concerning consumer perception of fuel rating labels. Does this new information indicate that the Rule should be modified? If so, why, and how? If not, why not?

(8) Please provide any evidence that has become available since 1993 concerning consumer interest in particular fuel rating issues. Does this new information indicate that the Rule should be modified? If so, why, and how? If not, why not?

(9) What benefits, if any, has the Rule provided to businesses, and in particular to small businesses? What evidence supports the asserted benefits?

(10) What modifications, if any, should be made to the Rule to increase its benefits to businesses, and particularly to small businesses?

(a) What evidence supports your proposed modifications?

(b) How would these modifications affect the costs and benefits of the Rule for consumers?

(c) How would these modifications affect the costs and benefits of the Rule for businesses?

(11) What significant costs, including costs of compliance, has the Rule imposed on businesses, particularly small businesses? What evidence supports the asserted costs?

(12) What modifications, if any, should be made to the Rule to reduce the costs imposed on businesses, and particularly on small businesses?

(a) What evidence supports your proposed modifications?

(b) How would these modifications affect the costs and benefits of the Rule for consumers?

(c) How would these modifications affect the costs and benefits of the Rule for businesses?

(13) What evidence is available concerning the degree of industry compliance with the Rule? Does this evidence indicate that the Rule should be modified? If so, why, and how? If not, why not?

(14) Are any of the Rule's requirements no longer needed? If so, explain. Please provide supporting evidence.

(15) What potentially unfair or deceptive practices concerning the rating, certifying, and posting of the rating of automotive fuels, if any, are not covered by the Rule?

(a) What evidence demonstrates the existence of such practices?

(b) With reference to such practices, should the Rule be modified? If so, why, and how? If not, why not?

(16) What modifications, if any, should be made to the Rule to account for changes in relevant technology, including development of new liquid alternative fuels, or economic conditions?

(a) What evidence supports the proposed modifications?

(b) How would these modifications affect the costs and benefits of the Rule for consumers and businesses, particularly small businesses?

(17) Does the Rule overlap or conflict with other federal, state, or local laws or regulations? If so, how?

(a) What evidence supports the asserted conflicts?

(b) With reference to the asserted conflicts, should the Rule be modified? If so, why, and how? If not, why not?

(c) Is there evidence concerning whether the Rule has assisted in promoting national consistency with respect to the rating, certifying, and posting the rating of automotive fuels? If so, please provide that evidence.

(18) Are there foreign or international laws, regulations, or standards with respect to the rating, certifying, and posting the rating of automotive fuels that the Commission should consider as it reviews the Rule? If so, what are they?

(a) Should the Rule be modified in order to harmonize with these foreign or international laws, regulations, or standards? If so, why, and how? If not, why not?

(b) How would such harmonization affect the costs and benefits of the Rule for consumers and businesses, particularly small businesses?

List of Subjects in 16 CFR Part 306

Fuel ratings, Trade practices.

Authority: 15 U.S.C. 2801 *et seq*; 42 U.S.C. 17021

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. E9–4282 Filed 2–27–09: 8:45 am]

BILLING CODE 6750–01–S

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: Proposed rule.

SUMMARY: The Equal Employment Opportunity Commission (''EEOC'' or ''Commission'') is issuing a proposed rule that would 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 is proposing these rules under that authority to provide all persons subject to Title II of GINA additional guidance with regard to the law's requirements. The Commission invites written comments from members of the public on these proposed rules and on any specific issues related to this proposal.

DATES: Comments regarding this proposal must be received by the Commission on or before May 1, 2009. Please see the section below entitled **ADDRESSES** and **SUPPLEMENTARY INFORMATION** for additional information on submitting comments.

ADDRESSES: You may submit comments by any of the following methods:

By mail to Stephen Llewellyn, Executive Officer, Executive Secretariat, Equal Employment Opportunity Commission, 131 M Street, NE., Suite 6NE03F, 20507.

