

S. RES. 331

Whereas, in the case of United States v. Ellen Rose Hart, CR-F 99-5275 AWI, pending in the United States District Court for the Eastern District of California, testimony has been requested from Eric Vizcaino, an employee in the office of Senator Boxer, and Monica Borvice, an employee in the office of Senator Feinstein;

Whereas, pursuant to sections 703(a) and 704(a)(2) of the Ethics in Government Act of 1978, 2 U.S.C. §§288b(a) and 288c(a)(2), the Senate may direct its counsel to represent employees of the Senate with respect to any subpoena, order, or request for testimony relating to their official responsibilities;

Whereas, by the privileges of the Senate of the United States and Rule XI of the Standing Rules of the Senate, no evidence under the control or in the possession of the Senate may, by the judicial or administrative process, be taken from such control or possession but by permission of the Senate;

Whereas, when it appears that evidence under the control or in the possession of the Senate may promote the administration of justice, the Senate will take such action as will promote the ends of justice consistently with the privileges of the Senate: Now, therefore, be it

Resolved, That Eric Vizcaino, Monica Borvice, and any other employee of the Senate from whom testimony or document production may be required are authorized to testify and produce documents in the case of United States v. Ellen Rose Hart, except concerning matters for which a privilege should be asserted.

SEC. 2. The Senate Legal Counsel is authorized to represent Eric Vizcaino, Monica Borvice, and any Member or employee of the Senate in connection with the testimony and document production authorized in section one of this resolution.

AMENDMENTS SUBMITTED

DEPARTMENT OF LABOR
APPROPRIATIONS ACT, 2001

DASCHLE (AND OTHERS)
AMENDMENT NO. 3688

Mr. HARKIN (for Mr. DASCHLE (for himself, Mr. KENNEDY, Mr. HARKIN, Mr. DODD, and Mr. ROBB)) proposed an amendment to the bill (H.R. 4577) making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 2001, and for other purposes; as follows:

On page 92, between lines 4 and 5, insert the following:

**TITLE GENETIC NONDISCRIMINATION
IN HEALTH INSURANCE AND EMPLOYMENT**

SEC. 01. SHORT TITLE.

This title may be cited as the "Genetic Nondiscrimination in Health Insurance and Employment Act of 2000".

Subtitle A—Prohibition of Health Insurance Discrimination on the Basis of Predictive Genetic Information

SEC. 11. AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT.

(a) AMENDMENTS RELATING TO THE GROUP MARKET.—

(1) PROHIBITION OF HEALTH INSURANCE DISCRIMINATION ON THE BASIS OF PREDICTIVE 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: "(or information about a request for or the receipt of genetic services by an individual or a family member of such individual)".

(B) NO DISCRIMINATION IN GROUP RATE BASED ON PREDICTIVE GENETIC INFORMATION.—

(i) IN GENERAL.—Subpart 2 of part A of title XXVII of the Public Health Service (42 U.S.C. 300gg-4 et seq.) is amended by adding at the end the following:

"SEC. 2707. PROHIBITING DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

"A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not deny eligibility to a group or adjust premium or contribution rates for a group on the basis of predictive genetic information concerning an individual in the group (or information about a request for or the receipt of genetic services by such individual) or family member of such individual."

(ii) CONFORMING AMENDMENTS.—

(I) Section 2702(b)(2)(A) of the Public Health Service Act (42 U.S.C. 300gg-1(b)(2)(A)) is amended to read as follows:

"(A) to restrict the amount that an employer may be charged for coverage under a group health plan, except as provided in section 2707; or"

(II) Section 2721(a) of the Public Health Service Act (42 U.S.C. 300gg-21(a)) is amended by inserting "(other than subsections (a)(1)(F), (b) (with respect to cases relating to genetic information or information about a request or receipt of genetic services by an individual or family member of such individual), (c), (d), (e), (f), or (g) of section 2702 and section 2707)" after "subparts 1 and 3".

(2) LIMITATIONS ON GENETIC TESTING AND ON COLLECTION AND DISCLOSURE OF PREDICTIVE GENETIC INFORMATION.—Section 2702 of the Public Health Service Act (42 U.S.C. 300gg-1) is amended by adding at the end the following:

"(c) GENETIC TESTING.—

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

"(2) RULE OF CONSTRUCTION.—Nothing in this title shall be construed to limit the authority of a health care professional, who is providing treatment with respect to an individual and who is employed by a group health plan or a health insurance issuer, to request that such individual or family member of such individual undergo a genetic test. Such a health care professional shall not require that such individual or family member undergo a genetic test.

"(d) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—Except as provided in subsections (f) and (g), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request, require, collect, or purchase predictive genetic information concerning an individual (or information about a request for or the receipt of genetic services by such individual) or family member of such individual).

"(e) DISCLOSURE OF PREDICTIVE GENETIC INFORMATION.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not disclose predictive genetic information about an individual (or information about a request for or the receipt of genetic services by such individual or family member of such individual) to—

"(1) any entity that is a member of the same controlled group as such issuer or plan sponsor of such group health plan;

"(2) any other group health plan or health insurance issuer or any insurance agent, third party administrator, or other person subject to regulation under State insurance laws;

"(3) the Medical Information Bureau or any other person that collects, compiles, publishes, or otherwise disseminates insurance information;

"(4) the individual's employer or any plan sponsor; or

"(5) any other person the Secretary may specify in regulations.

"(f) INFORMATION FOR PAYMENT FOR GENETIC SERVICES.—

"(1) IN GENERAL.—With respect to payment for genetic services conducted concerning an individual or the coordination of benefits, a group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan, may request that the individual provide the plan or issuer with evidence that such services were performed.

