

Equal Employment Opportunity Comm.

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The purpose of this provision is to permit the development and administration of benefit plans in accordance with accepted principles of risk assessment. This provision is not intended to disrupt the current regulatory structure for self-insured employers. These employers may establish, sponsor, observe, or administer the terms of a bona fide benefit plan not subject to State laws that regulate insurance. This provision is also not intended to disrupt the current nature of insurance underwriting, or current insurance industry practices in sales, underwriting, pricing, administrative and other services, claims and similar insurance related activities based on classification of risks as regulated by the States.

The activities permitted by this provision do not violate part 1630 even if they result in limitations on individuals with disabilities, provided that these activities are not used as a subterfuge to evade the purposes of this part. Whether or not these activities are being used as a subterfuge is to be determined without regard to the date the insurance plan or employee benefit plan was adopted.

However, an employer or other covered entity cannot deny an individual with a disability who is qualified equal access to insurance or subject an individual with a disability who is qualified to different terms or conditions of insurance based on disability alone, if the disability does not pose increased risks. Part 1630 requires that decisions not based on risk classification be made in conformity with non-discrimination requirements. See Senate Report at 84-86; House Labor Report at 136-138; House Judiciary Report at 70-71. See the discussion of § 1630.5 Limiting, Segregating and Classifying.

[56 FR 35734, July 26, 1991, as amended at 65 FR 36327, June 8, 2000; 76 FR 17003, Mar. 25, 2011; 81 FR 31140, May 17, 2016; 89 FR 55521, July 5, 2024]

PART 1635—GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008

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

SOURCE: 75 FR 68932, Nov. 9, 2010, unless otherwise noted.

§ 1635.1 Purpose.

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

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

(2) Restricts employers and other entities subject to Title II of GINA from requesting, requiring, or purchasing genetic information;

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

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

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

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

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

§ 1635.2 Definitions—general.

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

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

(c) *Employee* means an individual employed by a covered entity, as well as an applicant for employment and a

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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 At-

mospheric Administration Commissioned Corps, the Government Printing Office, and the Smithsonian Institution; an employee of the federal judicial branch having a position in the competitive service; and an employee of the Library of Congress.

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

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

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

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

(h) *Labor organization* is defined at 42 U.S.C. 2000e(d) to mean an organization with fifteen or more members engaged in an industry affecting commerce, and any agent of such an organization in which employees participate and which exists for the purpose, in whole or in

part, of dealing with employers concerning grievances, labor disputes, wages, rates of pay, hours, or other terms or conditions of employment.

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

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

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

§ 1635.3 Definitions specific to GINA.

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

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

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

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

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

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

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

(b) *Family medical history*. Family medical history means information about the manifestation of disease or

disorder in family members of the individual.

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

(i) An individual's genetic tests;

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

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

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

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

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

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

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

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

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

(i) A test to determine whether someone has the BRCA1 or BRCA2 variant evidencing a predisposition to breast cancer, a test to determine whether

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someone has a genetic variant associated with hereditary nonpolyposis colon cancer, and a test for a genetic variant for Huntington's Disease;

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

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

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

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

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

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

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

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

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

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

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

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

(4) Alcohol and Drug Testing—

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

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

(g) *Manifestation* or *manifested* means, with respect to a disease, disorder, or pathological condition, that an indi-

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

§ 1635.4 Prohibited practices—in general.

(a) It is unlawful for an employer to discriminate against an individual on the basis of the genetic information of the individual in regard to hiring, discharge, compensation, terms, conditions, or privileges of employment.

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

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

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

§ 1635.5 Limiting, segregating, and classifying.

(a) A covered entity may not limit, segregate, or classify an individual, or fail or refuse to refer for employment any individual, in any way that would deprive or tend to deprive the individual of employment opportunities or otherwise affect the status of the individual as an employee, because of genetic information with respect to the individual. A covered entity will not be deemed to have violated this section if it limits or restricts an employee's job

duties based on genetic information because it was required to do so by a law or regulation mandating genetic monitoring, such as regulations administered by the Occupational and Safety Health Administration (OSHA). See 1635.8(b)(5) and 1635.11(a).

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

§ 1635.6 Causing a covered entity to discriminate.

A covered entity may not cause or attempt to cause another covered entity, or its agent, to discriminate against an individual in violation of this part, including with respect to the individual's participation in an apprenticeship or other training or retraining program, or with respect to a member's participation in a labor organization.

§ 1635.7 Retaliation.

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

§ 1635.8 Acquisition of genetic information.

