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Part 3

GENETIC INFORMATION NONDISCRIMINATION ACT OF 2007

MARCH 29, 2007.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. DINGELL, from the Committee on Energy and Commerce, submitted the following

REPORT

together with

ADDITIONAL VIEWS

[To accompany H.R. 493]

The Committee on Energy and Commerce, 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.

CONTENTS

59–006

AMENDMENT

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. 2. FINDINGS.

Congress makes the following findings:

(1) Deciphering the sequence of the human genome and other advances in genetics open major new opportunities for medical progress. New knowledge about the genetic basis of illness will allow for earlier detection of illnesses, often before symptoms have begun. Genetic testing can allow individuals to take steps to reduce the likelihood that they will contract a particular disorder. New knowledge about genetics may allow for the development of better therapies that are more effective against disease or have fewer side effects than current treatments. These advances give rise to the potential misuse of genetic information to discriminate in health insurance and employment.

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 Many of these State laws have since been repealed, and many have been modified to include essential constitutional requirements of due process and equal protection.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

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

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

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

TITLE I—GENETIC NONDISCRIMINATION IN HEALTH INSURANCE

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

(a) PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION 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 INFORMATION.—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 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 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).".

(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—

"(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.—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 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 EXERCISING REASONABLE DILIGENCE.—No penalty shall be imposed by subparagraph (A) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such penalty did not know, and exercising reasonable diligence would not have known, that such failure existed.

"(ii) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN CERTAIN PERIODS.—No penalty shall be imposed by subparagraph (A) on any failure if—

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

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

"(iii) OVERALL LIMITATION FOR UNINTENTIONAL FAILURES.—In the case of failures which are due to reasonable cause and not to willful neglect, the penalty imposed by subparagraph (A) for failures shall not exceed the amount equal to the lesser of—

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

"(II) $500,000.

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

(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 (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.".

(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 INFORMATION 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 INFORMATION.—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 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).".

(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) CERTAIN RULES 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 individual undergo a genetic test.

"(3) RULE OF CONSTRUCTION REGARDING PAYMENT.—

"(A) IN GENERAL.—Subject to subparagraph (B), nothing in paragraph (1) shall be construed to preclude a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, from conditioning payment on obtaining the results of a genetic test or informing members of such policies. For purpose of the preceding sentence, the term 'payment' includes reimbursement, billing, claims management, claims adjudication, review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges, and utilization review (including precertification, prior authorization, concurrent and retrospective review).

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

"(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).

"(e) GENETIC INFORMATION OF A FETUS OR EMBRYO.—Any reference in this section to genetic information concerning an individual or family member of an individual shall—

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

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

(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 or section 2701 or 2702(b)(1) with respect to genetic information.

"(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—

"(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 EXERCISING REASONABLE DILIGENCE.—No penalty shall be imposed by subparagraph (A) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such penalty did not know, and exercising reasonable diligence would not have known, that such failure existed.

"(ii) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN CERTAIN PERIODS.—No penalty shall be imposed by subparagraph (A) on any failure if—

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

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

"(iii) OVERALL LIMITATION FOR UNINTENTIONAL FAILURES.—In the case of failures which are due to reasonable cause and not to willful neglect, the penalty imposed by subparagraph (A) for failures shall not exceed the amount equal to the lesser of—

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

"(II) $500,000.

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

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

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

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

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

"(16) GENETIC INFORMATION.—

"(A) IN GENERAL.—The term 'genetic information' means 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) 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 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) PROHIBITION ON GENETIC INFORMATION AS PREEXISTING CONDITION.—A health insurance issuer offering health insurance coverage in the individual market may not, on the basis of genetic information (including information about a request for or receipt of genetic services by an individual or family member of such individual), impose any preexisting condition exclusion (as defined in section 2701(b)(1)(A)) with respect to such coverage.

"(d) GENETIC TESTING.—

"(1) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—A health insurance issuer offering health insurance coverage in the individual market shall not request or require an individual or a family member of such individual to undergo a genetic test.

"(2) CERTAIN RULES 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.

"(3) RULE OF CONSTRUCTION REGARDING PAYMENT.—

"(A) IN GENERAL.—Subject to subparagraph (B), nothing in paragraph (1) shall be construed to preclude a health insurance issuer offering health insurance coverage in the individual market from conditioning payment on obtaining the results of a genetic test or informing members of such policies. For purpose of the preceding sentence, the term 'payment' includes reimbursement, billing, claims management, claims adjudication, review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges, and utilization review (including precertification, prior authorization, concurrent and retrospective review).

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

"(e) GENETIC INFORMATION OF A FETUS OR EMBRYO.—Any reference in this section to genetic information concerning an individual or family member of an individual shall—

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

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

(2) REMEDIES AND ENFORCEMENT.—Section 2761(b) of the Public Health Service Act (42 U.S.C. 300gg–61(b)) is amended to read as follows:

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

(c) ELIMINATION OF OPTION OF NON-FEDERAL GOVERNMENTAL PLANS TO BE EXCEPTED FROM REQUIREMENTS CONCERNING GENETIC INFORMATION.—Section 2721(b)(2) of the Public Health Service Act (42 U.S.C. 300gg–21(b)(2)) is amended—

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

(2) by adding at the end the following:

"(D) ELECTION NOT APPLICABLE TO REQUIREMENTS CONCERNING GENETIC INFORMATION.—The election described in subparagraph (A) shall not be available with respect to the provisions of subsections (a)(1)(F) 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 TITLE XVIII OF THE SOCIAL SECURITY ACT RELATING TO MEDIGAP.

(a) NONDISCRIMINATION.—

(1) IN GENERAL.—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)(i) An issuer of a medicare supplemental policy shall not deny or condition the issuance or effectiveness of the policy, and shall not discriminate in the pricing of the policy (including the adjustment of premium rates) of an eligible individual on the basis of genetic information concerning the individual (or information about a request for, or the receipt of, genetic services by such individual or family member of such individual).

"(ii) For purposes of clause (i), the terms 'family member', 'genetic services', and 'genetic information' shall have the meanings given such terms in subsection (x).".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply with respect to a policy for policy years beginning after the date that is 18 months after the date of enactment of this Act.

(b) LIMITATIONS ON GENETIC TESTING.—

(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.—

"(1) GENETIC TESTING.—

"(A) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—An issuer of a medicare supplemental policy shall not request or require an individual or a family member of such individual to undergo a genetic test.

"(B) RULE OF CONSTRUCTION.—Nothing in this title shall be construed to—

"(i) 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;

"(ii) limit the authority of a health care professional who is employed by or affiliated with an issuer of a medicare supplemental policy 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

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

"(2) DEFINITIONS.—In this subsection:

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

"(i) the spouse of the individual;

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

"(iii) any other individuals related by blood to the individual or to the spouse or child described in clause (i) or (ii).

"(B) GENETIC INFORMATION.—

"(i) IN GENERAL.—Except as provided in clause (ii), 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.

"(ii) 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); or

"(iii) genetic education.

"(E) 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 the Social Security Act (42 U.S.C. 1395ss(o)) is amended by adding at the end the following:

"(4) The issuer of the medicare supplemental policy complies with subsection (s)(2)(E) and subsection (x).".

(3) EFFECTIVE DATE.—The amendments made by this subsection 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.

(c) 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 regulation incorporating the modifications shall be considered to be the appropriate regulation for the purposes of such section.

(4) DATE SPECIFIED.—

(A) IN GENERAL.—Subject to subparagraph (B), the date specified in this paragraph for a State is the earlier of—

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

(ii) 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. 104. PRIVACY AND CONFIDENTIALITY.

(a) APPLICABILITY.—Except as provided in subsection (d), the provisions of this section shall apply to group health plans and health insurance issuers that offers group health insurance coverage in connection with a group health plan, without regard to—

(1) section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191a(a));

(2) section 9831(a)(2) of the Internal Revenue Code of 1986.

(b) COMPLIANCE WITH CERTAIN CONFIDENTIALITY STANDARDS WITH RESPECT TO GENETIC INFORMATION.—

(1) IN GENERAL.—The regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) shall apply to the use or disclosure of genetic information by a group health plan or by a health insurance issuer that offers group health insurance coverage in connection with a group health plan.

(2) PROHIBITION ON UNDERWRITING AND PREMIUM RATING.—Notwithstanding paragraph (1), a group health plan or a health insurance issuer that offers group health insurance coverage in connection with a group health plan shall

not use or disclose genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determinations of eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or health benefits.

(c) PROHIBITION ON COLLECTION OF GENETIC INFORMATION.—

(1) IN GENERAL.—A group health plan or a health insurance issuer that offers group health insurance coverage in connection with a group health plan shall not request, require, or purchase genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determinations of eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or health benefits.

(2) LIMITATION RELATING TO THE COLLECTION OF GENETIC INFORMATION PRIOR TO ENROLLMENT.—A group health plan or a health insurance issuer that offers group health insurance coverage in connection with a group health plan shall not request, require, or purchase genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) concerning a participant, beneficiary, or enrollee prior to the enrollment, and in connection with such enrollment, of such individual under the plan or coverage.

(3) INCIDENTAL COLLECTION.—Where a group health plan obtains or a health insurance issuer that offers group health insurance coverage in connection with a group health plan genetic information incidental to the requesting, requiring, or purchasing of other information concerning a participant, beneficiary, or enrollee, such request, requirement, or purchase shall not be considered a violation of this subsection if—

(A) such request, requirement, or purchase is not in violation of paragraph (1); and

(B) any genetic information (including information about a request for or receipt of genetic services) requested, required, or purchased is not used or disclosed in violation of subsection (b).

(d) APPLICATION OF CONFIDENTIALITY STANDARDS.—The provisions of subsections (b) and (c) shall not apply—

(1) to group health plans or health insurance issuers that are not otherwise covered under the regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note); and

(2) to genetic information that is not considered to be individually-identifiable health information under the regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

(e) ENFORCEMENT.—A group health plan or a health insurance issuer that offers group health insurance coverage in connection with a group health plan that violates a provision of this section shall be subject to the penalties described in sections 1176 and 1177 of the Social Security Act (42 U.S.C. 1320d–5 and 1320d–6) in the same manner and to the same extent that such penalties apply to violations of part C of title XI of such Act.

(f) PREEMPTION.—

(1) IN GENERAL.—A provision or requirement under this section or a regulation promulgated under this section shall supersede any contrary provision of State law unless such provision of State law imposes requirements, standards, or implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed under this section or such regulations. No penalty, remedy, or cause of action to enforce such a State law that is more stringent shall be preempted by this section.

(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed to establish a penalty, remedy, or cause of action under State law if such penalty, remedy, or cause of action is not otherwise available under such State law.

(g) COORDINATION WITH PRIVACY REGULATIONS.—The Secretary shall implement and administer this section in a manner that is consistent with the implementation and administration by the Secretary of the regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

(h) DEFINITIONS.—In this section:

(1) GENETIC INFORMATION; GENETIC SERVICES.—The terms "family member", "genetic information", "genetic services", and "genetic test" have the meanings given such terms in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91), as amended by this Act.

(2) GROUP HEALTH PLAN; HEALTH INSURANCE ISSUER.—The terms "group health plan" and "health insurance issuer" include only those plans and issuers that are covered under the regulations described in subsection (d)(1).

(3) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

SEC. 104A. PRIVACY AND CONFIDENTIALITY.

(a) PHSA PROVISIONS.—

(1) GROUP HEALTH PLANS.—

(A) IN GENERAL.—Title XXVII of the Public Health Service Act is amended by inserting after section 2702 the following new section:

"SEC. 2703. PRIVACY AND CONFIDENTIAL OF GENETIC INFORMATION.

"(a) COMPLIANCE WITH CERTAIN CONFIDENTIALITY STANDARDS WITH RESPECT TO GENETIC INFORMATION.—

"(1) IN GENERAL.—The regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) shall apply to the use or disclosure of genetic information by a group health plan or by an health insurance issuer in connection with health insurance coverage offered in connection with a group health plan.