By facsimile (''FAX'') machine to (202) 663–4114. (There is no toll free FAX number.) Only comments of six or fewer pages will be accepted via FAX transmittal, in order to assure access to the equipment. Receipt of FAX transmittals will not be acknowledged, except that the sender may request confirmation of receipt by calling the Executive Secretariat staff at (202) 663–4070 (voice) or (202) 663–4074 (TTY). (These are not toll free numbers.)

By the Federal eRulemaking Portal: *http://www.regulations.gov*. After accessing this Web site, follow its instructions for submitting comments.

Instructions: All comment submissions must include the agency name and docket number or the Regulatory Information Number (RIN) for this rulemaking. Comments need be submitted in only one of the above-listed formats, not all three. All comments received will be posted without change to *http://www.regulations.gov*, including any personal information you provide. Copies of the received comments also will be available for inspection in the EEOC Library, FOIA Reading Room, by advanced appointment only, from 9 a.m. to 5 p.m., Monday through Friday except legal holidays, from March 2, 2009 until the Commission publishes the rule in final form. Persons who schedule an appointment in the EEOC Library, FOIA Reading Room, and need

assistance to view the comments will be provided with appropriate aids upon request, such as readers or print magnifiers. To schedule an appointment to inspect the comments at the EEOC Library, FOIA Reading Room, contact the EEOC Library by calling (202) 663–4630 (voice) or (202) 663–4641 (TTY). (These are not toll free numbers.)

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 notice also is available in the following formats: large print, Braille, audio tape, and electronic file on computer disk. Requests for this notice 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 Bush signed the Genetic Information Nondiscrimination Act of 2008 (''GINA''), Pub. L. 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, 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 16, 2008).

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 increase, 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 among 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 applies 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] Title I generally prohibits 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 places 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 provides a clarification with respect to the treatment of genetic information under privacy regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Title II of GINA prohibits use of genetic information in the employment context, restricts the deliberate acquisition of genetic information by employers and other entities covered by Title II, 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]

Summary of the Proposed Regulation

GINA section 211, 42 U.S.C. 2000ff–10, requires the EEOC to issue regulations implementing Title II of the Act within one year of its enactment. The Commission is issuing this proposed rule in compliance with this requirement and pursuant to the Administrative Procedures Act, 5 U.S.C. 553. The Commission seeks public comment on the proposed rule, the discussion in this preamble, and other Title II issues not addressed in either document.

The report for the bill introduced into the Senate in 2007 noted that ''[a]s a guiding principle, [GINA] is designed to extend to individuals in the area of genetic discrimination the same procedures and remedies as are provided under Title VII of the Civil Rights Act of 1964, as amended [(''Title VII'')].'' S. Rep. No. 110–48 at 27. Although the Senate and House modified the bill between its initial introduction and final passage, the idea of extending Title VII protections to applicants and employees in the area of genetic information did not change.

In developing this proposed 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 proposed regulation expands on that reference by importing language from these statutes so that those using the proposed 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

[1] These regulations do 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] Currently, Executive Order 13145 prohibits federal executive branch agencies from discriminating against applicants and employees on the basis of genetic information and limits access to and use of genetic information. Upon its effective date in November 2009, GINA will protect federal employees from genetic discrimination.

[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.

test'' refers to ''analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes.'' None of these terms are common to employment discrimination law. For this reason, Commission staff sought and obtained technical assistance from the National Human Genome Research Institute, 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, 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. The HHS Office for Civil Rights is responsible for issuing the regulations applicable to GINA section 105. The National Association of Insurance Commissioners has issued conforming model regulations relating to section 104. 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. Title II of GINA restricts the deliberate acquisition of genetic information by covered entities, prohibits use of genetic information in employment decision-making, requires 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 places strict limits on disclosure of genetic information.

