

**Summary of Genetic Information Nondiscrimination Act of 2008
(GINA)**

Public Law 110-28

Title I: Genetic Nondiscrimination in Health Insurance

GINA Provision	Amends Current Law at	Summary
Section 101		Amends the Employee Retirement Income Security Act of 1974 (ERISA) to expand genetic nondiscrimination protections under group health plans.
101 (a) <i>Genetic discrimination in premiums</i>	Section 702(b) of ERISA	<p>Prohibits a group health plan from adjusting premium or contribution amounts for a group on the basis of genetic information.</p> <p>Provides that such prohibition does not limit a group health plan's health insurance carrier from adjusting the employer's group policy premium based on the manifested disease of an individual covered under the policy. However, the insurer must not use the manifested disease to further increase the employer's premium, since it also constitutes genetic information about family members covered under the policy.</p>
101 (b) <i>Requiring individuals to undergo genetic testing</i>	Section 702 of ERISA	<p>Prohibits a group health plan from requesting or requiring an individual or family member of an individual to undergo a genetic test. Provides that such prohibition does not: (1) limit the authority of a health care professional to request an individual to undergo a genetic test; or (2) preclude a group health plan from obtaining or using the results of a genetic test to make a determination regarding payment. Requires the plan to request only the minimum amount of information necessary to accomplish the intended purpose.</p> <p><u>Research exception</u> - Allows a group health plan to request, but not require, a participant or beneficiary to undergo a genetic test for research purposes if certain requirements are met, including: (1) the plan clearly indicates that compliance is voluntary and that noncompliance will have no effect on enrollment status or premium or contribution amounts; (2) no genetic information collected or acquired is used for underwriting purposes; and (3) the plan notifies the Secretary of Health and Human Services that it is conducting activities pursuant to this exception and includes a description of the activities.</p>
101 (b) <i>Collection of genetic information</i>	Section 702 of ERISA	Prohibits a group health plan from requesting, requiring, or purchasing genetic information: (1) for underwriting purposes; or (2) with respect to any individual prior to such individual's enrollment in connection with such enrollment.

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		Provides that incidentally obtaining information is not a violation under certain circumstances.
101 (b) <i>Application to all group health plans</i>	Subsections (a)(1)(F), (b)(3), (c), and (d) and subsection (b)(1) of Section 702 of ERISA; also section 701 of ERISA with respect to genetic information	Applies genetic nondiscrimination protections to all group health plans, including very small group health plans.
101 (c) <i>Genetic information of embryo and fetus</i>	Section 702 of ERISA	Provides that any reference to genetic information concerning an individual or family member includes genetic information of: (1) a fetus carried by a pregnant woman, and (2) an embryo legally held by an individual or family member utilizing an assisted reproductive technology.
101 (d) <i>Definitions</i>	Section 733 (d) of ERISA	<p><u>Family member</u> – with respect to an individual, means a dependent of such individual, any other first-degree, second-degree, third-degree, or fourth-degree relative of such individual or the individual’s dependent.</p> <p><u>Genetic information</u> – means, with respect to any individual, information about such individual’s genetic tests, the genetic tests of family members of such individual, and the manifestation of a disease or disorder in family members of such individual. It shall also include, 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. It shall not include information about the sex or age of any individual.</p> <p><u>Genetic test</u> – means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes. It shall not include analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes, or 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.</p> <p><u>Genetic services</u> – means a genetic test, genetic counseling (including obtaining, interpreting, or assessing genetic information), or genetic education.</p> <p><u>Underwriting purposes</u> – means rules for, or</p>