"(2) PROHIBITION ON UNDERWRITING AND PREMIUM RATING.—Notwithstanding paragraph (1), a group health plan or a health insurance issuer (in connection with health insurance coverage offered in connection with a group health plan) shall not use or disclose genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determinations of eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or health benefits.

"(b) PROHIBITION ON COLLECTION OF GENETIC INFORMATION.—

"(1) IN GENERAL.—A group health plan or health insurance issuer (in connection with health insurance coverage offered in connection with a group health plan) shall not request, require, or purchase genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determinations of eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or health benefits.

"(2) LIMITATION RELATING TO THE COLLECTION OF GENETIC INFORMATION PRIOR TO ENROLLMENT.—A group health plan or health insurance issuer (in connection with health insurance coverage offered in connection with a group health plan) shall not request, require, or purchase genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) concerning a participant, beneficiary, or enrollee prior to the enrollment, and in connection with such enrollment, of such individual under the plan or coverage.

"(3) INCIDENTAL COLLECTION.—Where a group health plan or health insurance issuer (in connection with health insurance coverage offered in connection with a group health plan) obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning a participant or beneficiary, such request, requirement, or purchase shall not be considered a violation of this subsection if—

"(A) such request, requirement, or purchase is not in violation of paragraph (1); and

"(B) any genetic information (including information about a request for or receipt of genetic services) requested, required, or purchased is not used or disclosed in violation of subsection (a).

"(c) APPLICATION OF CONFIDENTIALITY STANDARDS.—The provisions of subsections (a) and (b) shall not apply—

"(1) to group health plans or health insurance issuers that are not otherwise covered under the regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note); and

"(2) to genetic information that is not considered to be individually-identifiable health information under the regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

"(d) COORDINATION WITH PRIVACY REGULATIONS.—The Secretary shall implement and administer this section in a manner that is consistent with the implementation and administration by the Secretary of the regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).".

(B) APPLICATION TO SMALL GROUP HEALTH PLANS.—Section 2721(a) of such Act (42 U.S.C. 300gg-21(a)) is amended by inserting "(other than section 2703)" after "subparts 1 and 3".

(2) INDIVIDUAL HEALTH INSURANCE.—Such title is further amended by inserting after section 2744 the following new section:

"SEC. 2744A. PRIVACY AND CONFIDENTIALITY OF GENETIC INFORMATION.

"(a) COMPLIANCE WITH CERTAIN CONFIDENTIALITY STANDARDS WITH RESPECT TO GENETIC INFORMATION.—

"(1) IN GENERAL.—The regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) shall apply to the use or disclosure of genetic information by an health insurance issuer in connection with individual health insurance coverage.

"(2) PROHIBITION ON UNDERWRITING AND PREMIUM RATING.—Notwithstanding paragraph (1), a health insurance issuer shall not use or disclose genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determinations of eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or health benefits in the individual market.

"(b) PROHIBITION ON COLLECTION OF GENETIC INFORMATION.—

"(1) IN GENERAL.—A health insurance issuer shall not request, require, or purchase genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determinations of eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or health benefits in the individual market.

"(2) LIMITATION RELATING TO THE COLLECTION OF GENETIC INFORMATION PRIOR TO ENROLLMENT.—A health insurance issuer offering health insurance coverage in the individual market shall not request, require, or purchase genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) concerning an enrollee prior to the enrollment, and in connection with such enrollment, of such individual under the coverage.

"(3) INCIDENTAL COLLECTION.—Where a health insurance issuer obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning an enrollee in the individual market, such request, requirement, or purchase shall not be considered a violation of this subsection if—

"(A) such request, requirement, or purchase is not in violation of paragraph (1); and

"(B) any genetic information (including information about a request for or receipt of genetic services) requested, required, or purchased is not used or disclosed in violation of subsection (a).

"(c) APPLICATION OF CONFIDENTIALITY STANDARDS.—The provisions of subsections (a) and (b) shall not apply—

"(1) to health insurance issuers that are not otherwise covered under the regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note); and

"(2) to genetic information that is not considered to be individually-identifiable health information under the regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

"(d) COORDINATION WITH PRIVACY REGULATIONS.—The Secretary shall implement and administer this section in a manner that is consistent with the implementation and administration by the Secretary of the regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.)

and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).".

(b) APPLICATION TO MEDICARE SUPPLEMENTAL POLICIES.—Section 1882 of the Social Security Act (42 U.S.C. 1395ss), as amended by section 103(b)(1), is amended by adding at the end the following new subsection:

"(y) PRIVACY AND CONFIDENTIALITY OF GENETIC INFORMATION.—

"(1) COMPLIANCE WITH CERTAIN CONFIDENTIALITY STANDARDS WITH RESPECT TO GENETIC INFORMATION.—

"(A) IN GENERAL.—The regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) shall apply to the use or disclosure of genetic information by an issuer of a medicare supplemental policy.

"(B) PROHIBITION ON UNDERWRITING AND PREMIUM RATING.—Notwithstanding subparagraph (A), an issuer of a medicare supplemental policy shall not use or disclose genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determinations of eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or health benefits in connection with such policy.

"(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 (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determinations of eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or health benefits in connection with such policy.

"(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 (including information about a request for or a receipt of genetic services by an individual or family member of such individual) concerning an enrollee prior to the enrollment, and in connection with such enrollment, of such individual under the policy.

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

"(i) such request, requirement, or purchase is not in violation of subparagraph (A); and

"(ii) any genetic information (including information about a request for or receipt of genetic services) requested, required, or purchased is not used or disclosed in violation of paragraph (1).

"(3) APPLICATION OF CONFIDENTIALITY STANDARDS.—The provisions of paragraphs (1) and (2) shall not apply—

"(A) to health insurance issuers that are not otherwise covered under the regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note); and

"(B) to genetic information that is not considered to be individually-identifiable health information under the regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

"(4) COORDINATION WITH PRIVACY REGULATIONS.—The Secretary shall implement and administer this subsection in a manner that is consistent with the implementation and administration by the Secretary of the regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).".

SEC. 105. 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 section 104.

SEC. 106. RELATIONSHIP TO TITLE II WITH RESPECT TO ENFORCEMENT.

With respect to the relationship between title II and this title (and the amendments made by this title):

(1) The genetic nondiscrimination requirements and remedies of this title (and such amendments) are exclusive for—

(A) group health plans;

(B) health or other insurance coverage issued in connection with group heath plans;

(C) individual health insurance coverage; and

(D) and medicare supplemental policies.

(2) Nothing in title II shall be construed to establish a requirement or remedy under such title with respect to group health plans, health or other insurance coverage issued in connection with group heath plans, individual health insurance coverage, or medicare supplemental policies, notwithstanding any provision of such title.

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 DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION

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 applies.

(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 information 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 workplace.

(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); or

(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 authorization;

(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 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 provides written notice of the genetic monitoring to the employee;

(B)(i) the employee provides prior, knowing, voluntary, and written authorization; 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.); and

(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 individual 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 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 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 authorization;

(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

(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 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)(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

(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 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 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 medical history of the member or family member of the member;

(2) where—

(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 authorization;

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

(B)(i) the member provides prior, knowing, voluntary, and written authorization; or

(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 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.); and

(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 programs—

(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 apprenticeship 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 individual 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 authorization;

(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

(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 labor-management 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.

(c) RELATIONSHIP TO HIPAA REGULATION.—

(1) IN GENERAL.—In the case of an entity that is subject to the regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note), the entity is not subject to the provisions of this title that regulate the use and disclosure of information to which such regulation applies.

(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall affect the application of protections under this title against discrimination in hiring, firing, promotion, or job placement and other unlawful employment practices that do not relate to the matters to which the regulations referred to in paragraph (1) apply.

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 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, 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 Nondiscrimination 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) 1 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 Representatives.

(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 Identification 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).

SEC. 213. EFFECTIVE DATE.

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.

PURPOSE AND SUMMARY

H.R. 493, the Genetic Information Nondiscrimination Act of 2007, amends the Employee Retirement Income Security Act of 1974 (ERISA) and the Public Health Service Act (PHSA) to expand the prohibition against discrimination by group health plans and health insurance issuers in the group and individual markets on the basis of genetic information or services to prohibit: (1) enrollment and premium discrimination based on information about a request for or receipt of genetic services; and (2) requiring genetic testing. The bill also sets forth penalties for violations of its requirements.

H.R. 493 amends title XVIII of the Social Security Act (Medicare) to prohibit issuers of Medicare supplemental policies from discriminating on the basis of genetic information. H.R. 493 also extends medical privacy and confidentiality rules to the disclosure of genetic information; makes it an unlawful employment practice for an employer, employment agency, labor organization, or training program to discriminate against an individual or deprive such individual of employment opportunities because of genetic information; prohibits the collection and disclosure of genetic information, with certain exceptions; and establishes a Genetic Nondiscrimination Study Commission to review the developing science of genetics and advise Congress on the advisability of providing for a disparate impact cause of action under the Civil Rights Act of 1964.

BACKGROUND AND NEED FOR LEGISLATION

Deciphering the sequence of the human genome and other advances in genetics have opened major new opportunities for medical progress. Science is only beginning to unlock the complex nature of the interaction between genes and the environment in common diseases and their respective contributions to the disease process. The information gleaned from the Human Genome Project will help, and is currently helping, scientists and clinicians to identify common genetic variations that contribute to disease. Knowledge of the potential relevance of genetic information to the clinical management of nearly all patients, coupled with the lack of complete information about the genetic and environmental factors underlying diseases, creates a challenging climate for public policymaking.

In many cases, the results of genetic testing may be used to guide clinical management of patients. For example, more frequent screening may be recommended for individuals at increased risk of certain diseases by virtue of their genetic make-up, such as colorectal and breast cancer. Decisions about course of treatment and dosing may also be guided by genetic testing. Many diseases, however, do not have any treatments available (for example, Huntington's Disease). In these cases, the benefits of genetic testing lie largely in the information they provide an individual about his or her risk of future disease or current disease status. The value of genetic information in these cases is personal to individuals, who may choose to utilize this information to help guide medical and other life decisions for themselves and their families. This information can affect decisions about reproduction, the types or amount of health, life, or disability insurance to purchase, or career and education choices.

These advances give rise to the potential misuse of genetic information to discriminate in health insurance and employment. Concerns about privacy and the use and misuse of genetic information need to be balanced with the potential of genetics and genetic technology to change how care is delivered and to personalize medical care and treatment of disease.

A January 20, 1998 joint report put forth by the Department of Labor, the Department of Health and Human Services (HHS), the Equal Employment Opportunity Commission (EEOC), and the Department of Justice (DoJ), entitled, "Genetic Information and the Workplace," summarized the various studies on discrimination based on genetic information and argued for the enactment of Federal legislation. The joint report stated that, "genetic predisposition or conditions can lead to workplace discrimination, even in cases where workers are healthy and unlikely to develop disease or where the genetic condition has no effect on the ability to perform work." With these misconceptions so prevalent, employers may come to rely on genetic testing to 'weed out' those employees who carry genes associated with diseases. The joint report concluded that existing protections are minimal and called for the enactment of legislation which states that: 1) employers should not require or request that employees or potential employees take a genetic test or provide genetic information as a condition of employment or benefits; 2) employers should not use genetic information to discriminate against, limit, segregate, or classify employees; and 3) employers should not obtain or disclose genetic information about employees or potential employees under most circumstances.