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 proposed regulation describes more fully the employees GINA protects. Moreover, GINA specifically provides that the term ''employee'' includes applicants, *see* 42 U.S.C. 2000ff–1(a)(1), and the Supreme Court has held that the term ''employee'' under Title VII includes former employees. *See Robinson* v. *Shell Oil Co.*, 519 U.S. 337, 346 (1997). Accordingly, the proposed regulation makes clear that the term ''employee'' includes an applicant and a former employee. Similarly, the proposed 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 proposed 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).

The proposed regulation includes a definition of ''covered entity.'' This proposed regulation 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. The proposed regulation uses the term ''covered entity'' when describing the requirements or prohibited practices applicable to all entities subject to Title II of GINA, thus avoiding 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 proposed 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). The term ''covered entity'' in this proposed regulation is not intended to be synonymous with use of the same term in Title I of GINA, in regulations implementing Title I of GINA or HIPAA, or in section 206(c) of GINA (which specifically refers to HIPAA covered entities).

The proposed 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 proposed regulation is appropriate to put 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 proposed regulation provides some additional guidance regarding these terms, and EEOC seeks comment both as to what is, and is not, included in this preamble or in the text of the proposed regulation. The Commission notes that DOL, HHS, and the Treasury have published a Request for Information (RFI) under GINA Title I. *See* 73 FR 60208 (October 10, 2008). All comments submitted under this proposed rule and the RFI are being shared among the Federal Agencies.

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. 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 through marriage, birth, adoption, or placement for adoption.[4]

Second, GINA includes as family members persons related from the first to the fourth degree of an individual. The degree of relationship, which reflects the average proportion of genes in common between two individuals, is determined by counting generational levels separating them. The GINA

[4] 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.

provisions thus include the individual's children, siblings, and parents (first degree) and extend to great-great grandparents and first cousins once removed (the children of a first cousin), as well as family members who are in between the individual and these persons (including parents, siblings, half-siblings, nieces, nephews, grandparents, great grandparents, aunts, uncles, great aunts and uncles, and first cousins).

Section 1635.3(b) Family Medical History

The proposed 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).[5]

[5] 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.

Section 1635.3(c) Genetic Information

GINA section 201(4) and the proposed regulation define genetic information to include information from genetic tests, the genetic tests of family members, family medical history, 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. Genetic information also includes information about an individual's or family member's request for or receipt of genetic services. The statute and proposed regulation exclude from coverage information about an individual's or family member's age or gender.

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 proposed 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.

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 invites comments on the scope of the term ''genetic test.'' The proposed regulation includes two examples of tests that are not genetic: a test for the presence of a virus that is not composed of human DNA, RNA, chromosomes, proteins, or metabolites and a test for drug or alcohol use. Another example of what is not a genetic test and might be mentioned, either in the text of the regulation or in the final preamble, is a test for infectious and communicable diseases that may be transmitted through food handling, which, the Commission believes, is not covered by the definition of ''genetic test.'' Similarly, routine tests such as complete blood counts, cholesterol tests, and liver-function tests would not be protected under GINA. We seek comment as to how the term should be applied, whether the proposed regulation should be more or less expansive, and whether it or the preamble should provide examples of what should be included or excluded.

The Commission further notes that the Title II definition of ''genetic test'' differs from the definition of this term in Title I. Specifically, the Title II definition of ''genetic test'' 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). Title II does not require this language of exclusion because Congress determined that these uses ''are not applicable in the employment context.'' S. Rep. No. 110–48 at 28. 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

We have added a definition of ''manifestation or manifested'' to the proposed regulation, 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 the National Human Genome Research Institute, an Institute within the National Institutes of Health. The proposed regulation defines ''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.

This understanding 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 id.* at 16, and with the notion, discussed above in conjunction with the definition of genetic test (section 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. However, if an individual is diagnosed with a condition, even if the condition relates to genetic information, the plan may impose a preexisting condition exclusion with respect to the condition, subject to other HIPAA portability requirements. *See* 29 CFR 2590.701–3(b)(6)(i). 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 2590.703(b)(6)(ii).

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.