"(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed to—

"(A) permit a group health plan or health insurance issuer to request (or require) the results of the services referred to in such paragraph; or

"(B) require that a group health plan or health insurance issuer make payment for services described in such paragraph where the individual involved has refused to provide evidence of the performance of such services pursuant to a request by the plan or issuer in accordance with such paragraph.

"(g) INFORMATION FOR PAYMENT OF OTHER CLAIMS.—With respect to the payment of claims for benefits other than genetic services, a group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan, may request that an individual provide predictive genetic information so long as such information—

"(1) is used solely for the payment of a claim;

"(2) is limited to information that is directly related to and necessary for the payment of such claim and the claim would otherwise be denied but for the predictive genetic information; and

"(3) is used only by an individual (or individuals) within such plan or issuer who needs access to such information for purposes of payment of a claim.

"(h) RULES OF CONSTRUCTION.—

"(1) COLLECTION OR DISCLOSURE AUTHORIZED BY INDIVIDUAL.—The provisions of subsections (d) (regarding collection) and (e) shall not apply to an individual if the individual (or legal representative of the individual) provides prior, knowing, voluntary, and written authorization for the collection or disclosure of predictive genetic information.

"(2) DISCLOSURE FOR HEALTH CARE TREATMENT.—Nothing in this section shall be construed to limit or restrict the disclosure of predictive genetic information from a health care provider to another health care provider

for the purpose of providing health care treatment to the individual involved.

“(i) DEFINITIONS.—In this section:

“(1) CONTROLLED GROUP.—The term ‘controlled group’ means any group treated as a single employer under subsections (b), (c), (m), or (o) of section 414 of the Internal Revenue Code of 1986.

“(2) GROUP HEALTH PLAN, HEALTH INSURANCE ISSUER.—The terms ‘group health plan’ and ‘health insurance issuer’ include a third party administrator or other person acting for or on behalf of such plan or issuer.”.

(3) 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 new paragraphs:

“(15) FAMILY MEMBER.—The term ‘family member’ means with respect to an individual—

“(A) the spouse of the individual;

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

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

“(16) GENETIC INFORMATION.—The term ‘genetic information’ means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member of such individual (including information about a request for or the receipt of genetic services by such individual or family member of such individual).

“(17) GENETIC SERVICES.—The term ‘genetic services’ means health services, including genetic tests, provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counselling.

“(18) GENETIC TEST.—The term ‘genetic test’ means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect genotypes, mutations, or chromosomal changes.

“(19) PREDICTIVE GENETIC INFORMATION.—

“(A) IN GENERAL.—The term ‘predictive genetic information’ means—

“(i) information about an individual’s genetic tests;

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

“(iii) information about the occurrence of a disease or disorder in family members.

“(B) LIMITATIONS.—The term ‘predictive genetic information’ shall not include—

“(i) information about the sex or age of the individual;

“(ii) information about chemical, blood, or urine analyses of the individual, unless these analyses are genetic tests; or

“(iii) information about physical exams of the individual, and other information relevant to determining the current health status of the individual.”.

(b) AMENDMENT RELATING TO THE INDIVIDUAL MARKET.—The first subpart 3 of part B of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-51 et seq.) is amended—

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

(2) by adding at the end the following:

“SEC. 2753. PROHIBITION OF HEALTH INSURANCE DISCRIMINATION AGAINST INDIVIDUALS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

“(a) IN ELIGIBILITY TO ENROLL.—A health insurance issuer offering health insurance coverage in the individual market shall not establish rules for eligibility to enroll in individual health insurance coverage that are based on predictive genetic information concerning the individual (or information about a request for or the receipt of genetic serv-

ices by such individual or family member of such individual).

“(b) IN PREMIUM RATES.—A health insurance issuer offering health insurance coverage in the individual market shall not adjust premium rates on the basis of predictive genetic information concerning an individual (or information about a request for or the receipt of genetic services by such individual or family member of such individual).

“SEC. 2754. LIMITATIONS ON GENETIC TESTING AND ON COLLECTION AND DISCLOSURE OF PREDICTIVE GENETIC INFORMATION.

“(a) GENETIC TESTING.—

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

“(2) RULE OF CONSTRUCTION.—Nothing in this title shall be construed to limit the authority of a health care professional, who is providing treatment with respect to an individual and who is employed by a group health plan or a health insurance issuer, to request that such individual or family member of such individual undergo a genetic test. Such a health care professional shall not require that such individual or family member undergo a genetic test.

“(b) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—Except as provided in subsections (d) and (e), a health insurance issuer offering health insurance coverage in the individual market shall not request, require, collect, or purchase predictive genetic information concerning an individual (or information about a request for or the receipt of genetic services by such individual or family member of such individual).

“(c) DISCLOSURE OF PREDICTIVE GENETIC INFORMATION.—A health insurance issuer offering health insurance coverage in the individual market shall not disclose predictive genetic information about an individual (or information about a request for or the receipt of genetic services by such individual or family member of such individual) to—

“(1) any entity that is a member of the same controlled group as such issuer or plan sponsor of such group health plan;

“(2) any other group health plan or health insurance issuer or any insurance agent, third party administrator, or other person subject to regulation under State insurance laws;

“(3) the Medical Information Bureau or any other person that collects, compiles, publishes, or otherwise disseminates insurance information;

“(4) the individual’s employer or any plan sponsor; or

“(5) any other person the Secretary may specify in regulations.