The joint report acknowledged that genetic testing has the unique ability to detect and prevent health disorders, but pointed out that this information can be misused to discriminate against or stigmatize individuals seeking health insurance. It is feared that a health insurance company might wrongly view the presence of a gene mutation to mean that the person would definitely contract the disease with which that gene is associated and improperly deny that person insurance coverage. The report cited a 1996 survey of individuals at risk of developing a genetic condition and parents of children with specific genetic conditions. This report identified more than 200 cases of genetic discrimination among the 917 people who responded. The cases involved discrimination by insurance companies, employers, and other organizations that use genetic information. Another survey of genetic counselors, primary care physicians, and patients, identified 550 people who had been denied employment or insurance based on their genetic predisposition to an illness. In addition, because an individual's genetic information has implications for his or her family members and future generations, misuse of genetic information could have inter-generational effects that are far broader than any individual incident of misuse. Furthermore, the joint report warned that many Americans are reluctant to take advantage of new breakthroughs in genetic testing for fear that the results will not be used to improve their health, but rather to deny them jobs or health insurance.

The appropriate use of genetic information offers enormous opportunities to save lives and prevent the onset of disease. However, the medical progress made possible by genetic research is dependent on the willingness of study volunteers and patients to undergo genetic testing. Such consent may be difficult to obtain today. Fears about the possible misuse or unauthorized disclosure of genetic information appear to adversely impact the desire of individuals to participate in genetic research. Such fears also extend to clinical practice, discouraging both patients and providers from taking full advantage of genetic tests and technologies. There is substantial reluctance among at-risk populations to undergo genetic testing—even when that testing may allow patients to take steps to lower their risks of contracting a disease. For example, only 43 percent of those at risk for hereditary colon cancer participated in a genetic testing program. Later studies found that 39 percent of those who declined testing cited fears about the potential effect of test results on their health insurance coverage as the primary reason for their refusal. Although other factors contribute to the decision not to get tested, such as the lack of an effective treatment, fear of genetic discrimination appears to be a primary reason that many people forgo getting genetic tests.

To fill the void created by the absence of clear protections at the Federal level, many States have enacted laws that seek to prohibit genetic discrimination in health insurance and employment. To date, 34 States, and the District of Columbia, have passed laws on genetic discrimination in employment and 48 have passed laws on genetic discrimination in health insurance. Among the States that prohibit discrimination in the issuing of health insurance, many cover only the group health insurance market and exclude individual health insurance policies, while others do the reverse. Many States exclude family medical histories from their definition of genetic information or include only the results of tests that are performed with the announced intention of detecting genetic mutations.

Regardless of the technical aspects of any particular State law, there is necessarily a significant gap in any State's ability to deter genetic discrimination in health insurance. Congress delegated to the States the authority to regulate most aspects of insurance through enacting the McCarran-Ferguson Act of 1945. However, employer-purchased plans were exempted from State regulation by the Employee Retirement Income Security Act of 1974. Under ERISA, no State may regulate the type of health insurance plans typically provided to employees as part of their employment benefits. Only the Congress can therefore enact a truly comprehensive law prohibiting genetic discrimination in all areas of health insurance.

Federal genetic nondiscrimination legislation addresses the need for national comprehensive protections. The legislation is supported by President Bush, whose Administration has issued two Statement of Administration Policies (SAPs) supporting Senate-passed genetic nondiscrimination legislation. The most recent SAP, issued on February 16, 2005, stated, "The Administration supports Senate passage of S. 306, as reported, which would prohibit group health plans and health insurers from denying coverage to a healthy individual or charging that person higher premiums based solely on a genetic predisposition to developing a disease in the future. The legislation would also bar employers from using individuals' genetic information when making hiring, firing, job placement, or promotion decisions."

The Committee believes the Secretary of HHS should consider periodically publishing non-binding guidance on whether a given type of analysis "detects a genotype, mutation, or chromosomal change" as those terms are used in GINA's definition of "genetic test". In so doing, the Secretary should utilize an open and inclusive process that affords an opportunity for experts and stakeholders to provide the Secretary with their advice and input. Further, the Committee intends that at no point in this process should any personally identifiable information, including any person's genetic information or family history, be utilized or disclosed.

CURRENT FEDERAL LAW ON GENETIC DISCRIMINATION IN HEALTH INSURANCE

The Health Insurance Portability and Accountability Act (HIPAA) has several important limitations in protecting Americans against genetic discrimination in health insurance. First, its protections against denying coverage on the basis of factors related to health status apply only to the group insurance market. HIPAA does not address discrimination in the individual market, and State laws vary considerably with regard to restrictions on using genetic information to set premiums or determine eligibility. In addition, HIPAA does not prohibit an insurance company from raising the premiums for the group health plan as a whole, based on the genetic information of an individual in that group.

HIPAA AND PRIVACY

HHS medical privacy regulations are of obvious relevance to the debate on genetic discrimination. While people fear discriminatory action based on their genes, they also fear the unauthorized disclosure or collection of genetic information. The need to protect the privacy of genetic information is important. Knowledge that a person has a particular medical condition or genetic trait may be embarrassing or damaging to that individual, or his or her family members. Although the HHS privacy regulations are extensive in many respects, they are limited by the underlying statutory framework of HIPAA, which authorized them to apply only to three named categories of entities: providers, payers and information clearinghouses. However, medical information may be widely dispersed beyond these 'covered entities'. Due to the underlying statutory constraints of HIPAA, the HHS privacy regulations cannot directly affect employers or other non-covered entities. Instead, the regulations require any non-covered entity (a 'business associate') to enter into a contract with a covered entity promising that it will respect the privacy of information transmitted from the covered entity to the non-covered entity. Further statutory provisions are needed to regulate directly the collection and disclosure of genetic information by employers and other workforce organizations not covered directly within the framework of the HIPAA regulations.

FEDERAL PROTECTIONS AGAINST GENETIC DISCRIMINATION IN EMPLOYMENT

Federal employees have considerable protection against genetic discrimination under the terms of Executive Order 13145 issued on February 10, 2000, 65 CFR 6877. Under this order, Federal employees may not be discharged or otherwise subjected to restrictions in their employment, or their employment-related benefits, on the basis of protected genetic information. The Executive Order also provides protections against improper collection of employees' genetic information and against unauthorized disclosure of that information. Despite these protections, the Executive Order has no enforcement provisions.

TITLE VII OF THE CIVIL RIGHTS ACT

Title VII of the Civil Rights Act of 1964 makes it illegal for an employer, labor organization, employment agency, or training program to 'discriminate against any individual . . . because of such individual's race, color, religion, sex, or national origin.' While this law provides robust guarantees against discrimination on the basis of these characteristics, its applicability to genetic discrimination is limited. The plain language of the statute provides no explicit protection against genetic discrimination. Title VII may indirectly offer some protections against discrimination on the basis of a person's genetic makeup when that discrimination disproportionately affects individuals on the basis of one of the characteristics named in the Act. For acts of genetic discrimination that do not have a discriminatory effect on members of class of individuals named in the Civil Rights Act, Title VII would provide no apparent protection against genetic discrimination.

HEARINGS

The Subcommittee on Health held a hearing on H.R. 493 on Thursday, March 8, 2007. The hearing was divided into two panels. Panel I consisted of testimony from the following: Francis S. Collins, M.D., Ph.D., Director, National Human Genome Research Institute, National Institutes of Health, Department of Health and Human Services; Christopher J. Kuczynski, J.D., Assistant Legal Counsel and Director, Americans with Disabilities Act Policy Division, Equal Employment Opportunity Commission; and Susan McAndrew, J.D., Deputy Director for Health Information Privacy, Office for Civil Rights, Department of Health and Human Services.

Panel II consisted of testimony from the following: Sharon F. Terry, M.A., L.H.D., Chair, Coalition for Genetic Fairness, President and CEO, Genetic Alliance; William Corwin, M.D., Medical Director, Clinical Policy, Harvard Pilgrim Health Care, on behalf of the America's Health Insurance Plans (AHIP); Burton J. Fishman, J.D., Esq., Fortney & Scott, LLC, on behalf of the Genetic Information Nondiscrimination in Employment Coalition (GINE); Karen Pollitz, M.P.P., Research Professor, Georgetown University Health Policy Institute; Frank Swain, J.D., Senior Vice President, B&D Consulting; Janet Trautwein, Executive Vice President and CEO, National Association of Health Underwriters; Kathy Hudson, Ph.D., Director, Genetics and Public Policy Center, Associate Professor, Berman Institute of Bioethics, Johns Hopkins University.

COMMITTEE CONSIDERATION

On Tuesday, March 13, 2007, the Subcommittee on Health met in open markup session and approved H.R. 493 for full Committee consideration, amended, by voice vote.

On Friday, March 23, 2007, the full Committee met in open markup session and ordered H.R. 493 favorably reported to the House, amended, by voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken on amendments or in connection with ordering H.R. 493 reported. A motion by Mr. Dingell to order H.R. 493 favorably reported to the House, amended, was agreed to by voice vote.

COMMITTEE OVERSIGHT FINDINGS

Regarding clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has not held oversight or legislative hearings on this legislation.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The goals and objectives of H.R. 493 are to protect individuals from discrimination in health insurance and employment on the basis of genetic information. Establishing these protections will allay concerns about the potential for discrimination and encourage individuals to participate in genetic research and to take advantage of genetic testing, new technologies, and new therapies. The legislation will provide substantive protections to those individuals who may suffer from actual genetic discrimination now and in the future.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 493 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARKS AND TAX AND TARIFF BENEFITS

In compliance with clause 9 of rule XXI of the Rules of the House of Representatives, H.R. 493 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(d), 9(e), or 9(f) of rule XXI.

COMMITTEE COST ESTIMATE

The Committee will adopt as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Regarding clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, a cost estimate by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not available as of the time of the filing of this report by the Committee.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in the provisions of Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act. H.R. 493 prohibits discrimination on the basis of genetic information with respect to health insurance and employment for Congressional and Executive Branch employees. With respect to health insurance, the provisions of H.R. 493 would indirectly apply to the Federal Employees Health Benefits Program (FEHBP), which contracts with insurance issuers and provides coverage to Members and employees of the legislative branch. The impact of this legislation on the FEHBP may not be relevant, however, given that the FEHBP already has broad non-discrimination rules in place, and given the fact that, pursuant to existing laws and regulations, eligibility for enrollment in the FEHBP is based solely on employment with the Federal Government, not medical conditions. With respect to employment, Executive Order 13145, issued February 10, 2000, prohibits discrimination in Federal employment based on genetic information, and current laws and regulations ensure that disqualification for Federal employment can only be based on job-related criteria.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title; table of contents

Section 1 establishes the short title as the "Genetic Information Nondiscrimination Act of 2007". This section also provides a table of contents.

Section 2. Findings

Section 2 provides findings that support the overall goals and objectives of the bill.

Title I—Genetic Non-Discrimination in Health Insurance

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

Subsection (a). Prohibition of health discrimination on the basis of genetic information or genetic services

Section 101(a)(1). No enrollment restriction for genetic services

Section 101(a)(1) amends ERISA 702(a)(1)(F) to include "information about a request for or receipt of genetics services by an individual or family member of such individual."

Section 101(a)(2). No discrimination in group premiums based on genetic information

Section 101(a)(2) amends ERISA 702(b) to prohibit a health insurance issuer offering group health coverage in connection with a group health plan from adjusting 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.

Section 101(b). Limitations on genetic testing

Section 101(b) amends section 702 of ERISA to include a prohibition on genetic testing. Specifically, this provision prohibits a group health plan or a health insurance issuer offering group health insurance coverage in connection with a group health plan from requesting or requiring an individual or a family member of such individual to undergo a genetic test. This section does not limit the authority of the treating health care professional to request that such individual or family member undergo a genetic test. Nor does it limit the authority of a health care professional who is employed by or affiliated with the group health plan or health insurance issuer and who is providing health care services to the enrolled individual as part of a bona fide wellness program from notifying such individual about the availability of a genetic test or providing information about the genetic test. Finally, this section does not authorize or permit a health care professional to require that an individual undergo a genetic test.

