

Genetic Information Nondiscrimination Act of 2008¹

The Genetic Information Nondiscrimination Act of 2008 (GINA) protects individuals' genetic information² from being used by employers, health plans and issuers in a discriminatory manner.

Title I – Genetic Nondiscrimination in Health Insurance

This title prohibits health plans and issuers from using genetic information to make eligibility, coverage, underwriting³ or premium-setting decisions about covered individuals,⁴ even if the plan obtained the information prior to the enactment of GINA.⁵ Health plans and issuers generally may not

¹ Genetic Information Nondiscrimination Act of 2008, Pub. L. 110-223, 122 Stat. 881, Title II codified at 42 U.S.C. 2000ff *et seq.* (2008) (available at <http://www.gpo.gov/fdsys/pkg/PLAW-110publ233/pdf/PLAW-110publ233.pdf>).

² Definition of “genetic information” includes family medical history, information from genetic tests and services, requests for/ receipt of genetic services and participation in clinical research that includes genetic services. GINA Title I, § 101(d) (amending ERISA, 29 U.S.C. 1191b(d)(6)-(8)); GINA Title I, § 102(a)(4) (amending PHS Act with respect to group markets, 42 U.S.C. 300gg-91(D)(16) – (18)); GINA Title I, § 103(d) (amending the IRS Code, 26 U.S.C. 9832(d)(7)-(9)); GINA Title I, § 104(b)(1) (amending the Social Security Act with respect to medigap, 42 U.S.C. 1395ss(x)(3)(B)-(D)); GINA Title I, § 105(a) (amending HIPAA, 42 U.S.C. 1320d-9(b)(1)). Genetic information also includes genetic information of a fetus or an embryo used in reproductive technology. GINA Title I, § 101(c) (amending ERISA, 29 U.S.C. 1182(f)); GINA Title I, § 102(a)(3) (amending PHS Act with respect to group markets, 42 U.S.C. 300gg-1(f)); GINA Title I, § 102(b)(1) (amending PHS Act with respect to individual markets, 42 U.S.C. 300gg-s3(f)); GINA Title I, § 103(c) (amending IRS Code, 26 U.S.C. 9802(f)); GINA Title I, § 104(b)(2) (amending Social Security Act with respect to medigap, 42 U.S.C. 1882(x)(4)). It does not include information directly related to a manifested disease, disorder or pathological condition.

³ Definition of “underwriting” includes rules for, or determination of, benefits eligibility, the computation of premium or contribution amounts, the application of any preexisting condition exclusion and, other activities related to the creation, renewal or replacement of a health insurance contract. GINA Title I, § 101(d) (amending ERISA, 29 U.S.C. 1191b(d)(9); GINA Title I, § 102(a)(4) (amending the PHS Act with respect to group markets, 42 U.S.C. 300gg-91(d)(19)); GINA Title I, § 103(d) (amending IRS Code, 26 U.S.C. 9832(d)(10)); GINA Title I, § 104(b)(1) (amending the Social Security Act with respect to medigap, 42 U.S.C. 1395ss(x)(3)(E)); GINA Title I, § 105(a) (amending HIPAA, 42 U.S.C. 1320d-9(b)(1)).

⁴ GINA Title I, § 101(a)(2) (amending ERISA, 29 U.S.C. 1182(b)(3)(A)); GINA Title I, § 102(a)(1) (amending the PHS Act with respect to group markets, 42 U.S.C. 300gg-1(b)(3)(A)) (prohibiting group-based discrimination by group health plans). GINA Title I, § 101(b) (amending ERISA, 29 U.S.C. 1182(d)(1), (2)); GINA Title I, § 102(a)(2) (amending the PHS Act with respect to group markets, 42 U.S.C. 300gg-1(d)(1), (2)); GINA Title I, § 103(b) (amending IRS Code, 26 U.S.C. 9802(d)(1), (2)); GINA Title I, § 104(b)(1) (amending Social Security Act with respect to medigap, 42 U.S.C. 4395(ss)(x)(2)(A), (B)) (prohibiting use of genetic information by group plans for underwriting purposes and prior to enrollment). GINA Title I, § 103(a)(2) (amending IRS Code, 26 U.S.C. 9802(b)(3)(A)) (prohibiting the use of genetic information by group plans in determining premium and contribution amounts). GINA Title I, § 102(b)(1) (amending the PHS Act with respect to individual markets, 42 U.S.C. 300gg-53(a)(1), (b)(1), (c)(1), (e)(1), (2)) (prohibiting use of genetic information by insurers in the individual market in making determinations for eligibility, coverage, preexisting conditions, premium and contribution rates, for underwriting purposes and prior to enrollment). GINA Title I, § 104(a) (amending Social Security Act with respect to medigap, 42 U.S.C. 1395ss(s)(2)(E)) (prohibiting use of genetic information by Medicare Supplemental Policies in making determinations for eligibility, coverage, preexisting condition, premium or contribution rates).

