that is, the program is not limited only to individuals who complete the portion of the HRA that requests genetic information);

- Provide financial incentives permitted under the appropriate title to individuals to participate in certain disease management or prevention programs. The incentives to participate in such programs must also be available to individuals who qualify for the program but have not volunteered genetic information through an HRA.

Under the Title II regulation, covered entities may contract with a third party to operate a wellness program or to provide other health or genetic services, or may provide such programs and services through an in-house health services office, as long as individually identifiable genetic information is accessible only to the individual and the health care provider involved in providing such services. Covered entities must ensure that individually identifiable genetic information is not accessible to managers, supervisors, or others who make employment decisions, or to anyone else in the workplace.

Family and Medical Leave Act: Third, GINA recognizes that individuals requesting leave to care for a seriously ill family member under the Family and Medical Leave Act (FMLA) or similar state or local law will be required to provide family medical history (for

example, when completing the certification form required by section 103 of the FMLA). A covered entity that receives family medical history under these circumstances would not violate GINA. This exception is needed because, unlike the situations discussed under the inadvertent acquisition exception, the receipt of genetic information in these circumstances is not inadvertent. By asking the employee to provide the information required by the FMLA certification form or similar state or local laws when seeking leave to care for a seriously ill family member, a covered entity is requesting family medical history from the employee.

One commenter expressed concern that businesses that are not covered by the FMLA or similar state or local laws, but who have company policies allowing the use of leave to care for seriously ill family members, would not be covered by this exception. *See* Comment of the Small Business Administration (SBA). We agree that it was unclear in the proposed rule whether acquisition of genetic information in such circumstances would be covered by the exception and therefore provide this clarification: This exception applies to an employer that is not covered by the FMLA or similar state or local laws but that has a policy allowing for the use of leave to care for ill family members, as long as that policy is applied evenhandedly by requiring all employees seeking leave to provide documentation about the health condition of the relevant family member.¹⁵

Of course, family medical history received from individuals requesting leave pursuant to the FMLA, similar state or local laws, or company policies, is still subject to GINA's confidentiality requirements and must be placed in a separate medical file and treated as a confidential medical record, as more fully described below.

Commercially and Publicly Available Information: Fourth, GINA provides an exception for the purchase of commercially and publicly available materials that may include family medical history. As with the exception applicable to the inadvertent acquisition of family medical history, the

¹⁵ Although we also received a comment requesting that the exception be limited to the acquisition of genetic information directly relevant to the leave request—e.g., if the request is to care for the employee's daughter, only information received about the daughter's condition would be covered by the exception—we find that such a requirement is beyond the scope of our enforcement authority as it would be an attempt to limit the actions of the employee's health care provider who completes the certification form. *See* Comment of World Privacy Foundation.

Commission reads this exception as applying to all genetic information, not just to family medical history. For example, an employer would not violate GINA if it learned that an employee had the breast cancer gene by reading a newspaper article profiling several women living with the knowledge that they have the gene.

The statute identifies newspapers, magazines, periodicals, and books as potential sources of genetic information. The proposed regulation added to that list information obtained through electronic media, such as the Internet, television, and movies. The exception does not include genetic information contained in medical databases or court records. Research databases available to scientists on a restricted basis, such as databases that NIH maintains for the scientific community, would not be considered "commercially and publicly available."

We received numerous comments in response to our queries as to whether the additional sources noted in the proposed regulation should remain part of the final regulation and whether there are sources similar in kind to those identified in the statute that may contain genetic information and should be included either in the group of excepted sources or the group of prohibited sources, such as personal Web sites or social networking sites. In general, civil rights groups and groups promoting genetic research, as well as others, indicated that excepted sources should be limited to widely available media with no heightened risk for containing genetic information, providing a variety of arguments in support of this position. *See* Comments of ACLU, APA, CGF, FDIC, GPPC, Genetic Alliance, LCCR, Members of PGEF, and World Privacy Forum. Several of these groups also noted that employers who access commercially and publicly available materials with a specific intent of searching for genetic information should not be permitted to take advantage of the exception. *See* Comments of CGF, FDIC, GPPC, Genetic Alliance, LCCR and World Privacy Forum. Employers and employer groups, on the other hand, maintained that media formats such as personal web pages, social networking sites, and blogs should be part of the exception arguing, among other things, that such sources are publicly available and that employers have legitimate reasons to access them. *See* Comments of Chamber/SHRM, EEAC, Navigenics, NFIB, SBA and TOC.¹⁶

¹⁶ Chamber/SHRM reiterated its comment that a covered entity must undertake an intentional act of

We conclude that a more detailed explanation of this exception is necessary. First, we agree that media sources with limited access should not be considered commercially and publicly available. Thus, if a media source requires permission for access from a specific individual, as opposed to a media source that simply requires users to obtain a username and/or password, or if access is conditioned on membership in a particular group (e.g., a professional organization), the acquisition of genetic information through that source will not be protected by this exception. For example, many Facebook, Linked In, My Space profiles, and other social networking platforms require permission from the creator of the profile to gain access to anything beyond basic information such as name and profession and therefore would not be considered commercially and publicly available, although the exception at 1635.8(b)(1) would still apply to any genetic information inadvertently obtained from such sources. On the other hand, most personal Web sites and blogs are not so limited, but may simply require users to obtain a username and/or password, and therefore would be considered commercially and publicly available. Of course, there are profiles or portions thereof on social networking sites that do not require permission to access, and there may be situations in which access to a social networking site is granted routinely, so that access cannot be said to be limited. There are also Web sites and blogs that do limit access. The determining factor, then, in deciding whether a media source is commercially and publicly available is whether access requires permission of an individual or is limited to individuals in a particular group, not whether the source is categorized as a social networking site, personal Web site, or blog.

Second, we agree that the exception does not apply to genetic information acquired by covered entities that access commercially and publicly available sources with the intent of obtaining genetic information. This exception was intended to protect from liability a covered entity that inadvertently obtains genetic information and not a covered entity that is actively searching for genetic information. *See* S. Rep. 110–48 at 30 (“The fourth exception, like the first, relates to the inadvertent

acquisition of family medical history.”). For example, an employer who acquires genetic information by conducting an Internet search for the name of an employee and a particular genetic marker will not be protected by this exception, even if the information the employer ultimately obtained was from a source that is commercially and publicly available. Conversely, an employer who inadvertently acquires genetic information while conducting an Internet search of an employee without reference to a genetic marker will be protected by this exception.

Third, we have concluded that the exception does not apply to the acquisition of genetic information through a media source, whether or not it is commercially and publicly available, if the covered entity is likely to acquire genetic information by accessing that source. Thus, a covered entity that acquires genetic information after accessing a Web site that focuses on issues such as genetic testing of individuals or a commercial database containing individually identifiable health information¹⁷ will not be able to take advantage of this exception. Finally, in response to comments from some employer groups that human resource professionals and other employers may access various media sources for personal reasons and not in their capacity as covered entities, we clarify that the requirements and prohibitions of GINA do not apply to acquisitions of genetic information outside the employment context. *See* Comments of NFIB and Navigenics.

In response to one comment we received, we further clarify that genetic information about an individual acquired through any media source, including one that is commercially and publicly available or a source accessed outside the employment context, may not be used to discriminate in employment decision-making and may not be disclosed in violation of Title II’s confidentiality provisions. *See* Comment of National Counsel of EEOC Locals no. 216, American Federation of Government Employees, AFL–CIO (AFGE).

Genetic Monitoring: The statute also permits a covered entity to engage in the genetic monitoring of the biological effects of toxic substances in the workplace, as long as that monitoring meets certain requirements. First, a covered entity must provide written notice of the monitoring and, where the

monitoring is not specifically required by federal or state law or regulation, must obtain an individual’s prior knowing, written, and voluntary authorization. Second, the regulation describes the type of authorization form the employer must provide in order to ensure that an individual’s authorization is knowing and voluntary. The authorization form must be written in a way that is reasonably likely to be understood by the person from whom the information is being sought, must describe the type of genetic information that will be obtained and the general purposes for which it will be used, and must describe the limitations on disclosure of the genetic information. Third, all monitoring must comply with all applicable provisions of the law and implementing regulations, including regulations promulgated pursuant to the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*), the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 *et seq.*), and the Atomic Energy Act of 1954 (42 U.S.C. 2011 *et seq.*).

Whether or not the monitoring is undertaken pursuant to federal or state law, GINA requires that the individual receive results of the monitoring and that the covered entity receive information only in aggregate terms that do not disclose the identity of specific individuals. As is the case with health or genetic services offered by a covered entity on a voluntary basis, we have concluded that there is no violation of GINA if a covered entity receives information only in aggregate terms, but is able to identify the genetic information of specific individuals for reasons outside the covered entity’s control and with no effort on its part (e.g., because of the small number of employees involved in the monitoring). We have revised the language in the final regulation to mirror the statutory language.

Several commenters mentioned the need for a provision in the final regulation that protects workers who refuse to participate in genetic monitoring that is not required by law. *See* Comments of ACLU, CGF, Genetic Alliance, GPPC and LCCR. These commenters also requested that the final regulation describe what actions a covered entity may legitimately take in response to such a refusal. *Id.* We agree with these groups that GINA prohibits a covered entity from retaliating or otherwise discriminating against an employee who refuses to participate in genetic monitoring that is not specifically required by law. An individual who refuses to participate in a voluntary genetic monitoring program

requesting, requiring or purchasing genetic information to violate the prohibition on acquisition and argued that accessing a social networking site that does not require payment is therefore outside the scope of Title II. As explained above, we reject this interpretation of the statute.

