GENETIC INFORMATION NONDISCRIMINATION ACT OF 2007

MARCH 26, 2007.—Ordered to be printed

Mr. RANGEL, from the Committee on Ways and Means, submitted the following

REPORT

together with

ADDITIONAL VIEWS

[To accompany H.R. 493]

[Including cost estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 493) to prohibit discrimination on the basis of genetic information with respect to health insurance and employment, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

- (a) SHORT TITLE.—This Act may be cited as the "Genetic Information Nondiscrimination Act of 2007".
- (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.
 Sec. 107. Regulations; effective date.

TITLE II—PROHIBITING EMPLOYMENT DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION

- Sec. 201. Definitions.
 Sec. 202. Employer practices.
 Sec. 203. Employment agency practices.
 Sec. 204. Labor organization practices.

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Sec. 205. Training programs.

Confidentiality of genetic information. Remedies and enforcement. Disparate impact. Sec. 206.

Sec 209 Construction

Medical information that is not genetic information.

Sec. 211. Regulations.

Authorization of appropriations

Sec. 213. Effective date.

TITLE III—MISCELLANEOUS PROVISION

Sec. 301. Severability.

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

(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.

 $(\hat{\mathbf{5}})$ 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) Prohibition of Health Discrimination on the Basis of Genetic Informa-TION OR GENETIC SERVICES.
 - (1) NO ENROLLMENT RESTRICTION FOR GENETIC SERVICES.—Section 702(a)(1)(F) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182(a)(1)(F)) is amended by inserting before the period the following: "(including information about a request for or receipt of genetic services by an individual or family member of such individual)".

(2) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON GENETIC INFORMA-TION.—Section 702(b) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182(b)) is amended—

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

(B) by adding at the end the following:

"(3) No discrimination in group premiums based on genetic information.—For purposes of this section, a group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not adjust premium or contribution amounts for a group on the basis of genetic information concerning an individual in the group or a family member of the individual (including information about a request for or receipt of genetic services by an individual or family member of such individual).".

(b) LIMITATIONS ON GENETIC TESTING.—Section 702 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182) is amended by adding at the end the

"(c) GENETIC TESTING.—

"(1) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—A group health plan, or 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.—Nothing in this part shall be construed to-"(A) limit the authority of a health care professional who is providing health care services with respect to an individual to request that such indi-

vidual or a family member of such individual undergo a genetic test;

"(B) limit the authority of a health care professional who is employed by or affiliated with a group health plan or a health insurance issuer and who is providing health care services to an individual as part of a bona fide wellness program to notify such individual of the availability of a genetic test or to provide information to such individual regarding such genetic

"(C) authorize or permit a health care professional to require that an in-

dividual undergo a genetic test.

"(d) APPLICATION TO ALL PLANS.—The provisions of subsections (a)(1)(F), (b)(3), and (c) shall apply to group health plans and health insurance issuers without regard to section 732(a)."

(c) REMEDIES AND ENFORCEMENT.—Section 502 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132) is amended by adding at the end the

following:

"(n) Enforcement of Genetic Nondiscrimination Requirements.

"(1) INJUNCTIVE RELIEF FOR IRREPARABLE HARM.—With respect to any violation of subsection (a)(1)(F), (b)(3), or (c) of section 702, a participant or beneficiary may seek relief under subsection 502(a)(1)(B) prior to the exhaustion of available administrative remedies under section 503 if it is demonstrated to the court, by a preponderance of the evidence, that the exhaustion of such remedies would cause irreparable harm to the health of the participant or beneficiary. Any determinations that already have been made under section 503 in such case, or that are made in such case while an action under this paragraph is pending, shall be given due consideration by the court in any action under this subsection in such case.

(2) EQUITABLE RELIEF FOR GENETIC NONDISCRIMINATION.—

"(A) REINSTATEMENT OF BENEFITS WHERE EQUITABLE RELIEF HAS BEEN AWARDED.—The recovery of benefits by a participant or beneficiary under a civil action under this section may include an administrative penalty under subparagraph (B) and the retroactive reinstatement of coverage under the plan involved to the date on which the participant or beneficiary was denied eligibility for coverage if-

(i) the civil action was commenced under subsection (a)(1)(B); and

- "(ii) the denial of coverage on which such civil action was based constitutes a violation of subsection (a)(1)(F), (b)(3), or (c) of section 702. "(B) Administrative penalty.-
 - (i) IN GENERAL.—An administrator who fails to comply with the requirements of subsection (a)(1)(F), (b)(3), or (c) of section 702 with respect to a participant or beneficiary may, in an action commenced under subsection (a)(1)(B), be personally liable in the discretion of the court, for a penalty in the amount not more than \$100 for each day in the noncompliance period.

"(ii) NONCOMPLIANCE PERIOD.—For purposes of clause (i), the term

'noncompliance period' means the period-

"(Î) beginning on the date that a failure described in clause (i) occurs; and

"(II) ending on the date that such failure is corrected

"(iii) PAYMENT TO PARTICIPANT OR BENEFICIARY.—A penalty collected under this subparagraph shall be paid to the participant or beneficiary involved.

"(3) Secretarial enforcement authority.—

(A) GENERAL RULE.—The Secretary has the authority to impose a penalty on any failure of a group health plan to meet the requirements of subsection (a)(1)(F), (b)(3), or (c) of section 702.

"(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 individual to whom such failure relates.

"(ii) NONCOMPLIANCE PERIOD.—For purposes of this paragraph, the term 'noncompliance period' means, with respect to any failure, the pe-

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

"(II) ending on the date such 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 exer-CISING 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.".
(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) the spouse of the individual;

"(B) a dependent child of the individual, including a child who is born to

or placed for adoption with the individual; and

(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (Å) or (B).

"(6) GENETIC INFORMATION.

(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'genetic information' means information about-

'(i) an individual's genetic tests;

"(ii) the genetic tests of family members of the individual; or

"(iii) the occurrence of a disease or disorder in family members of the individual.

"(B) Exclusions.—The term 'genetic information' shall not include information about the sex or age of an 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 (such as obtaining, interpreting, or assessing genetic information); or

"(C) genetic education."

(e) REGULATIONS AND EFFECTIVE DATE.-

(1) REGULATIONS.—Not later than 1 year after the date of enactment of this title, the Secretary of Labor shall issue final regulations in an accessible format 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 18 months after the date of enactment of this title.

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

(a) Amendments Relating to the Group Market.—

(1) Prohibition of health discrimination on the basis of genetic infor-MATION OR GENETIC SERVICES.

(A) NO ENROLLMENT RESTRICTION FOR GENETIC SERVICES.—Section 2702(a)(1)(F) of the Public Health Service Act (42 U.S.C. 300gg-1(a)(1)(F)) is amended by inserting before the period the following: "(including information about a request for or receipt of genetic services by an individual or family member of such individual)"

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

(i) in paragraph (2)(A), by inserting before the semicolon the following: ", except as provided in paragraph (3)"; and (ii) by adding at the end the following:

"(3) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON GENETIC INFORMA-TION.—For purposes of this section, a group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not adjust premium or contribution amounts for a group on the basis of genetic information concerning an individual in the group or a family member of the individual (including information about a request for or receipt of genetic services by an individual or family member of such individual)."

(2) LIMITATIONS ON GENETIC TESTING.—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, or 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.—Nothing in this part shall be construed to-

"(A) limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or a family member of such individual undergo a genetic test; "(B) limit the authority of a health care professional who is employed by or affiliated with a group health plan or a health insurance issuer and who is providing health care services to an individual as part of a bona fide wellness program to notify such individual of the availability of a genetic test or to provide information to such individual regarding such genetic test; or "(C) authorize or permit a health care professional to require that an in-

dividual undergo a genetic test. "(d) APPLICATION TO ALL PLANS.—The provisions of subsections (a)(1)(F), (b)(3), and (c) shall apply to group health plans and health insurance issuers without regard to section 2721(a)."

(3) 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 following provisions 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), or (c) of section 2702.

"(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 individual to whom such failure relates.

(ii) NONCOMPLIANCE PERIOD.—For purposes of this paragraph, the term 'noncompliance period' means, with respect to any failure, the pe-

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

"(II) ending on the date such 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 exer-CISING 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

"(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."

(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 an individual—

"(A) the spouse of the individual;

"(B) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and

"(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B). "(16) GENETIC INFORMATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'genetic information' means information about—

"(i) an individual's genetic tests;

"(ii) the genetic tests of family members of the individual; or

"(iii) the occurrence of a disease or disorder in family members of the individual.

"(B) EXCLUSIONS.—The term 'genetic information' shall not include information about the sex or age of an 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 (such as obtaining, interpreting, or assessing genetic information); or

"(C) genetic education.".

(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.—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 (including information about a request for or receipt of genetic services by an individual or family member of such individual).

"(b) Prohibition on Genetic Information in Setting Premium Rates.—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

(including information about a request for or receipt of genetic services by an individual or family member of such individual).

"(c) 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.—Nothing in this part shall be construed to—

"(A) limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or a family member of such individual undergo a genetic test;

"(B) limit the authority of a health care professional who is employed by or affiliated with a health insurance issuer and who is providing health care services to an individual as part of a bona fide wellness program to notify such individual of the availability of a genetic test or to provide information to such individual regarding such genetic test; or

(C) authorize or permit a health care professional to require that an in-

dividual undergo a genetic test.".

(2) REMEDIES AND ENFORCEMENT.—Section 2761(b) of the Public Health Serv-

ice 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 Ex-CEPTED 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) and (c) of section 2702 and the provisions of section 2702(b) to the extent that such provisions apply to genetic information (or information about a request for or the receipt of genetic services by an individual or a family member of such individual).

(d) REGULATIONS AND EFFECTIVE DATE.—

(1) REGULATIONS.—Not later than 1 year after the date of enactment of this title, the Secretary of Labor and the Secretary of Health and Human Services (as the case may be) shall issue final regulations in an accessible format 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 18 months after the date of enactment of this title; 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 18 months after the date of enactment of this title.