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		determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage; the computation of premium or contribution amounts under the plan or coverage; the application of any pre-existing condition exclusion under the plan or coverage; and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.
101 (e) <i>Enforcement</i>	Section 502 of ERISA	Authorizes the Secretary of Labor to impose a penalty against any sponsor of a group health plan for any failure to meet requirements of this Act. Allows a waiver or limitation on such penalty if the failure was not discovered after exercising reasonable diligence or was due to reasonable cause and not willful neglect, and to the extent that the Secretary determines payment of penalty would be excessive relative to failure involved.
101 (f) <i>Regulations and effective date</i>		Amendments made by this section apply with respect to group health plans for plan years beginning after May 21, 2009. Secretary of Labor shall issue regulations no later than May 21, 2009.
Section 102		Amends the Public Health Service Act (PHSA) to prohibit genetic discrimination in private health insurance.
102 (a) <i>Amendments relating to the group market</i>		Identical to Section 101
102 (a)(1) <i>Genetic discrimination in premiums</i>	Section 2702(b) of PHSA	Identical to Section 101
102(a)(2) <i>Requiring individuals to undergo genetic testing</i>	Section 2702 of PHSA	Identical to Section 101
102(a)(2) <i>Collection of genetic information</i>	Section 2702 of PHSA	Identical to Section 101
102(a)(2) <i>Application to all group plans</i>	Subsections (a)(1)(F), (b)(3), (c), and (d), and subsection (b)(1) of Section 2702 of PHSA, also Section 2701 of PHSA with respect to genetic information	Identical to Section 101
102(a)(3) <i>Genetic information of embryo and fetus</i>	Section 2702 of PHSA	Identical to Section 101
102 (a)(4) <i>Definitions</i>	Section 2791(d) of PHSA	Identical to Section 101

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102(a)(5) <i>Remedies and enforcement</i>	Section 2722(b) of PHSA	Authorizes Secretary of HHS to impose a penalty against any health insurance issuer in the group market for any failure to meet requirements of this Act. Penalties and authority to waive penalties are identical to those in Section 101. <u>Federal fallback authority</u> – Each State may require health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State to meet the requirements of this part. In the case of a determination by the Secretary that a State has failed to substantially enforce a provision (or provisions) in this part with respect to health insurance issuers in the State, the Secretary shall enforce such provision (or provisions) insofar as they relate to the issuance, sale, renewal, and offering of health insurance coverage in such State.
102 (b) <i>Amendments relating to the individual market</i>		
102(b)(1) <i>Prohibition of health discrimination on the basis of genetic information</i>	(New) Section 2753 of PHSA	Amends the PHSA to prohibit: (1) a health insurance issuer offering health insurance coverage in the individual market from establishing eligibility rules for enrollment based on genetic information; (2) discrimination on the basis of genetic information for health insurance offered in the individual market in the same manner as such discrimination is prohibited for group coverage; and (3) the imposition by a health insurance issuer offering health insurance coverage in the individual market of a preexisting condition exclusion on the basis of genetic information.
102 (b)(1) <i>Prohibition of genetic information as a condition of eligibility</i>	Section 2753(a) of PHSA	Prohibits a health insurance issuer offering health insurance coverage in the individual market from establishing eligibility rules for enrollment based on genetic information.
102 (b)(1) <i>Prohibition on genetic information in setting premium rates</i>	Section 2753 (b) of PHSA	Identical to Section 101
102 (b)(1) <i>Prohibition on genetic information as pre-existing condition</i>	Section 2753 (c) of PHSA	Prohibits a health insurance issuer offering health insurance coverage in the individual market from imposing any pre-existing condition exclusion on the basis of genetic information.
102 (b)(1) <i>Requiring individuals to undergo genetic testing</i>	Section 2753 (d) of PHSA	Identical to Section 101
102 (b)(1) <i>Collection of genetic</i>	Section 2753 (e) of PHSA	Identical to Section 101