¹⁷ For example, one commenter provided several lists of identifiable individuals with diabetes available for sale on the Internet. *See* Comment of World Privacy Forum.

should be informed of the potential dangers (*e.g.*, the consequences that might result if the effects of certain toxins in the workplace are not identified), but the covered entity is prohibited from taking any adverse action, as that term is understood under Title VII of the Civil Rights Act of 1964 and other civil rights laws, against the individual.

DNA Testing for Law Enforcement or Human Remains Identification Purposes: Finally, sections 202(b), covering employers, and 205(b), covering apprenticeship or other training programs, include a sixth exception for employers that engage in DNA testing for law enforcement purposes as a forensic lab or for purposes of human remains identification. GINA provides that these entities may request or require genetic information of such employer's employees, apprentices, or trainees, "but only to the extent that such genetic information is used for analysis of DNA identification markers for quality control to detect sample contamination." 42 U.S.C. 2000ff-1(b)(6) and 2000ff-4(b)(6). The genetic information may be maintained and disclosed in a manner consistent with this limited use. This is a very limited exception and, if the analysis is properly conducted, an employer or training program would not obtain health-related genetic information. Several comments, while expressing general agreement with EEOC's position, requested that the final regulation make clear that genetic information covered by this exception must be destroyed after a designated time period and that the samples and results be used solely for quality control and not be entered into any law enforcement database. *See* Comments of CGF, Genetic Alliance, and GPPC. We find that it is unnecessary to add any further limitations to those set forth in the statute and the proposed regulation. Both make clear that this is a very limited exception, allowing only for the use of genetic information for analysis of DNA identification markers for quality control and to detect sample contamination, and not for any other law enforcement purpose. Rather than specifying in the regulation how such information should be used, we believe it is sufficient to state, as the final rule does, that the information may be used in accordance with the purpose for which it was acquired.

Section 1635.8(c)

We have added a new provision to 1635.8. Subsection (c)(1) responds to a comment that said that information about an employee's manifested disease,

disorder, or pathological condition should not be considered genetic information (*i.e.* family medical history) about a family member working for the same employer. *See* Comment of Chamber/SHRM. We decline to take this position in the final rule, because we believe that the information would be family medical history that an employer could not use to discriminate against, or disclose with respect to, the second employee. We agree, however, that a request for information about whether an individual has a manifested disease, disorder, or pathological condition does not violate GINA simply because a family member of the individual to whom the request was made works for the same employer, is a member of the same labor organization, or is participating in the same apprenticeship program as the person from whom the information was requested. We have modified the final rule to reflect this more limited point.

Section 1635.8(c)(2) addresses a related issue that may arise when an individual's family member who, although not an employee of the same employer, a member of the same labor organization, or a participant in the same apprenticeship program as the individual, nevertheless receives health or genetic services offered by a covered entity as permitted under 1635.8(b)(2). The collection of information about the manifested disease or disorder of a family member in the course of providing health or genetic services to the family member is not an unlawful acquisition of genetic information about the individual.

Section 1635.8(d)

We received several comments concerning the extent to which health care professionals may request genetic information (particularly family medical history) as part of a lawful medical examination (*e.g.*, a post-offer exam or fitness for duty exam) to determine whether an individual has a manifested disease, disorder, or pathological condition. A number of comments suggested that the final rule should not necessarily limit the scope of the inquiries a health care professional may make, but should ensure that any genetic information collected as part of the examination is not shared with the employer. *See* Comments of AMA, Chamber/SHRM, EEAC and IPMA; *see also* Comments of United States Customs and Immigration Service (requesting clarification on this point). We do not think it is sufficient for an employer or other covered entity merely to indicate to the health care professional conducting a medical

examination on its behalf that the covered entity does not want to receive genetic information acquired as part of the examination. The final rule says that the covered entity must tell the health care professional not to collect genetic information as part of a medical examination intended to determine the ability to perform a job, and must take additional reasonable measures within its control if it learns that genetic information is being requested or required. This could include no longer using the services of a health care professional who continues to request or require genetic information during medical examinations after being informed not to do so. Unlike the warning described in 1635.8(b)(1), which may not be necessary if a covered entity can show that it could not have known it would receive genetic information in response to a lawful request for medical documentation, the warning provided for in 1635.8(d) is required, because any time an employer sends an applicant or employee for a medical examination, the employer knows or should know that genetic information is likely to be requested. We note, however, that family medical history and other genetic information may be obtained as part of health or genetic services provided by the employer (*see* 29 CFR 1635.8(b)(2)), and that Title II of GINA does not apply at all to medical examinations conducted for the purpose of diagnosis and treatment that are unrelated to employment (*e.g.*, where an employee seeks health services from the same hospital where he or she works). *See* 1635.1(b)(1).

The preamble to the proposed rule suggested that there would never be situations in which genetic information (including family medical history) would be needed as part of a medical examination conducted to assess an individual's ability to perform a job. One federal agency asked whether the final rule would include an exception allowing an employer or other covered entity to collect family medical history (*e.g.*, questions about the prevalence of a psychiatric disability in family members of an individual) as part of the process of determining whether to grant or deny a security clearance. *See* Comments of United States Customs and Immigration Services. Neither the plain language of Title II, which enumerates very specific exceptions to the rule prohibiting acquisition of genetic information, nor GINA's legislative history references such an exception; therefore, the Commission declines to include one in the final rule.

In response to comments from some employers that genetic information may be needed to make a diagnosis of a manifested disease, disorder, or pathological condition, we considered adding a very narrow exception to the prohibition on acquiring genetic information to allow a covered entity or health care professional acting on the covered entity's behalf to request genetic information as part of a medical examination where doing so is necessary to determine whether an individual has a particular manifested disease, disorder, or pathological condition and where information about the particular disease, disorder, or pathological condition, as opposed to its signs and symptoms, is necessary to evaluate an individual's ability to perform a particular job. *See* Comments of AHIP, Chamber/SRHM, EEAC and SBA. We decided against creating this extra-statutory exception, however, because neither the commenters that raised this concern nor the experts with whom we consulted were able to provide an example that fits within it. Although there may be cases where a manifested disease, disorder, or pathological condition can only be positively diagnosed through use of genetic information, there does not appear to be a case in which the diagnosis, as opposed to the signs and symptoms, is necessary to evaluate an individual's ability to perform a particular job. For example, although experts at the National Institutes of Health noted that a genetic test may be used to confirm a diagnosis of cystic fibrosis based principally on the clinical analysis of the patient, the signs or symptoms of cystic fibrosis (including, for example, frequent lung infections, sinusitis, bronchitis and pneumonia, and nasal polyps, among others) would be sufficient, regardless of the specific disease, disorder, or pathological condition that may be causing them, to assess an individual's ability to do a job. Moreover, in the case of cystic fibrosis, it is extremely unlikely that an individual seeking employment would be unaware of his or her diagnosis. Because we have no information supporting the need for this type of exception, we decided not to add to the exceptions specifically described in the statute.

Section 1635.9 Confidentiality

GINA section 206 addresses confidentiality of genetic information generally, establishes permitted disclosures, and describes the relationship between GINA and HIPAA. Each of these items is discussed below.

Section 1635.9(a) Treatment of Genetic Information

Under GINA, covered entities are required to treat genetic information in their possession the same way they treat medical information generally. They must keep the information confidential and, if the information is in writing, must keep it apart from other personnel information in separate medical files.¹⁸ Congress made express the requirement that covered entities keep genetic information confidential by using the confidentiality regime required by the ADA generally for medical records. H.R. Rep. 110–28, part I, at 39. GINA does not require that covered entities maintain a separate medical file for genetic information. Genetic information may be kept in the same file as medical information subject to the ADA.

In response to questions raised by commenters, we note that although genetic information placed in personnel files prior to the effective date of GINA Title II need not be removed and an employer will not be liable under GINA for the mere existence of the information in the file, disclosing such information to a third party is prohibited. *See* Comments of EEAC and SBA. GINA's prohibitions on use and disclosure of genetic information apply to all genetic information that meets the statutory definition, including genetic information acquired prior to the effective date of GINA. *See* Comments of CGF, Genetic Alliance, and GPPC (requesting clarification of this point). We would not anticipate that removing genetic information in a personnel file acquired before GINA's effective date in response to a request to disclose the file would impose a significant burden on covered entities. Most genetic information is medical information that has been subject to the ADA's confidentiality requirements since 1992 (with respect to employers with 25 or more employees) or 1994 (with respect to employers with 15 to 24 employees). Consequently, although all covered entities must remove genetic information from personnel files prior to

¹⁸ Genetic information that a covered entity receives verbally and does not reduce to writing must still be kept confidential, except to the extent that GINA permits disclosure. As noted in the regulation at 1635.9(a)(3), a covered entity need not reduce to writing genetic information that it receives orally. Although one commenter requested that this language be altered to indicate that covered entities should not reduce genetic information that it receives orally to writing, we have decided to maintain the existing language. *See* Comment of DLRC. This language was inserted in the proposed rule to respond to concerns that GINA required employers to reduce to writing any genetic information received.

disclosing those files, we would anticipate that covered entities who have been complying with the ADA will have very few personnel files that contain genetic information.

We received one comment questioning what an employer should do if it is aware that employees are discussing genetic information of co-workers with other employees. *See* Comment of Navigenics. We do not think this has been a significant problem under the ADA, which has a similar confidentiality rule pertaining to employee medical information in general, and therefore do not think that many charges will be filed alleging that a covered entity violated GINA by allowing co-workers to share genetic information about another individual. However, we note that the analysis of an employer's responsibility to prevent harassment by co-workers is instructive—an employer is liable for harassment of an employee by co-workers if it knew or should have known of the misconduct, unless it can show that it took immediate and appropriate corrective action. *See* 29 CFR 1604.11(d). We believe a similar standard would work well in the case of an employer's responsibility to prevent individuals from discussing the genetic information of co-workers.