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 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 proposed 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 proposed regulation creates a cause of action for disparate impact. Section 208 of GINA specifically prohibits such actions, and establishes the Genetic Non-Discrimination 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 proposed regulation does not address the establishment of this Commission, which is scheduled to begin its work on May 21, 2014.

Section 1635.6 Causing an Employer To Discriminate

GINA sections 203(c), 204(c), and 205(d) 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 in an effort to affect the individual's employment prospects. Such conduct would violate sections 203(c) and 204(c).

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.

Section 1635.7 Retaliation

The proposed 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 addresses each of the exceptions. Covered entities are cautioned, however, that the use of genetic information to discriminate, no matter how that information may have been acquired, is prohibited.

Inadvertently Requesting or Requiring Genetic Information: First, 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 thus notes 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), or receives an unsolicited e-mail message from a co-worker that includes genetic information.

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 type of acquisition of genetic information 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.

The Commission also understands this exception to apply in any situation in which an employer might inadvertently acquire genetic information, not just situations involving conversations between co-workers that are overheard. The proposed regulation provides an illustrative list of situations where we believe the acquisition comes within Congress's intent. 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 health inquiry (e.g., ''How are you?'') or a question as to whether the individual has a manifested condition. Similarly, a casual question between colleagues, or between a supervisor and supervisee, concerning the health of a parent or child would not violate GINA (e.g., ''How's your son feeling today?'').

A covered entity that asks for family medical history or other genetic information as part of an inquiry or medical examination related to an applicant's or employee's manifested disease, disorder, or pathological condition will not be considered to have acquired such information inadvertently. Thus, even though the ADA allows an employer to require a medical examination of all employees to whom it has offered a particular job, for example, to determine whether they have heart disease that would affect their ability to perform a physically demanding job, GINA would prohibit inquiries about family medical history of heart disease as part of such an examination. Such a limitation will not affect an employer's ability to use a post-offer medical examination for the limited purpose of determining an applicant's current ability to perform a job.

Covered entities should ensure that any medical inquiries they make or any medical examinations they require are modified so as to comply with the requirements of GINA. In particular, we note that at present, the ADA permits employers to obtain medical information, including genetic information, from post-offer job applicants. As we interpret GINA, this will change on the November 21, 2009 effective date of Title II of GINA: Employers no longer will be permitted to obtain *any* genetic information, including family medical history, from post-offer applicants. Employers will likewise be prohibited from obtaining this type of information through any type of medical examination required of employees for the purpose of determining continuing fitness for duty.

However, Title II of GINA will not apply to information obtained by a health care professional in the course of a medical examination, diagnosis, or treatment unrelated to a determination of fitness for duty, except to the extent the information is obtained as part of an employer-provided voluntary wellness program subject to 1635.8(b)(2) of this proposed rule. For example, a doctor working at a hospital may ask for family medical history from a hospital employee who requests a medical examination. *See* 29 CFR 1635.8(b)(2) (allowing collection of genetic information, under certain specified conditions, when an employer offers health or genetic services as part of a voluntary wellness program).

The proposed regulation notes that when a covered entity seeks information from an individual who requests a reasonable accommodation under the ADA or other 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 (e.g., was not overly broad). For information on the type of medical information an employer may lawfully request in connection with a request for 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.* 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 (other than genetic information). The proposed regulation makes it clear that 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, including, for example, where a covered entity received genetic information in connection with the FMLA's employee return to work certification requirements.

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, unless the covered entity's request was overbroad. For example, a request for an employee's entire medical record or the entire medical record related to a particular impairment is likely to include family medical history. An employer who receives family medical history or other genetic information in response to such a broad request would violate GINA. 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, Questions 15–17 (July 27, 2000) (''Enforcement Guidance''), *available at http://www.eeoc.gov/policy/docs/guidance-inquiries.html.*

In addition to complying with relevant EEOC guidance, covered entities may wish to take proactive measures to avoid even the inadvertent acquisition of genetic information. For example, as a best practice, an employer that asks an employee to have a health care professional provide documentation about a disability in support of a request for accommodation could specifically indicate on a questionnaire provided for this purpose that family medical history or other genetic information about the employee should not be provided.