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.— 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) Limitations on Genetic Testing and Collection of Genetic Informa-TION.—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 Ťesting.-

"(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) EXCEPTION FOR HEALTH CARE PROFESSIONALS.—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) Provision of information not prohibited.—Paragraph (1) shall not be

construed to limit the authority of a group health plan—

"(A) to provide information generally about the availability of genetic

tests, or

"(B) to provide information about genetic tests to a health care professional with respect to the treatment of an individual to whom such professional is providing health care services.

"(d) Prohibition on Collection of Genetic Information.—

"(1) IN GENERAL.—A group health plan shall not request, require, or purchase genetic information for purposes of underwriting (as defined in section 9832).

"(2) Prohibition on collection of genetic information prior to enroll-MENT.—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) DEFINITIONS.—Subsection (d) of section 9832 of such Code is amended by add-

ing 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 occurrence of a disease or disorder in family members of such individual.

"(B) INCLUSION OF GENETIC SERVICES AND PARTICIPATION IN GENETIC RE-SEARCH.—Such term includes, with respect to any individual, any request for genetic services, receipt of genetic services, or participation in any clinical research, or any other program, which includes genetic services, by such individual or any family member of such individual.

"(C) EXCLUSIONS.—The term 'genetic information' shall not include infor-

mation about the sex or age of any individual.

(D) Application to family members covered under same plan.—Information described in clause (iii) of subparagraph (A) shall not be treated as genetic information to the extent that such information is taken into account only with respect to the individual in which such disease or disorder occurs and not as genetic information with respect to any other 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 (such as obtaining, interpreting, or assessing genetic information), and

"(C) genetic education.

"(10) UNDERWRITING.—The term 'underwriting' means, with respect to any group health plan-

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

"(B) the computation of premium or contribution amounts under the plan, "(C) the application of any pre-existing condition exclusion under the plan, and

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

(d) 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 chap-

ter 100 of such Code is amended by adding at the end the following new item: "Sec. 9834. Enforcement."

(e) REGULATIONS AND EFFECTIVE DATE.-

(1) REGULATIONS.—The Secretary of the Treasury shall issue regulations or other guidance not later than 1 year 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 18 months 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.".

(b) LIMITATIONS ON GENETIC TESTING AND COLLECTION OF GENETIC INFORMA-

(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 Collection of Genetic Informa-TION.

"(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) EXCEPTION FOR HEALTH CARE PROFESSIONALS.—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) PROVISION OF INFORMATION NOT PROHIBITED.—Subparagraph (A) shall not be construed to limit the authority of an issuer of a medicare sup-

plemental policy—

"(i) to provide information generally about the availability of genetic

"(ii) to provide information about genetic tests to a health care professional with respect to the treatment of an individual to whom such professional is providing health care services.

"(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 purposes of under-

"(B) Limitation relating to the collection of genetic information PRIOR TO ENROLLMENT.—An issuer of a medicare supplemental policy shall not request, require, or purchase genetic information concerning any indi-

vidual prior to such individual's enrollment under the policy or in connection with such enrollment.

(C) INCIDENTAL COLLECTION.—Where an issuer of a medicare supplemental policy obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning an enrollee, such request, requirement, or purchase shall not be considered a violation of this paragraph if such request, requirement, or purchase is not in violation of subparagraph (A).

"(3) DEFINITIONS.—In this subsection and subsection (s)(2)(E):

"(A) FAMILY MEMBER.—The term 'family member' means, with respect to any individual, any individual who is a first-degree, second-degree, thirddegree, 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) the occurrence 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 genetic services, receipt of genetic services, or participation in any clinical research, or any other program, 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 an 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 (such as obtaining, interpreting, or assessing genetic information); and

(iii) genetic education.

"(E) UNDERWRITING.—The term 'underwriting' means, with respect to a medicare supplemental policy

(i) rules for eligibility (including enrollment and continued eligibility) for, or determination of, 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) Conforming Amendment.—Section 1882(o) of such Act (42 U.S.C.

1395ss(o)) is amended by adding at the end the following:

"(4) The issuer of the medicare supplemental policy (as defined in subsection (x)) 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 18 months 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 June 30, 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 October 1, 2008, make the modifications described in such paragraph and such revised regula-tion 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) October 1, 2008.

- (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 2008 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, 2008. 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.

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 of Health and Human Services 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 plan, coverage, or 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 SUPPLE-MENTAL 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 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.".

SEC. 106. ASSURING COORDINATION.

(a) In General.—Except as provided in subsection (b), the Secretary of the Treasury, the Secretary of Health and Human Services, and the Secretary of Labor 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

(b) AUTHORITY OF THE SECRETARY.—The Secretary of Health and Human Services has the sole authority to promulgate regulations to implement the amendment made by section 104.

SEC. 107. REGULATIONS; EFFECTIVE DATE.

(a) REGULATIONS.—Not later than 1 year after the date of enactment of this title, the Secretary of Labor, the Secretary of Health and Human Services, and the Secretary of the Treasury shall issue final regulations in an accessible format to carry out this title.

(b) EFFECTIVE DATE.—Except as provided in section 103, the amendments made by this title shall take effect on the date that is 18 months after the date of enactment of this Act.

TITLE II—PROHIBITING EMPLOYMENT DIS-CRIMINATION ON THE BASIS OF GENETIC IN-FORMATION

SEC. 201. DEFINITIONS.

In this title:

- (1) COMMISSION.—The term "Commission" means the Equal Employment Opportunity Commission as created by section 705 of the Civil Rights Act of 1964 (42 U.S.C. 2000e–4).
- (2) Employee; employer; employment agency; labor organization; member.—

(A) IN GENERAL.—The term "employee" means—

- (i) an employee (including an applicant), as defined in section 701(f) of the Civil Rights Act of 1964 (42 U.S.C. 2000e(f));
- (ii) a State employee (including an applicant) described in section 304(a) of the Government Employee Rights Act of 1991 (42 U.S.C. 2000e–16c(a));
- (iii) a covered employee (including an applicant), as defined in section 101 of the Congressional Accountability Act of 1995 (2 U.S.C. 1301);
- (iv) a covered employee (including an applicant), as defined in section 411(c) of title 3, United States Code; or
- (v) an employee or applicant to which section 717(a) of the Civil Rights Act of 1964 (42 U.S.C. 2000e–16(a)) applies.

 (B) EMPLOYER.—The term "employer" means—
- (i) an employer (as defined in section 701(b) of the Civil Rights Act of 1964 (42 U.S.C. 2000e(b));
- (ii) an entity employing a State employee described in section 304(a) of the Government Employee Rights Act of 1991;

(iii) an employing office, as defined in section 101 of the Congressional Accountability Act of 1995;

(iv) an employing office, as defined in section 411(c) of title 3, United States Code; or

(v) an entity to which section 717(a) of the Civil Rights Act of 1964

(C) EMPLOYMENT AGENCY; LABOR ORGANIZATION.—The terms "employment agency" and "labor organization" have the meanings given the terms in section 701 of the Civil Rights Act of 1964 (42 U.S.C. 2000e).

(D) MEMBER.—The term "member", with respect to a labor organization, includes an applicant for membership in a labor organization.

(3) FAMILY MEMBER.—The term "family member" means with respect to an individual-

(A) the spouse of the individual;

(B) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and

(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

(4) Genetic information.

(A) In general.—Except as provided in subparagraph (B), the term "genetic information" means information about-

(i) an individual's genetic tests;

(ii) the genetic tests of family members of the individual; or

(iii) the occurrence of a disease or disorder in family members of the individual.

(B) Exceptions.—The term "genetic information" shall not include infor-

mation about the sex or age of an individual.
(5) GENETIC MONITORING.—The term "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, that may have developed in the course of employment due to exposure to toxic substances in the workplace, in order to identify, evaluate, and respond to the effects of or control adverse environmental exposures in the work-

(6) Genetic services.—The term "genetic services" means—

(A) a genetic test;

(B) genetic counseling (such as obtaining, interpreting or assessing genetic information); or

(C) genetic education.

(7) Genetic test.-

(A) IN GENERAL.—The term "genetic test" means the analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

(B) EXCEPTION.—The term "genetic test" does not mean an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes.

SEC. 202. EMPLOYER PRACTICES.

(a) USE OF GENETIC INFORMATION.—It shall be an unlawful employment practice for an employer

(1) to fail or refuse to hire or to discharge any employee, or otherwise to discriminate against any employee with respect to the compensation, terms, conditions, or privileges of employment of the employee, because of genetic information with respect to the employee (or information about a request for or the receipt of genetic services by such employee or family member of such employee);

(2) to limit, segregate, or classify the employees of the employer in any way that would deprive or tend to deprive any employee of employment opportunities or otherwise adversely affect the status of the employee as an employee, because of genetic information with respect to the employee (or information about a request for or the receipt of genetic services by such employee or family member of such employee).

(b) ACQUISITION OF GENETIC INFORMATION.—It shall be an unlawful employment practice for an employer to request, require, or purchase genetic information with respect to an employee or a family member of the employee (or information about a request for the receipt of genetic services by such employee or a family member of such employee) except-

(1) where an employer inadvertently requests or requires family medical history of the employee or family member of the employee;

(2) where-

(A) health or genetic services are offered by the employer, including such services offered as part of a bona fide wellness program;

(B) the employee provides prior, knowing, voluntary, and written author-

(C) only the employee (or family member if the family member is receiving genetic services) and the licensed health care professional or board certified genetic counselor involved in providing such services receive individually identifiable information concerning the results of such services; and

(D) any individually identifiable genetic information provided under subparagraph (C) in connection with the services provided under subparagraph (A) is only available for purposes of such services and shall not be disclosed to the employer except in aggregate terms that do not disclose the identity of specific employees;

(3) where an employer requests or requires family medical history from the employee to comply 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;

(4) where an employer purchases documents that are commercially and publicly available (including newspapers, magazines, periodicals, and books, but not including medical databases or court records) that include family medical his-

(5) where the information involved is to be used for genetic monitoring of the

biological effects of toxic substances in the workplace, but only if-

(A) the employer provides written notice of the genetic monitoring to the employee;

(B)(i) the employee provides prior, knowing, voluntary, and written au-

thorization; or

(ii) the genetic monitoring is required by Federal or State law; (C) the employee is informed of individual monitoring results;

(D) the monitoring is in compliance with-

(i) any Federal genetic monitoring regulations, including any such 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 (ii) 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.);

(E) the employer, excluding any licensed health care professional or board certified genetic counselor that is involved in the genetic monitoring program, receives the results of the monitoring only in aggregate terms that do not disclose the identity of specific employees;

(c) PRESERVATION OF PROTECTIONS.—In the case of information to which any of paragraphs (1) through (5) of subsection (b) applies, such information may not be used in violation of paragraph (1) or (2) of subsection (a) or treated or disclosed in

a manner that violates section 206

SEC. 203. EMPLOYMENT AGENCY PRACTICES.