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<i>information</i>		
102 (b)(1) <i>Genetic information of embryo and fetus</i>	Section 2753 (f) of PHSA	Identical to Section 101
102 (b)(2) <i>Remedies and Enforcement</i>	Section 2761(b) of PHSA	<p>Authorizes Secretary of Health and Human Services to impose a penalty against any health insurance issuer in the individual market for any failure to meet requirements of this Act. Individual market enforcement authority is the same in relation to the individual market as the Secretary has with respect to the small group market.</p> <p><u>Federal fallback authority</u> – Each State may require health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State to meet the requirements of this part. In the case of a determination by the Secretary that a State has failed to substantially enforce a provision (or provisions) in this part with respect to health insurance issuers in the State, the Secretary shall enforce such provision (or provisions) insofar as they relate to the issuance, sale, renewal, and offering of health insurance coverage in such State.</p>
102 (c) <i>Elimination of option of non-federal governmental plans to be excepted from requirements concerning genetic information</i>	Section 2721(b)(2) of PHSA	<p>Applies requirements for group health plans and issuers to nonfederal governmental plans. Requirements previously established by HIPAA to prevent genetic discrimination in group health plans also now apply to nonfederal governmental plans.</p> <ul style="list-style-type: none"> <input type="checkbox"/> PHSA Section 2702(a)(1)(F), prohibiting establishment of rules for eligibility (including continued eligibility) of any individual to enroll under the terms of a group health plan based on genetic information <input type="checkbox"/> PHSA Section 2701, prohibiting imposition of pre-existing condition exclusion periods based on genetic information <input type="checkbox"/> PHSA Section 2702(b), prohibiting requirement that an individual pay a premium or contribution that is greater than that for a similarly situated individual on the basis of genetic information
102 (d) <i>Regulations and effective date</i>		<p>Amendments made by this section shall apply:</p> <p>(1) with respect to health insurance coverage offered in connection with <u>group</u> health plans, for plan years beginning after May 21, 2009;</p> <p>(2) with respect to health insurance coverage that is offered, sold, issued, renewed, in effect, or operated in the <u>individual</u> market after May 21, 2009. Secretary of HHS shall issue regulations no later than May 21, 2009.</p>

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Section 103	Sections 9801, 9082, 9832, and Subchapter 9834 (new) of the IRC	Amends Internal Revenue Code (IRC) to expand genetic nondiscrimination protections under group health plans. Identical to Section 101
Section 104		Amends title XVIII (Medicare) of the Social Security Act (SSA) to prohibit genetic discrimination in Medicare supplemental policies on the basis of genetic information.
Section 104(a) <i>Nondiscrimination</i>	Section 1882(s)(2) of SSA	Prohibits issuer of a Medicare supplemental policy from: (1) denying or conditioning the issuance or effectiveness of the policy, including the imposition of any exclusion of benefits based on a preexisting condition; or (2) discriminating in the pricing of the policy, including the adjustment of premium rates.
Section 104(b)(1) <i>Requiring individuals to undergo genetic testing</i>	Section 1882 of SSA	Identical to Section 101
Section 104(b)(1) <i>Collection of genetic information</i>	Section 1882 of SSA	Identical to Section 101
Section 104(b)(1) <i>Definitions</i>	Section 1882 of SSA	Identical to Section 101
Section 104(b)(2) <i>Genetic information of embryo and fetus</i>	Section 1882 of SSA	Identical to Section 101
Section 104(c) <i>Effective Date</i>		Amendments made by this section shall apply with respect to an issuer of a Medigap policy for policy years beginning on or after May 21, 2009. If, as of a specified date, the Secretary identifies a State as requiring a change to its statutes or regulations to conform to GINA requirements, the State regulatory program shall be considered to be out of compliance. The specified date is the earlier of the date the State changes its statutes or regulations to conform to GINA requirements or July 1, 2009. For States whose legislatures are not scheduled to meet in 2009 in a legislative session, the specified date shall be the first day of the first calendar quarter beginning after the close of the next legislative session that begins on or after July 1, 2009.
Section 104(d) <i>Transition provisions and Secretarial enforcement</i>		By October 31, 2008, the NAIC should modify its model Medigap regulation to conform to amendments made by this section. If NAIC does not make such modifications by such date, the Secretary of HHS shall, not later than July 1, 2009, issue regulations implementing such changes.
Section 105	Section 1180 of SSA	Amends title XI (General Provisions, Peer Review,

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		<p>and Administrative Simplification) of SSA to require the Secretary of Health and Human Services to revise Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy regulations to: (1) treat genetic information as health information; and (2) prohibit the use or disclosure by a group health plan, health insurance coverage, or Medicare supplemental policy of genetic information about an individual for underwriting purposes.</p> <p>In addition to any other sanctions or remedies that may be available under law, a covered entity that violates the revised HIPAA privacy regulations with respect to the use or disclosure of genetic information shall be subject to the same penalties that apply to other violations of HIPAA privacy regulations.</p> <p>The Secretary shall issue final regulations to implement these changes no later than May 21, 2009.</p> <p>Amendments made by this subsection shall take effect on May 21, 2009.</p>
Section 106		<p>Requires the Secretaries of Health and Human Services, Labor, and the Treasury to ensure that their regulations, rulings, and interpretations under this title are administered so as to have the same effect at all times and that to adopt a coordinated enforcement strategy.</p>