⁵ Department of Labor website, “FAQs on the Genetic Nondiscrimination Information Act”, Question 7 (available at: www.dol.gov/ebsa/faqs/faq-GINA.html).

request or require that covered individuals undergo genetic testing or provide genetic information, subject to three primary exceptions.⁶

The first exception is for purposes of determining the medical appropriateness of covered items and services.⁷ Plans may only use the minimum amount of genetic information necessary to make such a determination. The second exception allows plans to request, in writing, that an individual voluntarily provide genetic information for research purposes, if the request explicitly states that non-compliance will not impact the individual's enrollment, premium or contribution amounts and that no information will be used for underwriting purposes.⁸ The third and final exception is an "incidental collection" exception that applies when the plan obtains genetic information ancillary to the requesting, requiring or purchasing of other information and does not use the genetic information for underwriting purposes.⁹

This title expands the protections provided by HIPAA by including genetic information within the definition of health information.¹⁰ Further, the regulation specifies that use or disclosure of genetic information for underwriting purposes is not a permitted use or disclosure,¹¹ and any covered entity that makes such a disclosure shall be subject to the standard HIPAA penalty provisions.¹² These penalties include fines up to \$250,000 and/or jail time up to 10 years, depending on the circumstances of the violation.¹³

Penalties are also available for health plans and issuers that commit violations of the provisions of Title I.¹⁴ These penalties include a fine of \$100 per day of the violation with respect to every affected

⁶ GINA Title I, § 101(b) (amending ERISA, 29 U.S.C. 1182(c)(1), (d)(1), (2)); GINA Title I, § 102(a)(2) (amending the PHS Act with respect to group markets, 42 U.S.C. 300gg-1(c)(1), (d)(1), (2)); GINA Title I, § 102(b)(1) (amending the PHS Act with respect to individual markets, 42 U.S.C. 300gg-53(d)(1), (e)(1), (2)); GINA Title I, § 103(b) (amending IRS Code, 26 U.S.C. 9802(c)(1), (d)(1), (2)); GINA Title I, § 104(b)(1) (amending the Social Security Act with respect to medigap, 42 U.S.C. 1395ss(x)(1)(A), (2)(A), (B)).

⁷ GINA Title I, § 101(b) (amending ERISA, 29 U.S.C. 1182(c)(3)); GINA Title I, § 102(a)(2) (amending the PHS Act with respect to group markets, 42 U.S.C. 300gg-1(c)(3)); GINA Title I, § 102(b)(1) (amending the PHS Act with respect to individual markets, 42 U.S.C. 300gg-53(d)(3)); GINA Title I, § 103(b) (amending IRS Code, 26 U.S.C. 9802(c)(3)); GINA Title I, § 104(b)(1) (amending the Social Security Act with respect to medigap, 42 U.S.C. 1395ss(s)(2)(F)).

⁸ GINA Title I, § 101(b) (amending ERISA, 29 U.S.C. 1182(c)(4)); GINA Title I, § 102(a)(2) (amending the PHS Act with respect to group markets, 42 U.S.C. 300gg-1(c)(3)); GINA Title I, § 102(b)(1) (amending the PHS Act with respect to individual markets, 42 U.S.C. 300gg-53(d)(4)); GINA Title I, § 103(b) (amending IRS Code, 26 U.S.C. 9802(c)(4)); GINA Title I, § 104(b)(1) (amending the Social Security Act with respect to medigap, 42 U.S.C. 1395ss(x)(1)(D)).

⁹ GINA Title I, § 101(b) (amending ERISA, 29 U.S.C. 1182(d)(3)); GINA Title I, § 102(a)(2) (amending the PHS Act with respect to group markets, 42 U.S.C. 300gg-1(d)(3)); GINA Title I, § 102(b)(1) (amending the PHS Act with respect to individual markets, 42 U.S.C. 300gg-53(e)(3)); GINA Title I, § 103(b) (amending IRS Code, 26 U.S.C. 9802(d)(3)); GINA Title I, § 104(b)(1) (amending the Social Security Act with respect to medigap, 42 U.S.C. 1395ss(x)(2)(C)).

¹⁰ GINA Title I, § 105(a) (amending HIPAA, 42 U.S.C. 1320d-9(a)(1)).

¹¹ GINA Title I, § 105(a) (amending HIPAA, 42 U.S.C. 1320d-9(a)(2)).

