

# Genetic Information Nondiscrimination Act (GINA) Compliance Guide

*An in-depth analysis of a new federal law that prohibits discrimination in health benefits and employment based upon an individual's genetic information. This plain language guidebook is intended to help you ensure your organization's complete compliance with this complex law.*



# **Genetic Information Nondiscrimination Act (GINA) Compliance Guide**

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# Introduction

About this Guidebook / Disclaimer

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On May 21, 2008, the Genetic Information Nondiscrimination Act of 2008 (GINA), referred to by its sponsors as the first civil rights act of the 21st century, was enacted. GINA prohibits discrimination based on genetic information by health insurers and employers. Title I of GINA addresses the use of genetic information in health insurance. Title II prohibits the **use** of genetic information in employment, restricts employers from **requesting, requiring, or purchasing** genetic information, and strictly limits the **disclosure** of genetic information.

GINA requires the Equal Employment Opportunity Commission (EEOC) to issue regulations implementing Title II of the Act, which it did on November 9, 2010 with an effective date of **January 10, 2011**.

The sequencing of the human genome and subsequent advances raise hope for genetic therapies to cure disease, but this scientific accomplishment is not without potential problems. An employer or health insurer could decide to take adverse action based on a genetic predisposition to disease. In addition, there is evidence that the fear of genetic discrimination has an adverse effect on those seeking genetic testing, as well as on participation in genetic research. GINA was enacted to remedy this situation.

Employers can learn an employee's genetic information through genetic testing, company medical exams, family history, or medical records. In addition, employers who self-insure have unique access to medical information. Some employers may seek to use genetic tests to discriminate against workers - even those who have not yet or who may never show signs of disease-because the employers fear the cost consequences. Based on genetic information, employers may try to avoid hiring workers who they believe are likely to take sick leave, resign, or retire early for health reasons (creating extra costs in recruiting and training new staff), file for workers' compensation, or use health care benefits excessively.

This guidebook provides background on genetic information, legal implications regarding the use of this information, and relevant laws. It also discusses the statutory provisions of GINA. An anti-discrimination/harassment policy as outlined herein can only be effective if taken seriously and followed through. Each company is unique. The needs of your company should be examined and implemented into the program in order to make it successful. It is essential that the employer demonstrate at all times their personal concern for their employees and the priority placed on them in your workplace. The policy must be clear. The employer shows its importance through their own actions.

Although federal law requires at least 15 employees on staff to file a discrimination claim, individual state law may allow a discrimination claim with as little as one employee. Therefore, even if a

company has less than 15 employees, a discrimination claim can still be filed with either the state's administrative agency, in court or both. Employers can abide by the federal laws outlined by the EEOC to ensure that they are in compliance with their state laws.

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## Implementation Procedures

The following implementation procedures are intended to provide specific instructions for correctly utilizing the various components of our Genetic Information Nondiscrimination Act Compliance Kit. If you have additional questions about this guidebook or other kit components, please contact Personnel Concepts at 800-333-3795.

1. Post the enclosed “What you need to know about Genetic Information Nondiscrimination” Poster conspicuously in the workplace where notices to employees are customarily posted. The purpose of this poster is to acknowledge your coverage under GINA and Title VII and to notify affected workers that genetic information discrimination is strictly prohibited in the workplace.
2. Review the Legal Brief addressing Genetic Information Nondiscrimination and Frequently Asked Questions that are included in this section. This overview is intended to ensure that you understand your establishment’s obligations under current genetic information discrimination law.
3. Review Chapter 2, “Title I of GINA – Health Insurance Provisions” with the individuals in your business who coordinate the health insurance benefits for employees so that they are knowledgeable about the legal practices of providers.
4. Review Chapter 3, “Title II of GINA – Employment Related Provisions” with the individuals in your business who are responsible for recruiting, hiring, employment policies, and time-off requests
5. Distribute the enclosed Genetic Information Training Handouts to supervisors, managers, and other affected individuals to ensure that your workforce understands what constitutes unlawful genetic information discrimination.
6. Refer to the “Regulatory Text” in Chapter on an as-needed basis when making employment decisions about individuals with genetic information issues or when receiving a complaint from a protected individual.
7. Utilize the “Sample Policies” in Chapter 5 to help in constructing a written Genetic Information Nondiscrimination policy for your workplace. Once your policy has been created, communicate the policy to your employees.
8. Use the enclosed GINA Policy Acknowledgement forms to document that each employee has read and understands the policy. This documentation can be used as evidence, in case of a lawsuit, that you adequately addressed genetic information nondiscrimination.
9. Reference Chapter 6, “Federal and State Laws” to address additional Federal or specific state laws that may apply to your workplace.
10. Contact a Compliance Specialist at 800-333-3795 to inquire about other products pertaining to employment discrimination, including the EEO Compliance Program, the Space Saver-7 All-On-One Workplace Policy Poster, and the Harassment in the Workplace Program.



## Legal Brief Addressing Genetic Information Nondiscrimination Act (2008) and the Final Rule – Guide for Employers

By Jessica Nogara, Esq.

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The *Genetic Information Nondiscrimination Act (GINA)* was specifically enacted to create a consistent level of protection against discrimination on the basis of genetic information across the United States. Title II of *GINA* prohibits such discrimination in the workplace and imposes restrictions on the acquisition and disclosure of genetic information. It applies to all Federal and state employers, all private employers with 15 or more employees and all employment agencies, labor organizations and joint-labor-management training programs.

The Equal Employment Opportunity Commission (EEOC) issued proposed regulations on March 2, 2009 with a request for comments on the regulations from interested parties and stakeholders. After a deliberation of public comments, a final rule was issued by the EEOC on November 9, 2010, which becomes effective on January 10, 2011.

### **Prohibitions under Title II**

Title II prohibits two kinds of unlawful employment practices with respect to job applicants, employees, and trainees and apprentices undertaking training programs:

(a) **Discrimination based on genetic information:** an employer must not fail or refuse to hire, or discharge, an employee, or otherwise discriminate against any employee with respect to compensation, terms, conditions or privileges of employment because of the employee's genetic information.

(b) Additionally, an employer must not limit, segregate, or employee of employment opportunities, or otherwise adversely affects their status of employment, because of genetic information with respect to the employee.

(c) **Acquisition of genetic information:** an employer must not request, require or purchase genetic information with respect to an employee, except under the following limited circumstances:

a. where genetic information was made available as a result of the employer's *inadvertent* request for, or requirement of, the family medical history of the employee or any family members. Called the "water-cooler" exception, this may apply to general or casual conversations between an employee and an employer, or in situations where the two parties are discussing a personal welfare issue of the employee, in which it transpires that a genetic malady of the employee or the employee's family is a cause for concern, and it was not the employer's intent to solicit his information.

b. where the employer offers health or genetic services to its employees, including those offered as part of a wellness program, and an employee provides prior, knowing, voluntary and written authorization with respect to the genetic services. Any genetic information

provided that represents *individually identifiable information* must be received by, and is available only to, the employee, and the licensed health care professional or board certified genetic counselor involved in the treatment, and must not be disclosed to the employer except in aggregate terms that do not disclose the identity of specific employees.

c. where the employer requests or requires family medical history from the employee to comply with Federal or State law with respect to family and medical leave eg, *Family and Medical Leave Act of 1993*;

d. where the employer purchases documents that are commercially and publicly available, including newspapers and magazines, periodicals and books, but not medical databases or court records, that include family medical history;

e. where the genetic information is used for genetic monitoring of the biological effects of toxic substances in the work place, and written notice of such genetic monitoring is provided to its employees, and either an employee provides prior, knowing, voluntary, and written authorization, or the genetic monitoring is required by Federal or State laws. Such genetic monitoring must be in compliance with any Federal or State genetic monitoring individual monitoring results, and the employer (excluding any licensed health care professional, or board certified genetic counselor involved in the genetic monitoring program) receives the results only in aggregate terms that do not disclose the identity of specific employees. The justification for this provision is for the maintenance of the personal welfare of the employee, and potential for compensation in the case of injury.

f. where the 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 from its employees for quality control.

Any genetic information collected or acquired by the employer under the exceptions above cannot be used to discriminate against the employee, and a prohibition against retaliation for opposing any unlawful act or practice, for filing a complaint, testifying, assisting or participating in investigations, proceedings or hearings under the Act.

At this stage, “disparate impact”, being discrimination through *application or impact of* a workplace policy, on the basis of genetic information does not give rise to a cause of action under Title II. Instead, the Act provides for a commission to be established 6 years after the date of enactment of *GINA* to review and make recommendations with respect to whether such discrimination should be made a cause of action under Title II.

Title II works in tandem with existing state and other Federal laws – where the level of protection in a state is less than that provided by *GINA*, the minimum level of protection will be that of the Federal Act. However, where the level of protection under state laws is greater than that provided by *GINA*, the additional protections afforded to the employee in the relevant state will not be effected.

## ***Meaning of Genetic Information***

It is important to note that *GINA* relates only to genetic information. The Act provides that “genetic information” encompasses the following types of information or requests:

- (a) information about an employee’s genetic tests;
- (b) information about the genetic tests of a employee’s family members, including a dependent or any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative;
- (c) information about the genetic tests of any fetus being carried by a pregnant woman who is an employee or a family member of an employee, or of any embryo legally held by an employee or a family member;
- (d) information on the manifestation of a disease or disorder in family members of the employee (*but not the employee*); and
- (e) any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual. Such genetic services include the following:
  - a. genetic test, meaning an analysis of human DNA, RNA, chromosomes, proteins or metabolites that detects genotypes, mutations or chromosomal changes, but the term does not include any analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes;
  - b. genetic counseling; and
  - c. genetic education.

Genetic information *does not* include information about the sex or age of any individual. Moreover, an employer shall not be considered in violation of Title II for the use, acquisition, or disclosure of medical information about a manifested disease, disorder, or pathological condition of an employee, including a manifested disease, disorder, or pathological condition that has or may have a genetic basis. In other words, the protection of employees under *GINA* does not extend to protection of employees with manifested diseases.

## ***Record-Keeping and Confidentiality Requirements***

*GINA* requires employers to maintain confidentiality of genetic information by imposing strict record-keeping requirements:

- (a) all genetic information must be treated as part of the confidential medical record of the employee, and must be maintained on separate forms in separate medical files. An employer shall be considered to be in compliance of the provision if records are maintained in accordance with, and treated as a confidential medical record under, the *Americans with Disabilities Act*.

(b) Additionally, an employer must not disclose genetic information concerning an employee except in the following circumstances:

- a. to the employee or family member receiving the genetic services at the written request of the employee;
- b. to the occupational or other health researcher if such research is conducted in compliance with Federal regulations and protections provided under Part 46, Title 45 Code of Federal Regulations (relating to research involving human subjects);
- c. in response to a court order – disclosure must be made as expressly authorized by the court order, and the employee must be informed of the court order and the genetic information;
- d. government officials investigating compliance of Title II;
- e. to the extent that such disclosure is made in compliance with Federal or state laws on family and medical leave;
- f. to any Federal, state or local public health agency in relation to any information on the manifestation of disease in a family member that may be contagious, and may present an imminent hazard of death or life-threatening illness. The employee must be notified of such disclosure.
- g. any disclosures made pursuant to HIPPA regulations.

### ***Employer-Sponsored Group Health Plans***

There are two aspects of Title I relating to employer-sponsored group health plans which employers should be aware of.

The first relates to the interaction between Title I and Title II – section 209(a)(2)(B) provides for a “firewall” provision intended to eliminate the possibility of double liability by preventing claims being made against employers under Title II, when it could have been made under Title I or under any other provisions contained in ERISA, the *Public Health Service Act* or the *Internal Revenue Code*.

However, the firewall does not prevent claims from arising under Title II against employers for decisions that “discriminate against any employee with respect to compensation, terms, conditions or privileges of employment because of the employee’s genetic information”. Specifically, this means that while all claims relating to discrimination with respect to the collection and use of genetic information by group health plans for underwriting purposes should be made under Title I, employers may still be liable under Title II if any discriminatory actions are taken as a result of the genetic information, for example, where an employer discharges an employee because of anticipated high health claims based on such genetic information.

Secondly, while provisions under Title I apply to group health plans and health insurers offering group health insurance coverage in connection with a group health plan, employers who sponsor such plans need to be aware of the prohibitions imposed by Title I with respect to the collection of genetic information pursuant to questions relating to the family medical history of an employee in pre *and* post-enrolment health risk assessment forms in the light of regulations issued by the Internal Revenue Service, the Department of Labor and the Department of Health and Human Services, applicable to plan years beginning after December 7, 2009, particularly if financial incentives are offered for completing the forms.

## ***Remedies and Enforcement***

GINA provides that the same remedies available under Title VII of the *Civil Rights Act of 1964* are available under Title II. Thus, an aggrieved individual may seek reinstatement, hiring, promotion, back pay, injunctive relief, pecuniary and non-pecuniary damages and attorneys' fees and costs. Title VII's cap on combined compensatory and punitive damages also applies to actions under Title II of GINA, which such cap ranging from \$50,000 for employers with 15-100 employees to \$300,000 for employers with more than 500 employees. Punitive damages are not available against Federal, state, or local government employers.

## **The Final Rule**

The regulations clarify certain terms and provisions in Title II, with most of the substantive provisions contained in the proposed regulations issued on March 2, 2009 remaining unchanged in the final rule. Specifically, the regulations cover the following:

- (a) application and scope of *GINA*;
- (b) prohibitions imposed on employers, employment agencies and labor organizations and exceptions to those prohibitions; and
- (c) confidentiality and restrictions on disclosure provisions under *GINA*.

Rules of construction, enforcement and remedies have also been clarified, including interaction between provisions under *GINA* and other statutes.

## ***Application and Scope***

Various definitions contained in *GINA* are clarified or expanded. For example:

- (a) the definition of 'employee' is expanded to include both applicants and former employees (§1635.2(c)).
- (b) 'family members' are clarified as people up to, and including, fourth-degree relatives. For clarity, fourth-degree relatives are non-exhaustively listed as great-great-grandparents and first cousins once-removed. The term also includes dependents that are or become related to an individual through marriage, birth, adoption or placement for adoption (§1635.3(a)).
- (c) 'genetic test' is expansively defined to include any test used to detect a gene variant associated with a specific disease or condition (§1635.3(f)). The regulations also provide a non-exhaustive list of tests that fit this definition. Such tests include, for instance:
  - a. amniocentesis tests on fetuses;
  - b. DNA tests to confirm paternity; and
  - c. tests for genetic predispositions.

With the exception of tests for the presence of alcohol, the regulations do not contain a list of tests that are not genetic tests, suggesting it is committed to an open definition of ‘genetic test,’ taking into account inevitable future advances.

- (d) in addition to the definition of ‘genetic information’ in s201(4) of *GINA*, which include results of genetic tests and information on family medical history, the regulations further specify that information about an individual or a family member’s request for, or receipt of, genetic services and genetic information of a fetus or embryo should fall within the meaning of ‘genetic information’. Nonetheless, ‘genetic information’ does not include information about race, ethnicity or age of the individual or their family members that is not derived from a genetic test (s1635.3(c)).
- (e) the term ‘manifested disease’ is clarified and defined as a disorder, disease or pathological condition that an individual could reasonably be diagnosed with by a health care professional with appropriate training and expertise in the field of medicine. It is not ‘manifested’ however, if the diagnosis is based principally on genetic information (s1635.3(g)).

### ***Specific and General Prohibitions and Exceptions***

The regulations further clarify the application and scope of prohibitions imposed by *GINA* and their corresponding exceptions. For example:

- (a) actions which limit, segregate or classify, or which has the purpose or effect of limiting, segregating or classifying, an employee because of genetic information are prohibited by *GINA*. The regulations provide an example of a prohibited action – where an employer reassigns an individual whom it learned has a family history of heart conditions to a less stressful job. Such action is barred even if the employer did it for the purpose of preventing a decline of its employee’s health (s1635.5).
- (b) the regulations reiterate that actions by a covered entity (being an employer, employment agency, labor organizations and joint-labor management training programs) which cause another covered entity to discriminate on the basis of genetic information are prohibited. Subsequent to submission of public comments, the final rule modified the proposed regulations slightly so that it leaves no doubt that no *GINA* covered entity may cause another covered entity to discriminate. Examples of prohibited conduct provided in the regulations include circumstances where an employment agency attempts to share genetic information with an employer or where an employer uses a recruitment session organized by a union to ask questions on the family medical history of applicants.
- (c) ‘requesting’ for genetic information is prohibited by *GINA*. Section 1635.8(a) of the regulations makes it clear that ‘requesting’ includes:

- a. conducting an internet search in a way that is likely to result in the entity obtaining genetic information about an individual;
- b. actively listening to third party conversations, or searching an individual's personal effects; and
- c. making requests for information about an individual's health status.

The regulations clarify that inadvertent receipt of genetic information or 'passive acquisitions' would not fall within the definition of 'request'. Further examples have been added in the final rule for clarity upon submission of public comments. These include the following:

- a. where the covered entity inadvertently requests, receives or requires genetic information pursuant to communication within a social setting eg, information derived from the question 'how are you?' or where the 'water cooler exception' applies;
- b. where the information is acquired from commercially and publicly available publications, provided that the research is not conducted for the purpose of acquiring information about a specific employee;
- c. where the information is acquired for law enforcement purposes or in accordance with, or for the purposes of, some other legislation; or
- d. where an entity offers health or genetic services, including as part of a voluntary wellness program, where the provision of the information is voluntary or the individual provides knowing, written, prior consent or where identifiable information is only provided to the health care practitioner and the individual or where such information is only available for such wellness services. Importantly for employers, the use of financial incentives to encourage participation in such wellness programs do not, of themselves, prevent the application of this exception to the prohibition.

An additional safe harbor provision may be used, such that if the entity prefaces lawful requests for medical information with the following statement, any acquisition of genetic information will generally 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."*

The regulations also clarify circumstances arising from requests of manifested disease information from an employee, which may amount to acquisition of genetic information where another employee who is a family member of the first is concerned. For instance, an employer may ask if an employee's diabetes is under control. This is not an unlawful acquisition of genetic information regarding the employee's family members who also work for the employer (s1635.8(c)). However, it is still an acquisition of family medical history, and must be treated with the confidentiality required by *GINA* (s1635.3(b)).

### ***Disclosure and Confidentiality***

Whilst the disclosure requirements apply to all genetic information, regardless of date of receipt, any genetic information received prior to November 21, 2009 and placed in personal files do not need to be removed. Any such information received after that date must be placed in a confidential file (s1635.9).

Nonetheless, employers should note that disclosure to third parties is prohibited and genetic information must be removed from the personal files prior to such disclosure. Several exceptions to the rule against disclosure of this information exist with respect to disclosure:

- (a) on written request by the individual to whom the information relates;
- (b) a person or entity on order of a court;
- (c) to occupational or health researchers;
- (d) for reasons of compliance with *GINA*.