Health or Genetic Services: Second, GINA permits covered entities to offer health or genetic services, and notes that a covered entity that meets specific requirements may offer such services as a part of a wellness program. The proposed regulation reiterates the statutory provision, but further notes that a wellness program seeking medical information must be voluntary, which is a requirement set forth in the ADA. The Commission notes that according to the Enforcement Guidance, a wellness program is voluntary ''as long as an employer neither requires participation nor penalizes employees who do not participate. *Id.,* Question 22. The Commission has not further addressed how the term ''voluntary'' should be defined for purposes of the ADA's application to wellness programs. We invite comments regarding the scope of this term.

The proposed regulation lists the specific requirements in the statute as prerequisites to the acquisition of genetic information when providing genetic services: A request in writing and in language reasonably likely to be understood by the individual from whom the information is sought; a description of the information being requested; and a description of the safeguards in place to protect against unlawful disclosure. The proposed regulation states 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. Although not stated in the proposed regulation, 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.

The Commission notes that although this provision permits covered entities to implement wellness programs that seek family medical history voluntarily, other provisions in GINA Title I place strict limits on the genetic information that group health plans may request or require from covered individuals. In this regard, the Commission further notes that DOL, HHS and the Treasury are responsible for addressing the limitations on group health plans and insurance issuers under Title I. Covered entities that sponsor, establish, or maintain group health plans that implement wellness programs or other health-related services are cautioned to consider carefully whatever limitations these Departments place on group health plans with respect to the acquisition of genetic information.

The Commission also notes that Congress made clear at section 206(c) that GINA's Title II provisions are not to be construed to interfere with or otherwise apply to uses and disclosures of health information that are governed by the privacy regulations promulgated pursuant to HIPAA (''the HIPAA Privacy Rule''). As discussed below, the proposed rule implements this general statutory provision at proposed 1635.11(d) by excluding from coverage genetic information that is health information otherwise protected by the HIPAA Privacy Rule. Consistent with proposed 1635.11(d), the Commission further notes that nothing in section 1635.8 should be read as applying to or otherwise restricting the use or disclosure of genetic information that is protected health information subject to the HIPAA Privacy Rule. Thus, where a health care provider covered by the HIPAA Privacy Rule is providing health or genetic services, that provider is subject to the requirements of the HIPAA Privacy Rule with regard to uses and disclosures of protected health information, including HIPAA's conditions on disclosures to employers, and not this proposed regulation's provisions.

Family and Medical Leave Act: Third, GINA recognizes that individuals requesting leave under the Family and Medical Leave Act (FMLA) or similar state or local law might provide family medical history. For example, an individual requesting FMLA leave to care for a seriously ill relative may disclose family medical history when completing the certification required by section 103 of the FMLA. A covered entity that receives family medical history under these circumstances would not violate GINA. Because this information is still subject to GINA's confidentiality requirements, however, the information must be placed in a separate medical file and must be

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 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 adds to that list information obtained through electronic media, such as the Internet, television, and movies. The exception does not include family medical history 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.'' The Commission invites public comment on whether there are sources similar in kind to those identified in the statute that may contain family medical history 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. Further, we would appreciate comment regarding whether the additional sources that are noted in the proposed regulation should be deemed similar in nature to those contained in the statute so as to remain a part of the regulation.

Genetic Monitoring: Fifth, the statute permits a covered entity to engage in the genetic monitoring of the biological effects of toxic substances in the workplace. The statute and proposed regulation note that monitoring must meet 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, must obtain an individual's prior knowing, written, and voluntary authorization. Second, the proposed regulation describes the type of authorization the employer must provide in order to ensure that it is knowing and voluntary. The authorization 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 noted above in the paragraph addressing genetic services, covered entities that engage in genetic monitoring, particularly when done on a voluntary basis, are cautioned where the monitoring encompasses only a few individuals: Information obtained in the aggregate may make a particular individual's genetic information identifiable.