¹² GINA Title I, § 105(a) (amending HIPAA, 42 U.S.C. 1320d-9(d)).

¹³ HIPAA, 42 U.S.C. 1320d-6.

¹⁴ GINA Title I, § 101(e) (amending ERISA, 29 U.S.C. 1132(c)(9)); GINA Title I, § 102(a)(5) (amending the PHS Act with respect to group markets, 42 U.S.C. 300gg-22(b)(3)); GINA Title I, § 102(b)(2) (amending the PHS Act with respect to

individual. If the plan or issuer is or should have been aware of the violation and does not correct it within 30 days of discovery, the penalty increases to \$2,500 per individual and to \$15,000 per individual for violations that are not “de minimis.” Medicare supplemental providers that violate this title will be subject to penalties imposed by their respective State programs.¹⁵

Title II – Prohibiting Employment Discrimination on the Basis of Genetic Information

This title prohibits employers, labor unions, employment agencies, joint labor-management training and apprenticeship programs (“employers”) from discriminating against employees or applicants¹⁶ based on genetic information and from using genetic information in employment decisions.¹⁷ It is generally illegal to acquire genetic information about an employee or applicant, subject to six primary exceptions.¹⁸

The first exception, similar to the incidental exception available to health plans and issuers is an “inadvertent collection” exception that applies in situations where an employer unintentionally acquires an employee’s genetic information.¹⁹ The second exception covers the acquisition of genetic information in conjunction with the provision of voluntary employer-sponsored health or genetic services.²⁰ The employer may acquire genetic information in aggregate terms that do not disclose the identity of any individual from such services if participating employees provide prior written authorization. The third exception allows employers to certify an employee’s family medical leave.²¹ The fourth exception permits acquisition of genetic information through commercially and publicly

individual markets, 42 U.S.C. 300GG-61(b)); GINA Title I, § 103(e)(1) (amending the IRS Code, Chapter 100, Subchapter C, Section 9834)).

¹⁵ GINA Title I, § 104(d)

¹⁶ Scope of application found in GINA Title II, § 201(2)(A), 42 U.S.C. 2000ff(2)(A).

¹⁷ GINA Title II, § 202(a), 42 U.S.C. 2000ff-1(a) (with respect to employers); GINA Title II, § 203(a), 42 U.S.C. 2000ff-2(a) (with respect to employment agencies); GINA Title II, § 204(a), 42 U.S.C. 2000ff-3(a) (with respect to labor organizations); GINA Title II, § 205(a), 42 U.S.C. 2000ff-4(a) (with respect to joint labor-management training and apprenticeship programs).

¹⁸ GINA Title II, § 202(b), 42 U.S.C. 2000ff-1(b) (with respect to employers); GINA Title II, § 203(b), 42 U.S.C. 2000ff-2(b) (with respect to employment agencies); GINA Title II, § 204(b), 42 U.S.C. 2000ff-3(b) (with respect to labor organizations); GINA Title II, § 205(b), 42 U.S.C. 2000ff-4(b) (with respect to joint labor-management training and apprenticeship programs).

¹⁹ GINA Title II, § 202(b)(1), 42 U.S.C. 2000ff-1(b)(1) (with respect to employers); GINA Title II, § 203(b)(1), 42 U.S.C. 2000ff-2(b)(1) (with respect to employment agencies); GINA Title II, § 204(b)(1), 42 U.S.C. 2000ff-3(b)(1) (with respect to labor organizations); GINA Title II, § 205(b)(1), 42 U.S.C. 2000ff-4(b)(1) (with respect to joint labor-management training and apprenticeship programs).

²⁰ GINA Title II, § 202(b)(2), 42 U.S.C. 2000ff-1(b)(2) (with respect to employers); GINA Title II, § 203(b)(2), 42 U.S.C. 2000ff-2(b)(2) (with respect to employment agencies); GINA Title II, § 204(b)(2), 42 U.S.C. 2000ff-3(b)(2) (with respect to labor organizations); GINA Title II, § 205(b)(2), 42 U.S.C. 2000ff-4(b)(2) (with respect to joint labor-management training and apprenticeship programs).