### **Recommendations for Employers**

Following the issuance of the final rule, employers should be aware of the scope and application of *GINA* and its impact on business and employment processes. In preparation for the January 10, 2011 effective date, employers should:

- (a) ensure that all employees are aware of the new rules on prohibition against discrimination based on genetic information by for example, issuing a memorandum on key aspects of *GINA*;
- (b) update their workplace policy/manuals, handbooks and training programs to include information, facts and examples of discrimination based upon genetic information;
- (c) ensure that proper record-keeping and confidentiality requirements are preserved by limiting access to such genetic information;
- (d) train managers and supervisors on key aspects of *GINA*;
- (e) work with their insurers to limit questions relating to the family medical history of employees in health risk assessment forms and questionnaires;



- (f) be aware of the expanded definitions of terms specified in GINA;
- (g) ensure that obligations and restrictions relating to the acquisition, use or disclosure of genetic information are observed and workplace guides, manuals and policies updated to include further practical examples of restrictions;
- (h) append the safe harbor provision clause to all lawful requests for personal information that could reasonably be expected to provide the employer with genetic information of the individual to which such information applies; and
- (i) implement regular reviews of workplace guides, manuals and policies as the EEOC has made it clear that *GINA* is capable of automatically expanding to include future medical technologies when genetic testing becomes more prevalent and pervasive in the future.

Finally, *all* employers, not just *GINA* covered entities, should check the applicability and standards of other relevant state and Federal laws.

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### Frequently Asked Questions: General Information

The Genetic Information Nondiscrimination Act (GINA) became law on May 21, 2008. Title I of GINA addresses the use of genetic information in health insurance. Title II prohibits the **use** of genetic information in employment, restricts employers from **requesting, requiring, or purchasing** genetic information, and strictly limits the **disclosure** of genetic information.

**Q: What's genetic discrimination?**

A: Genetic discrimination occurs if people are treated unfairly because of differences in their DNA that increase their chances of getting a certain disease. For example, a health insurer might refuse to give coverage to a woman who has a DNA difference that raises her odds of getting breast cancer. Employers also could use DNA information to decide whether to hire or fire workers.

**Q: Who needs protection from genetic discrimination?**

A: Everyone should care about the potential for genetic discrimination. Every person has dozens of DNA differences that could increase or decrease his or her chance of getting a disease such as diabetes, heart disease, cancer or Alzheimer's disease. It's important to remember that these DNA differences don't always mean someone will develop a disease, just that the risk to get the disease may be greater.

More and more tests are being developed to find DNA differences that affect our health. Called genetic tests, these tests will become a routine part of health care in the future. Health care providers will use information about each person's DNA to develop more individualized ways of detecting, treating and preventing disease. But unless this DNA information is protected, it could be used to discriminate against people.

**Q: What's the Genetic Information Nondiscrimination Act (GINA)?**

A: The Genetic Information Nondiscrimination Act of 2008, also referred to as GINA, is a new federal law that protects Americans from being treated unfairly because of differences in their DNA that may affect their health. The law prevents discrimination from health insurers and employers. The President signed the act into federal law on May 21, 2008. The parts of the law relating to health insurers took effect in May 21, 2009, and those relating to employers took effect in November 21, 2009.

**Q: Why was the law needed?**

A: The law was needed to help ease concerns about discrimination that might keep some people from getting genetic tests that could benefit their health. The law also enables people to take part in research studies without fear that their DNA information might be used against them in health insurance or the workplace.

**Q: What does GINA do?**

GINA generally prohibits discrimination in health coverage and employment on the basis of genetic information. GINA, together with already existing nondiscrimination provisions of the Health Insurance Portability and Accountability Act, generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or the individual's family members, or using it for decisions regarding coverage, rates, or preexisting conditions. The law

also prohibits most employers from using genetic information for hiring, firing, or promotion decisions, and for any decisions regarding terms of employment.

The statute defines 'genetic information' as information about:

- an individual's genetic tests (including genetic tests done as part of a research study);
- genetic tests of the individual's family members (defined as dependents and up to and including 4th degree relatives);
- genetic tests of any fetus of an individual or family member who is a pregnant woman, and genetic tests of any embryo legally held by an individual or family member utilizing assisted reproductive technology;
- the manifestation of a disease or disorder in family members (family history);
- any request for, or receipt of, genetic services or participation in clinical research that includes genetic services (genetic testing, counseling, or education) by an individual or family member.

Genetic information does not include information about the sex or age of any individual.

The statute defines 'genetic test' as an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes.

The results of routine tests that do not measure DNA, RNA, or chromosomal changes, such as complete blood counts, cholesterol tests, and liver-function tests, are not protected under GINA. Also, under GINA, genetic tests do not include analyses of proteins or metabolites that are 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.

**Q: What won't GINA do?**

- GINA's health coverage nondiscrimination protections do not extend to life insurance, disability insurance and long-term care insurance.
- GINA does not mandate coverage for any particular test or treatment.
- GINA's employment provisions generally do not apply to employers with fewer than 15 employees.
- For health coverage provided by a health insurer to individuals, GINA does not prohibit the health insurer from determining eligibility or premium rates for an individual based on the manifestation of a disease or disorder in that individual. For employment-based coverage provided by group health plans, GINA permits the overall premium rate for an employer to be increased because of the manifestation of a disease or disorder of an individual enrolled in the plan, but the manifested disease or disorder of one individual cannot be used as genetic information about other group members to further increase the premium.
- GINA does not prohibit health insurers or health plan administrators from obtaining and using genetic test results in making health insurance payment determinations.

**Q: How will the law be enforced and what are remedies available for violation of the law?**

A: The law will be enforced by various Federal agencies. The Department of Labor, the Department of the Treasury, and the Department of Health and Human Services are responsible for Title I of GINA, and the Equal Employment Opportunity Commission (EEOC) is responsible for Title II of GINA.

Remedies for violations include corrective action and monetary penalties. Under Title II of GINA, individuals may also have the right to pursue private litigation.

**Q: What are the penalties for noncompliance?**

A: GINA permits the Secretary to impose a penalty of \$100 per day per beneficiary or participant to whom the failure relates during a period of noncompliance with the provisions in Title I. Where willful neglect was found, there is established a minimum penalty of \$2,500, or \$15,000 for more severe or prolonged violations. There are three limitations to the penalties that may be imposed by the Secretary. First, the penalty does not apply if the person otherwise liable for the penalty did not know that the noncompliance occurred. Second, the penalty does not apply to failures corrected within 30 days (in cases not due to willful neglect). Finally, a limit to the total penalty for unintentional failures is set at \$500,000 or 10% of the aggregate amount paid or incurred by the plan sponsor during the preceding year for group health plans.

**Q: How does the federal law affect state laws?**

A: GINA provides a baseline level of protection against genetic discrimination for all Americans. Many states already have laws that protect against genetic discrimination in health insurance and employment situations. However, the degree of protection they provide varies widely, and while most provisions are less protective than GINA, some are more protective. All entities that are subject to GINA must, at a minimum, comply with all applicable GINA requirements, and may also need to comply with more protective State laws.

**Q: Is GINA retroactive?**

A: GINA will not be retroactive, i.e., it cannot apply to acts or omissions that occurred prior to GINA's effective dates. However, once GINA takes effect, it will prohibit certain uses of genetic information in connection with health coverage and employment, no matter when the information was collected. For example, a health insurer that has been collecting or using genetic information for underwriting would need to change its business practices once GINA takes effect. Likewise, certain employers requiring genetic tests or family history information from employees or prospective employees will no longer be able to do so after GINA takes effect and will be prohibited from discriminating based on any genetic information that they had already collected.

**Q: Does GINA have specific research provisions?**

A: Yes. GINA's prohibitions apply to 'genetic information' which is defined as including receipt of genetic services (genetic tests, genetic counseling, or genetic education) by an individual or family member participating in clinical research. There is, however, a research exception.

GINA provides a specific "research exception" to allow health insurers or group health plans engaged in research to request (but not require) that an individual undergo a genetic test. This exception permits the request to be made but imposes the following requirements:

- (1) the request must be made pursuant to research that complies with HHS regulations at 45 CFR part 46, or equivalent Federal regulations, and any applicable state or local laws for the protection of human subjects in research;
- (2) there must be clear indication that participation is voluntary and that non-compliance has no effect on enrollment or premiums or contribution amounts;

(3) no genetic information collected or acquired as part of the research may be used for underwriting purposes;

(4) the health insurer or group health plan must notify the Federal government in writing that it is conducting activities pursuant to this research exception and provide a description of the activities conducted; and

(5) the health insurer or group health plan must comply with any future conditions that the Federal government may require for activities conducted under this research exception.

#### Frequently Asked Questions: EEOC Final Rule on Title II

GINA requires the Equal Employment Opportunity Commission (EEOC) to issue regulations implementing Title II of the Act, which it did on November 9, 2010. The following questions and answers are intended to provide small businesses with practical information about the most important requirements of Title II of GINA and the EEOC's final rule.

#### **Q: Who must comply with Title II of GINA?**

A: Title II applies to private employers with 15 or more employees, employment agencies, labor unions, and joint labor-management training programs, among other entities. Laws in 34 states also prohibit employment discrimination on the basis of genetic information, but are not discussed here. Some of these laws may apply to employers with fewer than 15 employees.

#### **Q: When are businesses required to be in compliance with the final rule?**

A: Title II of the Act has an effective date of **January 10, 2011**

#### ***DEFINITIONS***

#### **Q: What is "genetic information"?**

A: The statute and the final rule say that "genetic information" includes:

- Information about an individual's genetic tests;
- Information about the genetic tests of a family member;
- Family medical history;
- Requests for, and receipt of, genetic services by an individual or a family member; and
- Genetic information about a fetus carried by an individual or family member, or about an embryo legally held by the individual or family member using assisted reproductive technology.

#### **Q: What are examples of tests that would, and would not, be considered genetic tests?**

A: Tests used to determine whether an individual has a certain genetic variant associated with an increased risk of acquiring a disease in the future are genetic tests. For example, a test to determine whether an individual has the genetic variants associated with a predisposition to certain types of breast cancer is a genetic test. Other examples of genetic tests include a test for a genetic variant for Huntington's Disease and carrier screenings of 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.

Examples of tests that are not genetic tests include an HIV test, a cholesterol test, and a test for the presence of drugs or alcohol.

**Q: Does GINA protect individuals from discrimination on the basis of impairments that have a genetic basis, such as certain forms of breast cancer?**

A: No. GINA is concerned primarily with protecting those individuals who may be discriminated against because an employer thinks they are at increased risk of acquiring a condition in the future. Someone who is discriminated against because she actually has breast cancer or another condition would not be protected by GINA, even if the condition has a genetic basis. The ADA, however, may protect such an individual whose cancer or other condition meets the definition of “disability.” Recent amendments to the ADA make it much easier for individuals with cancer and other kinds of impairments to establish that they have disabilities, and thus are entitled to the law’s protection.<sup>1</sup>

**PROHIBITION ON USE OF GENETIC INFORMATION IN MAKING EMPLOYMENT DECISIONS**

**Q: Are there any situations in which an employer may use genetic information to make employment decisions?**

A: No. An employer may never use genetic information in making employment decisions, since the possibility that someone may develop a disease or disorder in the future has nothing to do with his or her current ability to perform a job.

**Q: Does Title II of GINA prohibit harassment and retaliation?**

A: Yes. GINA includes language similar to that used in Title VII of the Civil Rights Act of 1964 and other equal employment opportunity statutes, prohibiting a wide range of discrimination, including harassment. GINA also includes a specific provision prohibiting employers from retaliating against employees who oppose employment practices made unlawful by GINA (e.g., by refusing to provide genetic information) or who participate in an investigation, proceeding, or hearing under GINA (e.g., by filing a charge or by assisting others in filing a charge with the EEOC).

**Q: May an employer use genetic information about an applicant or employee to make decisions concerning health benefits?**

A: No. Health benefits are part of the compensation, terms, conditions, and privileges of employment. For example, an employer that fires an employee because of anticipated high health claims based on genetic information would violate Title II of GINA.

Frequently Asked Questions: Restrictions on Acquisition of Genetic Information

Title II of GINA generally prohibits employers from requesting, requiring, or purchasing, an applicant’s or employee’s genetic information, even if it is never used. In addition to asking an applicant or employee directly about genetic information, the EEOC’s final rule says that a “request” for genetic information may include actions such as 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.

**Q: May an employer ask for family medical history as part of a medical examination of a job applicant or employee?**

A: No. Although an employer may conduct medical examinations after making a job offer or during employment as permitted by the Americans with Disabilities Act (ADA), the examination may not include collection of family medical history. An employer must tell its health care providers not to collect genetic information as part of an employment-related medical exam, and, if it finds out that family medical histories are being collected, the employer must take measures within its control (including not using the services of that health care provider) to prevent this from happening in the future.

**Q: Are there any situations in which a small business may obtain genetic information without violating GINA?**

A: Yes, there are six narrow exceptions to the rule that an employer may not request, require, or purchase genetic information about an applicant or employee:

- Where the information is acquired inadvertently;
- As part of health or genetic services, including wellness programs, provided on a voluntary basis;
- In the form of family medical history, to comply with the certification requirements of the Family and Medical Leave Act, state or local leave laws, or certain employer leave policies;
- When the information comes from sources that are commercially and publicly available, such as newspapers, books, magazines, and even electronic sources;
- As part of genetic monitoring that is either required by law or provided on a voluntary basis; and
- By employers who conduct DNA testing for law enforcement purposes as a forensic lab, or for human remains identification.

**Q: When is the acquisition of genetic information considered inadvertent?**

A: The EEOC's final rule discusses several situations in which the acquisition of genetic information may be inadvertent. For example, it would not violate GINA for a supervisor to overhear one employee tell another that her mother has breast cancer, or that the employee herself has had a test to determine whether she has the gene associated with increased risk for breast cancer. Similarly, this exception will apply when a supervisor receives genetic information in response to a question about an employee's general well-being ("How are you?" or "Did they catch it early?" asked of an employee who was just diagnosed with cancer), or a question about the general health of a family member ("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?"). Another example of inadvertent acquisition is when a supervisor receives an unsolicited communication about an employee's family member (e.g., an email indicating that an employee's mother has cancer). An employer that lawfully requests documentation about an employee's current medical condition may also inadvertently receive genetic information, particularly family medical history.

**Q: What does GINA say about the acquisition of genetic information when an employer offers health or genetic services, like a wellness program?**

A: GINA and the final rule say that an employer may acquire genetic information about an employee or his or her family members when it offers health or genetic services, including wellness programs, on a voluntary basis. The individual receiving the services must give prior, voluntary, knowing, and written authorization.

While individualized genetic information may be provided to the individual receiving the services and to his or her health or genetic service providers, genetic information may only be provided to the employer in aggregate form. However, if information provided in the aggregate makes identification of specific individuals' genetic information possible because of the small number of participants in a wellness program, the employer will not violate GINA.

The proposed rule sought comments on the extent to which an employer could offer financial inducements to encourage participation in health or genetic services, particularly wellness programs. The final rule says that while employers may offer certain kinds of financial inducements to encourage participation in health or genetic services under certain circumstances, they may not offer an inducement for individuals to provide genetic information. Thus, it would not violate Title II of GINA for an employer to offer individuals an inducement for completing a health risk assessment that includes some questions about family medical history or other genetic information, as long as the employer specifically identifies those questions and makes clear, in language reasonably likely to be understood by those completing the health risk assessment, that the individual need not answer the questions that request genetic information to receive the inducement.

Title II allows employers to offer financial inducements for participation in disease management programs or other programs that encourage healthy lifestyles, such as programs that provide coaching to employees attempting to meet particular health goals (e.g., achieving a certain weight, cholesterol level, or blood pressure). To avoid a violation of Title II of GINA, however, employers who offer such programs and inducements to individuals based on their voluntarily provided genetic information must also offer the programs and inducements to individuals with current health conditions, and/or to individuals whose lifestyle choices put them at risk of acquiring a condition.

**Q: Why do GINA and the final rule include an exception that allows an employer to acquire family medical history as part of the FMLA's certification process, under certain state or local laws that allow employees to take leave to care for a family member, or under certain employer leave policies?**

A: Proof that an employee is entitled to leave to care for a family member with a medical condition under the FMLA, similar state or local laws, or employer policies may require an employee to provide family medical history (i.e. information about the manifestation of a disease or disorder in the family member) to the employer. Without the exception, requiring family medical history under these circumstances would violate GINA.

**Q: When would the exception permitting acquisition of genetic information from sources that are publicly and commercially available apply?**

A: An employer is not liable under GINA for acquiring genetic information from sources that are commercially and publicly available, such as newspapers, books, magazines, periodicals, television shows, movies, or the Internet. For example, an employer would not be liable if it accidentally came across a newspaper article saying that an employee's father died of a sudden heart attack.

However, this exception does not apply to:

- medical databases, court records, or research databases available to scientists on a restricted basis;
- sources with limited access, such as pages on social networking sites that require the creator's permission to access and to which access is not routinely granted;



- commercially and publicly available sources that the employer accessed with the intent to obtain genetic information; or
- sources from which a covered entity that accesses them is likely to acquire genetic information, whether or not they are commercially and publicly available.

**Q: May an employer conduct genetic monitoring to see if employees are being affected by harmful substances in the workplace?**

A: Yes, if certain requirements are met. An employer that wants to do genetic monitoring that is not required by law must provide written notice of the monitoring program and must obtain an individual's prior, knowing, written, and voluntary authorization. If the monitoring is required by law, such as under standards issued by the Occupational Safety and Health Administration (OSHA), an employer must provide notice of the monitoring and otherwise comply with the requirements for conducting the monitoring program, but need not obtain the individual's prior, knowing, written, and voluntary consent.

Furthermore, while individualized genetic information may be disclosed to the employee, and to the doctors and certified genetic counselors involved in the monitoring, the employer may only be given genetic information in aggregate form. As in the case of health or genetic services offered by an employer on a voluntary basis, if information provided in the aggregate makes identification of specific individuals' genetic information possible because of the small number of participants in a monitoring program, the employer will not violate GINA.

The final rule clarifies that GINA prohibits an employer from retaliating or otherwise discriminating against an employee who refuses to participate in genetic monitoring that is not specifically required by law. An individual who refuses to participate in a voluntary genetic monitoring program should be informed of the potential dangers (e.g., the consequences that might result if the effects of certain toxins in the workplace are not identified), but the employer may not take any adverse action against the individual for refusing to participate. However, an employer does not violate Title II of GINA if it limits or restricts an employee's job duties based on genetic information because it was required to do so by law or regulation, such as regulations administered by OSHA.

**Q: What does GINA say about whether an employer may acquire genetic information for law enforcement purposes or for human remains identification?**

A: GINA permits employers that engage in DNA testing for law enforcement purposes as a forensic laboratory, or for purposes of human remains identification, to collect their employees' genetic information in certain limited circumstances. Specifically, these entities may request or require genetic information only to the extent that the information is used for analysis of DNA identification markers for quality control to detect sample contamination.

**HOW-TO: REQUESTING HEALTH-RELATED INFORMATION**

**Q: What should an employer do to comply with GINA when lawfully requesting health-related information from an employee?**

A: Although the proposed rule said that the acquisition of genetic information as the result of an inquiry about an individual's current health status would be considered inadvertent if the request was lawful, the final rule says that when an employer makes a request for health-related information (e.g., to support an employee's request for reasonable accommodation under the ADA or a request

for sick leave), it should warn the employee and/or health care provider from whom it requested the information not to provide genetic information. The warning may be in writing or oral (if the employer typically does not make such requests in writing).