(a) Use of Genetic Information.—It shall be an unlawful employment practice for an employment agency

(1) to fail or refuse to refer for employment, or otherwise to discriminate against, any individual because of genetic information with respect to the individual (or information about a request for or the receipt of genetic services by such individual or family member of such individual);

(2) to limit, segregate, or classify individuals or fail or refuse to refer for employment any individual in any way that would deprive or tend to deprive any individual of employment opportunities, or otherwise adversely affect the status of the individual as an employee, because of genetic information with respect to the individual (or information about a request for or the receipt of genetic services by such individual or family member of such individual); or

(3) to cause or attempt to cause an employer to discriminate against an indi-

vidual in violation of this title.

(b) ACQUISITION OF GENETIC INFORMATION.—It shall be an unlawful employment practice for an employment agency to request, require, or purchase genetic informa-tion with respect to an individual or a family member of the individual (or information about a request for the receipt of genetic services by such individual or a family member of such individual) except(1) where an employment agency inadvertently requests or requires family medical history of the individual or family member of the individual;

(2) where—

(A) health or genetic services are offered by the employment agency, including such services offered as part of a bona fide wellness program;

(B) the individual provides prior, knowing, voluntary, and written author-

ization;

(C) only the individual (or family member if the family member is receiving genetic services) and the licensed health care professional or board certified genetic counselor involved in providing such services receive individually identifiable information concerning the results of such services; and

(Ď) any individually identifiable genetic information provided under subparagraph (C) in connection with the services provided under subparagraph (A) is only available for purposes of such services and shall not be disclosed to the employment agency except in aggregate terms that do not disclose the identity of specific individuals;

(3) where an employment agency requests or requires family medical history from the individual to comply 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;

(4) where an employment agency purchases documents that are commercially and publicly available (including newspapers, magazines, periodicals, and books, but not including medical databases or court records) that include family medical history; or

(5) where the information involved is to be used for genetic monitoring of the biological effects of toxic substances in the workplace, but only if—

- (A) the employment agency provides written notice of the genetic monitoring to the individual;
- $(B)\check{(}i)$ the individual provides prior, knowing, voluntary, and written authorization; or
 - (ii) the genetic monitoring is required by Federal or State law; (C) the individual is informed of individual monitoring results;

(D) the monitoring is in compliance with—

(i) any Federal genetic monitoring regulations, including any such 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

et seq.), or the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.); or (ii) 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.);

(E) the employment agency, excluding any licensed health care professional or board certified genetic counselor that is involved in the genetic monitoring program, receives the results of the monitoring only in aggregate terms that do not disclose the identity of specific individuals;

(c) PRESERVATION OF PROTECTIONS.—In the case of information to which any of

(c) PRESERVATION OF PROTECTIONS.—In the case of information to which any of paragraphs (1) through (5) of subsection (b) applies, such information may not be used in violation of paragraph (1) or (2) of subsection (a) or treated or disclosed in a manner that violates section 206.

SEC. 204. LABOR ORGANIZATION PRACTICES.

(a) USE OF GENETIC INFORMATION.—It shall be an unlawful employment practice for a labor organization—

(1) 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 (or information about a request for or the receipt of genetic services by such member or family member of such member);

- (2) to limit, segregate, or classify the members of the organization, or fail or refuse to refer for employment any member, in any way that would deprive or tend to deprive any member of employment opportunities, or otherwise adversely affect the status of the member as an employee, because of genetic information with respect to the member (or information about a request for or the receipt of genetic services by such member or family member of such member); or
- (3) to cause or attempt to cause an employer to discriminate against a member in violation of this title.
- (b) ACQUISITION OF GENETIC INFORMATION.—It shall be an unlawful employment practice for a labor organization to request, require, or purchase genetic information

with respect to a member or a family member of the member (or information about a request for the receipt of genetic services by such member or a family member of such member) except-

(1) where a labor organization inadvertently requests or requires family med-

ical history of the member or family member of the member;

(A) health or genetic services are offered by the labor organization, including such services offered as part of a bona fide wellness program;

(B) the member provides prior, knowing, voluntary, and written author-

ization;

(C) only the member (or family member if the family member is receiving genetic services) and the licensed health care professional or board certified genetic counselor involved in providing such services receive individually identifiable information concerning the results of such services; and

(D) any individually identifiable genetic information provided under sub-paragraph (C) in connection with the services provided under subparagraph (A) is only available for purposes of such services and shall not be disclosed to the labor organization except in aggregate terms that do not disclose the identity of specific members:

(3) where a labor organization requests or requires family medical history from the members to comply with the certification provisions of section 103 of the Family and Medical Leave Act of 1993 (29 U.S.C. 2613) or such require-

ments under State family and medical leave laws;

(4) where a labor organization purchases documents that are commercially and publicly available (including newspapers, magazines, periodicals, and books, but not including medical databases or court records) that include family med-

(5) where the information involved is to be used for genetic monitoring of the

biological effects of toxic substances in the workplace, but only if-

(A) the labor organization provides written notice of the genetic monitoring to the member;

(B)(i) the member provides prior, knowing, voluntary, and written author-

(ii) the genetic monitoring is required by Federal or State law;

(C) the member is informed of individual monitoring results;

(D) the monitoring is in compliance with-

(i) any Federal genetic monitoring regulations, including any such 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 seg.), 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

(ii) 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.);

(E) the labor organization, excluding any licensed health care professional or board certified genetic counselor that is involved in the genetic monitoring program, receives the results of the monitoring only in aggregate terms that do not disclose the identity of specific members;

(c) PRESERVATION OF PROTECTIONS.—In the case of information to which any of paragraphs (1) through (5) of subsection (b) applies, such information may not be used in violation of paragraph (1) or (2) of subsection (a) or treated or disclosed in a manner that violates section 206.

SEC. 205. TRAINING PROGRAMS

(a) USE OF GENETIC INFORMATION.—It shall be an unlawful employment practice for any employer, labor organization, or joint labor-management committee controlling apprenticeship or other training or retraining, including on-the-job training pro-

(1) to discriminate against any individual because of genetic information with respect to the individual (or information about a request for or the receipt of genetic services by such individual or a family member of such individual) in admission to, or employment in, any program established to provide apprentice-

ship or other training or retraining;
(2) to limit, segregate, or classify the applicants for or participants in such apprenticeship or other training or retraining, or fail or refuse to refer for employment any individual, in any way that would deprive or tend to deprive any individual of employment opportunities, or otherwise adversely affect the status of the individual as an employee, because of genetic information with respect to the individual (or information about a request for or receipt of genetic services by such individual or family member of such individual); or

(3) to cause or attempt to cause an employer to discriminate against an applicant for or a participant in such apprenticeship or other training or retraining

in violation of this title.

(b) ACQUISITION OF GENETIC INFORMATION.—It shall be an unlawful employment practice for an employer, labor organization, or joint labor-management committee described in subsection (a) to request, require, or purchase genetic information with respect to an individual or a family member of the individual (or information about a request for the receipt of genetic services by such individual or a family member of such individual) except—

(1) where the employer, labor organization, or joint labor-management committee inadvertently requests or requires family medical history of the indi-

vidual or family member of the individual;

(2) where—

(A) health or genetic services are offered by the employer, labor organization, or joint labor-management committee, including such services offered as part of a bona fide wellness program;

(B) the individual provides prior, knowing, voluntary, and written author-

ization;

(C) only the individual (or family member if the family member is receiving genetic services) and the licensed health care professional or board certified genetic counselor involved in providing such services receive individually identifiable information concerning the results of such services;

(D) any individually identifiable genetic information provided under subparagraph (C) in connection with the services provided under subparagraph (A) is only available for purposes of such services and shall not be disclosed to the employer, labor organization, or joint labor-management committee except in aggregate terms that do not disclose the identity of specific individuals:

(3) where the employer, labor organization, or joint labor-management committee requests or requires family medical history from the individual to comply 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;

(4) where the employer, labor organization, or joint labor-management committee purchases documents that are commercially and publicly available (including newspapers, magazines, periodicals, and books, but not including medical databases or court records) that include family medical history; or

(5) where the information involved is to be used for genetic monitoring of the

biological effects of toxic substances in the workplace, but only if-

(A) the employer, labor organization, or joint labor-management committee provides written notice of the genetic monitoring to the individual; (B)(i) the individual provides prior, knowing, voluntary, and written authorization; or

- (ii) the genetic monitoring is required by Federal or State law;
- (C) the individual is informed of individual monitoring results;

(D) the monitoring is in compliance with—

(i) any Federal genetic monitoring regulations, including any such 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

et seq.), or the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.); or (ii) 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

(E) the employer, labor organization, or joint labor-management committee, excluding any licensed health care professional or board certified genetic counselor that is involved in the genetic monitoring program, receives the results of the monitoring only in aggregate terms that do not disclose the identity of specific individuals;

(c) PRESERVATION OF PROTECTIONS.—In the case of information to which any of paragraphs (1) through (5) of subsection (b) applies, such information may not be used in violation of paragraph (1) or (2) of subsection (a) or treated or disclosed in a manner that violates section 206.

SEC. 206. CONFIDENTIALITY OF GENETIC INFORMATION.

(a) Treatment of Information as Part of Confidential Medical Record.— If an employer, employment agency, labor organization, or joint labor-management committee possesses genetic information about an employee or member (or information about a request for or receipt of genetic services by such employee or member or family member of such employee or member), such information shall be maintained on separate forms and in separate medical files and be treated as a confidential medical record of the employee or member.