Application to All Plans—This provision applies the requirements of the amendments made by section 101 of the Genetic Information Nondiscrimination Act to small group health plans (and group health insurance coverage offered in connection with a group health plan) that are otherwise exempt, under section 732(a) of ERISA, from the other non-discrimination prohibitions under section 702 of ERISA. The requirements of such amendments apply to a group health plan (and group health insurance coverage offered in connection with a group health plan) that, on the first day of the plan year, has less than two participants who are current employees for any plan year. Such amendments also apply to retiree only group health plans (and group health insurance coverage offered in connection with a group health plan).

Section 101(c). Remedies and enforcement

Section 101(c) amends section 502 of ERISA to clarify and strengthen remedies available to group health plan participants for violations of the genetic nondiscrimination provisions added by title I.

Secretarial Enforcement Authority—The Secretary is provided specific authority to issue administrative penalties for violation of sections 101 and 104(b).

Amount of Penalty—The Secretary of Labor may impose a civil penalty against a group health plan sponsor or issuer for any violation of this section in the amount of $100 for each day of non-compliance with respect to each individual to whom such failure relates. A higher penalty of $2,500 for each day of non-compliance shall be applied where there is one or more failures with respect to an individual involved and where the plan did not correct the failure within the specified time. A penalty of $15,000 shall be applied if the violation under this title in any year is more than de minimis.

Section 101(d). Definitions

Section 101(d) adds new definitions to section 733(d) of ERISA with respect to genetic non-discrimination.

Family Member—Means the spouse of the individual, a dependent child, including adopted children; and all other individuals related by blood to the individual or the spouse or child.

Genetic Information—Means information about an individual's genetic tests, the genetic tests of family members of the individual, or the occurrence of a disease or disorder in family members of the individual. It does not include information about the sex or age of an individual.

Genetic Test—Means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes. It does not mean an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes or an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

Genetic Services—Means a genetic test; genetic counseling (including obtaining, interpreting, or assessing genetic information or providing genetic advice); or genetic education.

Section 101(e). Regulations and effective date

Section 101(e) states that the Secretary of Labor shall issue final regulations not later than one year after enactment. The amendments made by this act shall apply to group health plans for plan years beginning 18 months after enactment.

Section 102. Amendments to the Public Health Service Act

Subsection (a). Amendments relating to the group market

(1) Prohibition of Health Discrimination on the Basis of Genetic Information or Genetic Services—Sections 2702(a)(1)(F) and 2702(b) of the Public Health Service Act currently prohibit a group

health plan and a health insurance issuer offering group health insurance coverage in connection with a group health plan from discriminating—in eligibility for enrollment or premium contributions—against an individual in the group based on the individual's health status related factors, including genetic information. In general, this section clarifies and expands this provision by prohibiting discrimination based on genetic information, including information about a request for or receipt of genetic services by an individual or family member of the individual.

(A) No Enrollment Restriction for Genetic Services—This provision clarifies that within the existing prohibition banning discrimination in enrollment against an individual in the group that the term genetic information includes "information about a request for or receipt of genetics services by an individual or family member of such individual."

(B) No Discrimination in Group Premiums Based on Genetic Information—This provision prohibits a health insurance issuer offering group health coverage in connection with a group health plan from adjusting premiums 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.

(2) Limitations on Genetic Testing—This section amends section 2702 of the Public Health Service Act to include a prohibition on genetic testing. Specifically, this provision prohibits a group health plan or a health insurance issuer offering group health insurance coverage in connection with a group health plan from requesting or requiring an individual or a family member of such individual to undergo a genetic test. Section 102 does not limit the authority of the treating health care professional to request that such individual or family member undergo a genetic test. Nor does it limit the authority of a health care professional who is employed by or affiliated with the group health plan or health insurance issuer and who is providing health care services to the enrolled individual as part of a wellness program (as defined under regulations implementing PHSA section 2702 at 45 CFR 146.121(f)) from notifying such individual about the availability of a genetic test or providing information about the genetic test. This section does not authorize or permit a health care professional to require that an individual undergo a genetic test. Finally, this section clarifies that a health insurance company can condition payment of an insurance claim on obtaining the results of a genetic test or informing members of such policies. However, the insurance company can only request the minimum amount of information necessary to accomplish their intended purpose. An example of why this would be necessary could include a situation where someone was getting colonoscopies every 6 months and asking their health insurance provider to pay for these services. A health insurance company should have the ability to ask why these tests are occurring so frequently and should be able to require evidence as to why this is medically necessary.

Application to All Plans—This provision applies the requirements of the amendments made by section 102(a) of the Genetic Information Nondiscrimination Act to small group health plans (and group health insurance coverage offered in connection with a group health plan) that are otherwise exempt, under section 2721(a) of the Public Health Service Act, from the nondiscrimination prohibitions under section 2702.

Genetic Information of a Fetus or Embryo—This section amends title I to state that any reference to genetic information concerning an individual or family member shall also include the genetic information of any fetus carried by a pregnant woman and shall include the genetic information of an embryo legally held by an individual or family member (i.e., with respect to assisted reproductive technology, such as in-vitro fertilization).

(3) Remedies and Enforcement—This section amends section 2722(b) of the Public Health Service Act to allow for enforcement of the requirements the amendments made by section 102(a) against health insurance issuers offering group health insurance coverage in connection with a group health plan. The enforcement mechanism is the same as that created by HIPAA to enforce existing non-discrimination provisions against health insurance issuers offering group health insurance coverage in connection with a group health plan under section 2702 of the PHSA.

Enforcement Authority Relating to Genetic Discrimination—In cases where the Secretary of HHS determines that a State has failed to substantially enforce the requirements of the amendments made by section 102(a) against a health insurance issuer offering group health insurance coverage, the Secretary has the authority to impose a civil monetary penalty on the issuer.

Amount of Penalty—The Secretary of HHS may impose a civil penalty against a group health plan for any violation of the amendments made by section 102(a) in the amount of $100 for each day of noncompliance with respect to each individual to whom such failure relates. A higher penalty of $2,500 for each day of non-compliance shall be applied where there are one or more failures with respect to an individual and where the plan did not correct the failure within the specified time. A penalty of $15,000 shall be applied where the violation under the amendments made by section 102(a) in any year is more than *de minimis.*

Limitations—No penalty applies under this paragraph if the Secretary determines that the person did not know, or through reasonable diligence would not have known, that such failure existed. No penalty shall be imposed on any failures due to reasonable cause and not willful neglect; and if such failure is corrected within 30 days of discovery. The overall limitation for unintentional failures due to reasonable cause shall not exceed the lesser of 10 percent of the amount paid or incurred by the employer during the preceding taxable year for group health plans or $500,000. The Secretary may waive all or part of any penalty imposed by this section if the penalty would be excessive relative to the failure involved.

(4) Definitions—This section adds new definitions to section 2791(d) of the PHSA with respect to genetic non-discrimination. A 'Family Member' means, with respect to an individual, a dependent of such individual as outlined in section 2701(f)(2) and any other individual up to the fourth-degree relative of such individual or dependent. 'Genetic Information' is defined as information about an individual's genetic test; the genetic tests of family members; or the occurrence of a disease or disorder in family members of the individual. This section clarifies that genetic information with respect to participation in clinical trials is included within the scope of

GINA's definition of genetic information. Information about the sex or age of an individual is not included. The definitions for 'Genetic Test' and 'Genetic Services' are identical to the definitions applicable to group health plans under section 101.

Subsection (b). Amendment relating to the individual market

(b)(1). This section adds a new section 2753 to subpart 2 to title XXVII of the PHSA relating to genetic nondiscrimination.

Section 2753(a)—Prohibition on genetic information as a condition of eligibility

A health insurance issuer in the individual market may not establish rules for eligibility (including continued eligibility) for an individual to enroll for 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).

Section 2753(b)—Prohibition on genetic information in setting premium rates

A health insurance issuer in the individual market shall not adjust the premium or contribution amounts for an individual on the basis of such individual's genetic information (including information about a request for or receipt of genetic services).

Section 2753(c).—Prohibition on genetic information as preexisting condition

A health insurance issuer in the individual market shall not impose any preexisting condition exclusion for an individual on the basis of such individual's genetic information (including information about a request for or receipt of genetic services).

Section 2753(d).—Genetic testing

This provision prohibits a health insurance issuer in the individual market from requesting or requiring an individual or a family member of such individual to undergo a genetic test. This provision does not limit the authority of the treating health care professional to request that such individual or family member undergo a genetic test. Nor does it limit the authority of a health care professional who is employed by or affiliated with the group health plan or health insurance issuer and who is providing health care services to the enrolled individual as part of a wellness program (as defined under regulations implementing PHSA section 2702 at 45 CFR 146.121(f)) from notifying such individual about the availability of a genetic test or providing information about the genetic test. Finally, this provision does not authorize or permit a health care professional to require that an individual undergo a genetic test.

Genetic Information of a Fetus or Embryo—This section states that any reference to genetic information concerning an individual or family member shall also include the genetic information of any fetus carried by a pregnant woman and shall include the genetic information of an embryo legally held by an individual or family member (i.e., with respect to assisted reproductive technology, such as in-vitro fertilization).

(2) Remedies and Enforcement—This section amends section 2761 of the PHSA to establish the same enforcement mechanism and Secretarial authority against health insurance issuers in the individual market as is provided for enforcing the genetic non-discrimination provisions against health insurance issuers in the group market.

Subsection (c). Elimination of option of non-federal governmental plans to be excepted from requirements concerning genetic information

This subtitle creates an exception to the existing opt-out provision under section 2721(a)(1)(2) of the PHSA that provides non-Federal governmental plans the ability to opt out of certain requirements created by HIPAA. Therefore, all non-Federal governmental health plans must comply with the genetic non-discrimination requirements created by this Act in the same manner as other non-governmental group health plans.

Subsection (d).—Regulations and effective date

Not later than one year after the date of enactment of this title, the Secretary of Labor and the Secretary of HHS (as the case may be) shall issue final regulations to carry out the amendments made by this section. The amendments made by this section shall apply to group health plans and insurance for plan years beginning after the date that is 18 months after the date of the enactment of this title. The amendments made by this section shall apply to insurance in the individual market 18 months after the date of enactment.

Section 103. Amendments to Title XVIII of the Social Security Act relating to Medigap

Subsection (a). Nondiscrimination

Section 103(a)(1). In general

Section 103(a)(1) amends section 1882(s)(2) of the Social Security Act by adding the following:

An issuer of a Medicare supplemental policy shall not deny or condition the issuance or effectiveness of the policy, and shall not discriminate in the pricing of the policy (including premium rate adjustments) of an individual on the basis of genetic information (or information about a request for, or receipt of, genetic services by such individual or family member of such individual).

Section 103(a)(2). Effective date

Section 103(a)(2) states that the amendment made in section 103(a)(1) applies to a policy for policy years beginning after the date that is 18 months after the date of enactment.

Section 103(b)(1). Limitation on genetic testing

Section 103(b)(1) amends section of 1882 of the Social Security Act to prohibit an issuer of a Medicare supplemental policy from requesting or requiring an individual or a family member of such individual to undergo a genetic test. This provision does not limit the authority of the treating health care professional to request that such individual or family member undergo a genetic test. Nor does it limit the authority of a health care professional who is employed by or affiliated with the issuer of the Medicare supplemental policy and who is providing health care services to the enrolled individual as part of a wellness program from notifying such individual about the availability of a genetic test or providing information about the genetic test. Finally, this provision does not authorize or permit a health care professional to require that an individual undergo a genetic test.

Definitions—The definitions of 'family member,' 'genetic information,' and 'genetic test,' and 'genetic services' are identical to the definitions applying to group health plans under section 101. This subsection includes the following additional definition:

Issuer of a Medicare Supplemental Policy—includes a third-party administrator or other person acting for or on behalf of such issuer.

Section 103(b)(2). Conforming amendment

Section 103(b)(2) requires an issuer to conform to and abide by the protections against genetic discrimination described in this section in order to be certified by the Secretary as an issuer of a Medigap policy.