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 and maintained in a manner consistent with such use.'' This is a very limited exception and, if properly conducted, an employer or training program would not obtain health-related genetic information. The EEOC invites comments on the impact of this exception on law enforcement.

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 the same way they treat medical information generally. That is, covered entities in possession of genetic information must keep the information confidential and, if the information is in writing, must keep it apart from other personnel information in separate medical files.[6] 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.

As noted above, a covered entity does not violate GINA when it acquires genetic information available through publicly available sources. 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 information 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 publicly available sources, 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 publicly available information 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) 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

[6] 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.

requests disclosure in writing. Second, the section states that genetic information may be provided to an occupational health researcher ''if the research is being conducted in compliance with the regulations under'' 45 CFR part 46.

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 and the covered entity must inform the individual about the order and what information it disclosed. This exception does not allow disclosures in other circumstances during litigation, such as in response to discovery requests that are not governed by an order specifying the genetic information that must be disclosed.

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 proposed 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 proposed 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 proposed regulation provide the following:

- The enforcement mechanism applicable and remedies available to employees and others covered by Title VII apply to GINA as well. 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. 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. These 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 proposed 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, the proposed regulation notes that covered entities are required to post notices in conspicuous places describing GINA's applicable provisions. The Commission, prior to GINA's effective date, will publish in the **Federal Register** appropriate language for use in such notices.

Section 1635.11 Construction

GINA section 209 and this section of the proposed 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.

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 40 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.

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, upon the effective date of GINA, 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.

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 for a violation of 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 for a violation or violations of 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. Section 209(a)(1)(B) eliminates ''double liability'' 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 requirements or prohibitions are addressed and remedied through ERISA, the Public Health Service Act, or the Internal Revenue Code and not through Title II and other employment discrimination procedures. The proposed 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.

The Commission notes that the firewall does not immunize covered entities from liability for decisions and actions taken that violate Title II, including employment decisions based on 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, acts or omissions relating to health plan eligibility, benefits, or premiums, or a health plan's request for or collection of genetic information remain subject to enforcement under Title I exclusively.

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 GINA Title I or the provisions identified in GINA section 209(a)(2)(B)(i)–(iv), including any implementing regulations thereunder. The section and the proposed 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

Proposed section 1635.11(d) implements section 206(c) of GINA Title II by providing, as a general rule of construction, that this proposed regulation does not apply to 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.

Section 1635.12 Medical Information That Is Not Genetic Information

The proposed 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 Americans with Disabilities Act, 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.

Regulatory Procedures

Executive Order 12866

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

benefit assessment of the proposed regulation is not required.

Paperwork Reduction Act

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

Regulatory Flexibility Act

Title II of GINA applies to all employers with 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 proposed rule will not have a significant economic impact on a substantial number of small entities because it imposes no reporting burdens and only minimal costs on such firms. 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 the cost of revising post-offer medical questionnaires to eliminate questions about family medical history would not impose significant costs.

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 conducted over 700 outreach events directed specifically toward small businesses, reaching 35,515 small business representatives. In FY 2009, we expect to include information about GINA in our outreach programs in general and to offer numerous GINA-specific outreach programs, once the regulations implementing Title II of GINA become 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 the typical human resources professional 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 $45.00. *See* Bureau of Labor Statistics, Occupational Employment and Wages, May 2007 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 providing appropriate training will be between approximately $135.00 and $675.00, at the high end. EEOC does not believe that this cost will be significant for the impacted small entities.

We urge small entities to submit comments concerning EEOC's estimates of the number of small entities impacted, as well as the cost to those entities.

Unfunded Mandates Reform Act of 1995

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

Dated: February 23, 2009.

For the Commission.

Stuart J. Ishimaru,

Acting Chairman.

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 proposes to amend 29 CFR chapter XIV by adding part 1635 to read as follows:

PART 1635—GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008

Sec.