Chamber/SHRM requested that the final regulation clarify that certain communications are exempt from GINA's confidentiality provisions, such as communications to a contractor performing relevant business functions (e.g., storing medical information on behalf of an employer) or to attorneys for purposes of litigation or legal assessment. This clarification is not necessary. First, it is apparent that a covered entity's attorney or a business with whom it has contracted to store medical information on its behalf is an agent of the covered entity and would therefore be permitted access to relevant genetic information. Second, as noted above, GINA uses the confidentiality regime required by the ADA generally for medical records. This regime does not include specific exceptions for communications to attorneys for the purposes of litigation or to contractors performing relevant business functions; yet we have not seen any charges challenging these types of communications.

As noted above, a covered entity does not violate GINA when it acquires genetic information through sources that are publicly and commercially available, as long as it does not research those sources with the intent of acquiring genetic information or access sources that are likely to include genetic

information. For example, an employer that purchased a newspaper with an obituary about a family member of an employee indicating that the employee's relative died of a disease or disorder that has a genetic component would not violate GINA. Similarly, a labor organization may lawfully acquire a magazine or periodical with an article about a member that includes family medical history about the member's parent, sibling, or child. In neither instance, nor in any similar instance where a covered entity acquires family medical history through sources that are publicly and commercially available, must the covered entity place the information into a confidential medical file. Moreover, inasmuch as one of GINA's purposes is the protection from disclosure of otherwise private genetic information, disclosure of genetic information obtained through sources that are commercially and publicly available does not violate the Act. However, a covered entity may not use family medical history to make employment decisions, even if the information was acquired through commercially and publicly available sources.

Section 1635.9(b) Exceptions to Limitations on Disclosure

GINA permits disclosure of genetic information in limited circumstances. First, a covered entity may disclose genetic information to the individual to whom it relates, if the individual requests disclosure in writing. Second, the section states that genetic information may be provided to an occupational or other health researcher "if the research is being conducted in compliance with the regulations under" 45 CFR part 46 (regulating research involving human subjects). One commenter requested that this type of disclosure only be permitted if participation in the research is voluntary and the information obtained is not used for secondary research purposes. *See* Comment of ACLU. The requirements of 45 CFR part 46 itself, however, include obtaining the informed consent of research participants, which involves fully informing participants of the purposes and risks of the research, as well as the extent to which confidentiality of identifying records will be maintained. *See* 45 CFR 46.116. We need not adopt further safeguards in these circumstances.

The third exception permits disclosure in compliance with a court order. It provides that the disclosure of genetic information must be carefully tailored to the terms of the order.

Moreover, the language of the regulation, taken from the statute, notes that if the court order was secured without the knowledge of the employee or member to whom the information refers, the covered entity must inform the employee or member of the court order and the information that was disclosed. Because the covered entity may not know whether the employee or member is aware of the court order, it should inform the employee or member of the court order and the disclosed information unless it knows that the employee or member already has this information. This exception does not allow disclosures in other circumstances during litigation, such as in response to discovery requests or subpoenas that are not governed by an order specifying that genetic information must be disclosed. Thus, a covered entity's refusal to provide genetic information in response to a discovery order, subpoena, or court order that does not specify that genetic information must be disclosed is consistent with the requirements of GINA.

The fourth exception permits disclosure of relevant genetic information to government officials investigating compliance with the statute. The fifth exception permits disclosure consistent with the requirements of the FMLA or similar state or local leave law. For example, an employee's supervisor who receives a request for FMLA leave from an employee who wants to care for a child with a serious health condition may forward this request to persons with a need to know the information because of responsibilities relating to the handling of FMLA requests. Finally, the sixth exception permits disclosure of family medical history to federal, state, or local public health officials in connection with a contagious disease that presents an imminent hazard of death or life-threatening illness. The statute requires the covered entity to notify the employee of any release of a family member's medical history information when undertaken for this purpose.

Section 1635.9(c) Relationship to HIPAA Privacy Regulations

GINA section 206(c) provides that the provisions of Title II of GINA are not intended to apply to uses and disclosures of health information governed by the HIPAA Privacy Rule. Accordingly, and consistent with the general rule of construction implementing this statutory provision at 1635.11(d), this rule provides at 1635.9(c) that nothing in 1635.9 should

be construed as applying to the use or disclosure of genetic information that is protected health information subject to the HIPAA Privacy Rule. *See* discussion of Section 1635.11(d), *infra*, for an example of the interaction under GINA between the HIPAA Privacy Rule and this regulation.

Section 1635.10 Enforcement and Remedies

In crafting GINA's enforcement and remedies section, Congress recognized the advisability of using the existing mechanisms in place for redress of other forms of employment discrimination. In particular, the Senate noted that this section intends to take "advantage of the expertise and process of the EEOC." S. Rep. No. 110-48, at 31 & n.17. In this regard, GINA and the final regulation provide the following:

- The enforcement mechanism applicable and remedies available to employees and others covered by Title VII of the Civil Rights Act of 1964 apply to GINA as well.¹⁹ The statute references sections 705-707, 709-711, and 717 of Title VII, 42 U.S.C. 2000e-4, *et seq.* The Commission notes that its implementing regulations found at 29 CFR parts 1601 (procedural regulations), 1602 (recordkeeping and reporting requirements under Title VII and the ADA), and 1614 (federal sector employees) apply here as well.
- The procedures applicable and remedies available to employees covered by sections 302 and 304 of the Government Employee Rights Act of 1991, 42 U.S.C. 2000e-16(b) & (c) (GERA) apply under GINA.²⁰ EEOC regulations applicable to GERA are found at 29 CFR part 1603.
- The procedures applicable and remedies available to employees covered by 3 U.S.C. 401 *et seq.* are set forth in 3 U.S.C. 451-454.²¹ These

¹⁹ As defined by section 701 of the Civil Rights Act of 1964, 42 U.S.C. 2000e, an employee is an individual employed by a person engaged in an industry affecting commerce who has fifteen or more employees for each working day in each of twenty or more calendar weeks in the current or preceding calendar year and any agent of such a person.

²⁰ As defined by section 304(a) of GERA, 42 U.S.C. 2000e-16c(a), an employee is a person chosen or appointed by an individual elected to public office by a State or political subdivision of a State to serve as part of the personal staff of the elected official, to serve the elected official on a policy-making level, or to serve the elected official as the immediate advisor on the exercise of the elected official's constitutional or legal powers.

²¹ As defined by, and subject to the limitations in, section 2(a) of the Presidential and Executive Office Accountability Act, 3 U.S.C. 411(c), these employees include any employee of the executive branch not otherwise covered by section 717 of the Civil Rights Act of 1964, 42 U.S.C. 2000e-16, section 15 of the Age Discrimination in

sections provide for counseling and mediation of employment discrimination allegations and the formal process of complaints before the Commission using the same administrative process generally applicable to employees in the Executive Branch of the Federal government; that is, the process set forth in 29 CFR part 1614.

Employees covered through the Congressional Accountability Act of 1995 must use the procedures set forth in that statute. The Commission has no authority with respect to the enforcement of GINA as to employees covered through this provision.

The final regulation includes a separate reference to the remedies provisions applicable to GINA. Similar to other federal anti-discrimination laws, GINA provides for recovery of pecuniary and non-pecuniary damages, including compensatory and punitive damages. The statute's incorporation by reference of section 1977A of the Revised Statutes of the United States (42 U.S.C. 1981a) also imports the limitations on the recovery of compensatory damages for future pecuniary losses, emotional pain, suffering, etc., and punitive damages applicable generally in employment discrimination cases, depending on the size of the employer. Punitive damages are not available in actions against the federal government, or against state or local government employers.

Finally, at 1635.10(c) the regulation notes that covered entities are required to post notices in conspicuous places describing GINA's applicable provisions. The Commission issued a revised EEO poster that may be used for this purpose prior to GINA's effective date (November 21, 2009). It is available to order or print on EEOC's Web site at <http://www1.eeoc.gov/employers/poster.cfm>.

Section 1635.11 Construction

GINA section 209 and this section of the regulation set forth rules of construction applicable to GINA's coverage and prohibitions. They address principally GINA's relationship to other federal laws covering discrimination, health insurance, and other areas of potential conflict.

Employment Act of 1967, 29 U.S.C. 633a, or section 501 of the Rehabilitation Act of 1973, 29 U.S.C. 791, whether appointed by the President or any other appointing authority in the executive branch, including an employee of the Executive Office of the President.

Section 1635.11(a) Relationship to Other Laws Generally

The subsection first addresses the relationship of Title II of GINA to other federal, state, local, and tribal laws governing genetic discrimination, the privacy of genetic information, and discrimination based on disability. Over 30 states have laws addressing genetic discrimination in employment. Some may be more stringent than GINA; others less so. GINA makes clear that it does not preempt any other state or local law that provides equal or greater protections than GINA from discrimination on the basis of genetic information or improper access or disclosure of genetic information. Additionally, Title II of GINA does not limit the rights or protections under federal, state, local or tribal laws that provide greater privacy protection to genetic information. The EEOC will provide information on our public Web site about state and local laws that prohibit employment discrimination on the basis of genetic information. See Comment of SBA (requesting more information about state and local laws addressing genetic information).

Similarly, GINA does not affect an individual's rights under the ADA, the Rehabilitation Act, or state or local laws that prohibit discrimination against individuals based on disability. So, for example, an individual could challenge the disclosure of genetic information under the ADA where the information is also considered medical information subject to that law. Additionally, even though information that an employee currently has a disease, such as cancer, is not subject to GINA's confidentiality provisions, such information would be protected under the ADA, and an employer would be liable under that law for disclosing the information, unless a specific ADA exception applied.