(b) LIMITATION ON DISCLOSURE.—An employer, employment agency, labor organization, or joint labor-management committee shall not disclose genetic information concerning an employee or member (or information about a request for or receipt of genetic services by such employee or member or family member of such employee

or member) except-

(1) to the employee (or family member if the family member is receiving the genetic services) or member of a labor organization at the request of the employee or member of such organization;

(2) to an occupational or other health researcher if the research is conducted in compliance with the regulations and protections provided for under part 46 of title 45, Code of Federal Regulations;

(3) in response to an order of a court, except that—

(A) the employer, employment agency, labor organization, or joint labormanagement committee may disclose only the genetic information expressly

authorized by such order; and

(B) if the court order was secured without the knowledge of the employee or member to whom the information refers, the employer, employment agency, labor organization, or joint labor-management committee shall provide the employee or member with adequate notice to challenge the court order:

(4) to government officials who are investigating compliance with this title if

the information is relevant to the investigation; or

(5) to the extent that such disclosure is made in connection with the 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.

SEC. 207. REMEDIES AND ENFORCEMENT.

(a) Employees Covered by Title VII of the Civil Rights Act of 1964.—

(1) IN GENERAL.—The powers, remedies, and procedures provided in sections 705, 706, 707, 709, 710, and 711 of the Civil Rights Act of 1964 (42 U.S.C. 2000e—4 et seq.) to the Commission, the Attorney General, or any person, alleging a violation of title VII of that Act (42 U.S.C. 2000e et seq.) shall be the powers, remedies, and procedures this title provides to the Commission, the Attorney General, or any person, respectively, alleging an unlawful employment practice in violation of this title against an employee described in section 201(2)(A)(i), except as provided in paragraphs (2) and (3).

(2) COSTS AND FEES.—The powers, remedies, and procedures provided in subsections (b) and (c) of section 722 of the Revised Statutes (42 U.S.C. 1988), shall be powers, remedies, and procedures this title provides to the Commission, the

Attorney General, or any person, alleging such a practice.

(3) DAMAGES.—The powers, remedies, and procedures provided in section 1977A of the Revised Statutes (42 U.S.C. 1981a), including the limitations contained in subsection (b)(3) of such section 1977A, shall be powers, remedies, and procedures this title provides to the Commission, the Attorney General, or any person, alleging such a practice (not an employment practice specifically excluded from coverage under section 1977A(a)(1) of the Revised Statutes).

(b) Employees Covered by Government Employee Rights Act of 1991.

(1) IN GENERAL.—The powers, remedies, and procedures provided in sections 302 and 304 of the Government Employee Rights Act of 1991 (42 U.S.C. 2000e-16b, 2000e-16c) to the Commission, or any person, alleging a violation of section 302(a)(1) of that Act (42 U.S.C. 2000e–16b(a)(1)) shall be the powers, remedies, and procedures this title provides to the Commission, or any person, respectively, alleging an unlawful employment practice in violation of this title against an employee described in section 201(2)(A)(ii), except as provided in paragraphs (2) and (3).

(2) COSTS AND FEES.—The powers, remedies, and procedures provided in subsections (b) and (c) of section 722 of the Revised Statutes (42 U.S.C. 1988), shall be powers, remedies, and procedures this title provides to the Commission, or

any person, alleging such a practice.

(3) DAMAGES.—The powers, remedies, and procedures provided in section 1977A of the Revised Statutes (42 U.S.C. 1981a), including the limitations contained in subsection (b)(3) of such section 1977A, shall be powers, remedies, and procedures this title provides to the Commission, or any person, alleging such a practice (not an employment practice specifically excluded from coverage under section 1977A(a)(1) of the Revised Statutes).

(c) Employees Covered by Congressional Accountability Act of 1995.

(1) IN GENERAL.—The powers, remedies, and procedures provided in the Congressional Accountability Act of 1995 (2 U.S.C. 1301 et seq.) to the Board (as defined in section 101 of that Act (2 U.S.C. 1301)), or any person, alleging a violation of section 201(a)(1) of that Act (42 U.S.C. 1311(a)(1)) shall be the powers, remedies, and procedures this title provides to that Board, or any person, alleging an unlawful employment practice in violation of this title against an employee described in section 201(2)(A)(iii), except as provided in paragraphs (2) and (3).

(2) Costs and fees.—The powers, remedies, and procedures provided in subsections (b) and (c) of section 722 of the Revised Statutes (42 U.S.C. 1988), shall be powers, remedies, and procedures this title provides to that Board, or any

person, alleging such a practice.

(3) DAMAGES.—The powers, remedies, and procedures provided in section 1977A of the Revised Statutes (42 U.S.C. 1981a), including the limitations contained in subsection (b)(3) of such section 1977A, shall be powers, remedies, and procedures this title provides to that Board, or any person, alleging such a practice (not an employment practice specifically excluded from coverage under section 1977A(a)(1) of the Revised Statutes).

(4) OTHER APPLICABLE PROVISIONS.—With respect to a claim alleging a practice described in paragraph (1), title III of the Congressional Accountability Act of 1995 (2 U.S.C. 1381 et seq.) shall apply in the same manner as such title applies with respect to a claim alleging a violation of section 201(a)(1) of such

Act (2 U.S.C. 1311(a)(1)). (d) Employees Covered by Chapter 5 of Title 3, United States Code.

(1) IN GENERAL.—The powers, remedies, and procedures provided in chapter 5 of title 3, United States Code, to the President, the Commission, the Merit Systems Protection Board, or any person, alleging a violation of section 411(a)(1) of that title, shall be the powers, remedies, and procedures this title provides to the President, the Commission, such Board, or any person, respectively, alleging an unlawful employment practice in violation of this title against an employee described in section 201(2)(A)(iv), except as provided in paragraphs (2) and (3).

(2) COSTS AND FEES.—The powers, remedies, and procedures provided in subsections (b) and (c) of section 722 of the Revised Statutes (42 U.S.C. 1988), shall be powers, remedies, and procedures this title provides to the President, the

Commission, such Board, or any person, alleging such a practice.

(3) DAMAGES.—The powers, remedies, and procedures provided in section 1977A of the Revised Statutes (42 U.S.C. 1981a), including the limitations contained in subsection (b)(3) of such section 1977A, shall be powers, remedies, and procedures this title provides to the President, the Commission, such Board, or any person, alleging such a practice (not an employment practice specifically excluded from coverage under section 1977A(a)(1) of the Revised Statutes).

(e) Employees Covered by Section 717 of the Civil Rights Act of 1964.— (1) IN GENERAL.—The powers, remedies, and procedures provided in section 717 of the Civil Rights Act of 1964 (42 U.S.C. 2000e–16) to the Commission, the Attorney General, the Librarian of Congress, or any person, alleging a violation of that section shall be the powers, remedies, and procedures this title provides to the Commission, the Attorney General, the Librarian of Congress, or any person, respectively, alleging an unlawful employment practice in violation of this title against an employee or applicant described in section 201(2)(A)(v), except as provided in paragraphs (2) and (3).

(2) COSTS AND FEES.—The powers, remedies, and procedures provided in subsections (b) and (c) of section 722 of the Revised Statutes (42 U.S.C. 1988), shall be powers, remedies, and procedures this title provides to the Commission, the Attorney General, the Librarian of Congress, or any person, alleging such a

(3) DAMAGES.—The powers, remedies, and procedures provided in section 1977A of the Revised Statutes (42 U.S.C. 1981a), including the limitations contained in subsection (b)(3) of such section 1977A, shall be powers, remedies, and procedures this title provides to the Commission, the Attorney General, the Librarian of Congress, or any person, alleging such a practice (not an employment practice specifically excluded from coverage under section 1977A(a)(1) of the Revised Statutes).

(f) DEFINITION.—In this section, the term "Commission" means the Equal Employment Opportunity Commission.

SEC. 208. DISPARATE IMPACT.

- (a) GENERAL RULE.—Notwithstanding any other provision of this Act, "disparate impact", as that term is used in section 703(k) of the Civil Rights Act of 1964 (42 U.S.C. 2000e–2(k)), on the basis of genetic information does not establish a cause of action under this Act.
- (b) COMMISSION.—On the date that is 6 years after the date of enactment of this Act, there shall be established a commission, to be known as the Genetic Non-discrimination Study Commission (referred to in this section as the "Commission") to review the developing science of genetics and to make recommendations to Congress regarding whether to provide a disparate impact cause of action under this Act.

(c) Membership.-

- (1) IN GENERAL.—The Commission shall be composed of 8 members, of which-
 - (A) 1 member shall be appointed by the Majority Leader of the Senate; (B) 1 member shall be appointed by the Minority Leader of the Senate;

 - (C) 1 member shall be appointed by the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate;
 - (D) I member shall be appointed by the ranking minority member of the Committee on Health, Education, Labor, and Pensions of the Senate;
 - (E) 1 member shall be appointed by the Speaker of the House of Representatives:
 - (F) 1 member shall be appointed by the Minority Leader of the House of Representatives;
 - (G) 1 member shall be appointed by the Chairman of the Committee on Education and the Workforce of the House of Representatives; and
 - (H) 1 member shall be appointed by the ranking minority member of the Committee on Education and the Workforce of the House of Representa-
- (2) Compensation and expenses.—The members of the Commission shall not receive compensation for the performance of services for the Commission, but shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Commission.
- (d) Administrative Provisions.
 - (1) Location.—The Commission shall be located in a facility maintained by the Equal Employment Opportunity Commission.
 - (2) DETAIL OF GOVERNMENT EMPLOYEES.—Any Federal Government employee may be detailed to the Commission without reimbursement, and such detail shall be without interruption or loss of civil service status or privilege.
 - (3) Information from federal agencies.—The Commission may secure directly from any Federal department or agency such information as the Commission considers necessary to carry out the provisions of this section. Upon request of the Commission, the head of such department or agency shall furnish
 - such information to the Commission.

 (4) HEARINGS.—The Commission may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Commission considers advisable to carry out the objectives of this section, except that, to the extent possible, the Commission shall use existing data and research.
- (5) Postal services.—The Commission may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.
- (e) REPORT.—Not later than 1 year after all of the members are appointed to the Commission under subsection (c)(1), the Commission shall submit to Congress a report that summarizes the findings of the Commission and makes such recommendations for legislation as are consistent with this Act.
- (f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Equal Employment Opportunity Commission such sums as may be necessary to carry out this section.