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

§ 1635.1 Purpose.

The purpose of this part is to implement Title II of the Genetic Information Non-Discrimination Act of 2008, 42 U.S.C. 2000ff, *et seq.* Title II of GINA prohibits use of genetic information in employment decision-making, restricts deliberate acquisition of genetic information, requires that genetic information be maintained as a confidential medical record, and places strict limits on disclosure of genetic information. The law provides remedies for individuals whose genetic information is acquired, used, or disclosed in violation of its protections.

§ 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, children, and half-siblings.

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

(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 or the sex or age of family members.

(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 control adverse environmental exposures in the workplace.

(e) *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.

(i) An analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes is not a genetic test.

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

(2) *Alcohol and drug testing.* (i) A test for the presence of alcohol or 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 or on the results of one or more genetic tests.

§ 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.

(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 an employer to discriminate.

An employment agency, labor organization, or joint labor-management training or apprenticeship program may not cause or attempt to cause an employer, 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, except as specifically provided in paragraph (b) of this section.

(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. This exception to the acquisition of genetic information applies in, but is not necessarily limited to, situations where—

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

(ii) A manager, supervisor, union representative, or employment agency personnel learns genetic information about an individual by receiving it from the individual or third-parties without having solicited or sought the information;

(iii) An individual provides genetic information as part of 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;

(iv) An employer requests medical information (other than genetic information) as permitted by Federal, State, or local law from an individual, who responds by providing, among other information, genetic information;

(v) An individual provides genetic information 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; or

(vi) A covered entity 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;

(2) Where a covered entity offers health or genetic services, including such services offered as part of a voluntary wellness program. This exception applies only where—

(i) The individual provides prior knowing, voluntary, and written authorization 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 type of genetic information that will be obtained and the general purposes for which it will be used; and

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

(ii) 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 professional or board certified genetic counselor involved in providing such services; and

(iii) 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.

(3) Where the employer 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.

(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 a covered entity may not research medical databases or court records, even where such databases may be publicly and commercially available, for the purpose of obtaining genetic information about an individual.

(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. This exception further provides that such monitoring:

(i) Either is required by federal or state law, or conducted only where an individual gives prior knowing, voluntary and written authorization to the monitoring 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;

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

(ii) Ensures that the individual is informed of individual monitoring results;

(iii) 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

(iv) 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 that conducts DNA analysis for law enforcement purposes as a forensic laboratory or for purposes of human remains identification 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 maintained in a manner consistent with such use.

(c) A covered entity may not use genetic information obtained pursuant to the exceptions in § 1635.8(b) of this part 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 publicly available sources, as provided by § 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.

(b) *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 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 individual to whom the information refers, the covered entity shall inform the individual 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).

§ 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.* 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 for a violation of:

(1) Amendments made by Title I of GINA.

(2) Section 701(a) of the Employee Retirement Income Security Act (29 U.S.C. 1181) (ERISA), section 2701(a) of the Public Health Service Act (42 U.S.C. 300gg(a)), 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 29 U.S.C. 1181(b)(1)(B), 42 U.S.C. 300gg(b)(1)(B), and 26 U.S.C. 9801(b)(1)(B), 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;

(3) Section 702(a)(1)(F) of ERISA (29 U.S.C. 1182(a)(1)(F)), section 2702(a)(1)(F) of the Public Health Service Act (42 U.S.C. 300gg–1(a)(1)(F)), 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

(4) Section 702(b)(1) of ERISA (29 U.S.C. 1182(b)(1)), section 2702(b)(1) of the Public Health Service Act (42 U.S.C. 300gg–1(b)(1), 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.

(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 1635.7 and 1635.9 of this part.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 160, 161, 164, and 165

[USCG–2005–21869]

RIN 1625–AA99

Vessel Requirements for Notices of Arrival and Departure, and Automatic Identification System

AGENCY: Coast Guard, DHS.

ACTION: Notice of second public meeting; request for comments.