GINA does limit, however, an employer's ability to obtain genetic information as a part of a disability-related inquiry or medical examination. For example, an employer will no longer be able to obtain family medical history or conduct genetic tests of post-offer job applicants, as it currently may do under the ADA. We reiterate, however, that family medical history and other genetic information may be acquired in connection with employer-provided health or genetic services, including wellness programs, that are provided on a voluntary basis (see 1635.8(b)(2)), and that Title II of GINA does not apply to genetic information acquired as part of a medical examination conducted for the purpose

of diagnosis and treatment that is wholly unrelated to employment (e.g., where an employee seeks health services from the hospital where he or she works).

Other provisions in this section clarify that GINA does not (1) limit or expand rights or obligations under workers' compensation laws; (2) limit or expand the rights of federal agencies to conduct or support occupational or other health research conducted in accordance with the rules found in 45 CFR part 46; or (3) limit the statutory or regulatory authority of the Occupational Safety and Health Administration or the Mine Safety and Health Administration or other workplace health and safety laws and regulations. Another provision addresses the exemption from GINA of the Armed Forces Repository of Specimen Samples for the Identification of Remains.

The final provision in this subsection makes clear that GINA does not require that a covered entity provide individuals with any specific benefits or specialized health coverage. A covered entity does not have to offer health benefits that relate to any specific genetic disease or disorder. GINA merely requires that the covered entity not discriminate against those covered by the Act on the basis of genetic information.

Section 1635.11(b) Relationship to Other Federal Laws Governing Health Coverage

GINA section 209(a)(2)(B) includes four subsections that address the relationship between Title II and requirements or prohibitions that are subject to enforcement under other federal statutes addressing health coverage. Section 209(a)(2)(B)(i) states that nothing in Title II provides for enforcement of, or penalties for, violations of requirements or prohibitions subject to enforcement under GINA Title I. The three following subsections, sections 209(a)(2)(B)(ii)–(iv), state that nothing in Title II provides for enforcement of, or penalties for, any requirement or prohibition subject to enforcement under various sections of ERISA, the Public Health Service Act, and the Internal Revenue Code, which generally prohibit a group health plan or health insurance issuer in the group market from:

- Imposing a preexisting condition exclusion based solely on genetic information, in the absence of a diagnosis of a condition;
- Discriminating against individuals in eligibility and continued eligibility for benefits based on genetic information; and

• Discriminating against individuals in premium or contribution rates under the plan or coverage based on genetic information, although such a plan or issuer may adjust premium rates for an employer based on the manifestation of a disease or disorder of an individual enrolled in the plan.

The intent of this section is to create a clear “firewall” between GINA Titles I and II so that health plan or issuer provisions or actions are addressed and remedied through GINA Title I, ERISA, the Public Health Service Act, or the Internal Revenue Code and not through Title II and other employment discrimination procedures.

We received a variety of comments requesting further clarification of the firewall provision. Employer groups argued that the final regulation should make very clear that the firewall is broad. *See* Comments of ABC, Blue Cross and Blue Shield Association (BCBSA), Chamber/SHRM and NFIB. Some of these same groups requested that more specific language about the lack of double liability be inserted into the regulation itself and provided model language for this purpose. *See* Comments of ABC, Blue Cross and Blue Shield Association, (BSBCA), and Chamber/SHRM. Civil rights groups, groups promoting genetic research, and others argued that the final rule should clarify that the firewall was not intended to immunize from liability decisions and actions that violate Title II, simply because those decisions involve health benefits governed by Title I. *See* Comments of CGF, Congressional Committee on Education and Labor (CCEL) (offering specific model language), Genetic Alliance, and GPPC. CCEL argued that the proposed regulation failed to make clear that liability under GINA is based on the actor who discriminates (i.e., employers or health plans/insurers) and not the act of discrimination. *See* Comment of CCEL. Commenters also requested that the final regulation include additional examples illustrating how the firewall will work, with one commenter providing specific examples for this purpose. *See* Comments of CCEL (providing specific examples and model language), Navigenics and SBA. We agree that further clarification of the firewall is required and, after careful review of the comments received, have made the necessary changes to the preamble and the final regulation.

Section 209(a)(1)(B) eliminates “double liability” for health plans and insurers by preventing Title II causes of action from being asserted regarding matters subject to enforcement under Title I or the other genetics provisions

for group coverage in ERISA, the Public Health Service Act, and the Internal Revenue Code. The firewall seeks to ensure that health plan or issuer provisions or actions are addressed and remedied through ERISA, the Public Health Service Act, or the Internal Revenue Code, while actions taken by employers and other GINA Title II entities are remedied through GINA Title II. The regulation reiterates the language of the section, noting the specific sections from ERISA, the Public Health Service Act, and the Internal Revenue Code that the section covers.

Employers and other GINA Title II covered entities, however, would remain liable for any of their actions that violate Title II, even where those actions involve access to health benefits, because such benefits are within the definition of compensation, terms, conditions, or privileges of employment. For example, an employer that fires an employee because of anticipated high health claims based on genetic information remains subject to liability under Title II. On the other hand, health plan or issuer provisions or actions related to the imposition of a preexisting condition exclusion; a health plan’s or issuer’s discrimination in health plan eligibility, benefits, or premiums based on genetic information; a health plan’s or issuer’s request that an individual undergo a genetic test; and/or a health plan’s or issuer’s collection of genetic information remain subject to enforcement under Title I exclusively. Below are a few examples of how the firewall is intended to operate:

- If an employer contracts with a health insurance issuer to request genetic information, the employer has committed a Title II violation. In addition, the plan and issuer may have violated Title I of GINA.
- If an employer directs its employees to undergo mandatory genetic testing in order to be eligible for health benefits, the employer has committed a Title II violation.
- If an employer or union amends a health plan to require an individual to undergo a genetic test, then the employer or union is liable for a violation of Title II. In addition, the health plan’s implementation of the requirement may violate Title I.

Section 1635.11(c) Relationship to Authorities Under GINA Title I

The final subsection in GINA section 209 provides that nothing in GINA Title II prohibits a group health plan or group health insurance issuer from engaging in any activity that is authorized under the GINA Title I provisions identified in GINA section 209(a)(2)(B)(i)–(iv),

including any implementing regulations thereunder. The section and the implementing regulation reiterate the limitations imposed on Title II in the area of group health coverage.

Section 1635.11(d) Relationship to HIPAA Privacy Regulations

Final § 1635.11(d) implements section 206(c) of GINA Title II by providing, as a general rule of construction, that this regulation does not apply to protected health information subject to the HIPAA Privacy Rule. Thus, entities subject to the HIPAA Privacy Rule must continue to apply the requirements of the HIPAA Privacy Rule, and not the requirements of GINA Title II and these implementing regulations, to genetic information that is protected health information. For example, if a hospital subject to the HIPAA Privacy Rule treats a patient who is also an employee of the hospital, any genetic information that is obtained or created by the hospital in its role as a health care provider is protected health information and is subject to the requirements of the HIPAA Privacy Rule and not those of GINA. In contrast, however, any genetic information obtained by the hospital in its role as employer, for example, as part of a request for leave by the employee, would be subject to GINA Title II and this rule. Similarly, a health care provider may share genetic information, consistent with the HIPAA Privacy Rule, in the course of providing genetic services as part of a voluntary wellness program.

Several commenters requested that the final regulation make clear that genetic information obtained by a health care provider covered by the HIPAA Privacy Rule may not be used in making employment decisions and must be kept separate from employment files. *See* Comments of CGF, Genetic Alliance and GPPC. Another commenter was concerned that the language in the proposed preamble suggested that an entity covered by both the HIPAA Privacy Rule and GINA can use genetic information to discriminate against applicants and employees because the requirements of GINA do not apply to it. *See* Comment of World Privacy Forum. In response to these comments, we clarify that all entities covered by Title II of GINA, whether or not they are also covered by the HIPAA Privacy Rule, must follow the requirements of GINA when they are acting as employers.

Section 1635.12 Medical Information That Is Not Genetic Information

The final regulation states that a covered entity does not violate GINA by

acquiring, using, or disclosing medical information about a manifested disease or disorder that is not genetic information, even if the disease or disorder may have a genetic basis or component. It further notes, however, that the ADA, and the applicable regulations issued in support of the Act, would limit the disclosure of genetic information that also is medical information and covered by the ADA. In response to a comment, we clarify that GINA prohibits discrimination based on genetic information and not on the basis of a manifested condition, while the ADA prohibits discrimination on the basis of manifested conditions that meet the definition of disability. *See* Comment of ICC. Although another commenter expressed concern that neither GINA nor the ADA protects individuals with a manifested genetic disease that is not yet substantially limiting, we note that we have no authority under these regulations to expand the coverage of GINA. *See* Comment of Burton Blatt Institute. Moreover, given the broader definition of disability that now exists under the Americans with Disabilities Act Amendments Act (ADAAA), it is less likely that a significant number of individuals will fall within this gap. Perhaps most notably, the revised definition of the “regarded as” definition of “disability” would apply to anyone against whom an employer or other covered entity takes a prohibited action (e.g., failure to hire or termination) based on an actual or perceived physical or mental impairment that is not transitory (lasting or expected to last for six months or less) and minor. *See* 42 U.S.C. 12102(3)(A).