SEC. 209. CONSTRUCTION.

Nothing in this title shall be construed to—

(1) limit the rights or protections of an individual under the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.), including coverage afforded to individuals under section 102 of such Act (42 U.S.C. 12112), or under the Rehabilitation Act of 1973 (29 U.S.C. 701 et seq.);

(2)(A) limit the rights or protections of an individual to bring an action under this title against an employer, employment agency, labor organization, or joint labor-management committee for a violation of this title; or

(B) establish a violation under this title for an employer, employment agency, labor organization, or joint labor-management committee of a provision of the amendments made by title I;

(3) limit the rights or protections of an individual under any other Federal or State statute that provides equal or greater protection to an individual than the rights or protections provided for under this title;
(4) apply to the Armed Forces Repository of Specimen Samples for the Identi-

fication of Remains:

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

(6) limit the authority of a Federal department or agency to conduct or sponsor occupational or other health research that is conducted in compliance with the regulations contained in part 46 of title 45, Code of Federal Regulations (or any corresponding or similar regulation or rule); and

(7) 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.

SEC. 210. MEDICAL INFORMATION THAT IS NOT GENETIC INFORMATION.

An employer, employment agency, labor organization, or joint labor-management committee shall not be considered to be in violation of this title 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, including a manifested disease, disorder, or pathological condition that has or may have a genetic basis.

SEC. 211. REGULATIONS.

Not later than 1 year after the date of enactment of this title, the Commission shall issue final regulations in an accessible format to carry out this title.

SEC. 212. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated such sums as may be necessary to carry out this title (except for section 208).

This title takes effect on the date that is 18 months after the date of enactment of this Act.

TITLE III—MISCELLANEOUS PROVISION

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.

I. SUMMARY AND BACKGROUND

A. Purpose and Summary

PURPOSE

The bill adopts national, uniform standards of protection against discrimination in health insurance and employment based on genetic information. Establishing these standards will allay concerns about the potential for discrimination and encourage individuals to participate in genetic research and to take advantage of genetic testing and new therapies. The standards will provide substantive protections to those individuals who may suffer from actual genetic discrimination now and in the future. The adoption of the standards is essential to fulfilling the promise of the human genome project and improving the health and longevity of the American people.

SUMMARY

The provisions of the bill, H.R. 493, as adopted by the Committee, are as follows:

- Section 103 prohibits a group health plan from adjusting premiums or contribution amounts for the group on the basis of genetic information and from requesting or requiring genetic testing. Section 103 also restricts a group health plan's collection of genetic information. The Committee bill enforces these prohibitions through the use of an excise tax on group health plans that fail to comply with these rules. This same enforcement mechanism is used under present law with respect to similar health care provisions, including provisions relating to mental heath parity, limitations on pre-existing condition exclusions, the prohibition on discrimination based on health status, and the rules relating to benefits for mothers and newborns.
- Section 104 prohibits an issuer of a Medicare supplemental policy from denying or conditioning the issuance of a policy, discriminating in the price of the policy, or applying pre-existing condition exclusions to the policy on the basis of genetic information. Section 104 also prohibits an issuer of a Medicare supplemental policy from requesting or requiring genetic testing and restricts an issuer's collection of genetic information.

 • Section 105 directs the Secretary of Health and Human

Services to conform our nation's privacy laws governing health information to the provisions in this bill.

• Sections 106 and 107 require that the Secretary of the Treasury, the Secretary of Health and Human Services, and the Secretary of Labor coordinate administration and enforcement and issue regulations with respect to the standards protecting against genetic discrimination.

B. BACKGROUND AND NEED FOR LEGISLATION

Advances in the science of genetics open major new opportunities for medical progress, including earlier detection of illnesses. These developments can provide individuals with the opportunity to take steps to reduce the likelihood that they will contract a particular disorder. These developments also facilitate more advanced treatments. These advances will also give rise to the potential for the misuse of genetic information to discriminate in the areas of health insurance and employment. Past experience with sterilization laws, as well as examples of current genetic discrimination, have created the need to protect against the misuse of genetic information.

C. Legislative History

BACKGROUND

H.R. 493 was introduced in the House of Representatives on January 16, 2007, and was referred to the Committee on Education

and Labor, the Committee on Energy and Commerce, and the Committee on Ways and Means for a period to be determined by the Speaker of the House, in each case for consideration of such provisions as fall within the jurisdiction of the Committee concerned. The bill, as amended, was favorably reported by the Committee on Education and Labor on March 5, 2007, H. Rept. No. 110-28.

COMMITTEE HEARINGS

The Subcommittee on Health of the Committee on Ways and Means conducted a hearing on the bill on March 14, 2007.

COMMITTEE ACTION

The Committee on Ways and Means marked up the bill on March 21, 2007, and ordered the bill, as amended, favorably reported.

II. EXPLANATION OF THE BILL

A. Prohibition of Discrimination Based on Genetic Testing (SECS. 103, 106, AND 107 OF THE BILL AND SEC. 9802 AND NEW SEC. 9834 OF THE INTERNAL REVENUE CODE)

PRESENT LAW

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") imposes a number of requirements with respect to group health coverage that are designed to provide protections to health plan participants. The requirements are enforced through the Internal Revenue Code of 1986, as amended (the "Code"), the Employee Retirement Income Security Act of 1974 ("ERISA"), and the Public Health Service Act ("PHSA").

Under present law, HIPAA provides certain protections against genetic discrimination. Among other things, HIPAA provides that a group health plan may not establish rules for eligibility of any individual to enroll under the plan based on genetic information. Under final regulations issued by the Department of Treasury pursuant to HIPAA, any restriction on benefits provided under a group health plan must apply uniformly to all similarly situated individuals and must not be directed at individual participants or beneficiaries based on genetic information of the participants or beneficiaries.2 A group health plan also may not require an individual to pay a premium or contribution which is greater than such premium or contribution for a similarly situated individual enrolled in the plan on the basis of genetic information of the individual or of a dependent enrolled under the plan.3

In addition, HIPAA generally provides that a pre-existing condition exclusion may be imposed with respect to a participant or beneficiary only if: (1) the exclusion relates to a condition (whether physical or mental), regardless of the cause of the condition, for which medical advice, diagnosis, care, or treatment was recommended or received within the 6-month period ending on the enrollment date; (2) the exclusion extends for a period of not more than 12 months after the enrollment date; and (3) the period of any

 $^{^{1}}$ Code sec. 9802(a). 2 Treas. Reg. sec. 54.9802–1(b)(2)(i)(B). 3 Code sec. 9802(b).

pre-existing condition exclusion is reduced by the length of the aggregate of the periods of creditable coverage (if any) applicable to the participant as of the enrollment date. The limitation on preexisting condition exclusions applies to exclusions on the basis of

genetic information.4

Under final regulations issued by the Department of Treasury, genetic information is defined as information about genes, gene products, and inherited characteristics that may derive from the individual or a family member. This includes information regarding carrier status and information derived from laboratory tests that identify mutations in specific genes or chromosomes, physical medical examinations, family histories, and direct analysis of genes or

The requirements do not apply to any governmental plan or any group health plan that has less than two participants who are current employees. A group health plan is defined as a plan (including a self-insured plan) of, or contributed to by, an employer (including a self-employed person) or employee organization to provide health care (directly or otherwise) to the employees, former employees, the employer, others associated or formerly associated with the em-

ployer in a business relationship, or their families.

The Code imposes an excise tax on group health plans which fail to meet these requirements.⁶ The excise tax is equal to \$100 per day during the period of noncompliance and is generally imposed on the employer sponsoring the plan if the plan fails to meet the requirements. The maximum tax that can be imposed during a taxable year cannot exceed the lesser of: (1) 10 percent of the employer's group health plan expenses for the prior year; or (2) \$500,000. No tax is imposed if the Secretary of the Treasury determines that the employer did not know, and in exercising reasonable diligence would not have known, that the failure existed.

REASONS FOR CHANGE

The advances in genetics open up many opportunities for medical progress with respect to the prevention, detection, and treatment of disease. However, this information also presents the possibility for misuse. The Committee is aware of examples of genetic discrimination in the workforce and with respect to insurance. In some cases, 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 genetic information. The Committee is concerned that the possibility of discrimination on the basis of genetic information may prohibit individuals from taking full advantage of the information that may be available. Thus, some individuals may not be receiving the best possible medical care. The Committee bill therefore adopts a uniform, national standard that prohibits discrimination based on genetic information. The Committee bill assures that the full array of enforcement mechanisms applicable to group health plans under the Code is available with respect to the prohibition on genetic discrimination under this provision.

 $^{^4}$ Code sec. 9801. 5 Treas. Reg. sec. 54.9801–2. 6 Code sec. 4980D.

EXPLANATION OF PROVISION

The provision modifies the group health plan requirements under the Code.

Under the provision, a group health plan may not adjust premium or contribution amounts for the group covered under such plan on the basis of genetic information. In the case of family members who are covered under the same group health plan, the group health plan is permitted to adjust premium or contribution amounts for the group on the basis of the occurrence of diseases or disorders in family members in the group, provided that such information is taken into account only with respect to the individual in which the disease or disorder occurs and not as genetic information with respect to family members in which the disease or disorder has not occurred.

The provision also requires that a group health plan may not request or require an individual or family member of such individual to undergo a genetic test. The provision does not 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. The provision also does not limit the authority of a group health plan to provide information generally about the availability of genetic tests, for example, in the case of a summary plan description, or to provide information about genetic tests to a health care professional with respect to the treatment of an individual to whom such professional is providing health care services, for example, during a quality assurance review.

The provision contains two rules with respect to a group health plan's collection of genetic information. First, a group health plan is prohibited from requesting, requiring, or purchasing genetic information for purposes of underwriting. Second, a group health plan is prohibited from requesting, requiring, or purchasing genetic information with respect to any individual prior to such individual's enrollment under the plan or in connection with such enrollment. The second prohibition is not violated where the collection of genetic information is incidental to the requesting, requiring, or purchasing of other information concerning the individual provided that such request, requirement or purchase is not for purposes of underwriting.