“(d) INFORMATION FOR PAYMENT FOR GENETIC SERVICES.—

“(1) IN GENERAL.—With respect to payment for genetic services conducted concerning an individual or the coordination of benefits, a health insurance issuer offering health insurance coverage in the individual market may request that the individual provide the plan or issuer with evidence that such services were performed.

“(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed to—

“(A) permit a health insurance issuer to request (or require) the results of the services referred to in such paragraph; or

“(B) require that a health insurance issuer make payment for services described in such paragraph where the individual involved has refused to provide evidence of the perform-

ance of such services pursuant to a request by the plan or issuer in accordance with such paragraph.

“(e) INFORMATION FOR PAYMENT OF OTHER CLAIMS.—With respect to the payment of claims for benefits other than genetic services, a health insurance issuer offering health insurance coverage in the individual market may request that an individual provide predictive genetic information so long as such information—

“(1) is used solely for the payment of a claim;

“(2) is limited to information that is directly related to and necessary for the payment of such claim and the claim would otherwise be denied but for the predictive genetic information; and

“(3) is used only by an individual (or individuals) within such plan or issuer who needs access to such information for purposes of payment of a claim.

“(f) RULES OF CONSTRUCTION.—

“(1) COLLECTION OR DISCLOSURE AUTHORIZED BY INDIVIDUAL.—The provisions of subsections (c) (regarding collection) and (d) shall not apply to an individual if the individual (or legal representative of the individual) provides prior, knowing, voluntary, and written authorization for the collection or disclosure of predictive genetic information.

“(2) DISCLOSURE FOR HEALTH CARE TREATMENT.—Nothing in this section shall be construed to limit or restrict the disclosure of predictive genetic information from a health care provider to another health care provider for the purpose of providing health care treatment to the individual involved.

“(g) DEFINITIONS.—In this section:

“(1) CONTROLLED GROUP.—The term ‘controlled group’ means any group treated as a single employer under subsections (b), (c), (m), or (o) of section 414 of the Internal Revenue Code of 1986.

“(2) GROUP HEALTH PLAN, HEALTH INSURANCE ISSUER.—The terms ‘group health plan’ and ‘health insurance issuer’ include a third party administrator or other person acting for or on behalf of such plan or issuer.”.

(c) ENFORCEMENT.—

(1) GROUP PLANS.—Section 2722 of the Public Health Service Act (42 U.S.C. 300gg-22) is amended by adding at the end the following:

“(c) VIOLATION OF GENETIC DISCRIMINATION OR GENETIC DISCLOSURE PROVISIONS.—In any action under this section against any administrator of a group health plan, or health insurance issuer offering group health insurance coverage in connection with a group health plan (including any third party administrator or other person acting for or on behalf of such plan or issuer) alleging a violation of subsections (a)(1)(F), (b) (with respect to cases relating to genetic information or information about a request or receipt of genetic services by an individual or family member of such individual), (c), (d), (e), (f), or (g) of section 2702 and section 2707 the court may award any appropriate legal or equitable relief. Such relief may include a requirement for the payment of attorney’s fees and costs, including the costs of expert witnesses.

“(d) CIVIL PENALTY.—The monetary provisions of section 308(b)(2)(C) of Public Law 101-336 (42 U.S.C. 12188(b)) shall apply for purposes of the Secretary enforcing the provisions referred to in subsection (c), except that any such relief awarded shall be paid only into the general fund of the Treasury.”.

(2) INDIVIDUAL PLANS.—Section 2761 of the Public Health Service Act (42 U.S.C. 300gg-45) is amended by adding at the end the following:

“(c) VIOLATION OF GENETIC DISCRIMINATION OR GENETIC DISCLOSURE PROVISIONS.—In any action under this section against any health insurance issuer offering health insurance coverage in the individual market (including any other person acting for or on behalf of such issuer) alleging a violation of section 2753 and 2754 the court in which the action is commenced may award any appropriate legal or equitable relief. Such relief may include a requirement for the payment of attorney’s fees and costs, including the costs of expert witnesses.

“(d) CIVIL PENALTY.—The monetary provisions of section 308(b)(2)(C) of Public Law 101-336 (42 U.S.C. 12188(b)) shall apply for purposes of the Secretary enforcing the provisions referred to in subsection (c), except that any such relief awarded shall be paid only into the general fund of the Treasury.”

(d) PREEMPTION.—

(1) GROUP MARKET.—Section 2723 of the Public Health Service Act (42 U.S.C. 300gg-23) is amended—

(A) in subsection (a)(1), by inserting “or (e)” after “subsection (b)”; and

(B) by adding at the end the following:

“(e) SPECIAL RULE IN CASE OF GENETIC INFORMATION.—With respect to group health insurance coverage offered by a health insurance issuer, the provisions of this part relating to genetic information (including information about a request for or the receipt of genetic services by an individual or a family member of such individual) shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect a standard, requirement, or remedy that more completely—

“(1) protects the confidentiality of genetic information (including information about a request for or the receipt of genetic services by an individual or a family member of such individual) or the privacy of an individual or a family member of the individual with respect to genetic information (including information about a request for or the receipt of genetic services by an individual or a family member of such individual); or

“(2) prohibits discrimination on the basis of genetic information than does this part.”