Regulatory Procedures

Executive Order 12866

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

Paperwork Reduction Act

This rule contains no new information collection requirements subject to review by the Office of

Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

Regulatory Flexibility Act

Title II of GINA applies to all employers with fifteen or more employees, approximately 822,000 of which are small firms (entities with 15–500 employees) according to data provided by the Small Business Administration Office of Advocacy. *See Firm Size Data at <http://sba.gov/advo/research/data.html#us>.*

The Commission certifies under 5 U.S.C. 605(b) that this final rule will not have a significant economic impact on a substantial number of small entities because it imposes no reporting burdens and only minimal costs on such firms. GINA is intended to prevent discrimination based on concerns that genetic information about an individual suggests an increased risk of, or predisposition to, acquiring a condition in the future. Because individuals protected under GINA do not have currently manifested conditions that would result in any workplace barriers, the law imposes no costs related to making workplace modifications. To the extent GINA requires businesses that obtain genetic information about applicants or employees to maintain it in confidential files, GINA permits them to do so using the same confidential files they are already required to maintain under Title I of the Americans with Disabilities Act.

The Act may require some modification to the post offer/pre-employment medical examination process of some employers, to remove from the process questions pertaining to family medical history. We do not have data on the number and size of businesses that obtain family medical history as part of a post-offer medical examination. However, our experience with enforcing the ADA, which required all employers with fifteen or more employees to remove medical inquiries from their application forms, suggests that revising post-offer medical questionnaires to eliminate questions about family medical history would not impose significant costs. We recognize that some employers who currently request medical information from employees verbally may decide to make such requests in writing and may create a form for this purpose, in response to the safe harbor described in 1635.8(b)(1)(i). We have no data that would enable us to determine how many businesses will change their practices, but do not believe the cost of creating a form for those businesses who choose to do so would be significant.

GINA will require that covered entities obtain and post revised notices informing covered individuals of their rights under the law. Employers will not incur any costs related to obtaining or posting these notices because the Commission provides employers, at no cost, a poster explaining the EEO laws that will be updated to include information about GINA.

To the extent that employers will need to expend resources to train human resources staff and others on the requirements of GINA, we note that the EEOC conducts extensive outreach and technical assistance programs, many of them at no cost to employers, to assist in the training of relevant personnel on EEO-related issues. In FY 2008, for example, EEOC’s outreach efforts included 5,360 education, training, and outreach events reaching over 270,000 people. EEOC District offices conducted 530 no-fee outreach events directed toward small businesses, including many events in partnership with employer associations, such as the Society for Human Resource Management, and the Industry Liaison Groups and other federal agencies, such as the National Labor Relations Board and the Office of Federal Contract Compliance Programs. Events included oral presentations, training and stakeholder input meetings involving 28,525 small business representatives. We expect to include information about GINA in our outreach programs in general and to offer numerous GINA-specific outreach programs once the regulation implementing Title II of GINA becomes final. We will also post technical assistance documents on our Web site explaining the basics of the new regulation, as we do with all of our new regulations and policy documents. We estimate that typical human resources professionals will need to dedicate, at most, three hours to gain a satisfactory understanding of the new requirements, either by attending an EEOC-sponsored event or reviewing the relevant materials on their own. We further estimate that the median hourly pay rate of an HR professional is approximately \$46.40. *See* Bureau of Labor Statistics, Occupational Employment and Wages, May 2009 at <http://www.bls.gov/oes/current/oes113049.htm#5#5>. Assuming that small entities have between one and five HR professionals/managers, we estimate that the cost per entity of getting appropriate training will be between approximately \$139.00 and \$696.00, at the high end. EEOC does not believe that this cost will be significant for the impacted small entities.

Although several commenters requested that EEOC provide training and technical assistance specifically geared towards small businesses, we received no comments disputing our estimates of the number of small entities impacted or the cost to those entities. See Comments of NFIB, NSBA and SBA. As noted above, EEOC will offer training on Title II of GINA in various formats, as well as issuing the necessary technical assistance guidance.

Unfunded Mandates Reform Act of 1995

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

Dated: October 29, 2010.

For the Commission.

Jacqueline A. Berrien,
Chair.

List of Subjects in 29 CFR Part 1635

Administrative practice and procedure, Equal employment opportunity.

■ For the reasons set forth in the preamble, the EEOC amends 29 CFR chapter XIV by adding part 1635 to read as follows:

PART 1635—GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008

Sec.

- 1635.1 Purpose.
- 1635.2 Definitions—general.
- 1635.3 Definitions specific to GINA.
- 1635.4 Prohibited practices—in general.
- 1635.5 Limiting, segregating, and classifying.
- 1635.6 Causing a covered entity to discriminate.
- 1635.7 Retaliation.
- 1635.8 Acquisition of genetic information.
- 1635.9 Confidentiality.
- 1635.10 Enforcement and remedies.
- 1635.11 Construction.
- 1635.12 Medical information that is not genetic information.

Authority: 110 Stat. 233; 42 U.S.C. 2000ff.

§ 1635.1 Purpose.

(a) The purpose of this part is to implement Title II of the Genetic Information Nondiscrimination Act of 2008, 42 U.S.C. 2000ff, *et seq.* Title II of GINA:

(1) Prohibits use of genetic information in employment decision-making;

(2) Restricts employers and other entities subject to Title II of GINA from

requesting, requiring, or purchasing genetic information;

(3) Requires that genetic information be maintained as a confidential medical record, and places strict limits on disclosure of genetic information; and

(4) Provides remedies for individuals whose genetic information is acquired, used, or disclosed in violation of its protections.

(b) This part does not apply to actions of covered entities that do not pertain to an individual's status as an employee, member of a labor organization, or participant in an apprenticeship program. For example, this part would not apply to:

(1) A medical examination of an individual for the purpose of diagnosis and treatment unrelated to employment, which is conducted by a health care professional at the hospital or other health care facility where the individual is an employee; or

(2) Activities of a covered entity carried on in its capacity as a law enforcement agency investigating criminal conduct, even where the subject of the investigation is an employee of the covered entity.

§ 1635.2 Definitions—general.

(a) *Commission* means the Equal Employment Opportunity Commission, as established by section 705 of the Civil Rights Act of 1964, 42 U.S.C. 2000e–4.

(b) *Covered Entity* means an employer, employing office, employment agency, labor organization, or joint labor-management committee.

(c) *Employee* means an individual employed by a covered entity, as well as an applicant for employment and a former employee. An employee, including an applicant for employment and a former employee, is:

(1) As defined by section 701 of the Civil Rights Act of 1964, 42 U.S.C. 2000e, an individual employed by a person engaged in an industry affecting commerce who has fifteen or more employees for each working day in each of twenty or more calendar weeks in the current or preceding calendar year and any agent of such a person;

(2) As defined by section 304(a) of the Government Employee Rights Act, 42 U.S.C. 2000e–16c(a), a person chosen or appointed by an individual elected to public office by a State or political subdivision of a State to serve as part of the personal staff of the elected official, to serve the elected official on a policy-making level, or to serve the elected official as the immediate advisor on the exercise of the elected official's constitutional or legal powers.

(3) As defined by section 101 of the Congressional Accountability Act, 2

U.S.C. 1301, any employee of the House of Representatives, the Senate, the Capitol Guide Service, the Capitol Police, the Congressional Budget Office, the Office of the Architect of the Capitol, the Office of the Attending Physician, the Office of Compliance, or the Office of Technology Assessment;

(4) As defined by, and subject to the limitations in, section 2(a) of the Presidential and Executive Office Accountability Act, 3 U.S.C. 411(c), any employee of the executive branch not otherwise covered by section 717 of the Civil Rights Act of 1964, 42 U.S.C.

2000e–16, section 15 of the Age Discrimination in Employment Act of 1967, 29 U.S.C. 633a, or section 501 of the Rehabilitation Act of 1973, 29 U.S.C. 791, whether appointed by the President or any other appointing authority in the executive branch, including an employee of the Executive Office of the President;

(5) As defined by, and subject to the limitations in, section 717 of the Civil Rights Act of 1964, 42 U.S.C. 2000e–16, and regulations of the Equal Employment Opportunity Commission at 29 CFR 1614.103, an employee of a federal executive agency, the United States Postal Service and the Postal Rate Commission, the Tennessee Valley Authority, the National Oceanic and Atmospheric Administration Commissioned Corps, the Government Printing Office, and the Smithsonian Institution; an employee of the federal judicial branch having a position in the competitive service; and an employee of the Library of Congress.

(d) *Employer* means any person that employs an employee defined in § 1635.2(c) of this part, and any agent of such person, except that, as limited by section 701(b)(1) and (2) of the Civil Rights Act of 1964, 42 U.S.C. 2000e(b)(1) and (2), an employer does not include an Indian tribe, or a bona fide private club (other than a labor organization) that is exempt from taxation under section 501(c) of the Internal Revenue Code of 1986.

(e) *Employing office* is defined in the Congressional Accountability Act, 2 U.S.C. 1301(9), to mean the personal office of a Member of the House of Representatives or of a Senator; a committee of the House of Representatives or the Senate or a joint committee; any other office headed by a person with the final authority to appoint, hire, discharge, and set the terms, conditions, or privileges of the employment of an employee of the House of Representatives or the Senate; or the Capitol Guide Board, the Capitol Police Board, the Congressional Budget Office, the Office of the Architect of the

Capitol, the Office of the Attending Physician, the Office of Compliance, and the Office of Technology Assessment.

(f) *Employment agency* is defined in 42 U.S.C. 2000e(c) to mean any person regularly undertaking with or without compensation to procure employees for an employer or to procure for employees opportunities to work for an employer and includes an agent of such a person.

(g) *Joint labor-management committee* is defined as an entity that controls apprenticeship or other training or retraining programs, including on-the-job training programs.

(h) *Labor organization* is defined at 42 U.S.C. 2000e(d) to mean an organization with fifteen or more members engaged in an industry affecting commerce, and any agent of such an organization in which employees participate and which exists for the purpose, in whole or in part, of dealing with employers concerning grievances, labor disputes, wages, rates of pay, hours, or other terms or conditions of employment.

(i) *Member* includes, with respect to a labor organization, an applicant for membership.