The term underwriting, with respect to any group health plan, means: (1) rules for determining eligibility for, or determination of, benefits under the plan; (2) the computation of premium or contribution amounts under the plan; (3) the application of any pre-existing condition exclusion under the plan; and (4) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

Under the provision, the current law requirement that a group health plan may not establish rules for eligibility based on genetic information is extended to governmental plans and group health plans with less than two participants who are current employees. The provisions requiring (1) that group premiums or contribution amounts may not be adjusted on the basis of genetic information of an individual in the group, (2) that a group health plan may not request or require an individual or family member of such individual undergo a genetic test, and (3) that group health plans not

collect genetic information for purposes of underwriting or in connection with enrollment also apply to all group health plans.

Genetic information means, with respect to any individual, information about: (1) such individual's genetic tests; (2) the genetic tests of family members of such individual; and (3) the occurrence of a disease or disorder in family members of such individual. The term genetic information also includes, with respect to any individual, any request for genetic services, receipt of genetic services, or participation in any clinical research, or any other program, which includes genetic services, by such individual or any family member of such individual. The term genetic information does not include the occurrence of a disease or disorder in family members of an individual to the extent that such information is taken into account only with respect to the individual in which such disease or disorder occurs and not as genetic information with respect to any other individual.

À genetic test is defined as an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes. The term genetic test does not include (1) an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes, or (2) 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.

Genetic services are defined as a genetic test, genetic counseling

(such as obtaining, interpreting, or assessing genetic information), and genetic education.

A family member means, with respect to an individual: (1) the spouse of the individual; (2) a child of such individual (by birth, adoption, or placement for adoption); and (3) 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 (1) or (2). In general, it is intended that the term "family member" be interpreted broadly so as to provide the maximum protection against discrimination.

Under the provision, the Secretary of the Treasury is directed to issue regulations or other guidance to carry out the provision no later than one year after date of enactment. The Secretary of the Treasury is to coordinate administration and enforcement with the Secretary of Health and Human Services and the Secretary of Labor so that provisions over which two or more such Secretaries have jurisdiction are administered in the same manner and so as to avoid duplication of enforcement efforts.

EFFECTIVE DATE

The provision is effective with respect to group health plans for plan years beginning after the date that is 18 months after the date of enactment.

B. Medigap Provisions (Sec. 104 of the Bill and Section 1882 of the Social Security Act)

PRESENT LAW

Under the Medicare statute, all insurers offering Medigap policies are required to offer open enrollment for six months from the date on which the individual is 65 years of age or older and is enrolled for benefits under Part B. During this time an insurer cannot deny the issuance, or discriminate in the pricing of a policy because of an individual's "health status, claims experience, receipt of health care, or medical condition." However, the issuer may apply pre-existing condition exclusions for the policy during its first 6 months, based on a pre-existing condition for which the policy holder had received treatment or was otherwise diagnosed during the 6 month period before the policy became effective. If an individual applies for a Medigap policy after the open enrollment period, the company is permitted to use medical underwriting. This means that the company can use an individual's medical history to decide whether or not to accept the application and how much to charge for the policy.

The law also guarantees issuance of specified Medigap policies (without an exclusion based on a pre-existing condition) for certain persons whose previous supplementary coverage was terminated. Again, the insurer cannot deny the issuance, or discriminate in the pricing of a policy because of an individual's "health status, claims experience, receipt of health care, or medical condition." This right must be exercised within 63 days of termination of other enroll-

ment

The law states that no Medigap policy may be issued in a state unless: (1) the state's regulatory program has been approved by the Secretary as providing for the application and enforcement of the National Association of Insurance Commissioners' (NAIC's) Model Standards; or (2) (if the state's program has not been approved), the policy has been approved by the Secretary as meeting the standards. CMS published a Notice in the Federal Register on March 25, 2005, which recognized the latest version (with clarifications) adopted by the NAIC on September 8, 2004.

EXPLANATION OF PROVISION

The bill would prohibit an issuer of a Medigap policy from: (1) denying or conditioning the issuance or effectiveness of a policy; (2) discriminating in the pricing of a policy; or (3) applying pre-existing condition exclusions based on an individual's genetic information (as defined in the bill). In addition, the rules and definitions of section 103 of the bill (relating to genetic nondiscrimination standards applicable to group health plans) generally apply to the issuer of a Medigap policy, except that the definition of the term family member does not include the individual's spouse or dependent child (except to the extent that the child is a first, second, third, or fourth-degree relative of the individual).

A state identified by the Secretary as requiring a change in its statutes or regulations to conform its regulatory program to the requirements of this section would have until October 1, 2008, to make such a change before being considered out of compliance. States requiring a statutory change that do not meet in legislative

session in 2008 would be given additional time to come into compliance. The bill would give NAIC until June 30, 2008, to modify its model regulation to conform to the requirements of this section. If NAIC failed to meet that deadline, the Secretary would have until October 1, 2008, to make the modifications.

EFFECTIVE DATE

The provision is effective with respect to an issuer of a Medigap policy for policy years beginning on or after the date that is 18 months after the date of enactment.

C. Provisions Relating to Privacy and Confidentiality (Sec. 105 of the Bill and New Section 1180 of the Social Security Act)

PRESENT LAW

Standards to protect the privacy of health information were issued pursuant to HIPAA's Administrative Simplification provisions. The HIPAA privacy rule (45 CFR Parts 160, 164) applies to individually identifiable health (including genetic) information that is created or received by individual and group health plans (the term encompasses both private and government plans, and HMOs) and health care providers. The rule, which took effect in April 2003, gives patients the right of access to their medical information and places certain limitations on when and how plans and providers may use and disclose medical information. Generally, plans and providers may use and disclose health information for treatment, payment, and health care operations (broadly defined) without the individual's authorization and with few restrictions. Thus, the privacy rule permits a health plan to use or disclose health (including genetic) information for underwriting, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

EXPLANATION OF PROVISION

The bill would require the Secretary, by rulemaking, to revise the HIPAA privacy rule as follows. First, genetic information (as defined in the bill) would be treated as health information under the privacy rule. This is already the case, but it is not made explicit in the rule. Second, the use and disclosure of genetic information by a group health plan, health insurance issuer, or issuer of a Medigap policy for underwriting and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits would be prohibited.

EFFECTIVE DATE

The bill would require the Secretary to publish a revision to the privacy rule in the Federal Register, not later than 60 days after enactment. The revision would take effect upon publication, but may be further modified, after opportunity for public comment.

III. VOTES OF THE COMMITTEE

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the votes of the Committee on Ways and Means in its consideration of the bill, H.R. 493, the Genetic Nondiscrimination Act of 2007.

The bill, HR. 493, as amended, was ordered favorably reported by voice vote (with a quorum being present).

IV. BUDGET EFFECTS OF THE BILL

A. COMMITTEE ESTIMATE OF BUDGETARY EFFECTS

In compliance with clause 3(d)(2) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the effects on the budget of the revenue provisions of the bill, H.R. 493 as reported.

The effects of the bill on Federal budget receipts is presented in the cost estimate provided by the Congressional Budget Office (see below).

B. STATEMENT REGARDING NEW BUDGET AUTHORITY AND TAX EXPENDITURES BUDGET AUTHORITY

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee states that the bill involves no new or increased budget authority.

C. Cost Estimate Prepared by the Congressional Budget Office

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, requiring a cost estimate prepared by the CBO, the following statement by CBO is provided.

H.R. 493—Genetic Information Nondiscrimination Act of 2007

H.R. 493 would amend the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act, Title XVIII of the Social Security Act, and the Internal Revenue Code of 1986 to prohibit the use of genetic information (including results of genetic tests and family history of disease) by employers in employment decisions and by health insurers and health plans in making enrollment determinations and setting insurance premiums.

CBO estimates that enacting the bill would increase the number of individuals who obtain health insurance by about 600 people per year, nearly all of whom would obtain insurance in the individual market. The bill would affect federal revenues because the premiums paid by some of those newly insured individuals would be tax-deductible.

CBO estimates that enacting H.R. 493 would reduce revenues by less than \$500,000 in each year from 2008 through 2017, by \$1 million over the 2008–2012 period, and by \$2 million over the 2008–2017 period. (These estimates include reductions in off-budget receipts from Social Security payroll taxes of less than \$500,000 over the 2008–2012 period, and slightly less than \$1 million over the 2008–2017 period.) The bill's requirements would apply to Medicare supplemental insurance, which could affect direct spending for Medicare. However, we estimate that the bill would have no significant effect on direct spending.

The bill would require the Secretaries of Health and Human Services (HHS), Labor, and the Treasury to issue regulations to carry out the provisions of this bill, and would require the Secretaries of HHS and Labor to enforce those provisions. In addition, six years after enactment, the bill would establish a commission to review the science of genetics and to make recommendations to the Congress on the need to establish a disparate impact standard for genetic discrimination. The bill would authorize the appropriation of such sums as necessary to establish the commission and to carry out the other provisions of the bill. Assuming the availability of appropriated funds, CBO estimates that implementing H.R. 493 would incur discretionary costs of less than \$500,000 in 2008 and \$2 million over the 2008–2017 period.

Because H.R. 493 would limit state and local employment practices and broaden an existing preemption of state law, it contains intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). The bill would restrict how state and local governments use genetic information in employment practices and in the provision of health care to employees. It also would broaden the scope of federal regulations that govern the confidentiality of health information to include genetic information, and in so doing, it would preempt state laws that apply to such information. There is little indication that state, local, or tribal governments currently engage in or are likely to engage in the activities that would be prohibited by the bill. Consequently, CBO estimates that the costs of the mandates would not be significant and would not exceed the threshold established in UMRA (\$66 million in 2007, adjusted annually for inflation).

The bill also contains private-sector mandates on health insurers, health plans, employers, labor unions, and other organizations by restricting how those entities use genetic information in employment practices and in the provision of health care to employees. CBO estimates that the direct cost of those requirements would not exceed the annual threshold specified in UMRA (\$131 million in 2007, adjusted annually for inflation) in any of the first five years

the mandates would be effective.