(2) INDIVIDUAL MARKET.—Section 2762 of the Public Health Service Act (42 U.S.C. 300gg-46) is amended—

(A) in subsection (a), by inserting “and except as provided in subsection (c),” after “Subject to subsection (b).”; and

(B) by adding at the end the following:

“(c) SPECIAL RULE IN CASE OF GENETIC INFORMATION.—With respect to individual health insurance coverage offered by a health insurance issuer, the provisions of this part (or part C insofar as it applies to this part) relating to genetic information (including information about a request for or the receipt of genetic services by an individual or a family member of such individual) shall not be construed to supersede any provision of State law (as defined in section 2723(d)) which establishes, implements, or continues in effect a standard, requirement, or remedy that more completely—

“(1) protects the confidentiality of genetic information (including information about a request for or the receipt of genetic services of an individual or a family member of such individual) or the privacy of an individual or a family member of the individual with respect to genetic information (including information about a request for or the receipt of genetic services by an individual or a family member of such individual) than does this part (or part C insofar as it applies to this part); or

“(2) prohibits discrimination on the basis of genetic information than does this part (or part C insofar as it applies to this part).”

(e) 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), (c), (d), (e), (f), and (g) of section 2702 and section 2707, and the provisions of section 2702(b) to the extent that they 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).”

(f) AMENDMENT CONCERNING SUPPLEMENTAL EXCEPTED BENEFITS.—

(1) GROUP MARKET.—Section 2721(d)(3) of the Public Health Service Act (42 U.S.C. 300gg-23(d)(3)) is amended by inserting “; other than the requirements of subsections (a)(1)(F), (b) (in cases relating 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), (c), (d), (e), (f) and (g) of section 2702 and section 2707,” after “The requirements of this part”.

(2) INDIVIDUAL MARKET.—Section 2763(b) of the Public Health Service Act (42 U.S.C. 300gg-47(b)) is amended—

(A) by striking “The requirements of this part” and inserting the following:

“(1) IN GENERAL.—Except as provided in paragraph (2), the requirements of this part”; and

(B) by adding at the end the following:

“(2) LIMITATION.—The requirements of sections 2753 and 2754 shall apply to excepted benefits described in section 2791(c)(4).”

(g) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by this section shall apply with respect to—

(A) group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning; and

(B) health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market, after July 1, 2001.

(2) SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.—In the case of a group health plan maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers ratified before the date of the enactment of this Act, the amendments made by this section shall not apply to plan years beginning before the later of—

(A) the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of the enactment of this Act); or

(B) July 1, 2001.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement of the amendments made by this section shall not be treated as a termination of such collective bargaining agreement.

SEC. 12. AMENDMENTS TO EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

(a) PROHIBITION OF HEALTH INSURANCE DISCRIMINATION ON THE BASIS OF GENETIC SERVICES OR PREDICTIVE GENETIC INFORMATION.—Subpart B of Part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185 et seq.) is amended by adding at the end the following:

“SEC. 714. PROHIBITING DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

“Each group health plan, and health insurance issuer offering group health insurance coverage in connection with a group health plan, shall comply with the genetic non-discrimination provisions of subsections (a)(1)(F) and (c) through (g) of section 2702, and section 2707 of the Public Health Service Act, and each health insurance issuer shall comply with such provisions with respect to group health insurance coverage it offers, and such provisions shall be deemed to be incorporated into this subsection.”

(b) ENFORCEMENT.—Section 502 (29 U.S.C. 1132) is amended by adding at the end the following:

“(n) VIOLATION OF GENETIC DISCRIMINATION OR GENETIC DISCLOSURE PROVISIONS.—In any action under this section against any administrator of a group health plan, or health insurance issuer offering group health insurance coverage in connection with a group health plan (including any third party administrator or other person acting for or on behalf of such plan or issuer) alleging a violation of section 714, the court may award any appropriate legal or equitable relief. Such relief may include a requirement for the payment of attorney’s fees and costs, including the costs of expert witnesses.

“(o) CIVIL PENALTY.—The monetary provisions of section 308(b)(2)(C) of Public Law 101-336 (42 U.S.C. 12188(b)) shall apply for purposes of the Secretary enforcing the provisions referred to in subsection (n), except that any such relief awarded shall be paid only into the general fund of the Treasury.”

(c) PREEMPTION.—Section 731 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191) is amended—

(1) in subsection (a)(1), by inserting “or (e)” after “subsection (b)”; and

(2) by adding at the end the following:

“(e) SPECIAL RULE IN CASE OF GENETIC INFORMATION.—With respect to group health insurance coverage offered by a health insurance issuer, the provisions of this part relating to genetic information (including information about a request for or the receipt of genetic services by an individual or a family member of such individual) shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect a standard, requirement, or remedy that more completely—

“(1) protects the confidentiality of genetic information (including information about a request for or the receipt of genetic services by an individual or a family member of such individual) or the privacy of an individual or a family member of the individual with respect to genetic information (including information about a request for or the receipt of genetic services by an individual or a family member of such individual) than does this part; or

“(2) prohibits discrimination on the basis of genetic information than does this part.”

(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.—The term ‘genetic information’ means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member of such individual (including information about a request for or the receipt of genetic services by such individual or family member of such individual).

“(7) GENETIC SERVICES.—The term ‘genetic services’ means health services, including genetic tests, provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

“(8) GENETIC TEST.—The term ‘genetic test’ means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect genotypes, mutations, or chromosomal changes.

“(9) PREDICTIVE GENETIC INFORMATION.—

“(A) IN GENERAL.—The term ‘predictive genetic information’ means—

“(i) information about an individual’s genetic tests;

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

“(iii) information about the occurrence of a disease or disorder in family members.

“(B) LIMITATIONS.—The term ‘predictive genetic information’ shall not include—

“(i) information about the sex or age of the individual;

“(ii) information about chemical, blood, or urine analyses of the individual, unless these analyses are genetic tests; or

“(iii) information about physical exams of the individual, and other information relevant to determining the current health status of the individual.”