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

(b) *Exceptions.* The general prohibition against requesting, requiring, or

purchasing genetic information does not apply:

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

(i) Requests for Medical Information:

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

(B) If a covered entity uses language such as the following, any receipt of genetic information in response to the request for medical information will be deemed inadvertent: "The Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits employers and other entities covered by GINA Title II from requesting or requiring genetic information of an individual or family member of the individual, except as specifically allowed by this law. To comply with this law, we are asking that you not provide any genetic information when responding to this request for medical information. 'Genetic information' as defined by GINA, includes an individual's family medical history, the results of an individual's or family member's genetic tests, the fact that an individual or an individual's family member sought or received genetic services, and genetic information of a fetus carried by an individual or an individual's family member or an embryo lawfully held by an individual or family member receiving assistive reproductive services."

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

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

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

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

(3) Where a covered entity requests documentation to support a request for leave that is not governed by Federal, State, or local laws requiring leave, as long as the documentation required to support the request otherwise complies with the requirements of the Americans with Disabilities Act and other laws limiting a covered entity's access to medical information.

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

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

(B) A manager, supervisor, union representative, or employment agency representative learns genetic information about an individual by receiving it from the individual or third-parties during a casual conversation, including

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

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

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

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

(i) This exception applies only where—

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

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

(C) The individual provides prior knowing, voluntary, and written authorization, which may include authorization in electronic format. This re-

quirement is only met if the covered entity uses an authorization form that:

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

(2) Describes the type of genetic information that will be obtained and the general purposes for which it will be used; and

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

(D) Individually identifiable genetic information is provided only to the individual (or family member if the family member is receiving genetic services) and the licensed health care professionals or board certified genetic counselors involved in providing such services, and is not accessible to managers, supervisors, or others who make employment decisions, or to anyone else in the workplace; and

(E) Any individually identifiable genetic information provided under paragraph (b)(2) of this section is only available for purposes of such services and is not disclosed to the covered entity except in aggregate terms that do not disclose the identity of specific individuals (a covered entity will not violate the requirement that it receive information only in aggregate terms if it receives information that, for reasons outside the control of the provider or the covered entity (such as the small number of participants), makes the genetic information of a particular individual readily identifiable with no effort on the covered entity's part).

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

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the participant answers questions regarding genetic information.

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

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

(iii) [Reserved]

(iv) A covered entity may not, however, condition participation in an employer-sponsored wellness program or provide any inducement to an employee, or the spouse or other covered dependent of the employee, in exchange for an agreement permitting the sale, exchange, sharing, transfer, or other disclosure of genetic information, including information about the manifestation of disease or disorder of an employee's family member (except to the extent permitted by paragraph (b)(2)(i)(D) of this section, or otherwise waiving the protections of §1635.9.

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

(vi) A covered entity may offer financial inducements to encourage individuals who have voluntarily provided genetic information (*e.g.*, family medical history) that indicates that they are at increased risk of acquiring a health condition in the future to participate in disease management programs or

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

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

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

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

CFR 1630.2(o)(1)(iii) and 29 CFR 1630.9(a). In addition, if the employer's wellness program provides (directly, through reimbursement, or otherwise) medical care (including genetic counseling), the program may constitute a group health plan and must comply with the special requirements for employer-sponsored wellness programs that condition rewards on an individual satisfying a standard related to a health factor, including the requirement to provide an individual with a reasonable alternative (or waiver of the otherwise applicable standard) under HIPAA, when it is unreasonably difficult due to a medical condition to satisfy or medically inadvisable to attempt to satisfy the otherwise applicable standard. See section 9802 of the Internal Revenue Code (26 U.S.C. 9802, 26 CFR 54.9802-1 and 54.9802-3T), section 702 of the Employee Retirement Income Security Act of 1974 (ERISA) (29 U.S.C. 1182, 29 CFR 2590.702 and 2590.702-1), and section 2705 of the Public Health Service (PHS) Act (45 CFR 146.121, 146.122, and 147.110), as amended by section 1201 of the Affordable Care Act.

(3) Where the covered entity requests family medical history to comply with the certification provisions of the Family and Medical Leave Act of 1993 (29 U.S.C. 2601 *et seq.*) or State or local family and medical leave laws, or pursuant to a policy (even in the absence of requirements of Federal, State, or local leave laws) that permits the use of leave to care for a sick family member and that requires all employees to provide information about the health condition of the family member to substantiate the need for leave.