The final rule suggests language such as the following:

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.

If this type of warning is provided, any resulting acquisition of genetic information will be considered inadvertent, and therefore not in violation of GINA. In other words, use of this type of warning creates a “safe harbor” for employers who receive genetic information in response to a request for health-related information.

**Q: Must the warning be provided every time an employer requests health-related information from an employee?**

A: To take advantage of this safe harbor, the employer must do what is reasonably necessary to ensure that the warning is understood by employees or doctors submitting health-related information to the employer, at the time of submission. This is best accomplished by providing the warning each time health-related information is requested. But it may suffice to give the warning more generally, for example by including it on the employer’s leave and reasonable accommodations request forms, if doing so would reasonably ensure that it is understood at the time health-related information is submitted.

**Q: What if an employer does not provide a warning like the one the EEOC suggests when it requests health-related information and receives genetic information in response?**

If the employer’s request for health-related information was made in a way that was likely to result in the employer obtaining genetic information, the request violates GINA.

On the other hand, if the employer’s request was not made in a way that was likely to result in the acquisition of genetic information, any genetic information it acquires would be considered an inadvertent acquisition. For example, an employer who asks an employee to provide a doctor’s note explaining a five-day absence will not violate GINA if the doctor includes the family medical history taken as part of the employee’s medical examination, even if the employer has not warned the employee or the doctor against providing genetic information.

## CONFIDENTIALITY

### **Q: What are GINA's rules on confidentiality?**

A: An employer in possession of genetic information about applicants or employees must treat it the same way it treats medical information generally. It must keep the information confidential and, if the information is in writing, must keep it apart from other personnel information in separate medical files. Genetic information may be kept in the same file as medical information subject to the ADA.

There are limited circumstances under which an employer may disclose genetic information:

- To the employee or family member about whom the information pertains, upon receipt of the employee's or family member's written request;
- To an occupational or other health researcher conducting research in compliance with 45 CFR part 46;
- In response to a court order, except that the employer may disclose only the genetic information expressly authorized by the order;
- To government officials investigating compliance with Title II of GINA, if the information is relevant to the investigation;
- In accordance with the certification process for FMLA leave or state family and medical leave laws; or
- To a public health agency, but 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.

Genetic information placed in personnel files prior to GINA's effective date of November 21, 2009 need not be removed, and an employer will not be liable under GINA for the mere existence of that genetic information in a personnel file. However, disclosing that genetic information to a third party is prohibited.

## RELATIONSHIP TO OTHER LAWS

### **Q: What effect does Title II of GINA have on other laws addressing genetic discrimination in employment?**

A: State or local laws that provide equal or greater protections from employment discrimination on the basis of genetic information still apply. 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, and does not affect an individual's rights under the ADA, the Rehabilitation Act, or state or local disability discrimination laws.

## CHARGES OF DISCRIMINATION

### **Q: What happens when an employee files a charge under GINA?**

A: Someone who believes that his or her employment rights have been violated on the basis of genetic information may file a "charge of discrimination" with the EEOC within 180 days from the date of the alleged violation, or within 300 days if a state or local agency enforces a law that prohibits

employment discrimination on the basis of use or acquisition of genetic information or genetic testing.

If a charge is filed, the EEOC will notify the employer and provide the name and contact information of an investigator. The parties may choose to resolve the dispute through settlement, or in some cases mediation. If the dispute is not resolved voluntarily, the investigator will ask both parties for information. The employer may be asked to:

- provide a position statement;
- provide copies of policies, files, or other evidence;
- allow on-site visits; and
- make employees available for interview.

Once the investigation is complete, the EEOC will determine whether there is “reasonable cause” to believe discrimination occurred. If there is insufficient evidence to find reasonable cause, the EEOC will issue a Dismissal and Notice of Rights stating that the charging party has a right to file a lawsuit in federal court within 90 days of receipt of the notice.

If reasonable cause is found, the EEOC will issue a Letter of Determination and try to conciliate the charge. Where the charge cannot be resolved through conciliation, the EEOC will either file a court action, or issue a Notice of Right to Sue, stating that the charging party has a right to file a lawsuit in federal court within 90 days of receipt of the notice. A charging party may also request a Notice of Right to Sue from the EEOC 180 days after the charge was first filed with the EEOC.

For a detailed description of the process, please refer to the EEOC website at <http://www.eeoc.gov/employers/process.cfm>.

**Q: What are the remedies for a violation of GINA Title II?**

A: The same remedies available under Title VII of the Civil Rights Act of 1964 are available under Title II of GINA. An aggrieved individual may seek reinstatement, hiring, promotion, back pay, injunctive relief, monetary damages (including compensatory and punitive damages), and attorneys’ fees and costs. Title VII’s cap on combined compensatory and punitive damages also applies to actions under Title II of GINA. The cap on combined compensatory and punitive damages (excluding past monetary losses) ranges from \$50,000 for employers with 15-100 employees, to \$300,000 for employers with more than 500 employees.

# **Title I of GINA – Health Insurance Provisions**

## Advances in Genetics

In April 2003, the sequence of the human genome was deposited into public databases. Scientists involved in the Human Genome Project (HGP) reported that the finished sequence consists of overlapping fragments covering 99% of the coding regions of the human genome, with an accuracy of 99.999%. These rapid advances provide powerful tools for determining the causes of, and potentially the cures for, many common, complex diseases such as diabetes, heart disease, Parkinson's disease, bipolar disorder, and asthma.

These scientific advances in genetics, while promising, are not without potential problems. The ethical, social, and legal implications of genetic research have been the subject of significant scrutiny and a portion of the funds for the Human Genome Project were set aside to support the analysis and research of these issues. As scientific knowledge about genetics becomes increasingly widespread, numerous researchers and commentators, including Dr. Francis Collins, the Director of the National Human Genome Research Institute, have expressed concerns about how this information will be used. In congressional testimony, Dr. Collins stated:

While genetic information and genetic technology hold great promise for improving human health, they can also be used in ways that are fundamentally unjust. Genetic information can be used as the basis for insidious discrimination....The misuse of genetic information has the potential to be a very serious problem, both in terms of people's access to employment and health insurance and the continued ability to undertake important genetic research.

Studies have shown that public fear of discrimination is substantial and negatively influences the uptake of genetic testing and the use of genetic information by consumers and health professionals. The Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) learned that 68% of Americans are concerned about who would have access to their personal genetic information; 31% state this concern would prevent them from having a genetic test; and 68% agree that insurers would do everything possible to use genetic information to deny health coverage. A 2004 survey conducted by the Genetics and Public Policy Center found that 92% of Americans oppose employer access to personal genetic information and 80% oppose access to this information by health insurers.

On May 21, 2008, the Genetic Information Nondiscrimination Act of 2008 (GINA), referred to by its sponsors as the first civil rights act of the 21st century, was enacted. GINA addresses the fears that prevent individuals from partaking in genetic testing by prohibiting discrimination based on genetic information by health insurers and employers.

GINA contains a statement of findings which discusses the significance of the sequencing of the human genome, the history of discrimination based on genetics, and the inadequacy of current federal and state laws. The statute is then divided into three titles: Title I, which prohibits genetic discrimination in health insurance, Title II, which prohibits genetic discrimination in employment, and Title III, which contains miscellaneous provisions on severability and child labor protections.

## Nondiscrimination in Health Insurance

Genetic discrimination has a great impact on public health. Millions of people could benefit from knowing their genetic profile which would result in fewer seriously ill patients and thereby ease the stress on our already overburdened health care system. However, the risk of discrimination has prevented individuals from taking advantage of these preventive services that could deter illness, improve health outcomes, and reduce costs system-wide.

In many cases, health insurance organizations limit or deny coverage based on an individual's genetic information in an attempt to keep their costs down. Ironically, it is these actions that prevent people from pursuing genetic testing which in turn lead to delayed preventive treatment resulting in increased financial long-term burdens for everyone involved. Such burdens include financial and physical burden on health care providers, increased health care costs for employers, and strains on public health resources.

Title I of GINA strengthens and clarifies existing HIPAA nondiscrimination and portability provisions through amendments to the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Services Act (PHSA), and the Internal Revenue Code (IRC), as well as to the Social Security Act (SSA). In this way, group plans under ERISA, group and individual plans under the PHSA, Church Plans under the IRC, and Medigap plans under the SSA are all brought under the jurisdiction of the law. The complexity of the health care financing system required this multi-faceted approach in order to ensure protection for all individuals, regardless of their insurance situation.

### **Prohibited Health Insurer Practices**

Broadly, GINA prohibits health insurers from engaging in three practices:

- (1) using genetic information about an individual to adjust a group plan's premiums, or, in the case of individual plans, to deny coverage, adjust premiums, or impose a preexisting condition exclusion;
- (2) requiring or requesting genetic testing; and
- (3) requesting, requiring, or purchasing genetic information for underwriting purposes.

#### *Discrimination in Premium Setting and Eligibility Prohibited*

GINA prohibits health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies from adjusting a group or individual's premium based on genetic information about an individual in the group, an individual seeking individual coverage, or an individual's family members. It also prohibits individual insurers from conditioning eligibility or continuing eligibility on genetic information, and prohibits individual insurers from treating genetic information as a preexisting condition. Issuers of supplemental Medicare policies may not deny or condition the issuance of a policy based on genetic information (and may not impose a preexisting condition exclusion based on genetic information).

### *Genetic Testing Requirements Prohibited*

GINA prohibits health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies from requesting or requiring that individuals or their family members undergo a genetic test. This prohibition does not limit the authority of a health care professional to request that an individual undergo genetic testing as part of his or her course of health care. The act provides for a research exception to this provision, by allowing a group or individual insurance issuer to request, but not require, an individual to undergo genetic testing if specific conditions are met.

### *Collection and Use of Genetic Information Restricted*

GINA prohibits health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies from requesting, requiring, or purchasing genetic information for the purposes of underwriting prior to an individual's enrollment or in connection with enrollment. "Incidental collection" of genetic information would not be considered a violation.

### **Research Exception**

GINA includes a "research exception" to the general prohibition against health insurers or group health plans requesting that an individual undergo a genetic test. This exception allows health insurers and group health plans engaged in research to request (but not require) that an individual undergo a genetic test. This exception permits the request to be made but imposes the following requirements:

- The request must be made pursuant to research that complies with HHS regulations at 45 CFR part 46, or equivalent Federal regulations, and any applicable state or local laws for the protection of human subjects in research;
- There must be clear indication that participation is voluntary and that non-compliance has no effect on enrollment or premiums or contribution amounts;
- No genetic information collected or acquired as part of the research may be used for underwriting purposes;
- The health insurer or group health plan must notify the Federal government in writing that it is conducting activities pursuant to this research exception and provide a description of the activities conducted; and
- The health insurer or group health plan must comply with any future conditions that the Federal government may require for activities conducted under this research exception.

### **Application to Genetic Information of a Fetus or Embryo**

Title I of the act clarifies that genetic discrimination based on the genetic information of either the fetus of a pregnant woman or an embryo legally held by an individual or family member is prohibited.



## **Rule of Construction**

GINA provides clearly that nothing in the act should be construed to preclude the use of information about a manifested disease or disorder in an individual (or an individual's family member) by health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies to establish premiums or conditions of eligibility. In addition, nothing in the act should be construed to prohibit health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies from obtaining or using the results of genetic tests to determine payment. However, only the minimum amount of information required to achieve this purpose may be requested.

## **Privacy and Confidentiality**

GINA directs the Secretary of Health and Human Services to revise the HIPAA Privacy Rule to reflect that genetic information shall be treated as health information and the use or disclosure by a covered entity of protected health information (i.e., genetic information) for the purposes of underwriting shall not be a permitted use or disclosure. The Secretary, in consultation with the Secretaries of Labor and the Treasury, has 12 months after enactment of the act to issue final regulations to carry out these revisions.

## **Remedies and Enforcement**

GINA permits the Secretary to impose a penalty of \$100 per day per beneficiary or participant to whom the failure relates during a period of noncompliance with the provisions in Title I. Where willful neglect was found, there is established a minimum penalty of \$2,500, or \$15,000 for more severe or prolonged violations. There are three limitations to the penalties that may be imposed by the Secretary. First, the penalty does not apply if the person otherwise liable for the penalty did not know that the noncompliance occurred. Second, the penalty does not apply to failures corrected within 30 days (in cases not due to willful neglect). Finally, a limit to the total penalty for unintentional failures is set at \$500,000 or 10% of the aggregate amount paid or incurred by the plan sponsor during the preceding year for group health plans.

# **Title II of GINA – Employment Related Provisions**

## Nondiscrimination in Employment

A joint report by the Department of Labor, the Department of Health and Human Services, the EEOC, and the Department of Justice summarized the various studies on discrimination based on genetic information and argued for the enactment of federal legislation. The report stated that “genetic predisposition or conditions can lead to workplace discrimination, even in cases where workers are healthy and unlikely to develop a disease, or where the genetic condition has no effect on the ability to perform work” and that “because an individual’s genetic information has implications for his or her family members and future generations, misuse of genetic information could have intergenerational effects that are far broader than any individual incident of misuse.” Concluding that existing protections are minimal, the report went on to call for the enactment of legislation.

There are several ways to gather genetic information. It can be deduced from a family's medical history or during a physical examination. Routine laboratory tests that measure the body's output of specific substances might also suggest the genetic make-up of the individual. But the most direct approach to obtaining genetic information is through analysis of DNA, the material that makes up genes. Such genetic tests identify specific DNA features in people who have already developed a disease, in healthy people who may be at risk of developing a genetic disorder later in life, or in people who are at risk of having a child with an inherited disorder. Thus, genetic information includes information about genes, gene products, and inherited characteristics that may derive from individuals or their family members.

While genetic technology increases the ability to detect and prevent health disorders, it can also be misused to discriminate against or stigmatize individuals. A 1996 survey of individuals at risk of developing a genetic condition and parents of children with specific genetic conditions identified more than 200 cases of genetic discrimination among the 917 people who responded. The cases involved discrimination by insurance companies, employers, and other organizations that use genetic information. Another recent survey of genetic counselors, primary care physicians, and patients, identified 550 people who had been denied employment or insurance based on their genetic predisposition to an illness.

In addition, people have hidden genetic information about themselves due to fear of the effects of disclosure. For example, an 18-year-old man, at risk for inheriting Huntington's disease from one of his parents, who wished to enlist in the Marines to serve in the Persian Gulf War, believed that knowledge of his risk status would disqualify him from service, even though it was unlikely that he would become symptomatic during his tour of duty. He therefore answered "no" to questions regarding hereditary disorders on his application and did not include Huntington's disease in his family medical history. Another individual whose parent died of Huntington's disease also chose to hide the truth from his employer. Fearing adverse consequences at work if this cause of death was known, the individual arranged for the diagnosis of asphyxiation to be reported as the cause of death to avoid mention of the disease in an obituary. Fear of genetic discrimination and the consequences of this fear have been reported in both the scientific literature and the popular press.

Other employees have chosen to be upfront about their condition and found themselves victim to discrimination. For example, a 53-year-old man at a job interview with an insurance company revealed that he had hemochromatosis but was asymptomatic. During the second interview, he

was told that the company was interested in hiring him but would not be able to offer him health insurance because of his genetic condition. He agreed to this arrangement. During his third interview, the company representative told him that they would like to hire him, but were unable to do so because of his genetic condition.

In other instances, employers found out about an employee's condition through word of mouth or overhearing a conversation. This was the case when an employee's parent developed Huntington's disease-indicating that the employee had a 50 percent chance of inheriting the mutated gene that would cause her to develop the disease. She decided to be tested. A genetic counselor advised her to secure life and health insurance before testing, because a positive test result would not only mean that she would get the disease but would probably prevent her from obtaining insurance as well. A co-worker who overheard her making arrangements to be tested reported the employee's conversations to their boss. Initially, the boss seemed empathetic and offered to help. When the employee eventually shared the news that her test results indicated that she did carry the mutated gene, she was fired from her job. In the 8-month period prior to her termination, she had received three promotions and outstanding performance reviews. Frightened by their sister's experience, none of her siblings are willing to undergo genetic testing for fear of losing health insurance or jobs. Consequently, they must live with the uncertainty of not knowing whether they have inherited the genetic trait that leads to Huntington's disease.

### **Genetic Information in the Workplace**

Two types of genetic testing can occur in the workplace: genetic screening and genetic monitoring. Genetic screening examines the genetic makeup of employees or job applicants for specific inherited characteristics. It may be used to detect general heritable conditions that are not associated with workplace exposures in employees or applicants. For example, employers used genetic screening in the early 1970s to identify African Americans who carried a gene mutation for sickle cell anemia. Those carrying the gene mutation were denied jobs-even though many of them were healthy and would never develop the disease. In these cases, genetic screening to identify the sickle cell trait often occurred without the consent of the individuals.

**Genetic screening** can also be used to detect the presence of genetically determined traits that render an employee susceptible, or "hyper-susceptible," to a certain disease if exposed to specific environmental factors or substances that may be present in the workplace. In theory, genetic screening for occupationally relevant traits has the potential to be used to assign employees who are genetically susceptible to certain occupational diseases away from harmful exposure. However, no consensus currently exists regarding the validity of the scientific evidence or the usefulness of the genetic tests reported to predict an individual's susceptibility to exposure.

**Genetic monitoring**, a second type of testing, ascertains whether an individual's genetic material has changed over time due to workplace exposure to hazardous substances. Evidence of genetic changes in a population of workers could be used to target work areas for increased safety and health precautions and to indicate a need to lower exposure levels for a group exposed to a previously unknown hazard. The ultimate goal of genetic monitoring is to prevent or reduce the risk of disease caused by genetic damage.

Although genetic changes such as chromosomal damage have been associated with exposure to radiation and some chemical mutagens or carcinogens, little is known about which changes are predictive of subsequent disease risk. Much more research is required to establish the relationship, if any, between those changes and subsequent disease risk for affected populations and individuals. For this reason, use of genetic monitoring results to make employment decisions is rarely justifiable.

In addition, some employers may seek to use genetic tests to discriminate against workers, even those who have not yet or who may never show signs of disease, because the employers fear the cost consequences. Based on genetic information, employers may try to avoid hiring workers who they believe are likely to take sick leave, resign, or retire early for health reasons (creating extra costs in recruiting and training new staff), file for workers' compensation, or use health care benefits excessively.

### Overview of Employment Provisions

GINA was passed in part, to address these concerns of workplace discrimination. Title II of GINA prohibits use of genetic information in making decisions related to any terms, conditions, or privileges of employment, prohibits covered entities from intentionally acquiring genetic information, requires confidentiality with respect to genetic information (with limited exceptions), and prohibits retaliation.

The law prohibits the use of genetic information in employment decisions, including hiring; firing; job assignments; and promotions by employers, unions, employment agencies, and labor-management training programs.