(e) AMENDMENT CONCERNING SUPPLEMENTAL EXCEPTED BENEFITS.—Section 732(c)(3) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191a(c)(3)) is amended by inserting “, other than the requirements of section 714,” after “The requirements of this part”.

(f) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in this section, this section and the amendments made by this section shall apply with respect to group health plans for plan years beginning after July 1, 2001.

(2) SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.—In the case of a group health plan maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers ratified before the date of the enactment of this Act, this section and the amendments made by this section shall not apply to plan years beginning before the later of—

(A) the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of the enactment of this Act), or

(B) July 1, 2001.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement of the amendments made by this section shall not be treated as a termi-

nation of such collective bargaining agreement.

SEC. 13. AMENDMENTS TO INTERNAL REVENUE CODE OF 1986.

(a) PROHIBITION OF HEALTH INSURANCE DISCRIMINATION ON THE BASIS OF GENETIC SERVICES OR PREDICTIVE GENETIC INFORMATION.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following:

“SEC. 9813. PROHIBITING DISCRIMINATION ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

“(a) IN GENERAL.—Each group health plan shall comply with the genetic non-discrimination provisions of subsections (a)(1)(F) and (c) through (i) of section 2702, and section 2707 of the Public Health Service Act and such provisions shall be deemed to be incorporated into this subsection.

“(b) VIOLATION OF GENETIC DISCRIMINATION OR GENETIC DISCLOSURE PROVISIONS.—In any action under this section against any administrator of a group health plan (including any third party administrator or other person acting for or on behalf of such plan) alleging a violation of subsection (a), the court may award any appropriate legal or equitable relief. Such relief may include a requirement for the payment of attorney’s fees and costs, including the costs of expert witnesses.

“(c) CIVIL PENALTY.—The monetary provisions of section 308(b)(2)(C) of Public Law 101-336 (42 U.S.C. 12188(b)) shall apply for purposes of the Secretary enforcing the provisions referred to in subsection (b), except that any such relief awarded shall be paid only into the general fund of the Treasury.”

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in this section, this section and the amendments made by this section shall apply with respect to group health plans for plan years beginning after July 1, 2001.

(2) SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.—In the case of a group health plan maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers ratified before the date of the enactment of this Act, this section and the amendments made by this section shall not apply to plan years beginning before the later of—

(A) the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of the enactment of this Act), or

(B) July 1, 2001.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement of the amendments made by this section shall not be treated as a termination of such collective bargaining agreement.

Subtitle B—Prohibition of Employment Discrimination on the Basis of Predictive Genetic Information

SEC. 21. DEFINITIONS.

In this subtitle:

(1) EMPLOYEE; EMPLOYER; EMPLOYMENT AGENCY; LABOR ORGANIZATION; MEMBER.—The terms “employee”, “employer”, “employment agency”, and “labor organization” have the meanings given such terms in section 701 of the Civil Rights Act of 1964 (42 U.S.C. 2000e), except that the terms “employee” and “employer” shall also include the meanings given such terms in section 717 of the Civil Rights Act of 1964 (42 U.S.C.

2000e-16). The terms “employee” and “member” include an applicant for employment and an applicant for membership in a labor organization, respectively.

(2) 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).

(3) 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.

(4) GENETIC SERVICES.—The term “genetic services” means health services, including genetic tests, provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

(5) GENETIC TEST.—The term “genetic test” means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect genotypes, mutations, or chromosomal changes.

(6) PREDICTIVE GENETIC INFORMATION.—

(A) IN GENERAL.—The term “predictive genetic information” means—

(i) information about an individual’s genetic tests;

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

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

(B) LIMITATIONS.—The term “predictive genetic information” shall not include—

(i) information about the sex or age of the individual;

(ii) information about chemical, blood, or urine analyses of the individual, unless these analyses are genetic tests; or

(iii) information about physical exams of the individual, and other information relevant to determining the current health status of the individual.

SEC. 22. EMPLOYER PRACTICES.

(a) IN GENERAL.—It shall be an unlawful employment practice for an employer—

(1) to fail or refuse to hire or to discharge any individual, or otherwise to discriminate against any individual with respect to the compensation, terms, conditions, or privileges of employment of the individual, because of predictive 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 the employees of the employer 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 predictive 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 request, require, collect or purchase predictive genetic information with respect to an individual or a family member of the individual except—

(A) where used for genetic monitoring of biological effects of toxic substances in the workplace, but only if—

(i) the employee has provided prior, knowing, voluntary, and written authorization;

(ii) the employee is informed of individual monitoring results;

(iii) the monitoring conforms to any genetic monitoring 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.) or the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 et seq.); and

(iv) the employer, excluding any licensed health care professional 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; or

(B) where genetic services are offered by the employer and the employee provides prior, knowing, voluntary, and written authorization, and only the employee or family member of such employee receives the results of such services.

(b) LIMITATION.—In the case of predictive genetic information to which subparagraph (A) or (B) of subsection (a)(3) applies, such information may not be used in violation of paragraph (1) or (2) of subsection (a).

SEC. 23. EMPLOYMENT AGENCY PRACTICES.

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 predictive 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 would limit the employment opportunities or otherwise adversely affect the status of the individual as an employee, because of predictive 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);

(3) to request, require, collect or purchase predictive genetic information with respect to an individual (or information about a request for or the receipt of genetic services by such individual or family member of such individual); or

(4) to cause or attempt to cause an employer to discriminate against an individual in violation of this subtitle.

SEC. 24. LABOR ORGANIZATION PRACTICES.