On March 2, 2007, CBO transmitted a cost estimate for H.R. 493, the Genetic Information Nondiscrimination Act of 2007, as ordered reported by the House Committee on Education and Labor on February 14, 2007. The Ways and Means Committee's version of H.R. 493 differs from the previous version in that it would also make conforming modifications to the Internal Revenue Code. CBO and the Joint Committee on Taxation estimate those conforming modifications would have no incremental budgetary effect. Thus, CBO's estimates for the two versions of the legislation are identical.

The CBO staff contacts for this estimate are Shinobu Suzuki (for federal costs), Leo Lex (for the state and local impact), and David Auerbach (for the private-sector impact). This estimate was approved by Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

D. MACROECONOMIC IMPACT ANALYSIS

In compliance with clause 3(h)(2) of rule XIII of the Rules of the House of Representatives, the following statement is made by the Joint Committee on Taxation with respect to the provisions of the

bill amending the Internal Revenue Code of 1986: the effects of the bill on economic activity are so small as to be incalculable within the context of a model of the aggregate economy.

E. PAY-GO RULE

In compliance with clause 10 of rule XXI of the Rules of the House of Representatives, the following statement is made concerning the effects on the budget of the revenue provisions of the bill, H.R. 493, as reported: the provisions of the bill affecting revenues have the following net effect on the deficit or surplus: (1) the bill would not increase the deficit or reduce the surplus in fiscal year 2007; (2) the bill would increase the deficit or reduce the surplus by \$1 million over the fiscal year 2008–2012 period; and (2) the bill would increase the deficit or reduce the surplus by \$2 million over the fiscal year 2008–2017 period.

V. OTHER MATTERS TO BE DISCUSSED UNDER THE RULES OF THE HOUSE

A. COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

With respect to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives (relating to oversight findings), the Committee advises that it is appropriate and timely to enact the provisions included in the bill as reported.

B. STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

With respect to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee advises that the bill contains no measure that authorizes funding, so no statement of general performance goals and objectives for which any measure authorizes funding is required.

C. CONSTITUTIONAL AUTHORITY STATEMENT

With respect to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives (relating to Constitutional Authority), the Committee states that the Committee's action in reporting this bill is derived from Article I of the Constitution, Section 8 ("The Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises . . ."), and from the 16th Amendment to the Constitution.

D. Information Relating to Unfunded Mandates

This information is provided in accordance with section 423 of the Unfunded Mandates Act of 1995 (Pub. L. No. 104–4).

The Committee has determined that the revenue provisions of the bill contain no Federal private sector mandates or Federal intergovernmental mandates on State, local, or tribal governments within the meaning of the Unfunded Mandates Act.

E. APPLICABILITY OF HOUSE RULE XXI 5(b)

Clause 5 of rule XXI of the Rules of the House of Representatives provides, in part, that "A bill or joint resolution, amendment, or conference report carrying a Federal income tax rate increase may not be considered as passed or agreed to unless so determined by a vote of not less than three-fifths of the Members voting, a quorum being present." The Committee has carefully reviewed the provisions of the bill, and states that the provisions of the bill do not involve any Federal income tax rate increases within the meaning of the rule.

F. TAX COMPLEXITY ANALYSIS

Section 4022(b) of the Internal Revenue Service Reform and Restructuring Act of 1998 (the "IRS Reform Act") requires the Joint Committee on Taxation (in consultation with the Internal Revenue Service and the Department of the Treasury) to provide a tax complexity analysis. The complexity analysis is required for all legislation reported by the Senate Committee on Finance, the House Committee on Ways and Means, or any committee of conference if the legislation includes a provision that directly or indirectly amends the Internal Revenue Code and has widespread applicability to individuals or small businesses.

The staff of the Joint Committee on Taxation has determined that a complexity analysis is not required under section 4022(b) of the IRS Reform Act because the bill contains no provisions that amend the Code and that have "widespread applicability" to individuals or small businesses.

G. LIMITED TAX BENEFITS

Pursuant to clause 9 of rule XXI of the Rules of the House of Representatives, the Ways and Means Committee has determined that the bill as reported contains no congressional earmarks, limited tax benefits, or limited tariff benefits within the meaning of that Rule.

VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

* * * * * * * * * *

TITLE I—PROTECTION OF EMPLOYEE BENEFIT RIGHTS

* * * * * * * * *

SUBTITLE B—REGULATORY PROVISIONS

* * * * * * * *

PART 5—ADMINISTRATION AND ENFORCEMENT

CIVIL ENFORCEMENT

SEC. 502. (a) * * *

* * * * * * *

- (n) Enforcement of Genetic Nondiscrimination Requirements.—
 - (1) Injunctive relief for irreparable Harm.—With respect to any violation of subsection (a)(1)(F), (b)(3), or (c) of section 702, a participant or beneficiary may seek relief under subsection 502(a)(1)(B) prior to the exhaustion of available administrative remedies under section 503 if it is demonstrated to the court, by a preponderance of the evidence, that the exhaustion of such remedies would cause irreparable harm to the health of the participant or beneficiary. Any determinations that already have been made under section 503 in such case, or that are made in such case while an action under this paragraph is pending, shall be given due consideration by the court in any action under this subsection in such case.

(2) Equitable relief for genetic nondiscrimination.—

(Å) REINSTATEMENT OF BENEFITS WHERE EQUITABLE RE-LIEF HAS BEEN AWARDED.—The recovery of benefits by a participant or beneficiary under a civil action under this section may include an administrative penalty under subparagraph (B) and the retroactive reinstatement of coverage under the plan involved to the date on which the participant or beneficiary was denied eligibility for coverage if—

(i) the civil action was commenced under subsection

(a)(1)(B); and

(ii) the denial of coverage on which such civil action was based constitutes a violation of subsection (a)(1)(F), (b)(3), or (c) of section 702.

(B) Administrative penalty.—

(i) IN GENERAL.—An administrator who fails to comply with the requirements of subsection (a)(1)(F), (b)(3), or (c) of section 702 with respect to a participant or beneficiary may, in an action commenced under subsection (a)(1)(B), be personally liable in the discretion of the court, for a penalty in the amount not more than \$100 for each day in the noncompliance period.

(ii) NONCOMPLIANCE PERIOD.—For purposes of clause (i), the term "noncompliance period" means the pe-

riod—

- (I) beginning on the date that a failure described in clause (i) occurs; and
- (II) ending on the date that such failure is corrected
- (iii) Payment to participant or beneficiary involved.

 A penalty collected under this subparagraph shall be paid to the participant or beneficiary involved.

(3) SECRETARIAL ENFORCEMENT AUTHORITY.—

- (A) GENERAL RULE.—The Secretary has the authority to impose a penalty on any failure of a group health plan to meet the requirements of subsection (a)(1)(F), (b)(3), or (c) of section 702.
 - (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 individual 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 oc-

curs; and

(II) ending on the date such 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 pe-

riod 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 dis-COVERED 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 im-

posed 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 fail-URES.—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.

* * * * * * *

PART 7—GROUP HEALTH PLAN REQUIREMENTS

SUBPART A—REQUIREMENTS RELATING TO PORTABILITY, ACCESS, AND RENEWABILITY

* * * * * * *

SEC. 702. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PAR-TICIPANTS AND BENEFICIARIES BASED ON HEALTH STA-TUS.

(a) IN ELIGIBILITY TO ENROLL.—

(1) IN GENERAL.—Subject to paragraph (2), a group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any of the following health status-related factors in relation to the individual or a dependent of the individual:

(A) * * *

`` ** * * * * * * *

(F) Genetic information (including information about a request for or receipt of genetic services by an individual or family member of such individual).

* * * * * * *

(b) IN PREMIUM CONTRIBUTIONS.—

(1) * *

- (2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed—
 - (A) to restrict the amount that an employer may be charged for coverage under a group health plan *except as* provided in paragraph (3); or

* * * * * * *

(3) No discrimination in group premiums based on general insurance insurance issuer offering group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not adjust premium or contribution amounts for a group on the basis of genetic information concerning an individual in the group or a family member of the individual (including information about a request for or receipt of genetic services by an individual or family member of such individual).

(c) Genetic Testing.—

(1) LIMITATION ON REQUESTING OR REQUIRING GENETIC TEST-ING.—A group health plan, or 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.—Nothing in this part shall be

construed to—

(A) limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or a family member of such individual values a genetic test.

of such individual undergo a genetic test;

(B) limit the authority of a health care professional who is employed by or affiliated with a group health plan or a health insurance issuer and who is providing health care services to an individual as part of a bona fide wellness program to notify such individual of the availability of a genetic test or to provide information to such individual regarding such genetic test; or

(C) authorize or permit a health care professional to re-

quire that an individual undergo a genetic test.

(d) APPLICATION TO ALL PLANS.—The provisions of subsections (a)(1)(F), (b)(3), and (c) shall apply to group health plans and health insurance issuers without regard to section 732(a).

* * * * * *

SUBPART C—GENERAL PROVISIONS

* * * * * * *

SEC. 733. DEFINITIONS.

(a) * * *

* * * * * * *

(d) OTHER DEFINITIONS.—For purposes of this part—
(1) * * *

respect to an individual—

(A) the spouse of the individual;

- (B) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and
- (C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

(6) Genetic information.—

(A) In General.—Except as provided in subparagraph (B), the term "genetic information" means information about—

(i) an individual's genetic tests;

(ii) the genetic tests of family members of the individual; or

(iii) the occurrence of a disease or disorder in family members of the individual.

(B) EXCLUSIONS.—The term "genetic information" shall not include information about the sex or age of an 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 (such as obtaining, interpreting, or assessing genetic information); or

(C) genetic education.

TITLE XXVII—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

PART A—GROUP MARKET REFORMS

Subpart 1—Portability, Access, and Renewability Requirements

SEC. 2702. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PAR-TICIPANTS AND BENEFICIARIES BASED ON HEALTH STA-TUS.

(a) IN ELIGIBILITY TO ENROLL.—

(1) In General.—Subject to paragraph (2), a group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any of the following health status-related factors in relation to the individual or a dependent of the individual:

(A) * * *

* * * * * *

(F) Genetic information (including information about a request for or receipt of genetic services by an individual or family member of such individual).