(j) *Person* is defined at 42 U.S.C. 2000e(a) to mean one or more individuals, governments, governmental agencies, political subdivisions, labor unions, partnerships, associations, corporations, legal representatives, mutual companies, joint-stock companies, trusts, unincorporated organizations, trustees, trustees in cases under title 11, or receivers.

(k) *State* is defined at 42 U.S.C. 2000e(i) and includes a State of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, Wake Island, the Canal Zone, and Outer Continental Shelf lands defined in the Outer Continental Shelf Lands Act (43 U.S.C. 1331 *et seq.*).

§ 1635.3 Definitions specific to GINA.

(a) *Family member* means with respect to any individual:

(1) A person who is a dependent of that individual as the result of marriage, birth, adoption, or placement for adoption; or

(2) A first-degree, second-degree, third-degree, or fourth-degree relative of the individual, or of a dependent of the individual as defined in § 1635.3(a)(1).

(i) First-degree relatives include an individual's parents, siblings, and children.

(ii) Second-degree relatives include an individual's grandparents, grandchildren, uncles, aunts, nephews, nieces, and half-siblings.

(iii) Third-degree relatives include an individual's great-grandparents, great grandchildren, great uncles/aunts, and first cousins.

(iv) Fourth-degree relatives include an individual's great-great-grandparents, great-great-grandchildren, and first cousins once-removed (i.e., the children of the individual's first cousins).

(b) *Family medical history*. Family medical history means information about the manifestation of disease or disorder in family members of the individual.

(c) *Genetic information*. (1) Genetic information means information about:

(i) An individual's genetic tests;

(ii) The genetic tests of that individual's family members;

(iii) The manifestation of disease or disorder in family members of the individual (family medical history);

(iv) An individual's request for, or receipt of, genetic services, or the participation in clinical research that includes genetic services by the individual or a family member of the individual; or

(v) The genetic information of a fetus carried by an individual or by a pregnant woman who is a family member of the individual and the genetic information of any embryo legally held by the individual or family member using an assisted reproductive technology.

(2) Genetic information does not include information about the sex or age of the individual, the sex or age of family members, or information about the race or ethnicity of the individual or family members that is not derived from a genetic test.

(d) *Genetic monitoring* means the periodic examination of employees to evaluate acquired modifications to their genetic material, such as chromosomal damage or evidence of increased occurrence of mutations, caused by the toxic substances they use or are exposed to in performing their jobs, in order to identify, evaluate, and respond to the effects of, or to control adverse environmental exposures in the workplace.

(e) *Genetic services*. Genetic services means a genetic test, genetic counseling (including obtaining, interpreting, or assessing genetic information), or genetic education.

(f) *Genetic test*—(1) *In general*. "Genetic test" means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes.

(2) Genetic tests include, but are not limited to:

(i) A test to determine whether someone has the BRCA1 or BRCA2 variant evidencing a predisposition to breast cancer, a test to determine whether someone has a genetic variant associated with hereditary nonpolyposis colon cancer, and a test for a genetic variant for Huntington's Disease;

(ii) Carrier screening for adults using genetic analysis to determine the risk of conditions such as cystic fibrosis, sickle cell anemia, spinal muscular atrophy, or fragile X syndrome in future offspring;

(iii) Amniocentesis and other evaluations used to determine the presence of genetic abnormalities in a fetus during pregnancy;

(iv) Newborn screening analysis that uses DNA, RNA, protein, or metabolite analysis to detect or indicate genotypes, mutations, or chromosomal changes, such as a test for PKU performed so that treatment can begin before a disease manifests;

(v) Preimplantation genetic diagnosis performed on embryos created using invitro fertilization;

(vi) Pharmacogenetic tests that detect genotypes, mutations, or chromosomal changes that indicate how an individual will react to a drug or a particular dosage of a drug;

(vii) DNA testing to detect genetic markers that are associated with information about ancestry; and

(viii) DNA testing that reveals family relationships, such as paternity.

(3) The following are examples of tests or procedures that are not genetic tests:

(i) An analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes;

(ii) A medical examination that tests for the presence of a virus that is not composed of human DNA, RNA, chromosomes, proteins, or metabolites;

(iii) A test for infectious and communicable diseases that may be transmitted through food handling;

(iv) Complete blood counts, cholesterol tests, and liver-function tests.

(4) Alcohol and Drug Testing—

(i) A test for the presence of alcohol or illegal drugs is not a genetic test.

(ii) A test to determine whether an individual has a genetic predisposition for alcoholism or drug use is a genetic test.

(g) *Manifestation or manifested* means, with respect to a disease, disorder, or pathological condition, that an individual has been or could reasonably be diagnosed with the disease, disorder, or pathological condition by a health care professional with appropriate training and expertise

in the field of medicine involved. For purposes of this part, a disease, disorder, or pathological condition is not manifested if the diagnosis is based principally on genetic information.

§ 1635.4 Prohibited practices—in general.

(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.

(b) It is unlawful for an employment agency to fail or refuse to refer any individual for employment or otherwise discriminate against any individual because of genetic information of the individual.

(c) It is unlawful for a labor organization to exclude or to expel from the membership of the organization, or otherwise to discriminate against, any member because of genetic information with respect to the member.

(d) It is an unlawful employment practice for any employer, labor organization, or joint labor-management committee controlling apprenticeship or other training or retraining programs, including on-the-job training programs to discriminate against any individual because of the individual's genetic information in admission to, or employment in, any program established to provide apprenticeship or other training or retraining.

§ 1635.5 Limiting, segregating, and classifying.

(a) A covered entity may not limit, segregate, or classify an individual, or fail or refuse to refer for employment any individual, in any way that would deprive or tend to deprive the individual of employment opportunities or otherwise affect the status of the individual as an employee, because of genetic information with respect to the individual. A covered entity will not be deemed to have violated this section if it limits or restricts an employee's job duties based on genetic information because it was required to do so by a law or regulation mandating genetic monitoring, such as regulations administered by the Occupational and Safety Health Administration (OSHA). See 1635.8(b)(5) and 1635.11(a).

(b) Notwithstanding any language in this part, a cause of action for disparate impact within the meaning of section 703(k) of the Civil Rights Act of 1964, 42 U.S.C. 2000e-2(k), is not available under this part.

§ 1635.6 Causing a covered entity to discriminate.

A covered entity may not cause or attempt to cause another covered entity,

or its agent, to discriminate against an individual in violation of this part, including with respect to the individual's participation in an apprenticeship or other training or retraining program, or with respect to a member's participation in a labor organization.

§ 1635.7 Retaliation.

A covered entity may not discriminate against any individual because such individual has opposed any act or practice made unlawful by this title or because such individual made a charge, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under this title.

§ 1635.8 Acquisition of genetic information.

(a) *General prohibition.* A covered entity may not request, require, or purchase genetic information of an individual or family member of the individual, except as specifically provided in paragraph (b) of this section. "Request" includes conducting an Internet search on an individual in a way that is likely to result in a covered entity obtaining genetic information; actively listening to third-party conversations or searching an individual's personal effects for the purpose of obtaining genetic information; and making requests for information about an individual's current health status in a way that is likely to result in a covered entity obtaining genetic information.

(b) *Exceptions.* The general prohibition against requesting, requiring, or purchasing genetic information does not apply:

(1) Where a covered entity inadvertently requests or requires genetic information of the individual or family member of the individual.

(i) Requests for Medical Information:

(A) If a covered entity acquires genetic information in response to a lawful request for medical information, the acquisition of genetic information will not generally be considered inadvertent unless the covered entity directs the individual and/or health care provider from whom it requested medical information (in writing, or verbally, where the covered entity does not typically make requests for medical information in writing) not to provide genetic information.

(B) If a covered entity uses language such as the following, any receipt of genetic information in response to the request for medical information will be deemed inadvertent: "The Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits employers and

other entities covered by GINA Title II from requesting or requiring genetic information of an individual or family member of the individual, except as specifically allowed by this law. To comply with this law, we are asking that you not provide any genetic information when responding to this request for medical information. 'Genetic information' as defined by GINA, includes an individual's family medical history, the results of an individual's or family member's genetic tests, the fact that an individual or an individual's family member sought or received genetic services, and genetic information of a fetus carried by an individual or an individual's family member or an embryo lawfully held by an individual or family member receiving assistive reproductive services."

(C) A covered entity's failure to give such a notice or to use this or similar language will not prevent it from establishing that a particular receipt of genetic information was inadvertent if its request for medical information was not "likely to result in a covered entity obtaining genetic information" (for example, where an overly broad response is received in response to a tailored request for medical information).

(D) Situations to which the requirements of subsection (b)(1)(i) apply include, but are not limited to the following:

(1) Where a covered entity requests documentation to support a request for reasonable accommodation under Federal, State, or local law, as long as the covered entity's request for such documentation is lawful. A request for documentation supporting a request for reasonable accommodation is lawful only when the disability and/or the need for accommodation is not obvious; the documentation is no more than is sufficient to establish that an individual has a disability and needs a reasonable accommodation; and the documentation relates only to the impairment that the individual claims to be a disability that requires reasonable accommodation;

(2) Where an employer requests medical information from an individual as required, authorized, or permitted by Federal, State, or local law, such as where an employee requests leave under the Family and Medical Leave Act (FMLA) to attend to the employee's own serious health condition or where an employee complies with the FMLA's employee return to work certification requirements; or

(3) Where a covered entity requests documentation to support a request for leave that is not governed by Federal,

State, or local laws requiring leave, as long as the documentation required to support the request otherwise complies with the requirements of the Americans with Disabilities Act and other laws limiting a covered entity's access to medical information.