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 individual because of predictive 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 the members of the organization, 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 would limit the employment opportunities or otherwise adversely affect the status of the individual as an employee, because of predictive 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);

(3) to request, require, collect or purchase predictive genetic information with respect to an individual (or information about a request for or the receipt of genetic services by such individual or family member of such individual); or

(4) to cause or attempt to cause an employer to discriminate against an individual in violation of this subtitle.

SEC. 25. TRAINING PROGRAMS.

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 predictive genetic information with respect to the individual (or information about a request for or the receipt of genetic services by 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 members of the organization, 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 would limit the employment opportunities or otherwise adversely affect the status of the individual as an employee, because of predictive 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);

(3) to request, require, collect or purchase predictive genetic information with respect to an individual (or information about a request for or receipt of genetic services by such individual or family member of such individual); or

(4) to cause or attempt to cause an employer to discriminate against an individual in violation of this subtitle.

SEC. 26. MAINTENANCE AND DISCLOSURE OF PREDICTIVE GENETIC INFORMATION.

(a) MAINTENANCE OF PREDICTIVE GENETIC INFORMATION.—If an employer possesses predictive genetic information about an employee (or information about a request for or receipt of genetic services by such employee or family member of such employee), such information shall be treated or maintained as part of the employee's confidential medical records.

(b) DISCLOSURE OF PREDICTIVE GENETIC INFORMATION.—An employer shall not disclose predictive genetic information (or information about a request for or receipt of genetic services by such employee or family member of such employee) except—

(1) to the employee who is the subject of the information at the request of the employee;

(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) under legal compulsion of a Federal court order, except that if the court order was secured without the knowledge of the individual to whom the information refers, the employer shall provide the individual with adequate notice to challenge the court order unless the court order also imposes confidentiality requirements; and

(4) to government officials who are investigating compliance with this subtitle if the information is relevant to the investigation.

SEC. 27. CIVIL ACTION.

(a) IN GENERAL.—One or more employees, members of a labor organization, or participants in training programs may bring an action in a Federal or State court of competent jurisdiction against an employer, employment agency, labor organization, or joint labor-management committee or training program who commits a violation of this subtitle.

(b) ENFORCEMENT BY THE EQUAL EMPLOYMENT OPPORTUNITY COMMISSION.—

(1) IN GENERAL.—The powers, remedies, and procedures set forth in sections 705, 706, 707, 709, 710, and 717 of the Civil Rights Act of 1964 (42 U.S.C. 2000e-4, 2000e-5, 2000e-6, 2000e-8, 2000e-9, and 2000e-16) shall be the powers, remedies, and procedures provided to the Equal Employment Opportunity Commission to enforce this subtitle. The Commission may promulgate regulations to implement these powers, remedies, and procedures.

(2) EXHAUSTION OF REMEDIES.—Nothing in this subsection shall be construed to require that an individual exhaust the administrative remedies available through the Equal Employment Opportunity Commission prior to commencing a civil action under this section, except that if an individual files a charge of discrimination with the Commission that alleges a violation of this subtitle, the individual shall exhaust the administrative remedies available through the Commission prior to commencing a civil action under this section.

(c) REMEDY.—A Federal or State court may award any appropriate legal or equitable relief under this section. Such relief may include a requirement for the payment of attorney's fees and costs, including the costs of experts.

SEC. 28. CONSTRUCTION.

Nothing in this subtitle 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;

(2) limit the rights or protections of an individual under the Rehabilitation Act of 1973 (29 U.S.C. 701 et seq.);

(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 accorded under this subtitle;

(4) apply to the Armed Forces Repository of Specimen Samples for the Identification of Remains; or

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

SEC. 29. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated such sums as may be necessary to carry out this subtitle.

SEC. 30. EFFECTIVE DATE.

This subtitle shall become effective on October 1, 2000.

SEC. 31. NO IMPACT ON SOCIAL SECURITY TRUST FUND.—

(1) IN GENERAL.—Nothing in this title shall be construed to alter or amend the Social Security Act (or any regulation promulgated under that Act).

(2) TRANSFERS.—

(A) ESTIMATE OF SECRETARY.—The Secretary of the Treasury shall annually estimate the impact that the enactment of this

title has on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401).

(B) TRANSFER OF FUNDS.—If, under subparagraph (A), the Secretary of the Treasury estimates that the enactment of this title has a negative impact on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401), the Secretary shall transfer, not less frequently than quarterly, from the general revenues of the Federal Government an amount sufficient so as to ensure that the income and balances of such trust funds are not reduced as a result of the enactment of such title.

SEC. 32. INFORMATION REQUIREMENTS.—

(1) INFORMATION FROM GROUP HEALTH PLANS.—Section 1862(b) of the Social Security Act (42 U.S.C. 1395y(b)) is amended by adding at the end the following:

“(7) INFORMATION FROM GROUP HEALTH PLANS.—

“(A) PROVISION OF INFORMATION BY GROUP HEALTH PLANS.—The administrator of a group health plan subject to the requirements of paragraph (1) shall provide to the Secretary such of the information elements described in subparagraph (C) as the Secretary specifies, and in such manner and at such times as the Secretary may specify (but not more frequently than 4 times per year), with respect to each individual covered under the plan who is entitled to any benefits under this title.

“(B) PROVISION OF INFORMATION BY EMPLOYERS AND EMPLOYEE ORGANIZATIONS.—An employer (or employee organization) that maintains or participates in a group health plan subject to the requirements of paragraph (1) shall provide to the administrator of the plan such of the information elements required to be provided under subparagraph (A), and in such manner and at such times as the Secretary may specify, at a frequency consistent with that required under subparagraph (A) with respect to each individual described in subparagraph (A) who is covered under the plan by reason of employment with that employer or membership in the organization.