²¹ GINA Title II, § 202(b)(3), 42 U.S.C. 2000ff-1(b)(3) (with respect to employers); GINA Title II, § 203(b)(3), 42 U.S.C. 2000ff-2(b)(3) (with respect to employment agencies); GINA Title II, § 204(b)(3), 42 U.S.C. 2000ff-3(b)(3) (with respect to labor organizations); GINA Title II, § 205(b)(3), 42 U.S.C. 2000ff-4(b)(3) (with respect to joint labor-management training and apprenticeship programs).

available documents,²² if the employer does not purchase the documents intending to acquire genetic information.²³ The fifth exception applies to monitoring the biological effects of toxic substances in the workplace, where such monitoring is either required by law or is voluntary and consented to by the employee in a prior written authorization.²⁴ In this circumstance, the employer may acquire genetic information in aggregate terms if the employer provides the employee with written notice of the monitoring, informs the employee of the results and complies with applicable Federal and State genetic monitoring regulations. The sixth and final exception applies to employers that analyze DNA for law enforcement purposes.²⁵ These employers may acquire genetic information to analyze DNA markers of employees in order to detect sample contamination.²⁶

This title also governs the confidentiality of acquired genetic information. This information must be kept confidential and in a medical record separate from the employee's personnel file.²⁷ Genetic information may be disclosed to the employee at his written request;²⁸ to an occupational or health researcher;²⁹ to comply with the FMLA or equivalent State law;³⁰ to a government entity investigating compliance with title II;³¹ to a public health organization, if the information concerns a contagious disease that presents an imminent threat of serious harm or death and the employee is informed of the disclosure,³² and pursuant to a court order³³ expressly authorizing disclosure of the information.³⁴

The provisions of Title II apply to public and private employers,³⁵ and the remedies available for violations of this title will be those remedies outlined within the regulations governing each type of

²² Commercially and publicly available documents include newspapers, magazines, periodicals and books, but does not include medical databases or court records. GINA Title II, § 202(b)(4), 42 U.S.C. 2000ff-1(b)(4) (with respect to employers); GINA Title II, § 203(b)(4), 42 U.S.C. 2000ff-2(b)(4) (with respect to employment agencies); GINA Title II, § 204(b)(4), 42 U.S.C. 2000ff-3(b)(4) (with respect to labor organizations); GINA Title II, § 205(b)(4), 42 U.S.C. 2000ff-4(b)(4) (with respect to joint labor-management training and apprenticeship programs).

²³ Equal Opportunity Employment Commission website, "Rules Against Acquiring Genetic Information" (*available at: www.eeoc.gov/laws/types/genetic.cfm*).

²⁴ GINA Title II, § 202(b)(5), 42 U.S.C. 2000ff-1(b)(5) (with respect to employers); GINA Title II, § 203(b)(5), 42 U.S.C. 2000ff-2(b)(5) (with respect to employment agencies); GINA Title II, § 204(b)(5), 42 U.S.C. 2000ff-3(b)(5) (with respect to labor organizations); GINA Title II, § 205(b)(5), 42 U.S.C. 2000ff-4(b)(5) (with respect to joint labor-management training and apprenticeship programs).

²⁵ These employers are forensic laboratories and businesses that analyze DNA for purpose of human remains identification. GINA Title II, § 202(b)(6), 42 U.S.C. 2000ff-1(b)(6) (with respect to employers); GINA Title II, § 205(b)(6), 42 U.S.C. 2000ff-4(b)(6) (with respect to joint labor-management training and apprenticeship programs).

²⁶ GINA Title II, § 202(b)(6), 42 U.S.C. 2000ff-1(b)(6) (with respect to employers); GINA Title II, § 205(b)(6), 42 U.S.C. 2000ff-4(b)(6) (with respect to joint labor-management training and apprenticeship programs).

²⁷ GINA Title II, § 206(a), 42 U.S.C. 2000ff-5(a)

²⁸ GINA Title II, § 206(b)(1), 42 U.S.C. 2000ff-5(b)(1).

²⁹ GINA Title II, § 206(b)(2), 42 U.S.C. 2000ff-5(b)(2).

³⁰ GINA Title II, § 206(b)(5), 42 U.S.C. 2000ff-5(b)(5).

³¹ GINA Title II, § 206(b)(4), 42 U.S.C. 2000ff-5(b)(4).

³² GINA Title II, § 206(b)(6), 42 U.S.C. 2000ff-5(b)(6).

³³ If the employee is unaware of the court order, the employer must inform him of the court order and what information it disclosed. GINA Title II, § 206(b)(3)(B), 42 U.S.C. 2000ff-5(b)(3)(B).

³⁴ GINA Title II, § 206(b)(3), 42 U.S.C. 2000ff-5(b)(3).

³⁵ GINA Title II, § 207.

employer group. For example, employers in the private sector subject to the enforcement provisions of Title VII of the Civil Rights Act of 1964³⁶ who discriminate against employees on the basis of genetic information would face the penalties listed within Title VII, which could include back pay, reinstatement and compensatory damages as high as \$300,000 for the largest employers.³⁷

³⁶ GINA Title II, § 207(a).

³⁷ Title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e-4 *et seq.*