(ii) The exception for inadvertent acquisition of genetic information also applies in, but is not necessarily limited to, situations where—

(A) A manager, supervisor, union representative, or employment agency representative learns genetic information about an individual by overhearing a conversation between the individual and others;

(B) A manager, supervisor, union representative, or employment agency representative learns genetic information about an individual by receiving it from the individual or third-parties during a casual conversation, including in response to an ordinary expression of concern that is the subject of the conversation. For example, the exception applies when the covered entity, acting through a supervisor or other official, receives family medical history directly from an individual following a general health inquiry (e.g., "How are you?" or "Did they catch it early?" asked of an employee who was just diagnosed with cancer) or a question as to whether the individual has a manifested condition. Similarly, a casual question between colleagues, or between a supervisor and subordinate, concerning the general well-being of a parent or child would not violate GINA (e.g., "How's your son feeling today?", "Did they catch it early?" asked of an employee whose family member was just diagnosed with cancer, or "Will your daughter be OK?"). However, this exception does not apply where an employer follows up a question concerning a family member's general health with questions that are probing in nature, such as whether other family members have the condition, or whether the individual has been tested for the condition, because the covered entity should know that these questions are likely to result in the acquisition of genetic information;

(C) A manager, supervisor, union representative, or employment agency representative learns genetic information from the individual or a third-party without having solicited or sought the information (e.g., where a manager or supervisor receives an unsolicited email about the health of an employee's family member from a co-worker); or

(D) A manager, supervisor, union representative, or employment agency representative inadvertently learns

genetic information from a social media platform which he or she was given permission to access by the creator of the profile at issue (e.g., a supervisor and employee are connected on a social networking site and the employee provides family medical history on his page).

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

(i) This exception applies only where—

(A) The provision of genetic information by the individual is voluntary, meaning the covered entity neither requires the individual to provide genetic information nor penalizes those who choose not to provide it;

(B) 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;

(C) 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

(D) 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) Consistent with the requirements of paragraph (b)(2)(i) of this section, a covered entity may not offer a financial inducement for individuals to provide

genetic information, but may offer financial inducements for completion of health risk assessments that include questions about family medical history or other genetic information, provided the covered entity makes clear, in language reasonably likely to be understood by those completing the health risk assessment, that the inducement will be made available whether or not the participant answers questions regarding genetic information. 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 inducement 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 inducement. This health risk assessment violates Title II of GINA.

(iii) A covered entity may offer financial inducements to encourage individuals who have voluntarily provided genetic information (e.g., family medical history) 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 voluntarily disclose a family medical history of diabetes, heart disease, or high blood pressure on a health risk assessment that meets the requirements of (b)(2)(ii) 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

inducement 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, and cholesterol levels, or for losing weight. This inducement would not violate Title II of GINA.

(iv) Nothing contained in § 1635.8(b)(2)(iii) 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 a financial inducement for participation in disease management programs or other programs that promote healthy lifestyles and/or require individuals to meet particular health goals, the employer must make reasonable accommodations to the extent required by the ADA, that is, the employer must make "modifications or adjustments that enable a covered entity's employee with a disability to enjoy equal benefits and privileges of employment as are enjoyed by its other similarly situated employees without disabilities" unless "such covered entity can demonstrate that the accommodation would impose an undue hardship on the operation of its business." 29 CFR 1630.2(o)(1)(iii); 29 CFR 1630.9(a). In addition, if the employer's wellness program provides (directly, through reimbursement, or otherwise) medical care (including genetic counseling), the program may constitute a group health plan and must comply with the special requirements for wellness programs that condition rewards on an individual satisfying a standard related to a health factor, including the requirement to provide an individual with a "reasonable alternative (or waiver of the otherwise applicable standard)" under HIPAA, when "it is unreasonably difficult due to a medical condition to satisfy" or "medically inadvisable to attempt to satisfy" the otherwise applicable standard. See section 9802 of the Internal Revenue Code (26 U.S.C. 9802, 26 CFR 54.9802-1 and 54.9802-3T), section 702 of the Employee Retirement Income Security Act of 1974 (ERISA) (29 U.S.C. 1182, 29 CFR 2590.702 and 2590.702-1), and section 2705 of the Public Health Service Act (45 CFR 146.121 and 146.122).

(3) Where the covered entity requests family medical history to comply with the certification provisions of the Family and Medical Leave Act of 1993 (29 U.S.C. 2601 *et seq.*) or State or local family and medical leave laws, or

pursuant to a policy (even in the absence of requirements of Federal, State, or local leave laws) that permits the use of leave to care for a sick family member and that requires all employees to provide information about the health condition of the family member to substantiate the need for leave.

(4) Where the covered entity acquires genetic information from documents that are commercially and publicly available for review or purchase, including newspapers, magazines, periodicals, or books, or through electronic media, such as information communicated through television, movies, or the Internet, except that this exception does not apply—

(i) To medical databases, court records, or research databases available to scientists on a restricted basis;

(ii) To genetic information acquired through sources with limited access, such as social networking sites and other media sources which require permission to access from a specific individual or where access is conditioned on membership in a particular group, unless the covered entity can show that access is routinely granted to all who request it;

(iii) To genetic information obtained through commercially and publicly available sources if the covered entity sought access to those sources with the intent of obtaining genetic information; or

(iv) To genetic information obtained through media sources, whether or not commercially and publicly available, if the covered entity is likely to acquire genetic information by accessing those sources, such as Web sites and on-line discussion groups that focus on issues such as genetic testing of individuals and genetic discrimination.

(5) Where the covered entity acquires genetic information for use in the genetic monitoring of the biological effects of toxic substances in the workplace. In order for this exception to apply, the covered entity must provide written notice of the monitoring to the individual and the individual must be informed of the individual monitoring results. The covered entity may not retaliate or otherwise discriminate against an individual due to his or her refusal to participate in genetic monitoring that is not required by federal or state law. This exception further provides that such monitoring:

(i) Is either required by federal or state law or regulation, or is conducted only where the individual gives prior knowing, voluntary and written authorization. The requirement for individual authorization is only met if

the covered entity uses an authorization form that:

(A) Is written so that the individual from whom the genetic information is being obtained is reasonably likely to understand the form;

(B) Describes the genetic information that will be obtained; and

(C) Describes the restrictions on disclosure of genetic information;

(ii) Is conducted in compliance with any Federal genetic monitoring regulations, including any regulations that may be promulgated by the Secretary of Labor pursuant to the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*), the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 *et seq.*), or the Atomic Energy Act of 1954 (42 U.S.C. 2011 *et seq.*); or State genetic monitoring regulations, in the case of a State that is implementing genetic monitoring regulations under the authority of the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*); and

(iii) Provides for reporting of the results of the monitoring to the covered entity, excluding any licensed health care professional or board certified genetic counselor involved in the genetic monitoring program, only in aggregate terms that do not disclose the identity of specific individuals.

(6) Where an employer conducts DNA analysis for law enforcement purposes as a forensic laboratory or for purposes of human remains identification and requests or requires genetic information of its employees, apprentices, or trainees, but only to the extent that the genetic information is used for analysis of DNA identification markers for quality control to detect sample contamination and is maintained and disclosed in a manner consistent with such use.

(c) *Inquiries Made of Family Members Concerning a Manifested Disease, Disorder, or Pathological Condition.* (1) A covered entity does not violate this section when it requests, requires, or purchases information about a manifested disease, disorder, or pathological condition of an employee, member, or apprenticeship program participant whose family member is an employee for the same employer, a member of the same labor organization, or a participant in the same apprenticeship program. For example, an employer will not violate this section by asking someone whose sister also works for the employer to take a post-offer medical examination that does not include requests for genetic information.

(2) A covered entity does not violate this section when it requests, requires, or purchases genetic information or

information about the manifestation of a disease, disorder, or pathological condition of an individual's family member who is receiving health or genetic services on a voluntary basis. For example, an employer does not unlawfully acquire genetic information about an employee when it asks the employee's family member who is receiving health services from the employer if her diabetes is under control.

(d) *Medical examinations related to employment.* The prohibition on acquisition of genetic information, including family medical history, applies to medical examinations related to employment. A covered entity must tell health care providers not to collect genetic information, including family medical history, as part of a medical examination intended to determine the ability to perform a job, and must take additional reasonable measures within its control if it learns that genetic information is being requested or required. Such reasonable measures may depend on the facts and circumstances under which a request for genetic information was made, and may include no longer using the services of a health care professional who continues to request or require genetic information during medical examinations after being informed not to do so.

(e) A covered entity may not use genetic information obtained pursuant to subparagraphs (b) or (c) of this section to discriminate, as defined by §§ 1635.4, 1635.5, or 1635.6, and must keep such information confidential as required by § 1635.9.

§ 1635.9 Confidentiality.

(a) *Treatment of genetic information.* (1) A covered entity that possesses genetic information in writing about an employee or member must maintain such information on forms and in medical files (including where the information exists in electronic forms and files) that are separate from personnel files and treat such information as a confidential medical record.

(2) A covered entity may maintain genetic information about an employee or member in the same file in which it maintains confidential medical information subject to section 102(d)(3)(B) of the Americans with Disabilities Act, 42 U.S.C. 12112(d)(3)(B).

(3) Genetic information that a covered entity receives orally need not be reduced to writing, but may not be disclosed, except as permitted by this part.

(4) Genetic information that a covered entity acquires through sources that are commercially and publicly available, as provided by, and subject to the limitations in, 1635.8(b)(4) of this part, is not considered confidential genetic information, but may not be used to discriminate against an individual as described in §§ 1635.4, 1635.5, or 1635.6 of this part.

(5) Genetic information placed in personnel files prior to November 21, 2009 need not be removed and a covered entity will not be liable under this part for the mere existence of the information in the file. However, the prohibitions on use and disclosure of genetic information apply to all genetic information that meets the statutory definition, including genetic information requested, required, or purchased prior to November 21, 2009.