Section 103(c). Transition provisions

Section 103(c) requires the Secretary of HHS to identify whether a State needs to change its statutes or regulations to comply with this section. A State has until the earlier of the date the State changes its statute or regulations to conform to this section, or October 1, 2008 to make the necessary changes and will not be considered out of compliance until such date. The National Association of Insurance Commissioners (NAIC) regulations shall be considered to be the applicable NAIC model regulation if such regulations are updated in a timely manner to be consistent with the Genetic Information Nondiscrimination Act. If the NAIC does not modify its model regulations in the timeframe established, the Secretary of HHS shall, not later than October 1, 2008, promulgate the regulation. If a State requires conforming legislation but its legislature is not scheduled to meet in 2008, the date of required compliance specified by 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 a State that has a 2-year legislative session, each year of such sessions shall be deemed to be a separate regular session of the State legislature.

Section 104. Privacy and confidentiality

Section 104(a). Applicability

The provisions in this section apply to all group health plans and health insurance issuers that offer group health insurance coverage in connection with a group health plan without regard to section 732(a) of ERISA and section 9831(a)(2) of the Internal Revenue Code of 1986.

Section 104(b). Compliance with certain confidentiality standards with respect to genetic information

In General—Part C of title XI of the Social Security Act and section 264 of HIPAA shall apply to the use and disclosure of genetic information by a group health plan or by a health insurance issuer that offers group health insurance coverage in connection with a group health plan.

Prohibition on Underwriting and Premium Rating—A group health plan or health insurance issuer of a group health plan shall not use or disclose genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determining eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or benefits.

Section 104(c). Prohibition on collection of genetic information

(1) In General—A group health plan, health insurance issuer, or issuer of a Medicare supplemental policy shall not request, require, or purchase genetic information for purposes of underwriting, determining eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage under the plan or for health insurance or benefits.

(2) Limitation Relating to the Collection of Genetic Information Prior to Enrollment—A group health plan, health insurance issuer, or issuer of Medicare supplemental policy shall not request, require, or purchase genetic information concerning a participant, beneficiary, or enrollee prior to the enrollment, and in connection with such enrollment, of such individual under the plan, coverage, or policy.

(3) Incidental Collection—Where a group health plan, health insurance issuer, or issuer of a Medicare supplemental policy obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning an individual, such request, requirement, or purchase shall not be considered a violation if it is not obtained for purposes of underwriting as defined under paragraph (1) and any genetic information obtained incidentally is not used or disclosed in violation of the HHS medical privacy regulations.

Section 104(d). Application of confidentiality standards

The requirements of this section apply only to group health plans, health insurance issuers, and issuers of Medicare supplemental policies that are otherwise covered under the HHS medical privacy regulations. Therefore, the health plan exceptions contained in the medical privacy regulations also apply with respect to the requirements under this section. The requirements of this section do not apply to genetic information that is not considered to be individually-identifiable under HHS medical privacy regulations.

Section 104(e). Enforcement

Covered entities under this section are subject to the same penalties that exist for medical privacy regulations under sections

1176 and 1177 of the Social Security Act for privacy and confidentiality violations of genetic information under section 104.

Section 104(f). Preemption

The preemption provision for this section is the same standard that exists for the medical privacy regulations. Specifically, a requirement under this section shall supersede any contrary provision of State law unless such provision of State law imposes requirements, standards, or implementation specifications that are more stringent than those imposed under this section. No penalty, remedy, or cause of action to enforce such State law that is more stringent shall be preempted by this section. This provision shall not be construed to establish a penalty, remedy, or cause of action under State law if it is not otherwise available under State law.

Section 104(g). Coordination with privacy regulations

The Secretary of HHS shall implement and administer this section in a manner that is consistent with the medical privacy regulations.

Section 104(h)(1). Definitions

The definitions of 'family member,' 'genetic information,' 'genetic services,' and 'genetic test' are identical to the definitions in section 2791 of the PHSA, as amended by the bill.

(2) Group Health Plan/Health Insurance Issuer—These terms include only those plans and issuers that are otherwise covered under subsection (d)(1).

(3) Secretary—This term means the Secretary of Health and Human Services.

Section 104A. Privacy and confidentiality

Section 104A(a). PHSA provisions

Section 104A(a)(1). Group health plans

This section amends title XXVII of the PHSA by adding a new section 2703:

Section 2703. Privacy and confidentiality of genetic information

(a) Compliance with Certain Confidentiality Standards with Respect to Genetic Information—The regulations established by the Secretary in part C of title XI of the Social Security Act and section 264 of HIPAA shall apply to the use or disclosure of genetic information in the group health market. A group health plan or health insurance insurer (in connection with health insurance coverage offered in connection with a group health plan) shall not use or disclose genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determining eligibility, setting premiums, or creating, renewing or replacing a health plan.

(b) Prohibition on Collection of Genetic Information—

(1) In General—A group health plan or health insurance issuer (in connection with health insurance coverage offered in connection with a group health plan) shall not request, require, or purchase genetic information (including information about a request for or a

receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determining eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage under the plan or for health insurance or benefits.

(2) Limitation Relating to the Collection of Genetic Information Prior to Enrollment—A group health plan or health insurance issuer (in connection with health insurance coverage offered in connection with a group health plan) shall not request, require, or purchase genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) concerning a participant, beneficiary, or enrollee prior to the enrollment, and in connection with such enrollment, of such individual under the plan or coverage.

(3) Incidental Collection—Where a group health plan or health insurance issuer (in connection with health insurance coverage offered in connection with a group health plan) obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning an individual, such request, requirement, or purchase shall not be considered a violation if it is not obtained for purposes of underwriting as defined under paragraph (1) and any genetic information obtained incidentally is not used or disclosed in violation of the HHS medical privacy regulations.

(c) Application of Confidentiality Standards—The requirements of this section apply only to group health plans and health insurance issuers that are otherwise covered under the HHS medical privacy regulations. Therefore, the health plan exceptions contained in the medical privacy regulations also apply with respect to the requirements under this section. The requirements of this section do not apply to genetic information that is not considered to be individually-identifiable under HHS medical privacy regulations.

(d) Coordination with Privacy Regulations—The Secretary of HHS shall implement and administer this section in a manner that is consistent with the medical privacy regulations.

(B) Application to Small Group Health Plans

This section amends section 2721(a) of the PHSA. Certain small group health plans are currently exempt from the requirements of subparts 1 and 3 of title XXVII of the PHSA. These groups will continue to receive this exemption, but will not be exempt from section 2703 of the PHSA.

Section 104A(a)(2). Individual health insurance

This section amends title XXVII of the PHSA by adding a new section 2745:

Section 2745. Privacy and confidentiality of genetic information

(a) Compliance with Certain Confidentiality Standards with Respect to Genetic Information—The regulations established by the Secretary in part C of title XI of the Social Security Act and section 264 of HIPAA shall apply to the use or disclosure of genetic information in the individual health insurance market. A health insurance insurer shall not use or disclose genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determining eligibility, setting premiums, or creating, renewing or replacing a health plan.

(b) Prohibition on Collection of Genetic Information—

(1) In General—A health insurance issuer shall not request, require, or purchase genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determining eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage under the plan or for health insurance or benefits.

(2) Limitation Relating to the Collection of Genetic Information Prior to Enrollment—A health insurance issuer shall not request, require, or purchase genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) concerning a participant, beneficiary, or enrollee prior to the enrollment, and in connection with such enrollment, of such individual under the coverage.

(3) Incidental Collection—Where a health insurance issuer obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning an individual, such request, requirement, or purchase shall not be considered a violation if it is not obtained for purposes of underwriting as defined under paragraph (1) and any genetic information obtained incidentally is not used or disclosed in violation of the HHS medical privacy regulations.

(c) Application of Confidentiality Standards—The requirements of this section apply only to health insurance issuers that are otherwise covered under the HHS medical privacy regulations. Therefore, the health plan exceptions contained in the medical privacy regulations also apply with respect to the requirements under this section. The requirements of this section do not apply to genetic information that is not considered to be individually-identifiable under HHS medical privacy regulations.

(d) Coordination with Privacy Regulations—The Secretary of HHS shall implement and administer this section in a manner that is consistent with the medical privacy regulations.

Section 104A(b). Application to Medicare supplemental policies

This section amends section 1882 of the Social Security Act by adding a new section (x):

(x) Privacy and Confidentiality of Genetic Information.

(1) Compliance with Certain Confidentiality Standards with Respect to Genetic Information—The regulations established by the Secretary in part C of title XI of the Social Security Act and section 264 of HIPAA shall apply to the use or disclosure of genetic information in by an issuer of a medicare supplemental policy. An issuer of a medicare supplemental policy shall not use or disclose genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determining eligibility, setting premiums, or creating, renewing or replacing a plan, contract or coverage.

(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 (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determining eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage.

(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 (including information about a request for or a receipt of genetic services by an individual or family member of such individual) concerning an enrollee prior to the enrollment, and in connection with such enrollment, of such individual under the policy.

(C) Incidental Collection—Where the 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 if it is not obtained for purposes of underwriting as defined under paragraph (1) and any genetic information obtained incidentally is not used or disclosed in violation of the HHS medical privacy regulations.

(3) Application of Confidentiality Standards—The requirements of this section apply only to health insurance issuers that are otherwise covered under the HHS medical privacy regulations. Therefore, the health plan exceptions contained in the medical privacy regulations also apply with respect to the requirements under this section. The requirements of this section do not apply to genetic information that is not considered to be individually-identifiable under HHS medical privacy regulations.

(d) Coordination with Privacy Regulations—The Secretary of HHS shall implement and administer this section in a manner that is consistent with the medical privacy regulations.

Section 105. Assuring coordination

Section 105 states that the Secretaries of Health and Human Services, Labor and Treasury shall ensure, through the execution of an interagency memorandum of understanding, that regulations, rulings, and interpretations are administered to have the same effect when there are two or more agencies of jurisdiction. Such Secretaries shall pursue coordinated enforcement strategies and assign priorities in enforcement.

Section 106. Relationship to title II with respect to enforcement

Section 106 states that the requirements of title I apply to group health plans; health or other insurance coverage issued in connection with group health plans, individual health insurance coverage, and medicare supplemental policies. Nothing in title II shall affect these entities.

Section 107. Regulations; effective date

Section 107 states that no later than one year after the date of enactment, the Secretaries of HHS, Labor and Treasury shall issue final regulations. The amendments made by this title shall take effect 18 months after enactment, except as provided in section 103.

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

Section 201. Definitions

Section 201 defines the term Commission and the parties covered by the act—employee, employer, employment agency, labor organization, member—and ensures that State, Federal and congressional employees receive the same protections as other employees who are covered by this act. Family members are defined as the spouse or dependent child of an individual, including a child who is born to or placed for adoption with the individual, and all other individuals related by blood to the individual or his/her spouse. Genetic information is defined as information about genetic tests of an individual or his/her family member. Genetic information also means information about the occurrence of disease or disorder in family members of the individual. It does not, however, include information about the sex or age of an individual. Genetic monitoring is defined as the periodic examination of employees to evaluate acquired modifications to their genetic material that may have occurred during employment. Genetic test is defined as the analysis of human DNA, RNA, chromosomes, proteins, or metabolites for certain reasons. It does not, however, include analysis that does not detect genotypes, mutations, or chromosomal changes. The section defines genetic services consistent with title I.

Section 202. Employer practices

Section 202 makes it unlawful for an employer to request, require or purchase genetic information. Several specific exceptions are included: where an employer inadvertently requests or requires family medical history information; pursuant to an employer-sponsored wellness program; where the information relating to a family member is requested or required to comply with the certification provisions of Federal or State family and medical leave laws; where an employer purchases family medical history information that is publicly available through such items as newspapers, periodicals and books; or where the information is used for genetic monitoring of the biological effects of toxic substances in the workplace. Despite lawful acquisition of the information through these exceptions, the section makes clear that the employer still may not use or disclose the information in violation of the title.