### **Acquisition of Genetic Information**

Employers may not request, require, or purchase genetic information with respect to an employee/applicant or family member of an employee/applicant. One exception to this rule applies to inadvertent acquisition of genetic information, such as overhearing an employee conversation, receiving genetic information verbally when asking a general question about an employee's health, or receiving unsolicited genetic information as part of a documented request for a disability accommodation or leave of absence.

### **Confidentiality**

Covered entities in possession of genetic information about applicants or employees must treat it the same way they treat medical information generally. They must keep the information confidential and, if the information is in writing, must keep it apart from other personnel information in separate medical files. A covered entity may keep genetic information in the same file as medical information subject to the Americans with Disabilities Act.

## **Definition of Employee and Employer**

GINA defines employees and employers as those defined in Section 701(b) and (f) of Title VII of the Civil Rights Act of 1964, a state employee or employer as defined in Section 304(a) of the Government Employee Rights Act of 1991, and a covered employee or employing office as defined in Section 101 of the Congressional Accountability Act. Generally, this includes employees and applicants working in the private sector for an employer who employs 15 or more employees, Federal and state governments, as well as congressional employees. The corresponding employers of these individuals, as well as employment agencies, labor organizations, and training programs, also are covered by the law.

## **Exceptions to the Rule**

There are exceptions to the prohibition on employers, employment agencies, labor unions, and training programs. The first exception applies when one of these entities inadvertently requests or requires family medical history of the employee, individual, union member, or a family member. The House Education and Labor Report noted that this exception “addresses the so-called ‘water cooler’ problem, in which an employer unwittingly receives otherwise protected genetic information in the form of family medical history through casual conversations with a worker.”

The second exception is for health or genetic services offered by the entity as part of a wellness program. To qualify for the exemption:

- the employee, individual, or union member must provide prior, knowing, voluntary, and written authorization;
- only the employee, individual, union member, or family member and the licensed health care profession or board certified genetic counselor involved in providing such services can receive individually identifiable information concerning the results of the services; and
- any individually identifiable genetic information is only available for such services and shall not be disclosed to the employer except in aggregate terms that do not identify individuals.

The third exception is for information necessary for certification procedures under Federal and state family and medical leave laws. This exception was described as “eliminat[ing] the potential for conflict with existing laws.”

The fourth exception, like the first, concerns the inadvertent acquisition of genetic information by the purchase of documents, such as newspapers, that are commercially and publicly available and that include family medical history. This exception was intended to address the concern that GINA could be violated by such actions as the purchase of a newspaper “containing the obituary of an employee’s parent who died of breast cancer.”

The fifth exception applies when the information involved is to be used for genetic monitoring of the biological effects of toxic substances in the workplace. However, in order for this exception to apply:

- the employer, employment agency, labor union, or training program must provide written notice of the genetic monitoring to the employee;
- the employee, individual, or union member must provide prior, knowing, voluntary, and written authorization; or the genetic monitoring is required by federal or state law;
- the employee, individual, or union member must be informed of individual monitoring results;
- the monitoring must be in compliance with federal genetic monitoring regulations, or state genetic monitoring regulations; and
- the employer, employment agency, labor union, or training program, excluding any licensed health care professional or board certified genetic counselor, must receive the results only in aggregate terms that do not disclose the identity of specific employees.

There is a sixth exception for employers and training programs but not for employment agencies or labor unions. This exception, which was changed by H.Con.Res. 340, would allow employers and training programs that conduct DNA analysis for law enforcement purposes as a forensic laboratory or for purposes of human remains identification to request or require genetic information from their employees, but only when it is used for analysis of DNA identification markers for quality control to detect sample contamination.

GINA also provides that, even if an exception applies, genetic information may not be used in a manner that violates nondiscrimination or confidentiality requirements.

### **Confidentiality of Genetic Information**

Generally, GINA requires that genetic information shall be maintained on separate forms and in separate medical files and be treated as a confidential medical record, and prohibits employers, employment agencies, labor unions, and joint labor-management committees from disclosing genetic information. These entities are considered to be in compliance with the maintenance of information requirements if the genetic information is treated as a confidential record under § 102(d)(3)(B) of the Americans with Disabilities Act. However, the general prohibition on disclosure is subject to six exceptions. Genetic information may be disclosed:

- to the employee or member of a labor union (or family member receiving genetic services) at the written request of the employee or member;
- to an occupational or other health researcher if the research is conducted in compliance with 45 CFR Part 46, which provides for protection of human research subjects;
- in response to a court order except that only the genetic information expressly authorized by the order shall be disclosed; if the court order was obtained without the knowledge of the employee or member to whom the information refers, the employee or member shall be informed of the court order and the information may be disclosed;
- to government officials who are investigating compliance with Title II of GINA, if the information is relevant;
- where such disclosure is made in connection with the certification provisions of the Family and Medical Leave Act or state family and medical leave laws; or

- to a federal, state, or local public health agency regarding a contagious disease that presents an imminent hazard of death or life threatening illness, and there is notification.

GINA also contains a provision concerning the relationship of the confidentiality provisions with the HIPAA Privacy Rule. GINA does not prohibit an entity covered under HIPAA “from any use or disclosure of health information that is authorized for the covered entity under such regulations.”

### **Remedies and Enforcement**

Generally, GINA uses the remedies and enforcement mechanisms available in Title VII of the Civil Rights Act of 1964, although for employees covered by the Government Employee Rights Act of 1991, the Congressional Accountability Act of 1995, chapter 5 of Title 3 of the U.S. Code, or Section 717 of the Civil Rights Act of 1964, the remedies and procedures track those acts and statutory provisions. Under Title VII, complaints of discrimination are filed with the Equal Employment Opportunity Commission (EEOC) and may result in the award of back pay, hiring, promotion, reinstatement, front pay, or other equitable relief that will make an individual “whole.” Remedies also may include payment of attorneys’ fees, expert witness fees, and court costs.

### **Disparate Impact**

Section 703(k) of Title VII of the Civil Rights Act of 1964 provides for a cause of action based on the disparate impact of a particular employment practice on employment based on race, color, religion, sex, or national origin. GINA specifically provides that such disparate impact does not create a cause of action under its provisions. However, GINA requires that a commission be established six years after the date of enactment to review the science of genetics and make recommendations to Congress regarding whether to provide a disparate impact cause of action under GINA.

### **Construction**

GINA contains several rules of construction, including a provision concerning the relationship between Title I and Title II of the act. GINA provides that nothing in Title II is to be construed to limit the rights or protections of an individual under any federal or state statute that provides equal or greater protection. In addition, nothing in Title II is to limit the rights or protections of an individual to bring an action, or provide for enforcement of, or penalties for, any violation under Title I of GINA, certain sections of ERISA, the Public Health Services Act, and the Internal Revenue Code. This provision has been referred to as a “firewall” between Titles I and II, and has been described as clarifying “that employers are not liable for health insurance violations under civil rights laws unless the employer has separately violated a provision of Title II governing employers.” GINA also states that it does not:

- apply to the Armed Forces repository of specimen samples for the identification of remains;



- limit or expand the protections, rights, or obligations of employees or employers under applicable workers' compensation laws;
- limit the authority of a federal department or agency to conduct or sponsor health research conducted in compliance with rules for research on human subjects;
- limit the statutory or regulatory authority of the Occupational Safety and Health Administration or the Mine Safety and Health Administration regarding workplace safety and health laws and regulations; or
- require any specific benefit for an employee or member or a family member under any group health plan.

GINA also specifies that any reference in Title II to genetic information concerning an individual or family member also includes the genetic information of any fetus carried by a pregnant woman. In addition, genetic information on any embryo legally held by the individual or family member would also be included in the reference to genetic information.

Finally, section 1635.11 provides that Title II does not prohibit the activity of a group health plan or health insurance issuer offering group health insurance coverage that is authorized by Title I, and certain sections of ERISA, the Public Health Services Act, and the Internal Revenue Code.

### **Manifested Disease**

GINA clarifies that the act does not cover medical information that is not genetic information about a manifested disease, disorder, or pathological condition, including a manifested disease, disorder, or pathological condition that has or may have a genetic basis.

# Regulatory Text

## **The Genetic Information Nondiscrimination Act of 2008**

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An Act

To prohibit discrimination on the basis of genetic information with respect to health insurance and employment.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

### **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

(a) Short Title.--This Act may be cited as the "Genetic Information Nondiscrimination Act of 2008".

(b) Table of Contents.--The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings.

### **TITLE I--GENETIC NONDISCRIMINATION IN HEALTH INSURANCE**

Sec. 101. Amendments to Employee Retirement Income Security Act of 1974.

Sec. 102. Amendments to the Public Health Service Act.

Sec. 103. Amendments to the Internal Revenue Code of 1986.

Sec. 104. Amendments to title XVIII of the Social Security Act relating to medigap.

Sec. 105. Privacy and confidentiality.

Sec. 106. Assuring coordination.

### **TITLE II--PROHIBITING EMPLOYMENT DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION (FINAL RULE)**

Sec.1635.1 Purpose.

Sec.1635.2 Definitions--general.

Sec.1635.3 Definitions specific to GINA.

Sec.1635.4 Prohibited practices--in general.

Sec.1635.5 Limiting, segregating, and classifying.

Sec.1635.6 Causing a covered entity to discriminate.

Sec.1635.7 Retaliation.

Sec.1635.8 Acquisition of genetic information.

Sec.1635.9 Confidentiality.

Sec.1635.10 Enforcement and remedies.

Sec.1635.11 Construction.

Sec.1635.12 Medical information that is not genetic information.

### **TITLE III--MISCELLANEOUS PROVISIONS**

Sec. 301. Severability.

Sec. 302. Child labor protections.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Deciphering the sequence of the human genome and other advances in genetics open major new opportunities for medical progress. New knowledge about the genetic basis of illness will allow for earlier detection of illnesses, often before symptoms have begun. Genetic testing can allow individuals to take steps to reduce the likelihood that they will contract a particular disorder. 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.

(2) The early science of genetics became the basis of State laws that provided for the sterilization of persons having presumed genetic “defects” such as mental retardation, mental disease, epilepsy, blindness, and hearing loss, among other conditions. The first sterilization law was enacted in the State of Indiana in 1907. By 1981, a majority of States adopted sterilization laws to “correct” apparent genetic traits or tendencies. Many of these State laws have since been repealed, and many have been modified to include essential constitutional requirements of due process and equal protection. However, the current explosion in the science of genetics, and the history of sterilization laws by the States based on early genetic science, compels Congressional action in this area.

(3) Although genes are facially neutral markers, many genetic conditions and disorders are associated with particular racial and ethnic groups and gender. Because some genetic traits are most prevalent in particular groups, members of a particular group may be stigmatized or discriminated against as a result of that genetic information. This form of discrimination was evident in the 1970s, which saw the advent of programs to screen and identify carriers of sickle cell anemia, a disease which afflicts African-Americans. Once again, State legislatures began to enact discriminatory laws in the area, and in the early 1970s began mandating genetic screening of all African Americans for sickle cell anemia, leading to discrimination and unnecessary fear. To alleviate some of this stigma, Congress in 1972 passed the National Sickle Cell Anemia Control Act, which withholds Federal funding from States unless sickle cell testing is voluntary.

(4) Congress has been informed of examples of genetic discrimination in the workplace. These include the use of pre-employment genetic screening at Lawrence Berkeley Laboratory, which led to a court decision in favor of the employees in that case *Norman-Bloodsaw v. Lawrence Berkeley Laboratory* (135 F.3d 1260, 1269 (9th Cir. 1998)). Congress clearly has a compelling public interest in relieving the fear of discrimination and in prohibiting its actual practice in employment and health insurance.

(5) Federal law addressing genetic discrimination in health insurance and employment is incomplete in both the scope and depth of its protections. Moreover, while many States have enacted some type of genetic non-discrimination law, these laws vary widely with respect to their approach, application, and level of protection. Congress has collected substantial evidence that the American public and the medical community find the existing patchwork of State and Federal laws to be confusing and inadequate to protect them from discrimination. Therefore Federal legislation establishing a national and uniform basic standard is necessary to fully protect the public from discrimination and allay their concerns about the potential for discrimination, thereby allowing individuals to take advantage of genetic testing, technologies, research, and new therapies.

**TITLE I--GENETIC NONDISCRIMINATION IN HEALTH INSURANCE**

**SEC. 101. AMENDMENTS TO EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.**

(a) No Discrimination in Group Premiums Based on Genetic Information.--Section 702(b) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182(b)) is amended--

(1) in paragraph (2)(A), by inserting before the semicolon the following: “except as provided in paragraph (3)”;

and (2) by adding at the end the following:

“(3) No group-based discrimination on basis of genetic information.--

“(A) In general.--For purposes of this section, a group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not adjust premium or contribution amounts for the group covered under such plan on the basis of genetic information.

“(B) Rule of construction.--Nothing in subparagraph (A) or in paragraphs (1) and (2) of subsection (d) shall be construed to limit the ability of a health insurance issuer offering health insurance coverage in connection with a group health plan to increase the premium for an employer based on the manifestation of a disease or disorder of an individual who is enrolled in the plan. In such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members and to further increase the premium for the employer.”

(b) Limitations on Genetic Testing; Prohibition on Collection of Genetic Information; Application to All Plans.--Section 702 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182) is amended by adding at the end the following:

“(c) Genetic Testing.--

“(1) Limitation on requesting or requiring genetic testing.--A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require an individual or a family member of such individual to undergo a genetic test.

“(2) Rule of construction.--Paragraph (1) shall not be construed to limit the authority of a health care professional who is providing health care services to an individual to request that such individual undergo a genetic test.

“(3) Rule of construction regarding payment.--

“(A) In general.--Nothing in paragraph (1) shall be construed to preclude a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, from obtaining and using the results of a genetic test in making a determination regarding payment (as such term is defined for the purposes of applying the regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act and section 264 of the Health Insurance Portability and Accountability Act of 1996, as may be revised from time to time) consistent with subsection (a).

“(B) Limitation.--For purposes of subparagraph (A), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health

plan, may request only the minimum amount of information necessary to accomplish the intended purpose.

“(4) Research exception.--Notwithstanding paragraph (1), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, may request, but not require, that a participant or beneficiary undergo a genetic test if each of the following conditions is met:

“(A) The request is made, in writing, pursuant to research that complies with part 46 of title 45, Code of Federal Regulations, or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

“(B) The plan or issuer clearly indicates to each participant or beneficiary, or in the case of a minor child, to the legal guardian of such beneficiary, to whom the request is made that—

“(i) compliance with the request is voluntary; and

“(ii) non-compliance will have no effect on enrollment status or premium or contribution amounts.

“(C) No genetic information collected or acquired under this paragraph shall be used for underwriting purposes.

“(D) The plan or issuer notifies the Secretary in writing that the plan or issuer is conducting activities pursuant to the exception provided for under this paragraph, including a description of the activities conducted.

“(E) The plan or issuer complies with such other conditions as the Secretary may by regulation require for activities conducted under this paragraph.

“(d) Prohibition on Collection of Genetic Information.--

“(1) In general.--A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request, require, or purchase genetic information for underwriting purposes (as defined in section 733).

“(2) Prohibition on collection of genetic information prior to enrollment.--A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request, require, or purchase genetic information with respect to any individual prior to such individual’s enrollment under the plan or coverage in connection with such enrollment.

“(3) Incidental collection.--If a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual, such request, requirement, or purchase shall not be considered a violation of paragraph (2) if such request, requirement, or purchase is not in violation of paragraph (1).

“(e) Application to All Plans.--The provisions of subsections (a)(1)(F), (b)(3), (c), and (d), and subsection (b)(1) and section 701 with respect to genetic information, shall apply to group health plans and health insurance issuers without regard to section 732(a).”.

(c) Application to Genetic Information of a Fetus or Embryo.--Such section is further amended by adding at the end the following:

“(f) Genetic Information of a Fetus or Embryo.--Any reference in this part to genetic information concerning an individual or family member of an individual shall--

“(1) with respect to such an individual or family member of an individual who is a pregnant woman, include genetic information of any fetus carried by such pregnant woman; and

“(2) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.”.

(d) Definitions.--Section 733(d) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191b(d)) is amended by adding at the end the following:

“(5) Family member.--The term ‘family member’ means, with respect to an individual--

“(A) a dependent (as such term is used for purposes of section 701(f)(2)) of such individual, and

“(B) any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative of such individual or of an individual described in subparagraph (A).

“(6) Genetic information.--

“(A) In general.--The term ‘genetic information’ means, with respect to any individual, information about--

“(i) such individual’s genetic tests,

“(ii) the genetic tests of family members of such individual, and

“(iii) the manifestation of a disease or disorder in family members of such individual.

“(B) Inclusion of genetic services and participation in genetic research.--Such term includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual.

“(C) Exclusions.--The term ‘genetic information’ shall not include information about the sex or age of any individual. “

(7) Genetic test.--

“(A) In general.--The term ‘genetic test’ means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

“(B) Exceptions.--The term ‘genetic test’ does not mean--

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

“(ii) 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.

“(8) Genetic services.--The term ‘genetic services’ means—

“(A) a genetic test;

“(B) genetic counseling (including obtaining, interpreting, or assessing genetic information); or

“(C) genetic education.

“(9) Underwriting purposes.--The term ‘underwriting purposes’ means, with respect to any group health plan, or health insurance coverage offered in connection with a group health plan—

“(A) rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage;

“(B) the computation of premium or contribution amounts under the plan or coverage;

“(C) the application of any pre-existing condition exclusion under the plan or coverage; and

“(D) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.”.

(e) ERISA Enforcement.--Section 502 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132) is amended—

(1) in subsection (a)(6), by striking “(7), or (8)” and inserting “(7), (8), or (9)”;

(2) in subsection (b)(3), by striking “The Secretary” and inserting “Except as provided in subsections (c)(9) and (a)(6) (with respect to collecting civil penalties under subsection (c)(9)), the Secretary”; and

(3) in subsection (c), by redesignating paragraph (9) as paragraph (10), and by inserting after paragraph (8) the following new paragraph:

“(9) Secretarial enforcement authority relating to use of genetic information.--

“(A) General rule.--The Secretary may impose a penalty against any plan sponsor of a group health plan, or any health insurance issuer offering health insurance coverage in connection with the plan, for any failure by such sponsor or issuer to meet the requirements of subsection (a)(1)(F), (b)(3), (c), or (d) of section 702 or section 701 or 702(b)(1) with respect to genetic information, in connection with the plan.

“(B) Amount.--



“(i) In general.--The amount of the penalty imposed by subparagraph (A) shall be \$100 for each day in the noncompliance period with respect to each participant or beneficiary to whom such failure relates.

“(ii) Noncompliance period.--For purposes of this paragraph, the term ‘noncompliance period’ means, with respect to any failure, the period—

“(I) beginning on the date such failure first occurs; and

“(II) ending on the date the failure is corrected.

“(C) Minimum penalties where failure discovered.-- Notwithstanding clauses (i) and (ii) of subparagraph (D):

“(i) In general.--In the case of 1 or more failures with respect to a participant or beneficiary--

“(I) which are not corrected before the date on which the plan receives a notice from the Secretary of such violation; and

“(II) which occurred or continued during the period involved; the amount of penalty imposed by subparagraph (A) by reason of such failures with respect to such participant or beneficiary shall not be less than \$2,500.