SUMMARY: In response to requests received, the Coast Guard announces a second public meeting, to be held March 25, 2009, in Seattle, WA, to receive comments on a notice of proposed rulemaking to amend Coast Guard regulations governing Notice of Arrival and Departure (NOAD) and Automatic Identification System (AIS) requirements. This is an additional meeting to the one previously announced for March 5, 2009, in Washington, DC.

DATES: A public meeting will be held in Seattle, WA, on March 25, 2009, from 1 p.m. to 3:30 p.m. The comment period for the proposed rule closes April 15, 2009. All written comments and related material must be received by the Coast Guard on or before April 15, 2009.

ADDRESSES: The March 25, 2009, public meeting will be held at the following location:

• Seattle, WA—Henry M. Jackson Federal Building, 915 Second Ave., Fourth Floor North Auditorium, Seattle, WA 98174–1067.

A government-issued photo identification will be required for entrance to the building.

Written comments and related material may also be submitted to Coast Guard personnel specified at that meeting. All comments and related material submitted after the meeting must be submitted using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov* under docket number USCG–2005–21869.

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods.

FOR FURTHER INFORMATION CONTACT: If you have questions concerning the NOAD portion of this proposed rulemaking or concerning the public meeting, please contact Lieutenant Sharmine Jones, Office of Vessel Activities (CG–543), Coast Guard, *Sharmine.N.Jones@uscg.mil*, telephone 202–372–1234. If you have questions on the AIS portion of this proposed rulemaking, contact Mr. Jorge Arroyo, Office of Navigation Systems (CG–5413), Coast Guard, *Jorge.Arroyo@uscg.mil*, telephone 202–372–1563. If you have questions on viewing or submitting material to the docket, call Ms. Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Background and Purpose

We published a notice of proposed rulemaking (NPRM) in the **Federal Register** on December 16, 2008 (73 FR 76295), entitled ''Vessel Requirements for Notices of Arrival and Departure, and Automatic Identification System.'' In it we stated our intention to hold a public meeting, and to publish a notice to announce the location and date of the public meeting. 73 FR 76296. In this notice, we announce an additional public meeting, to the one previously announced for March 5, 2009, in Washington, DC (74 FR 7534), to receive comments on this proposed rule.

In the NPRM, we proposed to expand the applicability of Notice of Arrival and Departure (NOAD) and Automatic Identification System (AIS) requirements to more commercial vessels, modify NOAD reporting requirements, establish a mandatory method for electronic data submission and establish a separate requirement for certain vessels to submit notices of departure. The proposed rulemaking would also clarify existing AIS requirements and extend the applicability of AIS requirements to additional vessels and beyond Vessel Traffic Service areas to all U.S. navigable waters.

You may view the NPRM in our online docket, in addition to supporting documents prepared by the Coast Guard (Regulatory Analysis & Initial Regulatory Flexibility Analysis, Valuing Mortality Risk Reductions in Homeland Security Regulatory Analyses—Final Report June 2008, and an Environmental Checklist), and comments submitted thus far by going to *http://www.regulations.gov.* Once there, select the Advanced Docket Search option on the right side of the screen, insert USCG–2005–21869 in the Docket ID box, press Enter, and then click on the item in the Docket ID column. If you do not have access to the Internet, you may view the docket by visiting the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

We encourage you to participate in this rulemaking by submitting comments either orally at the meeting or in writing. If you bring written comments to the meeting, you may submit them to Coast Guard personnel specified at the meeting to receive written comments. These comments will be submitted to our online public docket. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Information on Service for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the public meeting, contact Lieutenant Sharmine Jones at the telephone number indicated under the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Public Meeting

The Coast Guard will hold a public meeting regarding this proposed rulemaking on March 25, 2009, from 1 p.m. to 3:30 p.m., in Seattle, WA, at the Henry M. Jackson Federal Building, 915 Second Ave., Fourth Floor North Auditorium, Seattle, WA 98174–1067.