Section 203. Employment agency practices

Section 203 extends parallel obligations and exceptions to employment agencies as apply to employers under section 202.

Section 204. Labor organization practices

Section 204 extends parallel obligations and exceptions to labor organizations as apply to employers under section 202.

Section 205. Training programs

Section 205 extends parallel obligations and exceptions to joint labor-management committees as apply to employers under section 202.

Section 206. Confidentiality of genetic information

Section 206 provides that an individual's genetic information shall be treated and maintained as part of the individual's confidential medical records. The information shall be maintained on separate forms and in separate medical files.

Disclosure is prohibited, except to: the individual; an occupational or health researcher; in response to an order of a court; to government officials investigating compliance with this title; or to the extent that disclosure is made in connection with the employee's compliance with the certification provisions of section 103 of the Family and Medical Leave Act, or such requirements under State family and medical leave laws.

This section also states that HIPAA-covered entities will remain covered by HIPAA. Non-HIPAA covered entities will be covered by this Act.

Section 207. Remedies and enforcement

Section 207 incorporates by reference the powers, remedies, and procedures set forth in title VII of the Civil Rights Act of 1964, as amended. Similar powers, remedies and procedures are specified for State, Federal and congressional employees.

Section 208. Disparate impact

Section 208 prohibits claims based on disparate impact, and establishes a commission to review the science of genetics and make recommendations to Congress regarding whether to provide a disparate impact cause of action under the Civil Rights Act of 1964.

Section 209. Construction

Section 209 provides several rules of construction to clarify the intent of the Committee and to assist courts in interpreting the title. The section makes clear that this title shall not be construed to limit the rights or protections of individuals under the Americans with Disabilities Act or the Rehabilitation Act of 1973. Similarly, the section clarifies that title II does not create violations for employers, employment agencies, labor organizations, or joint labor-management committees of provisions under title I; section 106 also relates to this issue. The section clarifies that the Act sets the floor for individual rights and protections and does not limit the rights and protections under other Federal or State laws. Workers compensation laws are neither expanded nor restricted by the bill. Finally, the section provides rules of construction to ensure the proper operation of Federal programs and laws, including the Armed Services Repository of Specimen Samples, occupational health and safety research, and workplace safety and health laws and regulations.

Section 210. Medical information that is not genetic information

Section 210 makes clear that the Act does not extend to manifested diseases and illnesses.

Section 211. Regulations

Section 211 states that not later than one year after the date of enactment of this title, the Genetic Nondiscrimination Study Commission shall issue final regulations to carry out this title.

Section 212. Authorization of appropriations

Section 212 authorizes the appropriation of such sums as may be necessary to carry out this title, except for section 208.

Section 213. Effective date

Section 213 states that this title takes effect 18 months after the date of enactment.

Title III—Miscellaneous

Section 301. Severability

Section 301 states that if any provision of this Act is held to be unconstitutional, the remainder of the Act shall not be affected thereby.

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) * * *

* * * * * * *

(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 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).

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PART 7—GROUP HEALTH PLAN REQUIREMENTS

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

* * * * * * *

SEC. 702. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.

(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 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).

(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 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).

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SUBPART C—GENERAL PROVISIONS

* * * * * * *

SEC. 733. DEFINITIONS.

(a) * * *

* * * * * * *

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

(1) * * *

* * * * * * *

(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 (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.

* * * * * * *

PUBLIC HEALTH SERVICE ACT

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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 PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.

(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 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).".

(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) Certain rules 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 individual undergo a genetic test.

(3) Rule of construction regarding payment.—

(A) In general.—Subject to subparagraph (B), nothing in paragraph (1) shall be construed to preclude a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, from conditioning payment on obtaining the results of a genetic test or informing members of such policies. For purpose of the preceding sentence, the term "payment" includes reimbursement, billing, claims management, claims adjudication, review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges, and utilization review (including precertification, prior authorization, concurrent and retrospective review).

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

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

(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).

(e) GENETIC INFORMATION OF A FETUS OR EMBRYO.—Any reference in this section to genetic information concerning an individual or family member of an individual shall—

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

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

SEC. 2703. PRIVACY AND CONFIDENTIAL OF GENETIC INFORMATION.

(a) COMPLIANCE WITH CERTAIN CONFIDENTIALITY STANDARDS WITH RESPECT TO GENETIC INFORMATION.—

(1) IN GENERAL.—The regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) shall apply to the use or disclosure of genetic information by a group health plan or by an health insurance issuer in connection with health insurance coverage offered in connection with a group health plan.

(2) PROHIBITION ON UNDERWRITING AND PREMIUM RATING.—Notwithstanding paragraph (1), a group health plan or a health insurance issuer (in connection with health insurance coverage offered in connection with a group health plan) shall not use or disclose genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determinations of eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or health benefits.

(b) PROHIBITION ON COLLECTION OF GENETIC INFORMATION.—

(1) IN GENERAL.—A group health plan or health insurance issuer (in connection with health insurance coverage offered in connection with a group health plan) shall not request, require, or purchase genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determinations of eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or health benefits.

(2) LIMITATION RELATING TO THE COLLECTION OF GENETIC INFORMATION PRIOR TO ENROLLMENT.—A group health plan or health insurance issuer (in connection with health insurance coverage offered in connection with a group health plan) shall not request, require, or purchase genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) concerning a participant, beneficiary, or enrollee prior to the enrollment, and in connection with such enrollment, of such individual under the plan or coverage.

(3) INCIDENTAL COLLECTION.—Where a group health plan or health insurance issuer (in connection with health insurance coverage offered in connection with a group health plan) obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning a participant or beneficiary, such request, requirement, or purchase shall not be considered a violation of this subsection if—

(A) such request, requirement, or purchase is not in violation of paragraph (1); and

(B) any genetic information (including information about a request for or receipt of genetic services) requested, required, or purchased is not used or disclosed in violation of subsection (a).

(c) APPLICATION OF CONFIDENTIALITY STANDARDS.—The provisions of subsections (a) and (b) shall not apply—

(1) to group health plans or health insurance issuers that are not otherwise covered under the regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note); and

(2) to genetic information that is not considered to be individually-identifiable health information under the regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

(d) COORDINATION WITH PRIVACY REGULATIONS.—The Secretary shall implement and administer this section in a manner that is consistent with the implementation and administration by the Secretary of the regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

* * * * * * *

Subpart 4—Exclusion of Plans; Enforcement; Preemption

SEC. 2721. EXCLUSION OF CERTAIN PLANS.

(a) EXCEPTION FOR CERTAIN SMALL GROUP HEALTH PLANS.—The requirements of subparts 1 and 3 *(other than section 2703)* shall not apply to any group health plan (and health insurance coverage offered in connection with a group health plan) for any plan year if, on the first day of such plan year, such plan has less than 2 participants who are current employees.

(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 subparts 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 or section 2701 or 2702(b)(1) with respect to genetic information.

(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—

(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 EXERCISING REASONABLE DILIGENCE.—No penalty shall be imposed by subparagraph (A) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such penalty did not know, and exercising reasonable diligence would not have known, that such failure existed.

(ii) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN CERTAIN PERIODS.—No penalty shall be imposed by subparagraph (A) on any failure if—

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

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

(iii) OVERALL LIMITATION FOR UNINTENTIONAL FAILURES.—In the case of failures which are due to reasonable cause and not to willful neglect, the penalty imposed by subparagraph (A) for failures shall not exceed the amount equal to the lesser of—

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

(II) $500,000.

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

* * * * * * *

SEC. 2744A. PRIVACY AND CONFIDENTIALITY OF GENETIC INFORMATION.

(a) COMPLIANCE WITH CERTAIN CONFIDENTIALITY STANDARDS WITH RESPECT TO GENETIC INFORMATION.—

(1) IN GENERAL.—The regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) shall apply to the use or disclosure of genetic information by an health insurance issuer in connection with individual health insurance coverage.

(2) PROHIBITION ON UNDERWRITING AND PREMIUM RATING.—Notwithstanding paragraph (1), a health insurance issuer shall not use or disclose genetic information (including information about a request for or a receipt of genetic services by an indi-

vidual or family member of such individual) for purposes of underwriting, determinations of eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or health benefits in the individual market.

(b) PROHIBITION ON COLLECTION OF GENETIC INFORMATION.—

(1) IN GENERAL.—A health insurance issuer shall not request, require, or purchase genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determinations of eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or health benefits in the individual market.

(2) LIMITATION RELATING TO THE COLLECTION OF GENETIC INFORMATION PRIOR TO ENROLLMENT.—A health insurance issuer offering health insurance coverage in the individual market shall not request, require, or purchase genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) concerning an enrollee prior to the enrollment, and in connection with such enrollment, of such individual under the coverage.

(3) INCIDENTAL COLLECTION.—Where a health insurance issuer obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning an enrollee in the individual market, such request, requirement, or purchase shall not be considered a violation of this subsection if—

(A) such request, requirement, or purchase is not in violation of paragraph (1); and

(B) any genetic information (including information about a request for or receipt of genetic services) requested, required, or purchased is not used or disclosed in violation of subsection (a).

(c) APPLICATION OF CONFIDENTIALITY STANDARDS.—The provisions of subsections (a) and (b) shall not apply—

(1) to health insurance issuers that are not otherwise covered under the regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note); and

(2) to genetic information that is not considered to be individually-identifiable health information under the regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

(d) COORDINATION WITH PRIVACY REGULATIONS.—The Secretary shall implement and administer this section in a manner that is consistent with the implementation and administration by the Secretary of the regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and

section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

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PART B—INDIVIDUAL MARKET RULES

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Subpart [3] *2*—Other Requirements

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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) PROHIBITION ON GENETIC INFORMATION AS PREEXISTING CONDITION.—A health insurance issuer offering health insurance coverage in the individual market may not, on the basis of genetic information (including information about a request for or receipt of genetic services by an individual or family member of such individual), impose any preexisting condition exclusion (as defined in section 2701(b)(1)(A)) with respect to such coverage.

(d) GENETIC TESTING.—

(1) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—A health insurance issuer offering health insurance coverage in the individual market shall not request or require an individual or a family member of such individual to undergo a genetic test.

(2) CERTAIN RULES 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.

(3) RULE OF CONSTRUCTION REGARDING PAYMENT.—

(A) IN GENERAL.—Subject to subparagraph (B), nothing in paragraph (1) shall be construed to preclude a health insurance issuer offering health insurance coverage in the individual market from conditioning payment on obtaining the results of a genetic test or informing members of such policies. For purpose of the preceding sentence, the term "payment" includes reimbursement, billing, claims management, claims adjudication, review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges, and utilization review (including precertification, prior authorization, concurrent and retrospective review).

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

(e) GENETIC INFORMATION OF A FETUS OR EMBRYO.—Any reference in this section to genetic information concerning an individual or family member of an individual shall—

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

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

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.

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PART C—DEFINITIONS; MISCELLANEOUS PROVISIONS

SEC. 2791. DEFINITIONS.

(a) * * *

* * * * * * *

(d) OTHER DEFINITIONS.—

(1) * * *

* * * * * * *

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

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

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

(16) GENETIC INFORMATION.—

(A) IN GENERAL.—The term "genetic information" means 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) 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 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.

SOCIAL SECURITY ACT

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

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TITLE XVIII OF THE SOCIAL SECURITY ACT

PART E—MISCELLANEOUS PROVISIONS

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CERTIFICATION OF MEDICARE SUPPLEMENTAL HEALTH INSURANCE POLICIES

SEC. 1882. (a) * * *

* * * * * * *

(o) The requirements of this subsection are as follows:

(1) * * *

* * * * * * *

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

* * * * * * *

(s)(1) * * *

(2)(A) * * *

* * * * * * *

(E)(i) An issuer of a medicare supplemental policy shall not deny or condition the issuance or effectiveness of the policy, and shall not discriminate in the pricing of the policy (including the adjustment of premium rates) of an eligible individual on the basis of genetic information concerning the individual (or information about a request for, or the receipt of, genetic services by such individual or family member of such individual).