“(ii) Higher minimum penalty where violations are more than de minimis.--To the extent violations for which any person is liable under this paragraph for any year are more than de minimis, clause (i) shall be applied by substituting ‘\$15,000’ for ‘\$2,500’ with respect to such person. “(D) Limitations.--

“(i) Penalty not to apply where failure not discovered exercising reasonable diligence.-- No penalty shall be imposed by subparagraph (A) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such penalty did not know, and exercising reasonable diligence would not have known, that such failure existed.

“(ii) Penalty not to apply to failures corrected within certain periods.--No penalty shall be imposed by subparagraph (A) on any failure if--

“(I) such failure was due to reasonable cause and not to willful neglect; and

“(II) such failure is corrected during the 30-day period beginning on the first date the person otherwise liable for such penalty knew, or exercising reasonable diligence would have known, that such failure existed.

“(iii) Overall limitation for unintentional failures.--In the case of failures which are due to reasonable cause and not to willful neglect, the penalty imposed by subparagraph (A) for failures shall not exceed the amount equal to the lesser of--

“(I) 10 percent of the aggregate amount paid or incurred by the plan sponsor (or predecessor plan sponsor) during the preceding taxable year for group health plans; or

“(II) \$500,000.

“(E) Waiver by secretary.--In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the penalty imposed by subparagraph (A) to the extent that the payment of such penalty would be excessive relative to the failure involved.

“(F) Definitions.--Terms used in this paragraph which are defined in section 733 shall have the meanings provided such terms in such section.”.

(f) Regulations and Effective Date.--

(1) Regulations.--The Secretary of Labor shall issue final regulations not later than 12 months after the date of enactment of this Act to carry out the amendments made by this section.

(2) Effective date.--The amendments made by this section shall apply with respect to group health plans for plan years beginning after the date that is 1 year after the date of enactment of this Act.

**SEC. 102. AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT.**

(a) Amendments Relating to the Group Market.—

(1) No discrimination in group premiums based on genetic information.--Section 2702(b) of the Public Health Service Act (42 U.S.C. 300gg-1(b)) is amended--

(A) in paragraph (2)(A), by inserting before the semicolon the following: “except as provided in paragraph (3)”;

(B) by adding at the end the following: “

(3) No group-based discrimination on basis of genetic information.--

“(A) In general.--For purposes of this section, a group health plan, and health insurance issuer offering group health insurance coverage in connection with a group health plan, may not adjust premium or contribution amounts for the group covered under such plan on the basis of genetic information.

“(B) Rule of construction.--Nothing in subparagraph (A) or in paragraphs (1) and (2) of subsection (d) shall be construed to limit the ability of a health insurance issuer offering health insurance coverage in connection with a group health plan to increase the premium for an employer based on the manifestation of a disease or disorder of an individual who is enrolled in the plan. In such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members and to further increase the premium for the employer.”.

(2) Limitations on genetic testing; prohibition on collection of genetic information; application to all plans.-- Section 2702 of the Public Health Service Act (42 U.S.C. 300gg- 1) is amended by adding at the end the following:

“(c) Genetic Testing.--

“(1) Limitation on requesting or requiring genetic testing.--A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall

not request or require an individual or a family member of such individual to undergo a genetic test.

“(2) Rule of construction.--Paragraph (1) shall not be construed to limit the authority of a health care professional who is providing health care services to an individual to request that such individual undergo a genetic test.

“(3) Rule of construction regarding payment.--

“(A) In general.--Nothing in paragraph (1) shall be construed to preclude a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, from obtaining and using the results of a genetic test in making a determination regarding payment (as such term is defined for the purposes of applying the regulations promulgated by the Secretary under part C of title XI of the Social Security Act and section 264 of the Health Insurance Portability and Accountability Act of 1996, as may be revised from time to time) consistent with subsection (a).

“(B) Limitation.--For purposes of subparagraph (A), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, may request only the minimum amount of information necessary to accomplish the intended purpose.

“(4) Research exception.--Notwithstanding paragraph (1), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, may request, but not require, that a participant or beneficiary undergo a genetic test if each of the following conditions is met:

“(A) The request is made pursuant to research that complies with part 46 of title 45, Code of Federal Regulations, or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

“(B) The plan or issuer clearly indicates to each participant or beneficiary, or in the case of a minor child, to the legal guardian of such beneficiary, to whom the request is made that--

“(i) compliance with the request is voluntary; and

“(ii) non-compliance will have no effect on enrollment status or premium or contribution amounts.

“(C) No genetic information collected or acquired under this paragraph shall be used for underwriting purposes.

“(D) The plan or issuer notifies the Secretary in writing that the plan or issuer is conducting activities pursuant to the exception provided for under this paragraph, including a description of the activities conducted.

“(E) The plan or issuer complies with such other conditions as the Secretary may by regulation require for activities conducted under this paragraph.

“(d) Prohibition on Collection of Genetic Information.--

“(1) In general.--A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request, require, or purchase genetic information for underwriting purposes (as defined in section 2791).

“(2) Prohibition on collection of genetic information prior to enrollment.--A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request, require, or purchase genetic information with respect to any individual prior to such individual’s enrollment under the plan or coverage in connection with such enrollment.

“(3) Incidental collection.--If a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual, such request, requirement, or purchase shall not be considered a violation of paragraph (2) if such request, requirement, or purchase is not in violation of paragraph (1).

“(e) Application to All Plans.--The provisions of subsections (a)(1)(F), (b)(3), (c) , and (d) and subsection (b)(1) and section 2701 with respect to genetic information, shall apply to group health plans and health insurance issuers without regard to section 2721(a).”.

(3) Application to genetic information of a fetus or embryo.--Such section is further amended by adding at the end the following:

“(f) Genetic Information of a Fetus or Embryo.--Any reference in this part to genetic information concerning an individual or family member of an individual shall--

“(1) with respect to such an individual or family member of an individual who is a pregnant woman, include genetic information of any fetus carried by such pregnant woman; and

“(2) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.”.

(4) Definitions.--Section 2791(d) of the Public Health Service Act (42 U.S.C. 300gg-91(d)) is amended by adding at the end the following:

“(15) Family member.--The term ‘family member’ means, with respect to any individual--

“(A) a dependent (as such term is used for purposes of section 2701(f)(2)) of such individual; and

“(B) any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative of such individual or of an individual described in subparagraph (A).

“(16) Genetic information.--

“(A) In general.--The term ‘genetic information’ means, with respect to any individual, information about--

“(i) such individual’s genetic tests,

“(ii) the genetic tests of family members of such individual, and

“(iii) the manifestation of a disease or disorder in family members of such individual.

“(B) Inclusion of genetic services and participation in genetic research.--Such term includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual.

“(C) Exclusions.--The term ‘genetic information’ shall not include information about the sex or age of any individual. “(17) Genetic test.--

“(A) In general.--The term ‘genetic test’ means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

“(B) Exceptions.--The term ‘genetic test’ does not mean--

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

“(ii) 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.

“(18) Genetic services.--The term ‘genetic services’ means--

“(A) a genetic test;

“(B) genetic counseling (including obtaining, interpreting, or assessing genetic information); or

“(C) genetic education.

“(19) Underwriting purposes.--The term ‘underwriting purposes’ means, with respect to any group health plan, or health insurance coverage offered in connection with a group health plan--

“(A) rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage;

“(B) the computation of premium or contribution amounts under the plan or coverage;

“(C) the application of any pre-existing condition exclusion under the plan or coverage; and

“(D) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.”.

(5) Remedies and enforcement.--Section 2722(b) of the Public Health Service Act (42 U.S.C. 300gg-22(b)) is amended by adding at the end the following:

“(3) Enforcement authority relating to genetic discrimination.--

“(A) General rule.--In the cases described in paragraph (1), notwithstanding the provisions of paragraph (2)(C), the succeeding subparagraphs of this paragraph shall apply with respect to an action under this subsection by the Secretary with respect to any failure of a health insurance issuer in connection with a group health plan, to meet the requirements of subsection (a)(1)(F), (b)(3), (c), or (d) of section 2702 or section 2701 or 2702(b)(1) with respect to genetic information in connection with the plan.

“(B) Amount.--

“(i) In general.--

The amount of the penalty imposed under this paragraph shall be \$100 for each day in the noncompliance period with respect to each participant or beneficiary to whom such failure relates.

“(ii) Noncompliance period.--For purposes of this paragraph, the term ‘noncompliance period’ means, with respect to any failure, the period--

“(I) beginning on the date such failure first occurs; and

“(II) ending on the date the failure is corrected.

“(C) Minimum penalties where failure discovered.-- Notwithstanding clauses (i) and (ii) of subparagraph (D):

“(i) In general.--In the case of 1 or more failures with respect to an individual--

“(I) which are not corrected before the date on which the plan receives a notice from the Secretary of such violation; and

“(II) which occurred or continued during the period involved; the amount of penalty imposed by subparagraph (A) by reason of such failures with respect to such individual shall not be less than \$2,500.

“(ii) Higher minimum penalty where violations are more than de minimis.-- To the extent violations for which any person is liable under this paragraph for any year are more than de minimis, clause (i) shall be applied by substituting ‘\$15,000’ for ‘\$2,500’ with respect to such person.

“(D) Limitations.--

“(i) Penalty not to apply where failure not discovered exercising reasonable diligence.--No penalty shall be imposed by subparagraph (A) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such penalty did not know, and exercising reasonable diligence would not have known, that such failure existed.

“(ii) Penalty not to apply to failures corrected within certain periods.--No penalty shall be imposed by subparagraph (A) on any failure if-

“(I) such failure was due to reasonable cause and not to willful neglect; and

“(II) such failure is corrected during the 30-day period beginning on the first date the person otherwise liable for such penalty knew, or exercising reasonable diligence would have known, that such failure existed.

“(iii) Overall limitation for unintentional failures.--In the case of failures which are due to reasonable cause and not to willful neglect, the penalty imposed by subparagraph (A) for failures shall not exceed the amount equal to the lesser of--

“(I) 10 percent of the aggregate amount paid or incurred by the employer (or predecessor employer) during the preceding taxable year for group health plans; or

“(II) \$500,000. “(E) Waiver by secretary.--In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the penalty imposed by subparagraph (A) to the extent that the payment of such penalty would be excessive relative to the failure involved.”.

(b) Amendment Relating to the Individual Market.--

(1) In general.--The first subpart 3 of part B of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-51 et seq.) (relating to other requirements) is amended--

(A) by redesignating such subpart as subpart 2; and

(B) by adding at the end the following:

“SEC. 2753.

**PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION.**

“(a) Prohibition on Genetic Information as a Condition of Eligibility.--

“(1) In general.--A health insurance issuer offering health insurance coverage in the individual market may not establish rules for the eligibility (including continued eligibility) of any individual to enroll in individual health insurance coverage based on genetic information.

“(2) Rule of construction.--Nothing in paragraph (1) or in paragraphs (1) and (2) of subsection (e) shall be construed to preclude a health insurance issuer from establishing rules for eligibility for an individual to enroll in individual health insurance coverage based on the manifestation of a disease or disorder in that individual, or in a family member of such individual where such family member is covered under the policy that covers such individual.

“(b) Prohibition on Genetic Information in Setting Premium Rates.--

“(1) In general.--A health insurance issuer offering health insurance coverage in the individual market shall not adjust premium or contribution amounts for an individual on the basis of genetic information concerning the individual or a family member of the individual.

“(2) Rule of construction.--Nothing in paragraph (1) or in paragraphs (1) and (2) of subsection (e) shall be construed to preclude a health insurance issuer from adjusting premium or contribution amounts for an individual on the basis of a manifestation of a disease or disorder in that individual, or in a family member of such individual where such family member is covered under the policy that covers such individual. In such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other individuals covered under the policy issued to such individual and to further increase premiums or contribution amounts.

“(c) Prohibition on Genetic Information as Preexisting Condition.--

“(1) In general.--A health insurance issuer offering health insurance coverage in the individual market may not, on the basis of genetic information, impose any preexisting condition exclusion (as defined in section 2701(b)(1)(A)) with respect to such coverage.

“(2) Rule of construction.--Nothing in paragraph (1) or in paragraphs (1) and (2) of subsection (e) shall be construed to preclude a health insurance issuer from imposing any preexisting condition exclusion for an individual with respect to health insurance coverage on the basis of a manifestation of a disease or disorder in that individual.

“(d) Genetic Testing.--

“(1) Limitation on requesting or requiring genetic testing.--A health insurance issuer offering health insurance coverage in the individual market shall not request or require an individual or a family member of such individual to undergo a genetic test.

“(2) Rule of construction.--Paragraph (1) shall not be construed to limit the authority of a health care professional who is providing health care services to an individual to request that such individual undergo a genetic test.

“(3) Rule of construction regarding payment.--

“(A) In general.--Nothing in paragraph (1) shall be construed to preclude a health insurance issuer offering health insurance coverage in the individual market from obtaining and using the results of a genetic test in making a determination regarding payment (as such term is defined for the purposes of applying the regulations promulgated by the Secretary under part C of title XI of the Social Security Act and section 264 of the Health Insurance Portability and Accountability Act of 1996, as may be revised from time to time) consistent with subsection (a) and (c).

“(B) Limitation.--For purposes of subparagraph (A), a health insurance issuer offering health insurance coverage in the individual market may request only the minimum amount of information necessary to accomplish the intended purpose.

“(4) Research exception.--Notwithstanding paragraph (1), a health insurance issuer offering health insurance coverage in the individual market may request, but not require, that an individual or a family member of such individual undergo a genetic test if each of the following conditions is met:

“(A) The request is made pursuant to research that complies with part 46 of title 45, Code of Federal Regulations, or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

“(B) The issuer clearly indicates to each individual, or in the case of a minor child, to the legal guardian of such child, to whom the request is made that--



“(i) compliance with the request is voluntary; and

“(ii) non-compliance will have no effect on enrollment status or premium or contribution amounts.

“(C) No genetic information collected or acquired under this paragraph shall be used for underwriting purposes.

“(D) The issuer notifies the Secretary in writing that the issuer is conducting activities pursuant to the exception provided for under this paragraph, including a description of the activities conducted.

“(E) The issuer complies with such other conditions as the Secretary may by regulation require for activities conducted under this paragraph.

“(e) Prohibition on Collection of Genetic Information.--

“(1) In general.--A health insurance issuer offering health insurance coverage in the individual market shall not request, require, or purchase genetic information for underwriting purposes (as defined in section 2791).

“(2) Prohibition on collection of genetic information prior to enrollment.--A health insurance issuer offering health insurance coverage in the individual market shall not request, require, or purchase genetic information with respect to any individual prior to such individual’s enrollment under the plan in connection with such enrollment.

“(3) Incidental collection.--If a health insurance issuer offering health insurance coverage in the individual market obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual, such request, requirement, or purchase shall not be considered a violation of paragraph (2) if such request, requirement, or purchase is not in violation of paragraph (1).

“(f) Genetic Information of a Fetus or Embryo.--Any reference in this part to genetic information concerning an individual or family member of an individual shall--

“(1) with respect to such an individual or family member of an individual who is a pregnant woman, include genetic information of any fetus carried by such pregnant woman; and

“(2) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.”.

(2) Remedies and enforcement.--Section 2761(b) of the Public Health Service Act (42 U.S.C. 300gg-61(b)) is amended to read as follows:

“(b) Secretarial Enforcement Authority.--The Secretary shall have the same authority in relation to enforcement of the provisions of this part with respect to issuers of health insurance coverage in the individual market in a State as the Secretary has under section 2722(b)(2), and section 2722(b)(3) with respect to violations of genetic nondiscrimination provisions, in relation to the enforcement of the provisions of part A with respect to issuers of health insurance coverage in the small group market in the State.”.

(c) Elimination of Option of Non-Federal Governmental Plans To Be Excepted From Requirements Concerning Genetic Information.--Section 2721(b)(2) of the Public Health Service Act (42 U.S.C. 300gg-21(b)(2)) is amended--

(1) in subparagraph (A), by striking “If the plan sponsor” and inserting “Except as provided in subparagraph (D), if the plan sponsor”; and

(2) by adding at the end the following:

“(D) Election not applicable to requirements concerning genetic information.--The election described in subparagraph (A) shall not be available with respect to the provisions of subsections (a)(1)(F), (b)(3), (c), and (d) of section 2702 and the provisions of sections 2701 and 2702(b) to the extent that such provisions apply to genetic information.”.

(d) Regulations and Effective Date.--

(1) Regulations.--Not later than 12 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue final regulations to carry out the amendments made by this section.

(2) Effective date.--The amendments made by this section shall apply--

(A) with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning after the date that is 1 year after the date of enactment of this Act; and

(B) with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after the date that is 1 year after the date of enactment of this Act.

#### SEC. 103. AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986.

(a) No Discrimination in Group Premiums Based on Genetic Information.--Subsection (b) of section 9802 of the Internal Revenue Code of 1986 is amended--

(1) in paragraph (2)(A), by inserting before the semicolon the following: “except as provided in paragraph (3)”; and

(2) by adding at the end the following:

“(3) No group-based discrimination on basis of genetic information.--

“(A) In general.--For purposes of this section, a group health plan may not adjust premium or contribution amounts for the group covered under such plan on the basis of genetic information.

“(B) Rule of construction.--Nothing in subparagraph (A) or in paragraphs (1) and (2) of subsection (d) shall be construed to limit the ability of a group health plan to increase the premium for an employer based on the manifestation of a disease or disorder of an individual who is enrolled in the plan. In such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members and to further increase the premium for the employer.”.

(b) Limitations on Genetic Testing; Prohibition on Collection of Genetic Information; Application to All Plans.--Section 9802 of such Code is amended by redesignating subsection (c) as subsection (f) and by inserting after subsection (b) the following new subsections:

“(c) Genetic Testing.--

“(1) Limitation on requesting or requiring genetic testing.--A group health plan may not request or require an individual or a family member of such individual to undergo a genetic test.

“(2) Rule of construction.--Paragraph (1) shall not be construed to limit the authority of a health care professional who is providing health care services to an individual to request that such individual undergo a genetic test.

“(3) Rule of construction regarding payment.--

“(A) In general.--Nothing in paragraph (1) shall be construed to preclude a group health plan from obtaining and using the results of a genetic test in making a determination regarding payment (as such term is defined for the purposes of applying the regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act and section 264 of the Health Insurance Portability and Accountability Act of 1996, as may be revised from time to time) consistent with subsection (a).

“(B) Limitation.--For purposes of subparagraph (A), a group health plan may request only the minimum amount of information necessary to accomplish the intended purpose.

“(4) Research exception.--Notwithstanding paragraph (1), a group health plan may request, but not require, that a participant or beneficiary undergo a genetic test if each of the following conditions is met:

“(A) The request is made pursuant to research that complies with part 46 of title 45, Code of Federal Regulations, or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

“(B) The plan clearly indicates to each participant or beneficiary, or in the case of a minor child, to the legal guardian of such beneficiary, to whom the request is made that--

“(i) compliance with the request is voluntary; and

“(ii) non-compliance will have no effect on enrollment status or premium or contribution amounts.