* * * * * * *

(b) In Premium Contributions.—

(1) * * *

(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

(A) to restrict the amount that an employer may be charged for coverage under a group health plan, *except as provided in paragraph* (3); or

* * * * * * *

(3) No discrimination in group premiums based on general information.—For purposes of this section, a group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not adjust premium or contribution amounts for a group on the basis of genetic information concerning an individual in the group or a family member of the individual (including information about a request for or receipt of genetic services by an individual or family member of such individual).

(c) GENETIC TESTING.—

(1) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—A group health plan, or 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.—Nothing in this part shall be

construed to-

(A) limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or a family member

of such individual undergo a genetic test;

(B) limit the authority of a health care professional who is employed by or affiliated with a group health plan or a health insurance issuer and who is providing health care services to an individual as part of a bona fide wellness program to notify such individual of the availability of a genetic test or to provide information to such individual regarding such genetic test; or

(C) authorize or permit a health care professional to re-

quire that an individual undergo a genetic test.

(d) APPLICATION TO ALL PLANS.—The provisions of subsections (a)(1)(F), (b)(3), and (c) shall apply to group health plans and health insurance issuers without regard to section 2721(a).

* * * * * * *

Subpart 4—Exclusion of Plans; Enforcement; Preemption

SEC. 2721. EXCLUSION OF CERTAIN PLANS.

(a) * * *

(b) Limitation on Application of Provisions Relating to Group Health Plans.—

(1)***

(2) Treatment of nonfederal governmental plans.—

(A) ELECTION TO BE EXCLUDED.—[If the plan sponsor] Except as provided in subparagraph (D), if the plan sponsor of a nonfederal governmental plan which is a group health plan to which the provisions of subparts 1 through 3 otherwise apply makes an election under this subparagraph (in such form and manner as the Secretary may by regulations prescribe), then the requirements of such sub-

parts insofar as they apply directly to group health plans (and not merely to group health insurance coverage) shall not apply to such governmental plans for such period except as provided in this paragraph.

* * * * * * *

(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) and (c) of section 2702 and the provisions of section 2702(b) to the extent that such provisions apply to genetic information (or information about a request for or the receipt of genetic services by an individual or a family member of such individual).

SEC. 2722. ENFORCEMENT.

- (a) * * *
- (b) SECRETARIAL ENFORCEMENT AUTHORITY.—

(1) * * *

* * * * * * *

- (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 following provisions 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), or (c) of section 2702.

(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 individual 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—

(İ) beginning on the date such failure first oc-

curs; and

(II) ending on the date such 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 pe-

riod 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 im-

posed 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.

PART B—INDIVIDUAL MARKET RULES

* * * * * * * * * * * Subpart [3] 2—Other Requirements

* * * * * *

SEC. 2753. PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION.

(a) Prohibition on Genetic Information as a Condition of Eligibility.—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 (including information about a request for or receipt of genetic services by an individual or family member of such individual).

(b) Prohibition on Genetic Information in Setting Premium RATES.—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 (including information about a request for or receipt of genetic services by an individual or family member of such individual).

(c) Genetic Testing.-

(1) Limitation on requesting or requiring genetic test-ING.—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.—Nothing in this part shall be construed to—

(A) limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or a family member

of such individual undergo a genetic test;
(B) limit the authority of a health care professional who is employed by or affiliated with a health insurance issuer and who is providing health care services to an individual as part of a bona fide wellness program to notify such individual of the availability of a genetic test or to provide information to such individual regarding such genetic test; or

(C) authorize or permit a health care professional to require that an individual undergo a genetic test.

Subpart 3—General Provisions

SEC. 2761. ENFORCEMENT.

(a) * * *

(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) 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.

(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.

PART C—DEFINITIONS; MISCELLANEOUS PROVISIONS

SEC. 2791. DEFINITIONS.

(a) * * *

(d) Other Definitions.—

(1) * * *(15) Family member.—The term "family member" means with respect to an individual-(Å) the spouse of the individual; (B) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; (C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B). (16) Genetic information.— (A) In General.—Except as provided in subparagraph (B), the term "genetic information" means information about-(i) an individual's genetic tests; (ii) the genetic tests of family members of the individual; or (iii) the occurrence of a disease or disorder in family members of the individual. (B) Exclusions.—The term "genetic information" shall not include information about the sex or age of an 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 (such as obtaining, interpreting, or assessing genetic information); or (C) genetic education.

INTERNAL REVENUE CODE OF 1986

Subtitle K—Group Health Plan Requirements

* * * * * * *

CHAPTER 100—GROUP HEALTH PLAN REQUIREMENTS

Subchapter A—Requirements Relating to Portability, Access, and Renewability

SEC. 9802. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PAR-TICIPANTS AND BENEFICIARIES BASED ON HEALTH STA-TUS.

- (a) * * *
- (b) In Premium Contributions.—
 - (1) * * *
 - (2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed
 - (A) to restrict the amount that an employer may be charged for coverage under a group health plan except as provided in paragraph (3); or

- (3) No group-based discrimination on basis of genetic INFORMATION.—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.
- (c) Genetic Testing.—
 - (1) Limitation on requesting or requiring genetic test-ING.—A group health plan may not request or require an individual or a family member of such individual to undergo a genetic test.
 - (2) Exception for health care professionals.—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
 - (3) Provision of information not prohibited.—Paragraph (1) shall not be construed to limit the authority of a group health plan-

(A) to provide information generally about the avail-

ability of genetic tests, or

- (B) to provide information about genetic tests to a health care professional with respect to the treatment of an individual to whom such professional is providing health care services.
- (d) Prohibition on Collection of Genetic Information.—

(1) In general.—A group health plan shall not request, require, or purchase genetic information for purposes of underwriting (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) shall apply to group health plans with-

out regard to section 9831(a).

[(c)] (f) Special rules for church plans.—A church plan (as defined in section 414(e)) shall not be treated as failing to meet the requirements of this section solely because such plan requires evidence of good health for coverage of—

(1)* * * * * * * * *

Subchapter C—General Provisions

Sec. 9831. General exceptions.

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Sec. 9834. Enforcement.

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SEC. 9832. DEFINITIONS.

(a) * * *

(d) OTHER DEFINITIONS.—For purposes of this chapter—

(1) * * * * * * * * * * *

(6) FAMILY MEMBER.—The term "family member" means, with respect to any individual—

ect to any inawiauai—
(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 occurrence 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 genetic services, receipt of genetic services, or participation in any clinical research, or any other program, 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 indi-

vidual.

(D) APPLICATION TO FAMILY MEMBERS COVERED UNDER SAME PLAN.—Information described in clause (iii) of subparagraph (A) shall not be treated as genetic information to the extent that such information is taken into account only with respect to the individual in which such disease or disorder occurs and not as genetic information with respect to any other 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

(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 (such as obtaining, interpreting, or assessing genetic information), and

(C) genetic education.

(10) Underwriting.—The term "underwriting" means, with

respect to any group health plan-

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

(B) the computation of premium or contribution amounts

under the plan,

(C) the application of any pre-existing condition exclusion

under the plan, and

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

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.

SOCIAL SECURITY ACT

TITLE XI—GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

PART C—ADMINISTRATIVE SIMPLIFICATION

* * * * * *

APPLICATION OF HIPAA REGULATIONS TO GENETIC INFORMATION

SEC. 1180. (a) IN GENERAL.—The Secretary of Health and Human Services 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 plan, coverage, or 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" means, with respect to a group health plan, health insurance coverage, or a medicare supplemental policy—

(A) rules for 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.

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TITLE XVIII OF THE SOCIAL SECURITY ACT

PART E—MISCELLANEOUS PROVISIONS

CERTIFICATION OF MEDICARE SUPPLEMENTAL HEALTH INSURANCE POLICIES

(4) The issuer of the medicare supplemental policy (as defined in subsection (x)) complies with subsection (x)(2)(E) and subsection (x).

(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.

* * * * * * *

(x) Limitations on Genetic Testing and Collection of Genetic 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) Exception for health care professionals.—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) Provision of information not prohibited.—Subparagraph (A) shall not be construed to limit the authority of an issuer of a medicare supplemental policy—

(i) to provide information generally about the availability of genetic tests or

ability of genetic tests, or

- (ii) to provide information about genetic tests to a health care professional with respect to the treatment of an individual to whom such professional is providing health care services.
- (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 purposes of underwriting.

(B) LIMITATION RELATING TO THE COLLECTION OF GE-NETIC INFORMATION PRIOR TO ENROLLMENT.—An issuer of a medicare supplemental policy shall not request, require, or purchase genetic information concerning any individual prior to such individual's enrollment under the policy or in connection with such enrollment.

(C) Incidental collection.—Where an issuer of a medicare supplemental policy obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning an enrollee, such request, require-ment, or purchase shall not be considered a violation of this paragraph if such request, requirement, or purchase is not in violation of subparagraph (A).

(3) DEFINITIONS.—In this subsection and subsection (s)(2)(E): (A) Family member" means, with respect to any individual, any 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) the occurrence of a disease or disorder in

family members of such individual.

(ii) INCLUSION OF GENETIC SERVICES AND PARTICIPA-TION IN GENETIC RESEARCH.—Such term includes, with respect to any individual, any request for genetic services, receipt of genetic services, or participation in any clinical research, or any other program, 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

an 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 chromo-

somal 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 (such as obtaining, interpreting, or assessing genetic information); and

(iii) genetic education.

(E) UNDERWRITING.—The term "underwriting" means, with respect to a medicare supplemental policy—

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

(ii) the computation of premium or contribution

amounts under the policy;

(iii) the application of any pre-existing condition ex-

clusion 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.

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VII. ADDITIONAL VIEWS

At the time of the Ways and Means Committee markup, a bipartisan compromise was being developed by the House Energy and Commerce Committee to extend protections to genetic information of a fetus or embryo. However, an agreement had not yet been reached. The Energy and Commerce Committee has since reached an agreement and adopted an amendment to extend these protections. We request that the changes brought about by this bipartisan compromise be incorporated into all relevant sections before the bill moves to the House floor.

JIM McCrery. Wally Herger. Ron Lewis. Dave Camp. Sam Johnson.

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