(ii) For purposes of clause (i), the terms "family member", "genetic services", and "genetic information" shall have the meanings given such terms in subsection (x).

* * * * * * *

(x) LIMITATIONS ON GENETIC TESTING.—

(1) GENETIC TESTING.—

(A) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—An issuer of a medicare supplemental policy shall not request or require an individual or a family member of such individual to undergo a genetic test.

(B) RULE OF CONSTRUCTION.—Nothing in this title shall be construed to—

(i) 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;

(ii) limit the authority of a health care professional who is employed by or affiliated with an issuer of a medicare supplemental policy 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

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

(2) DEFINITIONS.—In this subsection:

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

(i) the spouse of the individual;

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

(iii) any other individuals related by blood to the individual or to the spouse or child described in clause (i) or (ii).

(B) GENETIC INFORMATION.—

(i) IN GENERAL.—Except as provided in clause (ii), 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.

(ii) 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); or

(iii) genetic education.

(E) 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.

(y) PRIVACY AND CONFIDENTIALITY OF GENETIC INFORMATION.—

(1) COMPLIANCE WITH CERTAIN CONFIDENTIALITY STANDARDS WITH RESPECT TO GENETIC INFORMATION.—

(A) IN GENERAL.—The regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) shall apply to the use or disclosure of

genetic information by an issuer of a medicare supplemental policy.

(B) PROHIBITION ON UNDERWRITING AND PREMIUM RATING.—Notwithstanding subparagraph (A), an issuer of a medicare supplemental policy shall not use or disclose genetic information (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determinations of eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or health benefits in connection with such policy.

(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 (including information about a request for or a receipt of genetic services by an individual or family member of such individual) for purposes of underwriting, determinations of eligibility to enroll, premium rating, or the creation, renewal or replacement of a plan, contract or coverage for health insurance or health benefits in connection with such policy.

(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 (including information about a request for or a receipt of genetic services by an individual or family member of such individual) concerning an enrollee prior to the enrollment, and in connection with such enrollment, of such individual under the policy.

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

(i) such request, requirement, or purchase is not in violation of subparagraph (A); and

(ii) any genetic information (including information about a request for or receipt of genetic services) requested, required, or purchased is not used or disclosed in violation of paragraph (1).

(3) APPLICATION OF CONFIDENTIALITY STANDARDS.—The provisions of paragraphs (1) and (2) shall not apply—

(A) to health insurance issuers that are not otherwise covered under the regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note); and

(B) to genetic information that is not considered to be individually-identifiable health information under the regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and sec-

tion 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

(4) COORDINATION WITH PRIVACY REGULATIONS.—The Secretary shall implement and administer this subsection in a manner that is consistent with the implementation and administration by the Secretary of the regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

* * * * * * *

ADDITIONAL VIEWS

Although the Committee has made important improvements to H.R. 493, the "Genetic Information Non-Discrimination Act" (GINA), we believe it is imperative that all parties continue to work to improve this legislation and address the issues we raise in these additional views. We believe there are significant technical problems with the legislation in its current form. We respect the changes and the work of the Committee in the short period of time from the hearing to full committee markup. We note the inclusion of information on embryos, fetuses, and adopted children; a clear statement that Title II does not apply to group health plans and insurers; a clear statement that nothing affects claims processing and related items; and, an exemption from the unworkable Title II mandates for entities already subject to regulations governing personally identifiable health information. Among other things we believe these changes should be consistent with group health plans and health insurance issuers providing information to providers or individuals about genetic tests for coverage and benefits, treatment alternatives, disease management, case management, patient care management, care coordination and prevention programs. These programs are today improving the quality of health care and nothing in this bill should undermine such efforts. These are solid steps in the right direction,

The primary author of the House bill, Ms. Slaughter, has stated:

> GINA prohibits group health plans and health insurers from denying coverage to a healthy individual or charging that person higher premiums based solely on a genetic predisposition to develop a disease in the future. Furthermore, it bars employers from using an individual's genetic information when making hiring, firing, job placement or promotion decisions.

We want to focus the legislation on these objectives and not go beyond them. The drafting simply does not match, or at least is not tailored to, the statement of the primary sponsor. The legislation, in its current form, will needlessly disrupt and hinder positive activities and policies for employers, insurers and health care. These are not easy issues. The protagonists of GINA have delved into some sweeping and difficult arenas: the ability to define and segregate "genetic information" from other medical information, new permutations of civil rights laws, new restrictions on health information, occupational safety issues, and Federal-State relations are among them. We think the suggestions we make below could be very helpful.

The New Regulatory Regime in Title II for the Delivery of Health Care and Related Services That May Be Offered by or Sponsored by Employers is Inappropriate

CONCERNS REGARDING DELIVERY OF HEALTH CARE

Title III of GINA would launch a new health information regulatory scheme that would be administered out of the Equal Employment Opportunities Commission. Our understanding is this scheme would cover, in part, the communications of certain health care providers or companies providing electronic health record services. Specifically, if an employer is providing a health service or electronic record service, the provisions of Title II of GINA attach. Providing a service includes both in-house employees and contracts with other entities.

We fail to see why covering the delivery of health care and health services in Title II has anything to do with hiring, firing, job placement or promotion decisions. People delivering health care and health services are not hiring or firing people. Health information, including genetic information is critical to the delivery of care. If a company is providing a personal health record service it is technically problematic and detrimental to the patient to sanitize information like family medical history or other genetic information.

Here are the potential problems:

1. GINA provides that the medical decisions of certain health care providers in using genetic information can be a basis for a civil rights violation. That means the practice of medicine may be subject to claims of discrimination, even though they have nothing to do with hiring, firing, job placement or promotion.
2. Under section 202(b), 202(c) and 206(b) the communications in the process of health services are restricted well above what is appropriate under the extensive privacy regulations governed by the Department of Health and Human Services.
3. These restrictions will inhibit the coordination of care among health providers, slow down processing and care because of the need to evaluate each document to sanitize or specially handle information, and increase medical errors.
4. These restrictions will essentially make employer participation in electronic health record services and personal health record services extremely burdensome. Indeed, contracting with a company to provide such services for employees is covered under the information restrictions of Title II.
5. This health information regulatory regime would be inconsistent with the regime run by the Department of Health and Human Services.

We should not penalize the good that employers can do for their employees by providing health care services or electronic health record services. Sponsorship of the delivery of health care by an employer is not hiring, firing, job placement or promotion. And genetic information is important to the delivery of health care. We believe nothing in Title II should apply to the actions or communication respecting the delivery, administration, or operation of health care including any health services, pharmacies, health records services, health counseling, or health education. We also believe that nothing in either title should regulate actions or communications respecting the practice of medicine including but not limited to diagnosis, treatment, counseling and education. These activities clearly fall outside the scope of the author of GINA's stated intent. We would like to work with all parties and craft language that makes these points clear.

We are pleased at the amendments in Full Committee that would exempt covered entities within the meaning of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule from the unworkable mandates of Title II. This helps with respect to the concerns we raise in a number of instances, but not in others.

We have heard specific concerns regarding the application of sections 202(b) and 206(b) and the broad definitions and prohibitions as they might restrict or delay further adoption of electronic health records and personal health records.

We note that the exclusion for HIPAA covered entities is helpful but will not fully address the issues. We fear these points are just the tip of the iceberg. We see no reason that the delivery of health care should be regulated or restricted by Title II. These issues have nothing to do with Ms. Slaughter's stated purpose concerning making hiring, firing, job placement or promotion decisions. However, the current bill could drastically impede a much shared goal to transform our health care system through utilization of electronic health records.

The Information Regulations in Title II Are Overly Broad and Unworkable

A SWEEPING NEW REGULATORY SCHEME

Title II has sweeping breadth. It covers employers from the FBI to NASA to laboratories, to State and local governments, to nuclear power plants, to hospitals, and many more. Title II restricts information flow in numerous settings from employers involved in responses to pandemic flu outbreaks, to employers involved in judicial proceedings, to health and safety monitoring, and to employers administering or sponsoring benefits. We cannot today easily imagine all of the circumstances. The HIPAA Privacy Rule gives us a clue to this complexity. It is a complex series of extensively debated exceptions to prohibited uses and disclosures of information. The proposed rule received over 50,000 comments and the next proposed set of modifications received over 11,000 comments. Among other things, this draft document will point out below how section 202(b) and 206 and other provisions of GINA fail to include the numerous exclusions for use and disclosure that HHS had to address in the Privacy Rule. The Americans with Disabilities Act also has information regulations with respect to disability related inquiries and medical examinations. Rather than use the knowledge from either of these two models, GINA strikes out on a third, unworkable scheme. The biggest problem is that subsections like 202(b), 203(b), 204(b) and 206(b) start with sweeping prohibitions on either acquisition or disclosure of information. These subsections then follow with exactly five specific exemptions. Note that these exemptions are not even coextensive between subsections 202(b) and 206(b).

Based on this statutory structure, it may be impossible for the Equal Employment Opportunities Commission to argue that it could add to the list of statutory exemptions. Accordingly, the authors of GINA must assume Congress has contemplated all reasonable circumstances for acquisition and disclosure by employers or sponsored activities and set them out in the exemptions. Although the Privacy Rule starts out with bans on use and disclosure, there are dozens of important exceptions. For example, if you were to work with a contract organization to manage records, that would fall under the business associate provisions of the rule. Even disclosures for civil and criminal litigation, law enforcement, to heirs of decedents, for serious threats to health and safety, essential government functions, incidental uses, workers compensation, treatment, payment, health care operations all have specific exceptions. These exceptions are not in GINA. We are not saying all of the Privacy Rule map perfectly to the employer context. (We are saying that for delivery of health care). However, many of the Privacy Rule's permitted uses and disclosures include normal and routine uses and disclosures, including those important for the public good. These would seem to make sense and be necessary within the context of GINA.

EXAMPLES IN THE LAW ENFORCEMENT AND JUDICIAL SETTINGS

Moreover, even where GINA has exemptions they are not always logical. Consider this concern voiced in technical assistance from the FBI:

> Section 206, subpart (b)(3), permits an employer to provide genetic information concerning an employee or a request by the employee for genetic services in response to a court order ONLY after providing notice to the employee of the court order and permitting the employee to challenge the order. It doesn't distinguish between civil cases and criminal cases, or those situations in which the court order may require that the recipient not disclose the order. The section also does not describe how the recipient employer is supposed to handle notice if the employee no longer works for their company, or has moved from their last address known to the employer, or has died.

These are valid considerations. In fact, we are wondering why GINA would in any way suggest anything other than full compliance with a court order. And why would GINA impose a duty of notice concerning such an order to an employer. Notice to the employee to challenge any order should come through the court.

In fact, when compared with GINA, the HIPAA Privacy Rule permits disclosures pursuant to warrants, subpoenas and administrative orders. GINA does not. Is GINA forbidding response to such orders? The Privacy Rule would allow a covered entity to respond to the request of law enforcement officials for blood type information. As discussed below, blood typing seems to "detect a genotype" within the meaning of the GINA definitions. Why should GINA be more restrictive with respect to law enforcement and judicial proceedings that the current HIPAA regulations?

Some employers use DNA identification tests, which appear to be covered by the GINA definitions. For example, labs and some policy enforcement organizations may take DNA samples to help unravel contamination issues at labs or crime scenes. Some employers provide for medical monitoring programs to protect against injuries to employees. We received the following technical assistance from FBI:

> Section 201. Recommend narrowing the definition of "genetic test" to the following, and to strike the subsection on Exceptions:
>
> The term "genetic test" means—the analysis of human DNA, RNA, chromosomes, proteins, or certain metabolites in order to detect disease-related genotypes or related phenotypes. The term does not apply to any such testing which is conducted for the exclusive purposes of identification, where no information regarding the sample is to be provided to any entity for the purposes of determining any health related information regarding either the individual or members of the individual's family.