“(C) No genetic information collected or acquired under this paragraph shall be used for underwriting purposes.

“(D) The plan notifies the Secretary in writing that the plan is conducting activities pursuant to the exception provided for under this paragraph, including a description of the activities conducted.

“(E) The plan complies with such other conditions as the Secretary may by regulation require for activities conducted under this paragraph.

**“(d) Prohibition on Collection of Genetic Information.--**

“(1) In general.--A group health plan shall not request, require, or purchase genetic information for underwriting purposes (as defined in section 9832).

“(2) Prohibition on collection of genetic information prior to enrollment.--A group health plan shall not request, require, or purchase genetic information with respect to any individual prior to such individual’s enrollment under the plan or in connection with such enrollment.

“(3) Incidental collection.--If a group health plan obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual, such request, requirement, or purchase shall not be considered a violation of paragraph (2) if such request, requirement, or purchase is not in violation of paragraph (1).

**“(e) Application to All Plans.--**The provisions of subsections (a)(1)(F), (b)(3), (c), and (d) and subsection (b)(1) and section 9801 with respect to genetic information, shall apply to group health plans without regard to section 9831(a)(2).”.

**(c) Application to Genetic Information of a Fetus or Embryo.--**Such section is further amended by adding at the end the following:

**“(f) Genetic Information of a Fetus or Embryo.--**Any reference in this chapter to genetic information concerning an individual or family member of an individual shall--

“(1) with respect to such an individual or family member of an individual who is a pregnant woman, include genetic information of any fetus carried by such pregnant woman; and

“(2) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.”.

**(d) Definitions.--**Subsection (d) of section 9832 of such Code is amended by adding at the end the following:

**“(6) Family member.--**The term ‘family member’ means, with respect to any individual--

“(A) a dependent (as such term is used for purposes of section 9801(f)(2)) of such individual, and

“(B) any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative of such individual or of an individual described in subparagraph (A).

**“(7) Genetic information.--**

“(A) In general.--The term ‘genetic information’ means, with respect to any individual, information about--

“(i) such individual’s genetic tests,

“(ii) the genetic tests of family members of such individual, and

“(iii) the manifestation of a disease or disorder in family members of such individual.

“(B) Inclusion of genetic services and participation in genetic research.--Such term includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual.

“(C) Exclusions.--The term ‘genetic information’ shall not include information about the sex or age of any individual.

“(8) Genetic test.--

“(A) In general.--The term ‘genetic test’ means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

“(B) Exceptions.--The term ‘genetic test’ does not mean--

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

“(ii) 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.

“(9) Genetic services.--The term ‘genetic services’ means--

“(A) a genetic test;

“(B) genetic counseling (including obtaining, interpreting, or assessing genetic information); or

“(C) genetic education.

“(10) Underwriting purposes.--The term ‘underwriting purposes’ means, with respect to any group health plan, or health insurance coverage offered in connection with a group health plan--

“(A) rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage;

“(B) the computation of premium or contribution amounts under the plan or coverage;

“(C) the application of any pre-existing condition exclusion under the plan or coverage; and

“(D) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.”.

(e) Enforcement.--

(1) In general.--Subchapter C of chapter 100 of the Internal Revenue Code of 1986 (relating to general provisions) is amended by adding at the end the following new section:

“SEC. 9834. ENFORCEMENT.

“For the imposition of tax on any failure of a group health plan to meet the requirements of this chapter, see section 4980D.”. (2) Conforming amendment.--The table of sections for subchapter C of chapter 100 of such Code is amended by adding at the end the following new item:

“Sec. 9834. Enforcement.”.

(f) Regulations and Effective Date.--

(1) Regulations.--The Secretary of the Treasury shall issue final regulations or other guidance not later than 12 months after the date of the enactment of this Act to carry out the amendments made by this section.

(2) Effective date.--The amendments made by this section shall apply with respect to group health plans for plan years beginning after the date that is 1 year after the date of the enactment of this Act.

SEC. 104. AMENDMENTS TO TITLE XVIII OF THE SOCIAL SECURITY ACT RELATING TO MEDIGAP.

(a) Nondiscrimination.--Section 1882(s)(2) of the Social Security Act (42 U.S.C. 1395ss(s)(2)) is amended by adding at the end the following:

“(E) An issuer of a medicare supplemental policy shall not deny or condition the issuance or effectiveness of the policy (including the imposition of any exclusion of benefits under the policy based on a pre-existing condition) and shall not discriminate in the pricing of the policy (including the adjustment of premium rates) of an individual on the basis of the genetic information with respect to such individual.

“(F) Rule of construction.--Nothing in subparagraph (E) or in subparagraphs (A) or (B) of subsection (x)(2) shall be construed to limit the ability of an issuer of a medicare supplemental policy from, to the extent otherwise permitted under this title--

“(i) denying or conditioning the issuance or effectiveness of the policy or increasing the premium for an employer based on the manifestation of a disease or disorder of an individual who is covered under the policy; or

“(ii) increasing the premium for any policy issued to an individual based on the manifestation of a disease or disorder of an individual who is covered under the policy (in such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members and to further increase the premium for the employer).”.

(b) Limitations on Genetic Testing and Genetic Information.-- (1) In general.--Section 1882 of the Social Security Act (42 U.S.C. 1395ss) is amended by adding at the end the following:

“(x) Limitations on Genetic Testing and Information.--

“(1) Genetic testing.--

“(A) Limitation on requesting or requiring genetic testing.--An issuer of a medicare supplemental policy shall not request or require an individual or a family member of such individual to undergo a genetic test.

“(B) Rule of construction.--Subparagraph (A) shall not be construed to limit the authority of a health care professional who is providing health care services to an individual to request that such individual undergo a genetic test.

“(C) Rule of construction regarding payment.--

“(i) In general.--Nothing in subparagraph (A) shall be construed to preclude an issuer of a medicare supplemental policy from obtaining and using the results of a genetic test in making a determination regarding payment (as such term is defined for the purposes of applying the regulations promulgated by the Secretary under part C of title XI and section 264 of the Health Insurance Portability and Accountability Act of 1996, as may be revised from time to time) consistent with subsection (s)(2)(E).

“(ii) Limitation.--For purposes of clause (i), an issuer of a medicare supplemental policy may request only the minimum amount of information necessary to accomplish the intended purpose.

“(D) Research exception.--Notwithstanding subparagraph (A), an issuer of a medicare supplemental policy may request, but not require, that an individual or a family member of such individual undergo a genetic test if each of the following conditions is met:

“(i) The request is made pursuant to research that complies with part 46 of title 45, Code of Federal Regulations, or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

“(ii) The issuer clearly indicates to each individual, or in the case of a minor child, to the legal guardian of such child, to whom the request is made that--

“(I) compliance with the request is voluntary; and

“(II) non-compliance will have no effect on enrollment status or premium or contribution amounts.

“(iii) No genetic information collected or acquired under this subparagraph shall be used for underwriting, determination of eligibility to enroll or maintain enrollment status, premium rating, or the creation, renewal, or replacement of a plan, contract, or coverage for health insurance or health benefits.

“(iv) The issuer notifies the Secretary in writing that the issuer is conducting activities pursuant to the exception provided for under this subparagraph, including a description of the activities conducted.

“(v) The issuer complies with such other conditions as the Secretary may by regulation require for activities conducted under this subparagraph.

“(2) Prohibition on collection of genetic information.--

“(A) In general.--An issuer of a medicare supplemental policy shall not request, require, or purchase genetic information for underwriting purposes (as defined in paragraph (3)).

“(B) Prohibition on collection of genetic information prior to enrollment.--An issuer of a medicare supplemental policy shall not request, require, or purchase genetic information with respect to any individual prior to such individual’s enrollment under the policy in connection with such enrollment.

“(C) Incidental collection.--If an issuer of a medicare supplemental policy obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual, such request, requirement, or purchase shall not be considered a violation of subparagraph (B) if such request, requirement, or purchase is not in violation of subparagraph (A).

“(3) Definitions.--In this subsection:

“(A) Family member.--The term ‘family member’ means with respect to an individual, any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative of such individual.

“(B) Genetic information.--

“(i) In general.--The term ‘genetic information’ means, with respect to any individual, information about--

“(I) such individual’s genetic tests,

“(II) the genetic tests of family members of such individual, and

“(III) subject to clause (iv), the manifestation of a disease or disorder in family members of such individual.

“(ii) Inclusion of genetic services and participation in genetic research.--Such term includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual.

“(iii) Exclusions.--The term ‘genetic information’ shall not include information about the sex or age of any individual.

“(C) Genetic test.--

“(i) In general.--The term ‘genetic test’ means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

“(ii) Exceptions.--The term ‘genetic test’ does not mean--

“(I) an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or

“(II) 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.



“(D) Genetic services.--The term ‘genetic services’ means--

“(i) a genetic test;

“(ii) genetic counseling (including obtaining, interpreting, or assessing genetic information); or

“(iii) genetic education.

“(E) Underwriting purposes.--The term ‘underwriting purposes’ means, with respect to a medicare supplemental policy--

“(i) rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the policy;

“(ii) the computation of premium or contribution amounts under the policy;

“(iii) the application of any pre-existing condition exclusion under the policy; and

“(iv) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

“(F) Issuer of a medicare supplemental policy.--The term ‘issuer of a medicare supplemental policy’ includes a third-party administrator or other person acting for or on behalf of such issuer.”.

(2) Application to genetic information of a fetus or embryo.--Section 1882(x) of such Act, as added by paragraph (1), is further amended by adding at the end the following:

“(4) Genetic information of a fetus or embryo.--Any reference in this section to genetic information concerning an individual or family member of an individual shall--

“(A) with respect to such an individual or family member of an individual who is a pregnant woman, include genetic information of any fetus carried by such pregnant woman; and

“(B) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.”.

(3) Conforming amendment.--Section 1882(o) of the Social Security Act (42 U.S.C. 1395ss(o)) is amended by adding at the end the following: “(4) The issuer of the medicare supplemental policy complies with subsection (s)(2)(E) and subsection (x).”.

(c) Effective Date.--The amendments made by this section shall apply with respect to an issuer of a medicare supplemental policy for policy years beginning on or after the date that is 1 year after the date of enactment of this Act.

(d) Transition Provisions.--

(1) In general.--If the Secretary of Health and Human Services identifies a State as requiring a change to its statutes or regulations to conform its regulatory program to the changes made by this section, the State regulatory program shall not be considered to be out of compliance with the requirements of section 1882 of the Social Security Act due solely to failure to make such change until the date specified in paragraph (4).

(2) NAIC standards.--If, not later than October 31, 2008, the National Association of Insurance Commissioners (in this subsection referred to as the "NAIC") modifies its NAIC Model Regulation relating to section 1882 of the Social Security Act (referred to in such section as the 1991 NAIC Model Regulation, as subsequently modified) to conform to the amendments made by this section, such revised regulation incorporating the modifications shall be considered to be the applicable NAIC model regulation (including the revised NAIC model regulation and the 1991 NAIC Model Regulation) for the purposes of such section.

(3) Secretary standards.--If the NAIC does not make the modifications described in paragraph (2) within the period specified in such paragraph, the Secretary of Health and Human Services shall, not later than July 1, 2009, make the modifications described in such paragraph and such revised regulation incorporating the modifications shall be considered to be the appropriate regulation for the purposes of such section.

(4) Date specified.--

(A) In general.--Subject to subparagraph (B), the date specified in this paragraph for a State is the earlier of--

(i) the date the State changes its statutes or regulations to conform its regulatory program to the changes made by this section, or

(ii) July 1, 2009. (B) Additional legislative action required.--In the case of a State which the Secretary identifies as-- (i) requiring State legislation (other than legislation appropriating funds) to conform its regulatory program to the changes made in this section, but (ii) having a legislature which is not scheduled to meet in 2009 in a legislative session in which such legislation may be considered, the date specified in this paragraph is the first day of the first calendar quarter beginning after the close of the first legislative session of the State legislature that begins on or after July 1, 2009. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

#### SEC. 105. PRIVACY AND CONFIDENTIALITY.

(a) In General.--Part C of title XI of the Social Security Act is amended by adding at the end the following new section:

"application of hipaa regulations to genetic information

"Sec. 1180. (a) In General.--The Secretary shall revise the HIPAA privacy regulation (as defined in subsection (b)) so it is consistent with the following:

"(1) Genetic information shall be treated as health information described in section 1171(4)(B).

“(2) The use or disclosure by a covered entity that is a group health plan, health insurance issuer that issues health insurance coverage, or issuer of a medicare supplemental policy of protected health information that is genetic information about an individual for underwriting purposes under the group health plan, health insurance coverage, or medicare supplemental policy shall not be a permitted use or disclosure.

“(b) Definitions.--For purposes of this section:

“(1) Genetic information; genetic test; family member.--The terms ‘genetic information’, ‘genetic test’, and ‘family member’ have the meanings given such terms in section 2791 of the Public Health Service Act (42 U.S.C. 300gg-91), as amended by the Genetic Information Nondiscrimination Act of 2007.

“(2) Group health plan; health insurance coverage; medicare supplemental policy.--The terms ‘group health plan’ and ‘health insurance coverage’ have the meanings given such terms under section 2791 of the Public Health Service Act (42 U.S.C. 300gg- 91), and the term ‘medicare supplemental policy’ has the meaning given such term in section 1882(g).

“(3) HIPAA privacy regulation.--The term ‘HIPAA privacy regulation’ means the regulations promulgated by the Secretary under this part and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note).

“(4) Underwriting purposes.--The term ‘underwriting purposes’ means, with respect to a group health plan, health insurance coverage, or a medicare supplemental policy--

“(A) rules for, or determination of, eligibility (including enrollment and continued eligibility) for, or determination of, benefits under the plan, coverage, or policy;

“(B) the computation of premium or contribution amounts under the plan, coverage, or policy;

“(C) the application of any pre-existing condition exclusion under the plan, coverage, or policy; and

“(D) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

“(c) Procedure.--The revisions under subsection (a) shall be made by notice in the Federal Register published not later than 60 days after the date of the enactment of this section and shall be effective upon publication, without opportunity for any prior public comment, but may be revised, consistent with this section, after opportunity for public comment.

“(d) Enforcement.--In addition to any other sanctions or remedies that may be available under law, a covered entity that is a group health plan, health insurance issuer, or issuer of a medicare supplemental policy and that violates the HIPAA privacy regulation (as revised under subsection (a) or otherwise) with respect to the use or disclosure of genetic information shall be subject to the penalties described in sections 1176 and 1177 in the same manner and to the same extent that such penalties apply to violations of this part.”.

**(b) Regulations; Effective Date.--**

(1) Regulations.--Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue final regulations to carry out the revision required by section 1180(a) of the Social Security Act, as added by subsection (a). The Secretary has the sole authority to promulgate such regulations, but shall promulgate such regulations in consultation with the Secretaries of Labor and the Treasury.

(2) Effective date.--The amendment made by subsection (a) shall take effect on the date that is 1 year after the date of the enactment of this Act.

**SEC. 106. ASSURING COORDINATION.**

Except as provided in section 105(b)(1), the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall ensure, through the execution of an interagency memorandum of understanding among such Secretaries, that-- (1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which two or more such Secretaries have responsibility under this title (and the amendments made by this title) are administered so as to have the same effect at all times; and (2) coordination of policies relating to enforcing the same requirements through such Secretaries in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement.

**TITLE II--PROHIBITING EMPLOYMENT DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION**

**Sec. 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.

Sec. 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 Sec. 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.).

#### Sec. 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 Sec. 1635.3(a)(1).

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

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

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

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

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

(c) Genetic information.

(1) Genetic information means information about:

- (i) An individual's genetic tests;
- (ii) The genetic tests of that individual's family members;
- (iii) The manifestation of disease or disorder in family members of the individual (family medical history);
- (iv) An individual's request for, or receipt of, genetic services, or the participation in clinical research that includes genetic services by the individual or a family member of the individual; or
- (v) The genetic information of a fetus carried by an individual or by a pregnant woman who is a family member of the individual and the genetic information of any embryo legally held by the individual or family member using an assisted reproductive technology.

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

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

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

(f) Genetic test—

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

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

- i) A test to determine whether someone has the BRCA1 or BRCA2 variant evidencing a predisposition to breast cancer, a test to determine whether someone has a genetic variant associated with hereditary nonpolyposis colon cancer, and a test for a genetic variant for Huntington's Disease;
- (ii) Carrier screening for adults using genetic analysis to determine the risk of conditions such as cystic fibrosis, sickle cell anemia, spinal muscular atrophy, or fragile X syndrome in future offspring;
- (iii) Amniocentesis and other evaluations used to determine the presence of genetic abnormalities in a fetus during pregnancy;
- (iv) Newborn screening analysis that uses DNA, RNA, protein, or metabolite analysis to detect or indicate genotypes, mutations, or chromosomal changes, such as a test for PKU performed so that treatment can begin before a disease manifests;

- (v) Preimplantation genetic diagnosis performed on embryos created using invitro fertilization;
- (vi) Pharmacogenetic tests that detect genotypes, mutations, or chromosomal changes that indicate how an individual will react to a drug or a particular dosage of a drug;
- (vii) DNA testing to detect genetic markers that are associated with information about ancestry; and
- (viii) DNA testing that reveals family relationships, such as paternity.

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

- (i) An analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes;
- (ii) A medical examination that tests for the presence of a virus that is not composed of human DNA, RNA, chromosomes, proteins, or metabolites;
- (iii) A test for infectious and communicable diseases that may be transmitted through food handling;
- (iv) Complete blood counts, cholesterol tests, and liver-function tests.

(4) Alcohol and Drug Testing--

- (i) A test for the presence of alcohol or illegal drugs is not a genetic test.
- (ii) A test to determine whether an individual has a genetic predisposition for alcoholism or drug use is a genetic test.

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

Sec. 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.