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

- (i) To medical databases, court records, or research databases available to scientists on a restricted basis;
- (ii) To genetic information acquired through sources with limited access,

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

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

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

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

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

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

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

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

(ii) Is conducted in compliance with any Federal genetic monitoring regulations, including any regulations that may be promulgated by the Secretary

of Labor pursuant to the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*), the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 *et seq.*), or the Atomic Energy Act of 1954 (42 U.S.C. 2011 *et seq.*); or State genetic monitoring regulations, in the case of a State that is implementing genetic monitoring regulations under the authority of the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*); and

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

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

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

(2) A covered entity does not violate this section when it requests, requires, or purchases genetic information or information about the manifestation of a disease, disorder, or pathological condition of an individual's family member who is receiving health or genetic

services on a voluntary basis, as long as the requirements of paragraph (b)(2) of this section, including those concerning authorization and inducements, are met. For example, an employer does not unlawfully acquire genetic information about an employee when it asks the employee's family member who is receiving health services from the employer if her diabetes is under control. Nor does an employer unlawfully acquire genetic information about an employee when it seeks information—through a medical questionnaire, a medical examination, or both—about the manifestation of disease, disorder, or pathological condition of the employee's family member who is completing a health risk assessment on a voluntary basis in connection with the family member's receipt of health or genetic services (including health or genetic services provided as part of an employer-sponsored wellness program) offered by the employer in compliance with paragraph (b)(2) of this section.

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

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

[75 FR 68932, Nov. 9, 2010, as amended at 81 FR 31157, May 17, 2016; 83 FR 65297, Dec. 20, 2018]

§ 1635.9 Confidentiality.

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

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

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

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

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

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

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

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

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

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

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

(6) To a Federal, State, or local public health agency only with regard to information about the manifestation of a disease or disorder that concerns a contagious disease that presents an imminent hazard of death or life-threatening illness, provided that the individual whose family member is the subject of the disclosure is notified of such disclosure.

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

§ 1635.10 Enforcement and remedies.

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

(1) The powers and procedures provided to the Commission, the Attorney General, or any person by sections 705 through 707 and 709 through 711 of the Civil Rights Act of 1964, 42 U.S.C. 2000e-4 through 2000e-6 and 2000e-8 through

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2000e-10, where the alleged discrimination is against an employee defined in 1635.2(c)(1) of this part or against a member of a labor organization;

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

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

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

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

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

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

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

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

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

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tion and information pertinent to the filing of a complaint.

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

§ 1635.11 Construction.

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

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

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

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

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

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

(6) Require any specific benefit for an employee or member or a family member of an employee or member (such as additional coverage for a particular health condition that may have a genetic basis) under any group health plan or health insurance issuer offering group health insurance coverage in connection with a group health plan.

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

(i) Amendments made by Title I of GINA.

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

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

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

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

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

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

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

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

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

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(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.

[75 FR 68932, Nov. 9, 2010, as amended at 81 FR 31159, May 17, 2016]

§ 1635.12 Medical information that is not genetic information.

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

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

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

PART 1636—PREGNANT WORKERS FAIRNESS ACT

- Sec.
1636.1 Purpose.
1636.2 Definitions—general.
1636.3 Definitions—specific to the PWFA.
1636.4 Nondiscrimination with regard to reasonable accommodations related to pregnancy.
1636.5 Remedies and enforcement.

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- 1636.6 Waiver of State immunity.
1636.7 Relationship to other laws.
1636.8 Severability.

APPENDIX A TO PART 1636—INTERPRETIVE GUIDANCE ON THE PREGNANT WORKERS FAIRNESS ACT

AUTHORITY: 42 U.S.C. 2000gg *et seq.*

SOURCE: 89 FR 29182, Apr. 19, 2024, unless otherwise noted.

§ 1636.1 Purpose.

(a) The purpose of this part is to implement the Pregnant Workers Fairness Act, 42 U.S.C. 2000gg *et seq.* (PWFA).

(b) The PWFA:

(1) Requires a covered entity to make reasonable accommodation to the known limitations of a qualified employee related to pregnancy, childbirth, or related medical conditions, absent undue hardship;

(2) Prohibits a covered entity from requiring a qualified employee to accept an accommodation, other than a reasonable accommodation arrived at through the interactive process;

(3) Prohibits the denial of employment opportunities based on the need of the covered entity to make reasonable accommodation to the known limitations related to the pregnancy, childbirth, or related medical conditions of a qualified employee;

(4) Prohibits a covered entity from requiring a qualified employee to take leave if another reasonable accommodation can be provided to the known limitations related to the pregnancy, childbirth, or related medical conditions of the employee;

(5) Prohibits a covered entity from taking adverse actions in terms, conditions, or privileges of employment against a qualified employee on account of the employee requesting or using a reasonable accommodation for known limitations related to pregnancy, childbirth, or related medical conditions;

(6) Prohibits discrimination against an employee for opposing unlawful discrimination under the PWFA or participating in a proceeding under the PWFA;

(7) Prohibits coercion of individuals in the exercise of their rights under the PWFA; and