We received this point as technical assistance from staff in the Bureau of Alcohol, Tobacco, and Firearms (ATF):

> ". . . . Please let me know if there is anything we in the forensic DNA community can do to aid in the modification of this bill so it will not have the unintentional effects that it may have as written. I have outlined my concerns below. . . .
>
> Forensic DNA technology has progressed to the point that it is possible to obtain a DNA profile from handled objects or even a fingerprint. Because of this, most forensic DNA labs have created a staff DNA index. Any DNA profiles developed from evidence are then compared to the staff index. This accomplishes two things. First, if the DNA profile developed from the evidence is actually from an investigator or laboratory person and not the true perpetrator, a false exclusion might be made. Second, unknown profiles developed from evidence are typically uploaded to the Combined DNA Index System (CODIS). If the investigator's profile or laboratory scientist's profile is not caught through the use of a staff index, the profile would be uploaded to CODIS. If it happens again, two unrelated crimes could subsequently linked that are not truly linked."

We received this point as technical assistance from the staff of the Veterans Administration:

> This section does not authorize disclosure in administrative or court proceedings in which the employee has either placed the genetic condition at issue or raised a claim for which the information is clearly relevant. It would appear that VA, as an employer, could not provide the records to an administrative entity upon its request or order without first obtaining a Federal court order to produce the information.

EXAMPLES FOR HEALTH AND SAFETY MONITORING ISSUES

Beyond these judicial and law enforcement issues are safety issues:

Mr. Deal asked the witness from the EEOC the following question:

> We want your interpretation of section 202(b)(5)(B). Assume that genetic monitoring is not required by Federal or state law. The business nonetheless feels that safety requires such monitoring. If the employee says he does not want to be subject to such monitoring, does the employer still have the right to reassign him away from the position that needed the monitoring? Or must the employer allow the employee to continue without the monitoring?

Our understanding is the EEOC witness stated that reassigning an employee who refuses to provide information for monitoring described above would be subject to a claim of an illegal employer practice under GINA. This is a problem. Why would we take away from employers the ability to demand monitoring for worker safety?

We further note that the definition of acceptable genetic monitoring is only in the context of exposure at the work place. If an employer is monitoring for infectious diseases to protect public safety, such monitoring does not seem to have an exception to allow consideration of genetic information in that context.

WAYS TO REDUCE THE PROBLEMS

All of the above pieces of technical assistance, letters, or testimony identify unexpected problems with the prohibitions on acquisition and disclosure. We believe these are just the tip of the iceberg. The EEOC has provided some technical assistance that might provide for regulatory authority to create additional exemptions. In addition, employer stakeholders have been asking Congress to not use language like that in subsections 202(b) or 206(b). Employers note the model under the Americans with Disabilities Act is familiar to them and more workable. It seems entirely possible to use language similar to that under the ADA provisions to make this law consistent. Until there are changes to these sections, GINA poses many counterproductive results. We would like to work with all parties to eliminate these counterproductive results.

GINA Contains Inconsistent, Overly Broad and Unworkable Definitions of Genetic Test and Genetic Information

The terms genetic test and genetic information are overly broad in GINA. The definitions are inconsistent between titles and not matched to the policy purpose. Forty-three states have definitions. None of the state definitions are as broad or as unworkable as the definitions in GINA. GINA simply includes information well beyond tests intended to find a predictive genetic marker for a genetic disease. Title II of GINA covers blood typing, tissue typing, cancer tumor typing, DNA forensic information, genotypic information useful to reduce adverse reactions to treatments and therapies, and more. The definition of genetic information includes “the occurrence of a disease in a family member"—even when not used for predictive purposes.

Apparently, if we were to ask one of our staff how one of their children were doing with the flu or other disease, we would be requesting genetic information within the meaning of GINA. Apparently, if an employer is testing for drugs but that test also detects the blood type AB in an employee, that test detected a genotype and would be subject to the sanctions of this bill.

It is not alright to subject employers to vague and unworkable standards and levy the threat of sanctions for civil rights violations against them. The current language of this bill could have serious negative consequences to both the individual and public health by saddling health and safety monitoring, electronic health information systems, health care providers, emergency preparedness efforts, claims processing for workers compensation and many other items with the burden of separating legitimate medical information into two file folders.

As Dr. Francis Collins testified, genetic information is basically medical information. To treat it under a separate regulatory regime for items such as medical monitoring for employee safety or employee sponsored health services will remove vital information for vital purposes. This will create medical errors and needless bureaucracy.

PROBLEMS WITH THE SWEEP OF INCLUDING THE OCCURRENCE OF A DISEASE OR DISORDER IN FAMILY MEMBERS WITHOUT FURTHER LIMITATION OR CLARIFICATION

On the point concerning "the occurrence of a disease or disorder in a family member", under subsection 202(b) an employer may not request or require such information, unless pursuant to a specific exception. We realize that the occurrence of a disease or disorder could be part of a scheme to forecast a genetic disease in an employee. It is also useful information for many other purposes. We believe that the basic intent of the authors is to regulate a predictive assessment concerning an individual's propensity to get an inheritable genetic disease or disorder based on the occurrence of an inheritable genetic disease or disorder in the family member. After all, if an employer or insurer is not trying to make such a predictive assessment, they really are not within the scope of the policy purpose of the bill. By using the broader universe of information concerning "a disease or disorder in a family member" GINA opens up an incredible range of workability problems. Note that "a disease or disorder" does not have to be a genetic disease or disorder. It could just be a cold or a disease that came from poisoning.

If an employer sponsors a benefit for an employee to raise money for the employee's child's illness that employer seems to have violated both subsection 202(b) and 206(b). What if an employer wants information from an employee as back up for a worker absence that is not pursuant to the Family Medical Leave Act? What happens if an employer employs several family members. Does the "occurrence of a disease or disorder" language apply to each employee? If so, would record keeping on employee absences not be acceptable.

What if there are issues about infectious diseases? Under the National Pandemic Flu Preparedness Plan, employers would play a key role in information dissemination and assessment of the spread of the disease. There are no exceptions for such emergencies under GINA.

All of these problems would be unnecessary if the language were restricted to a predictive assessment concerning an individual's propensity to get an inheritable genetic disease or disorder based on the occurrence of an inheritable genetic disease or disorder in the family member.

NUMEROUS INCONSISTENCIES WITHIN THE BILL

On the definition of genetic test, we point out that the definitions are, for no apparent reason, different in Title I and Title II. In conjunction with this we note the treatment of manifested diseases and how they affect regulation are also different in Title I and Title II for no apparent reason. We further note that the treatment of tests which identify genotype, mutation, or chromosomal changes, based on protein or metabolite analysis in the context of manifested diseases are excluded under Title I. Yet a test which identifies the same things based on DNA or chromosome analyses are not excluded for purposes of Title I. There is no manifested disease exclusion in the definitions in Title II. This means some tests that can type a cancer tumor fall into one regulatory category and others do not. And this is all just in one bill. Please understand this bill will partially override 43 State definitions of genetic tests and genetic information creating maximum confusion.

FAILURE TO LIMIT DEFINITION TO GENETIC MARKERS FOR GENETIC DISEASES

Under GINA, the term 'genetic test' means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes. Francis Collins, head of the National Human Genome Research Institute said the GINA reference to detecting a genotype covered, among other things, tests to look at genetic profiles to select safer drugs, forensic DNA identification tests, tissue typing for organ donation; and paternity tests. He stated that the fact that someone has an O or AB blood type also detects that person has the O or AB genotype. He also made clear that certain DNA tests for tumor typing of cancer are covered by the definition. He further stated that the phrase "occurrence of a disease or disorder in family members of the individual" was not limited to inheritable genetic disease and that this might include infectious or contagious diseases of family members. We have tried to review definitions of genetic information or test under state laws. None of them have the breadth of the GINA definitions.

As confirmed by Committee Counsel during the markup we do not read any requirement that the detection of "genotypes" within this paragraph is limited to genotypes related to genetic diseases, disorders or pathological conditions. Our further concern is that more and more clinical diagnostics will "detect a genotype" in at least one part of the analysis. This may be true even if it is not the purpose of the test to look for genetic markers for disease. It may also be true if the basic purpose of the test is not to look for a blood type. Yet if the test detects a blood type, it would appear to be covered by the GINA definitions. This means a tremendous level of basic information is not defined as a genetic test or genetic information well beyond the core purposes of the bill.

We remain unclear on how tests for the effects of viruses or pathogens might fit in to GINA. Some types of viruses actually physically insert their genes into the host's genome (it is the defining feature of retroviruses, the family of viruses that includes HIV, the virus that causes AIDS). This incorporates the genes of that virus among the genes of the host cell for the life span of that cell. Beyond this some viruses, such as the Hepatitis C virus, also add material to human chromosomes or DNA.

We believe there may be analyses of human DNA, RNA, chromosomes, proteins, or metabolites that provide direct evidence of retroviruses or other viruses. These analyses may be construed to detect a human chromosomal change or mutation. We recognize the insertion into the human chromosome or mutation to DNA is, in part, an insertion of viral DNA. There nonetheless appears to be a change in the sequence of the human DNA, genotype or chromosome. We want to know whether the phrase "detects a genotype, mutation, chromosomal change" could refer to such mutations and chromosomal changes in humans caused by such viruses. If it can we have further concerns about the effect of this legislation with respect to health and safety monitoring and employer precautions.

Again, Ms. Slaughter's stated concern was discrimination "based solely on a genetic predisposition to develop a disease in the future." This would be consistent with the language in Executive Order 13145 which was limited to tests done "in order to detect disease-related genotypes or mutations." In the 108th Congress, Ms. Slaughter's bill exempted from the definition of protected genetic information any "information about physical exams of the individual and other information that indicates the current health status of the individual." This is a very useful exception. It's just not in GINA. We keep asking, what do DNA forensic evidence, blood typing, tissue typing, cancer tumor typing, or pharmacogenomics have to do with predicting a genetic disease?

The downsides of the inconsistent and overly broad definitions are many. Employers and employer sponsored benefit programs will have several information regimes for medical information. GINA force separation of such information which will be a bureaucratic nightmare, lead to medical errors, create inconsistencies in communications with providers, limit medical monitoring, create confusion in law enforcement and judicial functions. If important information related to viruses or contagious diseases are also covered, we may be compromising the ability of an employer to help in public safety efforts or to protect the public's health and safety. We would not want to see medical monitoring for infectious diseases precluded from an employers tool box for instances where public health and safety is at stake.

The discouraging part of this is that the 43 states that have definitions do not have these problems. They all limit regulations to genetic markers that predispose toward a future disease. Many specifically refer to inherited genetic material. Many have specific exceptions for items like HIV testing or drug and alcohol tests. Despite these problems we have been met with a seeming unwillingness from the protagonists to address any of these issues. We hope that is not the case.

GINA Will Create Confusion for the 43 States That Currently Have Laws Prohibiting Discrimination Based on Genetic Information

We have not done a complete survey but understand that 43 States already have programs and definitions. We would then want to ask Members if they find the programs in their state inadequate. If you were to superimpose the GINA requirements on those states it will involve a lot of confusion. Many exemptions and clear statements regarding HIV testing, drug testing, and other issues would appear to be wiped out. Even more frustrating for the regulatory community the operative Federal-state relationship rule is whatever part of a state law is more stringent survives. This means pieces of state law will apply while other pieces will be preempted. This would all have to be sorted out by the courts. We think there are better approaches. The worst approach is this partial preemption approach. For some programs there is across the board preemption. In other cases, a state is allowed to submit its program for evaluation as a whole. If such programs are adequate or substantially promoting the policy, they would stay intact. We believe our States are substantially meeting the policy and do not see the need for disruption. In any event, some Federal agency should at least sort out what law applies in advance so that the regulated community is not held hostage to more lawyers and uncertainty.

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