**Sec. 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.

**Sec. 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.

**Sec. 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.

**Sec. 1635.8 Acquisition of genetic information.**

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

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

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

(i) Requests for Medical Information:

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) This exception applies only where—

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

(B) The individual provides prior knowing, voluntary, and written authorization, which may include authorization in electronic format. This requirement is only met if the covered entity uses an authorization form that:

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

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

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

(C) Individually identifiable genetic information is provided only to the individual (or family member if the family member is receiving genetic services) and the licensed health care professionals or board certified genetic counselors involved in providing such services, and is

not accessible to managers, supervisors, or others who make employment decisions, or to anyone else in the workplace; and

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

(ii) Consistent with the requirements of paragraph (b)(2)(i) of this section, a covered entity may not offer a financial inducement for individuals to provide genetic information, but may offer financial inducements for completion of health risk assessments that include questions about family medical history or other genetic information, provided the covered entity makes clear, in language reasonably likely to be understood by those completing the health risk assessment, that the inducement will be made available whether or not the participant answers questions regarding genetic information. For example:

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

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

(iii) A covered entity may offer financial inducements to encourage individuals who have voluntarily provided genetic information (e.g., family medical history) that indicates that they are at increased risk of acquiring a health condition in the future to participate in disease management programs or other programs that promote healthy lifestyles, and/or to meet particular health goals as part of a health or genetic service. However, to comply with Title II of GINA, these programs must also be offered to individuals with current health conditions and/or to individuals whose lifestyle choices put them at increased risk of developing a condition. For example:

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

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

- (iv) Nothing contained in Sec. 1635.8(b)(2)(iii) limits the rights or protections of an individual under the Americans with Disabilities Act (ADA), as amended, or other applicable civil rights laws, or under the Health Insurance Portability and Accountability Act (HIPAA), as amended by GINA. For example, if an employer offers a financial inducement for participation in disease management programs or other programs that promote healthy lifestyles and/or require individuals to meet particular health goals, the employer must make reasonable accommodations to the extent required by the ADA, that is, the employer must make "modifications or adjustments that enable a covered entity's employee with a disability to enjoy equal benefits and privileges of employment as are enjoyed by its other similarly situated employees without disabilities" unless "such covered entity can demonstrate that the accommodation would impose an undue hardship on the operation of its business." 29 CFR 1630.2(o)(1)(iii); 29 CFR 1630.9(a). In addition, if the employer's wellness program provides (directly, through reimbursement, or otherwise) medical care (including genetic counseling), the program may constitute a group health plan and must comply with the special requirements for wellness programs that condition rewards on an individual satisfying a standard related to a health factor, including the requirement to provide an individual with a "reasonable alternative (or waiver of the otherwise applicable standard)" under HIPAA, when "it is unreasonably difficult due to a medical condition to satisfy" or "medically inadvisable to attempt to satisfy" the otherwise applicable standard. See section 9802 of the Internal Revenue Code (26 U.S.C. 9802, 26 CFR 54.9802-1 and 54.9802-3T), section 702 of the Employee Retirement Income Security Act of 1974 (ERISA) (29 U.S.C. 1182, 29 CFR 2590.702 and 2590.702-1), and section 2705 of the Public Health Service Act (45 CFR 146.121 and 146.122).
- (3) Where the covered entity requests family medical history to comply with the certification provisions of the Family and Medical Leave Act of 1993 (29 U.S.C. 2601 et seq.) or State or local family and medical leave laws, or pursuant to a policy (even in the absence of requirements of Federal, State, or local leave laws) that permits the use of leave to care for a sick family member and that requires all employees to provide information about the health condition of the family member to substantiate the need for leave.
- (4) Where the covered entity acquires genetic information from documents that are commercially and publicly available for review or purchase, including newspapers, magazines, periodicals, or books, or through electronic media, such as information communicated through television, movies, or the Internet, except that this exception does not apply--
- (i) To medical databases, court records, or research databases available to scientists on a restricted basis;
  - (ii) To genetic information acquired through sources with limited access, such as social networking sites and other media sources which require permission to access from a specific individual or where access is conditioned on membership in a particular group, unless the covered entity can show that access is routinely granted to all who request it;
  - (iii) To genetic information obtained through commercially and publicly available sources if the covered entity sought access to those sources with the intent of obtaining genetic information; or
  - (iv) To genetic information obtained through media sources, whether or not commercially and publicly available, if the covered entity is likely to acquire genetic information by accessing those sources, such as Web sites and on-line discussion groups that focus on issues such as genetic testing of individuals and genetic discrimination.

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

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

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

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

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

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

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

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

**(c) Inquiries Made of Family Members Concerning a Manifested Disease, Disorder, or Pathological Condition.**

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

(2) A covered entity does not violate this section when it requests, requires, or purchases genetic information or information about the manifestation of a disease, disorder, or pathological condition of an individual's family member who is receiving health or genetic services on a voluntary basis. For example, an employer does not unlawfully acquire genetic information about an employee when it

asks the employee's family member who is receiving health services from the employer if her diabetes is under control.

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

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

Sec. 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 Sec. Sec. 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 Sec. 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.

Sec. 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 Sec. 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 Sec. 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 Sec. 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 Sec. 1635.2(c)(5) of this part.

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

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

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

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

(c) Posting of Notices.

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

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

Sec. 1635.11 Construction.

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

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

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

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

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

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

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

(b) Relation to certain Federal laws governing health coverage.

(1) General: Nothing in GINA Title II provides for enforcement of, or penalties for, violation of any requirement or prohibition of a covered entity subject to enforcement under:

(i) Amendments made by Title I of GINA.

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

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

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

(2) Application. The application of paragraph (b)(1) of this section is intended to prevent Title II causes of action from being asserted regarding matters subject to enforcement under Title I or the other genetics provisions for group coverage in ERISA, the Public Health Service Act, and the Internal Revenue Code. The firewall seeks to ensure that health plan or issuer provisions or actions are addressed and remedied through ERISA, the Public Health Service Act, or the Internal Revenue Code, while actions taken by employers and other GINA Title II covered entities are remedied through GINA Title II. Employers and other GINA Title II covered entities would remain liable for any of their actions that violate Title II, even where those actions involve access to health benefits, because such benefits are within the definition of compensation, terms, conditions, or privileges of employment. For example, an employer that fires an employee because of anticipated high health claims based on genetic information remains subject to liability under Title II. On the other hand, health plan or issuer provisions or actions related to the imposition of a preexisting condition exclusion; a health plan's or issuer's discrimination in health plan eligibility, benefits, or premiums based on genetic information; a health plan's or issuer's request that an individual undergo a genetic test; and/or a health plan's or issuer's collection of genetic information remain subject to enforcement under Title I exclusively. For example:

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

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

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

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

Sec. 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 Sec. Sec. 1635.4 through 1635.9 of this part.

[FR Doc. 2010-28011 Filed 11-8-10; 8:45 am]BILLING CODE 6570-01-P

### **TITLE III--MISCELLANEOUS PROVISIONS**

#### **SEC. 301. SEVERABILITY.**

If any provision of this Act, an amendment made by this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of such provisions to any person or circumstance shall not be affected thereby.

#### **SEC. 302. CHILD LABOR PROTECTIONS.**

(a) In General.--Section 16(e) of the Fair Labor Standards Act of 1938 (29 U.S.C. 216(e)) is amended to read as follows:

“(e)(1)(A) Any person who violates the provisions of sections 12 or 13(c), relating to child labor, or any regulation issued pursuant to such sections, shall be subject to a civil penalty not to exceed--

“(i) \$11,000 for each employee who was the subject of such a violation; or

“(ii) \$50,000 with regard to each such violation that causes the death or serious injury of any employee under the age of 18 years, which penalty may be doubled where the violation is a repeated or willful violation.

“(B) For purposes of subparagraph (A), the term ‘serious injury’ means--

“(i) permanent loss or substantial impairment of one of the senses (sight, hearing, taste, smell, tactile sensation);

“(ii) permanent loss or substantial impairment of the function of a bodily member, organ, or mental faculty, including the loss of all or part of an arm, leg, foot, hand or other body part; or

“(iii) permanent paralysis or substantial impairment that causes loss of movement or mobility of an arm, leg, foot, hand or other body part.

“(2) Any person who repeatedly or willfully violates section 6 or 7, relating to wages, shall be subject to a civil penalty not to exceed \$1,100 for each such violation.

“(3) In determining the amount of any penalty under this subsection, the appropriateness of such penalty to the size of the business of the person charged and the gravity of the violation shall be considered. The amount of any penalty under this subsection, when finally determined, may be--

“(A) deducted from any sums owing by the United States to the person charged;

“(B) recovered in a civil action brought by the Secretary in any court of competent jurisdiction, in which litigation the Secretary shall be represented by the Solicitor of Labor; or

“(C) ordered by the court, in an action brought for a violation of section 15(a)(4) or a repeated or willful violation of section 15(a)(2), to be paid to the Secretary.

“(4) Any administrative determination by the Secretary of the amount of any penalty under this subsection shall be final, unless within 15 days after receipt of notice thereof by certified mail the person charged with the violation takes exception to the determination that the violations for which the penalty is imposed occurred, in which event final determination of the penalty shall be made in an administrative proceeding after opportunity for hearing in accordance with section 554 of title 5, United States Code, and regulations to be promulgated by the Secretary.

“(5) Except for civil penalties collected for violations of section 12, sums collected as penalties pursuant to this section shall be applied toward reimbursement of the costs of determining the violations and assessing and collecting such penalties, in accordance with the provision of section 2 of the Act entitled ‘An Act to authorize the Department of Labor to make special statistical studies upon payment of the cost thereof and for other purposes’ (29 U.S.C. 9a). Civil penalties collected for violations of section 12 shall be deposited in the general fund of the Treasury.”

(b) Effective Date.--The amendments made by this section shall take effect on the date of the enactment of this Act.

Approved May 21, 2008.

# Sample Policies

### Creating a Workplace Policy

A key aspect of prevention of discrimination and harassment in the workplace is the development and promotion of a written policy which makes it clear that these actions will not be tolerated under any circumstances. It generally is necessary for employers to establish, publicize, and enforce anti-discrimination and anti-harassment policies and complaint procedures. Even in instances where it is not specified within the text of the law, the Supreme Court warns that in cases of discrimination, failure to create and distribute an anti-discrimination policy, makes it difficult for an employer to prove that it exercised reasonable steps to prevent and correct discrimination " (Ellerth, 118 S. Ct. at 2270).

The policy and complaint procedure should be written in a way that will be understood by all employees in the employer's workforce. Other measures to ensure effective dissemination of the policy and complaint procedure include posting them in central locations and incorporating them into employee handbooks. If feasible, the employer should provide training to all employees to ensure that they understand their rights and responsibilities.

An anti-discrimination and anti-harassment policy and complaint procedure should contain, at a minimum, the following elements:

- A clear explanation of prohibited conduct;
- Assurance that employees who make complaints of discrimination/harassment or provide information related to such complaints will be protected against retaliation;
- A clearly described complaint process that provides accessible avenues of complaint;
- Assurance that the employer will protect the confidentiality of discrimination/harassment complaints to the extent possible;
- A complaint process that provides a prompt, thorough, and impartial investigation; and
- Assurance that the employer will take immediate and appropriate corrective action when it determines that discrimination/harassment has occurred.

A genetic information nondiscrimination policy can be added to an employer's general workplace policy which covers all forms of discrimination or it may be written as a standalone nondiscrimination policy. Both options are valid and it is up to employers to decide what is most appropriate for them. If a general policy is adopted, however, it is important that the different types of discrimination and harassment are well-defined and addressed comprehensively. If the policy is too broad or generic, its impact and clarity may be compromised.

An employer should provide every employee with a copy of the policy and complaint procedure, and redistribute it periodically. Policies can also be promoted by e-mailing copies to employees and putting a copy on the company Intranet. The policy should also be displayed on notice boards, included in personnel manuals, made accessible on computer networks and promoted at staff briefings and meetings where relevant.

Employers should provide the policy to new staff as a standard part of induction. Employers may want employees to sign a copy of the policy acknowledging that they received and understood

it. To ensure that the policy is widely promoted and regularly updated, responsibility for circulation and review should be allocated to a specific position or area.

The following pages include examples of EEO policies that companies have implemented.

**Example 1**

This company is committed to upholding the laws which provide employees Equal Employment Opportunity. As such, the following Genetic Information Nondiscrimination policy is strictly enforced:

1. No person shall be excluded from consideration for employment because of their genetic information. This includes recruitment, hiring practices, placement, promotion, transfer, rate of pay and termination.
2. Any employee who engages in discrimination or harassment based on genetic information will be subject to suspension or termination.
3. Executive, management and supervisory levels have the responsibility to implement and enforce this policy within the company. Any supervisor or managerial employee who knows that discriminatory or harassing behavior is taking place and fails to take immediate and appropriate corrective action will also be subject to disciplinary action.
4. Any individual who feels they have been harassed or discriminated against based on their genetic information should report the matter to their superior or a member of management. If that option appears futile, unsatisfactory or counterproductive, the employee should contact Human Resources.
5. A claim of discrimination or harassment will be promptly investigated and the appropriate action will be administered. Retaliation against claimants will not be tolerated. The company will protect the confidentiality of discrimination/harassment complaints to the extent possible.



## Example 2

This company is an equal opportunity employer and we do not engage in practices that discriminate against any person employed or seeking employment based on an individual's genetic information. Genetic information discrimination is illegal and employees are protected from such conduct under Title VII of the Civil Rights Act of 1964 and Title II of the Genetic Information Nondiscrimination Act (GINA).

GINA defines genetic information as information about an individual's genetic tests, genetic tests of a family member, and family medical history.

Genetic information does not include information about the sex or age of an individual or the individual's family members, or information that an individual *currently has* a disease or disorder. Genetic information also does not include tests for alcohol or drug use.

Title II of GINA prohibits use of genetic information in making decisions related to any terms, conditions, or privileges of employment, prohibits covered entities from intentionally acquiring genetic information, requires confidentiality with respect to genetic information (with limited exceptions), and prohibits retaliation.

GINA also extends protections to individuals with regard to health insurance. Title I of GINA prohibits health insurers from engaging in three practices:

- (1) using genetic information about an individual to adjust a group plan's premiums, or, in the case of individual plans, to deny coverage, adjust premiums, or impose a preexisting condition exclusion;
- (2) requiring or requesting genetic testing; and
- (3) requesting, requiring, or purchasing genetic information for underwriting purposes.

If you feel that you have been subjected to discrimination based on genetic information, by any person employed by or doing business with this company, please report the incident immediately to an HR manager.

Investigations and resolutions will be handled with as much privacy, discretion and confidentiality as possible without compromising diligence and fairness. Retaliation against the person filing the complaint is unlawful and will be subject to disciplinary action up to and including termination.

Example 3 (As part of an existing EEO policy)

**Discrimination is Unlawful**

This company is an equal opportunity employer and we do not engage in practices that discriminate against any person employed or seeking employment based on race, color, gender, religion, sex, national origin, age, marital status, sexual orientation, disability, genetic information, veterans' status, or any other protected status.

Discrimination by executives, supervisors, employees, clients, vendors and/or contractors will not be tolerated. In addition, retaliation against any individual who has complained about unlawful discrimination, or retaliation against individuals for cooperating with an investigation of a complaint of unlawful discrimination, also will not be tolerated. Persons who violate this policy will be subject to disciplinary action up to and including termination of employment, and/or termination of the contractual relationship.

**Discrimination Defined**

Black's Law Dictionary defines discrimination as the failure to treat all persons equally where no reasonable distinction can be found between those favored and those who are not favored. In the workplace, discrimination is the unfair treatment or denial of standard privileges of employment (such as benefits, working hours, pay increases, transfers, or promotions ) by the employer because of an individual's race, age, sex, nationality, pregnancy, religion, genetic information, marital or veteran status, or handicap whether physical or mental.

**Race or Color Discrimination** – Equal employment opportunity cannot be denied any person because of their racial group or perceived racial group, their race-linked characteristics (e.g., hair texture, color, facial features), or because their marriage to or association with someone of a particular race or color. Employment decisions based on stereotypes and assumptions about abilities, traits, or the performance of individuals of certain racial groups is also prohibited.

**National Origin Discrimination** – It is illegal to discriminate against an individual because of birthplace, ancestry, culture, or linguistic characteristics common to a specific ethnic group.

A rule requiring that employees speak only English on the job may violate Title VII unless an employer shows that the requirement is necessary for conducting business. If the employer believes such a rule is necessary, employees must be informed when English is required and the consequences for violating the rule.

**Sex Discrimination** – This includes practices ranging from direct requests for sexual favors to workplace conditions that create a hostile environment for persons of either gender, including same sex harassment.

**Pregnancy Based Discrimination** – Pregnancy, childbirth, and related medical conditions must be treated in the same way as other temporary illnesses or conditions.

**Age Discrimination** – Unlawful age discrimination is treating an employee or applicant who is 40 years of age or older differently than a person in a similar position who is substantially younger. Statements or specifications in job notices or advertisements of age preference and limitations is prohibited. An age limit may only be specified in the rare circumstance where age has been proven to be a bona fide occupational qualification.

An employer also cannot deny benefits to older employees. Benefits may be reduced based on age only if the cost of providing the reduced benefits to older workers is the same as the cost of providing benefits to younger workers.

**Disability Discrimination** – Employers cannot discriminate against an individual who has a physical or mental impairment that substantially limits at least one major life activity, such as walking, seeing, hearing, speaking, learning, or working. It also includes people who have a record of or is believed to have such impairment.

A qualified employee or applicant with a disability is an individual who, with or without reasonable accommodation, can perform the essential functions of the job in question.

**Religious Discrimination** – Employers may not treat employees or applicants more or less favorably because of their religious beliefs or practices. Employees cannot be forced to participate -- or not participate -- in a religious activity as a condition of employment.

Employers must reasonably accommodate employees' sincerely held religious practices unless doing so would impose an undue hardship on the employer.

**Genetic Information Discrimination** - Employers may not use genetic information for any decisions regarding terms of employment. Health Insurers and health plan administrators are prohibited from requesting or requiring genetic information of an individual or their family members, or using it for decisions regarding coverage, rates, or pre-existing conditions.

## **Equality is the Law**

**Title VII** of the Civil Rights Act of 1964 protects all employees and applicants from employment discrimination based on **race, color, sex** (gender), **religion** and **national origin**.

**The Americans with Disabilities Act (ADA)** of 1990 protects qualified individuals with disabilities from employment discrimination based on **disability**.

**The Age Discrimination in Employment Act (ADEA)** of 1967 protects employees and applicants who are 40 years of age or older from employment discrimination based on **age**.

**The Equal Pay Act (EPA)** of 1963 protects all employees and applicants from employment discrimination in wages based on sex (gender).

**Genetic Information Nondiscrimination Act (GINA)** of 2008 protects employees from being treated unfairly because of differences in their DNA that may affect their health.

## **Discrimination in the Workplace**

It is illegal to discriminate in any aspect of employment including:

*hiring and firing;*  
*compensation, assignment, or classification of employees;*  
*transfer, promotion, layoff, or recall;*  
*job advertisements;*  
*recruitment;*  
*testing;*  
*use of company facilities;*  
*training and apprenticeship programs;*

*fringe benefits;  
pay, retirement plans, and disability leave; or  
other terms and conditions of employment.*

### Examples of Discrimination

Harassment on the basis of race, color, religion, sex, national origin, disability, or age;

Retaliation against an individual for filing a charge of discrimination, participating in an investigation, or opposing discriminatory practices;

Employment decisions based on stereotypes or assumptions about the abilities, traits, or performance of individuals of a certain sex, race, age, religion, genetic information, or ethnic group, or individuals with disabilities;

Denying employment opportunities to a person because of marriage to, or association with, an individual of a particular race, religion, national origin, or an individual with a disability. Title VII also prohibits discrimination because of participation in schools or places of worship associated with a particular racial, ethnic, or religious group;

Verbal abuse, offensive innuendo or derogatory words, concerning a person's race, color, gender, age, sexual orientation, religion, ethnic or national origin, disability, veterans' status, or any other protected status;

Intentionally treating employees or applicants differently than others who hold or are applying for similar jobs. Disparate or unequal treatment can occur in any area of employment, including hiring, discipline, performance appraisal, termination, working conditions, and benefits. Harassment is a form of disparate treatment;

Having employer policies or procedures that appear neutral but have a particularly negative effect on a group with a common race, color, sex, national origin, religion, age, genetic information, or disability status. This is known as disparate impact and its effect does not have to be intended.