“(C) INFORMATION ELEMENTS.—The information elements described in this subparagraph are the following:

“(i) ELEMENTS CONCERNING THE INDIVIDUAL.—

“(I) The individual’s name.

“(II) The individual’s date of birth.

“(III) The individual’s sex.

“(IV) The individual’s social security insurance number.

“(V) The number assigned by the Secretary to the individual for claims under this title.

“(VI) The family relationship of the individual to the person who has or had current or employment status with the employer.

“(ii) ELEMENTS CONCERNING THE FAMILY MEMBER WITH CURRENT OR FORMER EMPLOYMENT STATUS.—

“(I) The name of the person in the individual’s family who has current or former employment status with the employer.

“(II) That person’s social security insurance number.

“(III) The number or other identifier assigned by the plan to that person.

“(IV) The periods of coverage for that person under the plan.

“(V) The employment status of that person (current or former) during those periods of coverage.

“(VI) The classes (of that person’s family members) covered under the plan.

“(iii) PLAN ELEMENTS.—

“(I) The items and services covered under the plan.

“(II) The name and address to which claims under the plan are to be sent.

“(iv) ELEMENTS CONCERNING THE EMPLOYER.—

“(I) The employer’s name.

“(II) The employer’s address.

“(III) The employer identification number of the employer.

“(D) USE OF IDENTIFIERS.—The administrator of a group health plan shall utilize a unique identifier for the plan in providing information under subparagraph (A) and in other transactions, as may be specified by the Secretary, related to the provisions of this subsection. The Secretary may provide to the administrator the unique identifier described in the preceding sentence.

“(E) PENALTY FOR NONCOMPLIANCE.—Any entity that knowingly and willfully fails to comply with a requirement imposed by the previous subparagraphs shall be subject to a civil money penalty not to exceed \$1,000 for each incident of such failure. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as those provisions apply to a penalty or proceeding under section 1128A(a).”

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect 180 days after the date of the enactment of this Act.

SEC. 33. OFFSET.—Amounts made available under this Act for the administrative and related expenses for departmental management for the Department of Labor and the Department of Health and Human Services shall be reduced on a pro rata basis by \$25,000,000.

ASHCROFT (AND OTHERS)
AMENDMENT NO. 3689

Mr. ASHCROFT (for himself, Mr. VOINOVICH, Mr. ALLARD, Mr. GRAMS, Mr. ABRAHAM, and Mr. FEINGOLD) proposed an amendment to the bill, H.R. 4577, supra; as follows:

At the end, insert the following:

SEC. ____ SOCIAL SECURITY AND MEDICARE SAFE DEPOSIT BOX ACT OF 2000.

(a) SHORT TITLE.—This section may be cited as the “Social Security and Medicare Safe Deposit Box Act of 2000”.

(b) PROTECTION OF SOCIAL SECURITY AND MEDICARE SURPLUSES.—

(1) MEDICARE SURPLUSES OFF-BUDGET.—Notwithstanding any other provision of law, the net surplus of any trust fund for part A of Medicare shall not be counted as a net surplus for purposes of—

(A) the budget of the United States Government as submitted by the President;

(B) the congressional budget; or

(C) the Balanced Budget and Emergency Deficit Control Act of 1985.

(2) POINTS OF ORDER TO PROTECT SOCIAL SECURITY AND MEDICARE SURPLUSES.—Section 312 of the Congressional Budget Act of 1974 is amended by adding at the end the following new subsection:

“(g) POINTS OF ORDER TO PROTECT SOCIAL SECURITY AND MEDICARE SURPLUSES.—

“(1) CONCURRENT RESOLUTIONS ON THE BUDGET.—It shall not be in order in the House of Representatives or the Senate to consider any concurrent resolution on the budget, or conference report thereon or amendment thereto, that would set forth an on-budget deficit for any fiscal year.

“(2) SUBSEQUENT LEGISLATION.—It shall not be in order in the House of Representatives

or the Senate to consider any bill, joint resolution, amendment, motion, or conference report if—

“(A) the enactment of that bill or resolution as reported;

“(B) the adoption and enactment of that amendment; or

“(C) the enactment of that bill or resolution in the form recommended in that conference report, would cause or increase an on-budget deficit for any fiscal year.

“(3) DEFINITION.—For purposes of this section, the term ‘on-budget deficit’, when applied to a fiscal year, means the deficit in the budget as set forth in the most recently agreed to concurrent resolution on the budget pursuant to section 301(a)(3) for that fiscal year.”

(3) SUPER MAJORITY REQUIREMENT.—

(A) POINT OF ORDER.—Section 904(c)(1) of the Congressional Budget Act of 1974 is amended by inserting “312(g),” after “310(d)(2).”

(B) WAIVER.—Section 904(d)(2) of the Congressional Budget Act of 1974 is amended by inserting “312(g),” after “310(d)(2).”

(C) PROTECTION OF SOCIAL SECURITY AND MEDICARE SURPLUSES.—

(1) IN GENERAL.—Chapter 11 of subtitle II of title 31, United States Code, is amended by adding before section 1101 the following:

“§ 1100. Protection of social security and medicare surpluses

“The budget of the United States Government submitted by the President under this chapter shall not recommend an on-budget deficit for any fiscal year covered by that budget.”

(2) CHAPTER ANALYSIS.—The chapter analysis for chapter 11 of title 31, United States Code, is amended by inserting before the item for section 1101 the following:

“1100. Protection of social security and medicare surpluses.”