(b) *Exceptions to limitations on disclosure.* A covered entity that possesses any genetic information, regardless of how the entity obtained the information (except for genetic information acquired through commercially and publicly available sources), may not disclose it except:

(1) To the employee or member (or family member if the family member is receiving the genetic services) about whom the information pertains upon receipt of the employee's or member's written request;

(2) To an occupational or other health researcher if the research is conducted in compliance with the regulations and protections provided for under 45 CFR part 46;

(3) In response to an order of a court, except that the covered entity may disclose only the genetic information expressly authorized by such order; and if the court order was secured without the knowledge of the employee or member to whom the information refers, the covered entity shall inform the employee or member of the court order and any genetic information that was disclosed pursuant to such order;

(4) To government officials investigating compliance with this title if the information is relevant to the investigation;

(5) To the extent that such disclosure is made in support of an employee's compliance with the certification provisions of section 103 of the Family and Medical Leave Act of 1993 (29 U.S.C. 2613) or such requirements under State family and medical leave laws; or

(6) To a Federal, State, or local public health agency only with regard to information about the manifestation of a disease or disorder that concerns a contagious disease that presents an

imminent hazard of death or life-threatening illness, provided that the individual whose family member is the subject of the disclosure is notified of such disclosure.

(c) *Relationship to HIPAA Privacy Regulations.* Pursuant to § 1635.11(d) of this part, nothing in this section shall be construed as applying to the use or disclosure of genetic information that is protected health information subject to the regulations issued pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

§ 1635.10 Enforcement and remedies.

(a) *Powers and procedures:* The following powers and procedures shall apply to allegations that Title II of GINA has been violated:

(1) The powers and procedures provided to the Commission, the Attorney General, or any person by sections 705 through 707 and 709 through 711 of the Civil Rights Act of 1964, 42 U.S.C. 2000e-4 through 2000e-6 and 2000e-8 through 2000e-10, where the alleged discrimination is against an employee defined in 1635.2(c)(1) of this part or against a member of a labor organization;

(2) The powers and procedures provided to the Commission and any person by sections 302 and 304 of the Government Employees Rights Act, 42 U.S.C. 2000e-16b and 2000e-16c, and in regulations at 29 CFR part 1603, where the alleged discrimination is against an employee as defined in § 1635.2(c)(2) of this part;

(3) The powers and procedures provided to the Board of Directors of the Office of Compliance and to any person under the Congressional Accountability Act, 2 U.S.C. 1301 *et seq.* (including the provisions of Title 3 of that act, 2 U.S.C. 1381 *et seq.*), where the alleged discrimination is against an employee defined in § 1635.2(c)(3) of this part;

(4) The powers and procedures provided in 3 U.S.C. 451 *et seq.*, to the President, the Commission, or any person in connection with an alleged violation of section 3 U.S.C. 411(a)(1), where the alleged discrimination is against an employee defined in § 1635.2(c)(4) of this part;

(5) The powers and procedures provided to the Commission, the Librarian of Congress, and any person by section 717 of the Civil Rights Act, 42 U.S.C. 2000e-16, where the alleged discrimination is against an employee defined in § 1635.2(c)(5) of this part.

(b) *Remedies.* The following remedies are available for violations of GINA sections 202, 203, 204, 205, 206, and 207(f):

(1) Compensatory and punitive damages as provided for, and limited by, 42 U.S.C. 1981a(a)(1) and (b);

(2) Reasonable attorney's fees, including expert fees, as provided for, and limited by, 42 U.S.C. 1988(b) and (c); and

(3) Injunctive relief, including reinstatement and hiring, back pay, and other equitable remedies as provided for, and limited by, 42 U.S.C. 2000e-5(g).

(c) *Posting of Notices.* (1) Every covered entity shall post and keep posted in conspicuous places upon its premises where notices to employees, applicants for employment, and members are customarily posted a notice to be prepared or approved by the Commission setting forth excerpts from or, summaries of, the pertinent provisions of this regulation and information pertinent to the filing of a complaint.

(2) A willful violation of this requirement shall be punishable by a fine of not more than \$100 for each separate offense.

§ 1635.11 Construction.

(a) *Relationship to other laws, generally.* This part does not—

(1) Limit the rights or protections of an individual under any other Federal, State, or local law that provides equal or greater protection to an individual than the rights or protections provided for under this part, including the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 *et seq.*), the Rehabilitation Act of 1973 (29 U.S.C. 701 *et seq.*), and State and local laws prohibiting genetic discrimination or discrimination on the basis of disability;

(2) Apply to the Armed Forces Repository of Specimen Samples for the Identification of Remains;

(3) Limit or expand the protections, rights, or obligations of employees or employers under applicable workers' compensation laws;

(4) Limit the authority of a Federal department or agency to conduct or sponsor occupational or other health research in compliance with the regulations and protections provided for under 45 CFR part 46;

(5) Limit the statutory or regulatory authority of the Occupational Safety and Health Administration or the Mine Safety and Health Administration to promulgate or enforce workplace safety and health laws and regulations; or

(6) Require any specific benefit for an employee or member or a family member of an employee or member (such as additional coverage for a particular health condition that may have a genetic basis) under any group

health plan or health insurance issuer offering group health insurance coverage in connection with a group health plan.

(b) *Relation to certain Federal laws governing health coverage.* (1) *General:* Nothing in GINA Title II provides for enforcement of, or penalties for, violation of any requirement or prohibition of a covered entity subject to enforcement under:

(i) Amendments made by Title I of GINA.

(ii) Section 701(a) of the Employee Retirement Income Security Act (29 U.S.C. 1181) (ERISA), section 2704(a) of the Public Health Service Act, and section 9801(a) of the Internal Revenue Code (26 U.S.C. 9801(a)), as such sections apply with respect to genetic information pursuant to section 701(b)(1)(B) of ERISA, section 2704(b)(1)(B) of the Public Health Service Act, and section 9801(b)(1)(B) of the Internal Revenue Code, respectively, of such sections, which prohibit a group health plan or a health insurance issuer in the group market from imposing a preexisting condition exclusion based solely on genetic information, in the absence of a diagnosis of a condition;

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

(iv) Section 702(b)(1) of ERISA (29 U.S.C. 1182(b)(1)), section 2705(b)(1) of the Public Health Service Act, and section 9802(b)(1) of the Internal Revenue Code (26 U.S.C. 9802(b)(1)), as such sections apply with respect to genetic information as a health status-related factor, which prohibit a group health plan or a health insurance issuer in the group market from discriminating against individuals in premium or contribution rates under the plan or coverage based on genetic information.

(2) *Application.* The application of paragraph (b)(1) of this section is intended to prevent Title II causes of action from being asserted regarding matters subject to enforcement under Title I or the other genetics provisions for group coverage in ERISA, the Public Health Service Act, and the Internal Revenue Code. The firewall seeks to ensure that health plan or issuer provisions or actions are addressed and remedied through ERISA, the Public Health Service Act, or the Internal Revenue Code, while actions taken by

employers and other GINA Title II covered entities are remedied through GINA Title II. Employers and other GINA Title II covered entities would remain liable for any of their actions that violate Title II, even where those actions involve access to health benefits, because such benefits are within the definition of compensation, terms, conditions, or privileges of employment. For example, an employer that fires an employee because of anticipated high health claims based on genetic information remains subject to liability under Title II. On the other hand, health plan or issuer provisions or actions related to the imposition of a preexisting condition exclusion; a health plan's or issuer's discrimination in health plan eligibility, benefits, or premiums based on genetic information; a health plan's or issuer's request that an individual undergo a genetic test; and/or a health plan's or issuer's collection of genetic information remain subject to enforcement under Title I exclusively. For example:

(i) If an employer contracts with a health insurance issuer to request genetic information, the employer has committed a Title II violation. In addition, the issuer may have violated Title I of GINA.

(ii) If an employer directs his employees to undergo mandatory genetic testing in order to be eligible for health benefits, the employer has committed a Title II violation.

(iii) If an employer or union amends a health plan to require an individual to undergo a genetic test, then the employer or union is liable for a violation of Title II. In addition, the health plan's implementation of the requirement may subject the health plan to liability under Title I.

(c) *Relationship to authorities under GINA Title I.* GINA Title II does not prohibit any group health plan or health insurance issuer offering group health insurance coverage in connection with a group health plan from engaging in any action that is authorized under any provision of law noted in § 1635.11(b) of this part, including any implementing regulations noted in § 1635.11(b).

(d) *Relationship to HIPAA Privacy Regulations.* This part does not apply to genetic information that is protected health information subject to the regulations issued by the Secretary of Health and Human Services pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

§ 1635.12 Medical information that is not genetic information.

(a) *Medical information about a manifested disease, disorder, or pathological condition.* (1) A covered entity shall not be considered to be in violation of this part based on the use, acquisition, or disclosure of medical information that is not genetic information about a manifested disease, disorder, or pathological condition of an employee or member, even if the disease, disorder, or pathological

condition has or may have a genetic basis or component.

(2) Notwithstanding paragraph (a)(1) of this section, the acquisition, use, and disclosure of medical information that is not genetic information about a manifested disease, disorder, or pathological condition is subject to applicable limitations under sections 103(d)(1)–(4) of the Americans with Disabilities Act (42 U.S.C. 12112(d)(1)–(4)), and regulations at 29 CFR 1630.13, 1630.14, and 1630.16.

(b) *Genetic information related to a manifested disease, disorder, or pathological condition.*

Notwithstanding paragraph (a) of this section, genetic information about a manifested disease, disorder, or pathological condition is subject to the requirements and prohibitions in sections 202 through 206 of GINA and §§ 1635.4 through 1635.9 of this part.

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