### Filing a Complaint

If you feel that you have been subjected to discrimination or harassment, by any person employed by or doing business with this company, or you have witnessed such activity, **please report the incident immediately to your supervisor**. If reporting the incident to your supervisor is inappropriate because your complaint involves your supervisor or you fear reprisal, then please report the incident to:

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*Name, Title and Phone Number*

Anyone that receives a complaint of discrimination or harassment must treat the matter seriously and conduct a prompt, impartial and thorough investigation and report it to:

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*Name, Title and Phone Number*

Investigations and resolutions will be handled with as much privacy, discretion and confidentiality as possible without compromising diligence and fairness. Everyone involved in the investigation process shall conduct themselves with professionalism and respect.

If, after investigation, it is found that inappropriate conduct occurred, immediate action will be taken, which may include but is not limited to reprimand, suspension, change in assignments, mandatory training, loss of privileges and/or termination. Retaliation against the person filing the complaint is unlawful and will be subject to disciplinary action up to and including termination.

In addition, a complaint of discrimination or harassment may be filed with either the appropriate state or federal agency listed below. Failure to first utilize the internal company complaint process available to you may result in an unfavorable ruling.

**U.S. Equal Employment Opportunity Commission**

P.O. Box 7033, Lawrence, Kansas 66044

800-669-4000 TTY 800-669-6820

[www.eeoc.gov](http://www.eeoc.gov)

State Office \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Phone \_\_\_\_\_

# **Federal and State Laws Addressing Genetic Discrimination**

## Federal Laws Addressing Genetic Discrimination

Prior to the enactment of GINA, there were no federal laws that directly and comprehensively protected against abuses in the gathering or use of genetic information in the workplace. A few protections exist incidentally under federal laws enacted to address other types of workplace discrimination. The incidental federal protections against workplace discrimination based on genetic information that do exist are narrow in scope. They are not sufficient to provide Americans with adequate protection against genetic discrimination in the workplace.

States continue to enact legislation in response to growing concern over the specter of genetic discrimination in the workplace. Existing state laws, however, differ in coverage, protections afforded, and enforcement schemes. Federal leadership is necessary to ensure that all workers are protected against discrimination based on genetic information.

GINA was enacted because Federal leadership was necessary to ensure that all workers are protected against discrimination based on genetic information. It is important that employers understand the various laws that address genetic information discrimination as well as the laws specific to their state.

### **Americans with Disabilities Act of 1990 (ADA)**

The most likely current source of protection against genetic discrimination in the workplace is provided by laws prohibiting discrimination based on disability. Title I of the Americans with Disabilities Act (ADA), enforced by the Equal Employment Opportunity Commission (EEOC), and similar disability-based antidiscrimination laws such as the Rehabilitation Act of 1973 do not explicitly address genetic information, but they provide some protections against disability-related genetic discrimination in the workplace.

- Prohibits discrimination against a person who is regarded as having a disability.
- Protects individuals with symptomatic genetic disabilities the same as individuals with other disabilities.
- Does not protect against discrimination based on unexpressed genetic conditions.
- Does not protect potential workers from requirements or requests to provide genetic information to their employers after a conditional offer of employment has been extended but before they begin work. (Note: this is a heightened concern because genetic samples can be stored.)
- Does not protect workers from requirements to provide medical information that is job related and consistent with business necessity.

In March 1995, the EEOC issued an interpretation of the ADA. The guidance, however, is limited in scope and legal effect. It is policy guidance that does not have the same legal binding effect on a court as a statute or regulation and has not been tested in court. According to the interpretation:

- Entities that discriminate on the basis of genetic predisposition are regarding the individuals as having impairments, and such individuals are covered by the ADA.

- Unaffected carriers of recessive and X-linked disorders, individuals with late-onset genetic disorders who may be identified through genetic testing or family history as being at high risk of developing the disease are not covered by the ADA.

The ADA has been interpreted by the EEOC as including genetic information relating to illness, disease, or other disorders. The legislative history was cited by the EEOC in its guidance to the definition of disability for its compliance manual. In this guidance, the EEOC examined the definition of disability under the ADA, noting that the definition was composed of three prongs:

- (1) a physical or mental impairment that substantially limits one or more of the major life activities of an individual,
- (2) a record of such an impairment, or
- (3) being regarded as having such an impairment.

It was under the third prong that the EEOC determined that discrimination based on genetic information relating to illness, disease, or other disorders was prohibited.

Although this EEOC interpretation was widely heralded as a significant step for the protection of rights for individuals whose genes indicate an increased susceptibility to illness, disease, or other disorders, it is limited in its application and may be even more limited after the recent Supreme Court decisions on the definition of disability. However, the EEOC has not withdrawn this guidance.

Although the combination of the ADA's legislative history and the EEOC's guidance has led some commentators to argue that the ADA would cover genetic discrimination, the merit of these arguments has been uncertain since there have been no reported cases holding that the ADA prohibits genetic discrimination. This uncertainty has increased in light of Supreme Court decisions on the definition of disability under the ADA. The Supreme Court's decisions do not directly address ADA coverage of genetic discrimination. They emphasize an individualized approach to the determination of whether an individual has a disability under the ADA. Although an argument could be made that the ADA would cover individuals with genetic defects in certain cases, the Court's decisions, particularly *Sutton* and *Murphy*, use reasoning that would make it unlikely that most ADA claims based on genetic discrimination would be successful.

In addition, even assuming the ADA was found to apply, it may not protect employees from having their employers have access to their genetic information. Although the ADA prohibits an employer from making medical inquiries prior to a job offer, the employer may obtain medical information in certain cases after the offer of employment has been made. Assuming that the prohibitions against discrimination in the ADA would apply, it is difficult to prove that genetic information was the reason for discrimination.

### **Health Insurance Portability and Accountability Act of 1996 (HIPAA)**

The Health Insurance Portability and Accountability Act (HIPAA) is the only federal law that directly addresses the issue of genetic discrimination. However, it applies to *employer-based and commercially issued group health insurance only*. There is no similar law applying to private individuals seeking health insurance in the individual market. HIPAA enforces the following:



- Prohibits group health plans from using any health status-related factor, including genetic information, as a basis for denying or limiting eligibility for coverage or for charging an individual more for coverage.
- Limits exclusions for preexisting conditions in group health plans to 12 months and prohibits such exclusions if the individual has been covered previously for that condition for 12 months or more.
- States explicitly that genetic information in the absence of a current diagnosis of illness shall not be considered a preexisting condition.
- Doesn't prohibit employers from refusing to offer health coverage as part of their benefits packages.

Title I of GINA extends the current HIPAA protections against discrimination by group health plans and issuers of health insurance in both the group and individual markets. HIPAA prohibits a group health plan or issuer of a group health plan from using genetic information to establish rules for eligibility or continued eligibility and provides that genetic information shall not be treated as a preexisting condition in the absence of the diagnosis of the condition related to such information. It also prohibits a group health plan or issuer of a group health plan from using genetic information in setting a premium contribution. These protections apply to individuals within the group plans; however, they do not apply to the acceptance of the whole group or to the premiums set for the group. Thus, HIPAA prohibits group health plans or issuers of group health plans from charging an individual a higher premium than a similarly situated individual; however, the law does not prevent an entire group from being charged more. The HIPAA nondiscrimination provisions do not apply to individual health insurance policies, and genetic information may be used to set premiums for individual policies (although HIPAA establishes both guaranteed issue for individuals who lose group coverage and guaranteed renewal for those with existing individual coverage).

HIPAA would not prohibit group health plans or issuers of plans (i.e., insurers) from requiring or requesting genetic information or testing and does not prevent them from excluding coverage for a particular condition or imposing lifetime caps on all benefits, or on specific benefits. HIPAA does not address the use of genetic information in contexts other than health insurance, such as employment. Under the HIPAA Privacy Rule, health plans and insurers may use or disclose health information for payment and other health care operations, including underwriting, premium rating, and other activities related to the creation, renewal, or replacement of an insurance contract.

### **Title VII of the Civil Rights Act of 1964**

Another federal law that may incidentally provide protection against some forms of genetic discrimination is Title VII of the Civil Rights Act of 1964. An argument could be made that genetic discrimination based on racially or ethnically linked genetic disorders constitutes unlawful race or ethnicity discrimination. Protection under Title VII, however, is only available where an employer engages in discrimination against a particular racial or ethnic group based on a genetic trait that is substantially related to a race or ethnic group. Since a strong nexus between race or national origin has been established for only a few diseases, Title VII will not be an effective tool for combating most forms of genetic discrimination.

### State Laws Addressing Genetic Discrimination

A number of states have addressed the issue of genetic discrimination in employment through state legislation. There are wide variations among these state laws. All laws prohibit discrimination based on the results of genetic tests; many extend the protections to inherited characteristics, and some include test results of family members, family history and information about genetic testing, such as the receipt of genetic services. Most states also restrict employer access to genetic information, with some prohibiting employers from requesting, requiring and obtaining genetic information or genetic test results, or directly or indirectly performing or administering genetic tests. Some states may also make exceptions to statutory requirements if, for example, genetic information may identify individuals who may be a safety risk in the workplace.

Some of the first state laws enacted prohibited discrimination against individuals with specific genetic traits or disorders, such as the sickle-cell trait (Florida and Louisiana) or the hemoglobin trait (North Carolina). Later laws cover broader categories of genetic traits and disorders. For example, a 1981 New Jersey statute (later broadened) prohibits discrimination in employment based on an "atypical hereditary cellular or blood trait," and a New York law prohibits employers from denying equal employment opportunities based on "unique genetic disorders."

Other state laws regulate both the use of genetic testing in employment decisions and the disclosure of genetic test results. These state laws generally prohibit employers from requiring workers and applicants to undergo genetic testing as a condition of employment. Wisconsin was the first state to ban genetic testing and discrimination in the workplace in 1991. Texas law prohibits employers, labor organizations, licensing agencies, and employment agencies from discriminating against any individual on the basis of the results of a genetic test or because of the individual's refusal to submit to genetic testing.

State laws regarding collection and use of genetic information have proliferated with the advancement of the scientific knowledge regarding human genetics and the human genome. In response to concerns regarding genetic discrimination, many state's legislatures have acted to protect against employer and insurer misuse of genetic information. Additionally, the technology and scientific understanding of genetic tests and the underlying genetic information they can convey is constantly evolving.

### **Health Insurance**

All but a few states have enacted genetic-specific health insurance legislation that restricts the use of genetic information in determining eligibility for health care insurance. Some states provide less protection. For example, three states' legislation provides only that genetic information cannot be considered a pre-existing condition by health insurers unless it is associated with a diagnosis. These states are Idaho, Nebraska, and North Dakota. While many states regulate the use of genetic information in group and individual policies offered by insurance companies, about one fourth of the state statutes apply to either individual or group insurance plans, leaving the other plans unregulated. Additionally, federal law preempts regulation of employer sponsored benefit plans, so state laws only reach health insurance policies that are not employer-based. Of the 46 states with some regulation of health insurance use of genetic information, approximately 40 states prohibit the use of genetic information for

selection or risk classification purposes. Smaller numbers of states restrict the collection of genetic test results, and 25 states require informed consent prior to disclosure of patient genetic information.

### **Life and Disability Insurance**

In general, the states appear more willing to accept use of genetic information by life, disability, or long-term care insurance companies than they are health care insurance companies. While a handful of states flatly prohibit use of genetic information to deny or rate coverage, more states place limitations on the use of genetic information or genetic test results. In regards to use of genetic information, North Carolina regulates only life insurance, Wyoming law applies only to disability insurance, and other states such as Maine ban discrimination in life, disability, and long-term care insurance. As in the health insurance setting, some states have limited the scope of their legislation in other ways, such as Colorado, which bans genetic discrimination in group disability and long-term care insurance policies.

### **Employment Nondiscrimination**

Like insurance laws, genetics laws that prohibit employment discrimination vary in coverage, protections, and penalties. Many states regulate the use of genetic information for determining hiring or terms of employment decisions. Delaware and Illinois, for example, limit employer use of genetic data, without regulating their ability to obtain employee genetic information. Other state laws regulate both the use of genetic testing in employment decisions and access to genetic test results. These state laws generally prohibit employers from requiring workers and applicants to undergo genetic testing as a condition of employment. (Connecticut, New Hampshire and Nevada are examples of states including such a provision.) Some states provide exceptions to nondiscrimination provisions, allowing employers' use of genetic information in certain circumstances. Investigation of a worker's compensation claim, determination of a worker's susceptibility to potentially toxic chemicals in the workplace, or a bona fide occupational qualification are various examples of exceptions drafted into state genetic nondiscrimination legislation. These statutes often require the worker to provide informed written consent for such testing, contain specific restrictions governing disclosure, and prevent the employer from taking adverse action against the employee.

### **Privacy or Property Rights in Genetic Information**

Genetic privacy laws in more than half the states require informed consent from the individual in either the case of genetic testing or acquisition, disclosure, or retention of genetic information by a third party. These privacy protections are integrated into nondiscrimination legislation in some states (Massachusetts, for example). In other states, the privacy provisions stand alone (Florida or Illinois legislation). Privacy legislation gives an individual control over his genetic information. Often statutes require informed consent to perform or require a genetic test, or to obtain, retain, or disclose genetic information. Some states create a personal property interest in genetic information. These laws state that genetic information is the "exclusive property" or "unique property" of the individual to whom the information pertains.

Since the degree of protection that state laws provide varies widely, Federal regulations were greatly needed to create consistency and clarification. GINA provides a baseline level of protection against genetic discrimination for all Americans. While most state provisions are less protective than GINA, some are more protective. All entities that are subject to GINA must, at a minimum, comply with all applicable GINA requirements, and may also need to comply with more protective State laws.

The following table, derived from research done by National Conference of State Legislatures, compares state laws pertaining to genetic information as it applies to employment nondiscrimination. The last column denotes individual state citations as they pertain to healthcare.

## State Specific Genetic Information Laws

State and Statute	Genetic discrimination prohibited in hiring, firing, and/or terms, conditions or privileges of employment	Prohibits Employer From				Health Insurance Provision Citation
		Requesting Genetic Information Genetic Test	Requiring Genetic Information Genetic Test	Performing Genetic Test	Obtaining Genetic Information Genetic Test Result	
Total	36	18	25	16	11	
Alabama						§§27-53-1 et seq.
Alaska						§§21.54.100, et seq.
Arizona §41-1463	X					§§20-448, 448.02
Arkansas §11-5-401 to 405	X	X	X		X	23§§86-304 et seq., 23§66-320
California 6Govt. §12926, Govt. §12940	X			X		Insurance Code: §§742.405, 7, 10140, 3, to 9, 9.1
Colorado						§10-3-1104.7
Connecticut §46a-60	X	X	X			38a§§ 816, 476
Delaware §19-710 to 711	X					§§16-1220, 18-2317
D.C. §2-1401.01	X					§§2-1401.01 et seq.
Florida						§§627.4301, 627.6419, 636.0201, 641.31071, 641.31073, 641.438
Georgia						§§33-54-1 to 8
Hawaii §378-01 to 10	X		X			§§431:10a-118 and 404.5, 432:1-607 and 404.5, 432d-26
Idaho	X	X	X		X	§§41-2221, 41-3940, 41-4708
Illinois §410-513/25 §215 ILCS 5/356v	X					215-97/20, 97/25, 410-513/10 to 45
Indiana						27§§4-1-4(23), 8-26-1 et seq.
Iowa §729.6	X	X	X	X		§513b.9a, 10(4)(a)(1)
Kansas §44-1002, §44-1009	X	X	X		X	§40-2259
Kentucky						§§304.12-085, 304.17a-200 et seq.
Louisiana §23:302 §23:303	X	X	X	X		22§213.7
Maine	X		X			24A§§2159-C(2), 2204, 2850-C, 22§1711-C

## State Specific Genetic Information Laws (cont.)

State and Statute	Genetic discrimination prohibited in hiring, firing, and/or terms, conditions or privileges of employment	Prohibits Employer From				Health Insurance Provision Citation
		Requesting Genetic Information Genetic Test	Requiring Genetic Information Genetic Test	Performing Genetic Test	Obtaining Genetic Information Genetic Test Result	
Maryland Human Relations Commission §49B-15 to 16	X	X	X			Ins §27-208, 909
Massachusetts §151B	X	X	X	X	X	111§70G; 175§120E; 176§3B; 176B§5B; 176G§24; 176I§4A
Michigan §37.1201, §37.1202	X		X	X	X	§§550.1401, 3407(b)
Minnesota §181.974	X	X	X	X	X	§72a.139
Mississippi						
Missouri §375.1300, §375.1306	X				X	§§375.1300 et seq.
Montana						§§33-18-901 et seq.
Nebraska §48-236	X		X			§§44-787, 524.02, 6910, 15, 16
Nevada §613.345	X	X	X	X		§§689a.417, 689b.069, 689c.076, 198
New Hampshire §141-H	X	X	X	X		§§141-H:1 et seq.
New Jersey §10:5-5, §10:5-12	X					10:5-43 et seq., §17B:30-12
New Mexico §24-21-1 to 7	X					§§24-21-1 et seq.
New York EXC §292, 296	X	X	X	X	X	Ins §2612
North Carolina §95-28.1A	X					§§58-3-25, 215
North Dakota						§§26.1-36.3-01 et seq.
Ohio						§§1751.65, 3901.491 et seq.
Oklahoma §36-3614.2	X	X	X	X	X	§36-3614.1
Oregon §659A.300 to 306	X	X	X	X	X	§746.135
Pennsylvania						
Rhode Island §28-6.7-1	X	X	X	X		§§27-18-52 et seq., 19-44 et seq., 20-39 et seq., 41-53 et seq.
South Carolina						§§38-93-10 to 60
South Dakota §60-2-20	X	X	X	X	X	§§58-18-45, 58-18B-27

## State Specific Genetic Information Laws (cont.)

State and Statute	Genetic discrimination prohibited in hiring, firing, and/or terms, conditions or privileges of employment	Prohibits Employer From				Health Insurance Provision Citation
		Requesting Genetic Information Genetic Test	Requiring Genetic Information Genetic Test	Performing Genetic Test	Obtaining Genetic Information Genetic Test Result	
Tennessee						§§56-7-2701 to 08
Texas Labor Code §21-402	X		X			Ins §546.001 et seq.
Utah §26-45-103	X	X	X		X	§26-45-101 to 106
Vermont §18-9333	X		X	X		§§8.4724, 18.9334
Virginia §40.1-28.7:1	X	X	X	X		§§38.2-508.4, 613
Washington §49.44.180	X		X			§70.02.010
West Virginia						§§33-15-2(a), (b)
Wisconsin §111.372	X	X	X	X		§§631.89, 632.746, 8
Wyoming						§26-19-102(g), 22-502

Source: National Conference of State Legislatures