(d) EFFECTIVE DATE.—This section shall take effect upon the date of its enactment and the amendments made by this section shall apply to fiscal year 2001 and subsequent fiscal years.

CONRAD (AND LAUTENBERG)
AMENDMENT NO. 3690

Mr. REID (for Mr. CONRAD (for himself, Mr. LAUTENBERG, and Mr. FEINGOLD)) proposed an amendment to the bill, H.R. 4577, supra; as follows:

Strike all after the first word and insert the following:

TITLE ____—SOCIAL SECURITY AND MEDICARE OFF-BUDGET LOCKBOX ACT OF 2000

SEC. ____ 1. SHORT TITLE.

This title may be cited as the “Social Security and Medicare Off-Budget Lockbox Act of 2000”.

SEC. ____ 2. STRENGTHENING SOCIAL SECURITY POINTS OF ORDER.

(a) IN GENERAL.—Section 312 of the Congressional Budget Act of 1974 (2 U.S.C. 643) is amended by inserting at the end the following:

“(g) STRENGTHENING SOCIAL SECURITY POINT OF ORDER.—It shall not be in order in the House of Representatives or the Senate to consider a concurrent resolution on the budget (or any amendment thereto or conference report thereon) or any bill, joint resolution, amendment, motion, or conference report that would violate or amend section 13301 of the Budget Enforcement Act of 1990.”

(b) SUPER MAJORITY REQUIREMENT.—

(1) POINT OF ORDER.—Section 904(c)(1) of the Congressional Budget Act of 1974 is amended by inserting “312(g),” after “310(d)(2).”

(2) WAIVER.—Section 904(d)(2) of the Congressional Budget Act of 1974 is amended by inserting “312(g),” after “310(d)(2).”

(c) ENFORCEMENT IN EACH FISCAL YEAR.—The Congressional Budget Act of 1974 is amended in—

(1) section 301(a)(7) (2 U.S.C. 632(a)(7)), by striking “for the fiscal year” through the period and inserting “for each fiscal year covered by the resolution”; and

(2) section 311(a)(3) (2 U.S.C. 642(a)(3)), by striking beginning with “for the first fiscal year” through the period and insert the following: “for any of the fiscal years covered by the concurrent resolution.”

SEC. 3. MEDICARE TRUST FUND OFF-BUDGET.

(a) IN GENERAL.—

(1) GENERAL EXCLUSION FROM ALL BUDGETS.—Title III of the Congressional Budget Act of 1974 is amended by adding at the end the following:

“EXCLUSION OF MEDICARE TRUST FUND FROM ALL BUDGETS

“SEC. 316. (a) EXCLUSION OF MEDICARE TRUST FUND FROM ALL BUDGETS.—Notwithstanding any other provision of law, the receipts and disbursements of the Federal Hospital Insurance Trust Fund shall not be counted as new budget authority, outlays, receipts, or deficit or surplus for purposes of—

“(1) the budget of the United States Government as submitted by the President;

“(2) the congressional budget; or

“(3) the Balanced Budget and Emergency Deficit Control Act of 1985.

“(b) STRENGTHENING MEDICARE POINT OF ORDER.—It shall not be in order in the House of Representatives or the Senate to consider a concurrent resolution on the budget (or any amendment thereto or conference report thereon) or any bill, joint resolution, amendment, motion, or conference report that would violate or amend this section.”

(2) SUPER MAJORITY REQUIREMENT.—

(A) POINT OF ORDER.—Section 904(c)(1) of the Congressional Budget Act of 1974 is amended by inserting “316,” after “313.”

(B) WAIVER.—Section 904(d)(2) of the Congressional Budget Act of 1974 is amended by inserting “316,” after “313.”

(b) EXCLUSION OF MEDICARE TRUST FUND FROM CONGRESSIONAL BUDGET.—Section 301(a) of the Congressional Budget Act of 1974 (2 U.S.C. 632(a)) is amended by adding at the end the following: “The concurrent resolution shall not include the outlays and revenue totals of the Federal Hospital Insurance Trust Fund in the surplus or deficit totals required by this subsection or in any other surplus or deficit totals required by this title.”

(c) BUDGET TOTALS.—Section 301(a) of the Congressional Budget Act of 1974 (2 U.S.C. 632(a)) is amended by inserting after paragraph (7) the following:

“(8) For purposes of Senate enforcement under this title, revenues and outlays of the Federal Hospital Insurance Trust Fund for each fiscal year covered by the budget resolution.”

(d) BUDGET RESOLUTIONS.—Section 301(i) of the Congressional Budget Act of 1974 (2 U.S.C. 632(i)) is amended by—

(1) striking “SOCIAL SECURITY POINT OF ORDER.—It shall” and inserting “SOCIAL SECURITY AND MEDICARE POINTS OF ORDER.—

“(1) SOCIAL SECURITY.—It shall”; and

(2) inserting at the end the following:

“(2) MEDICARE.—It shall not be in order in the House of Representatives or the Senate to consider any concurrent resolution on the budget (or amendment, motion, or conference report on the resolution) that would decrease the excess of the Federal Hospital Insurance Trust Fund revenues over Federal Hospital Insurance Trust Fund outlays in any of the fiscal years covered by the concurrent resolution. This paragraph shall not apply to amounts to be expended from the Hospital Insurance Trust Fund for purposes relating to programs within part A of Medicare as provided in law on the date of enactment of this paragraph.”

(e) MEDICARE FIREWALL.—Section 311(a) of the Congressional Budget Act of 1974 (2 U.S.C. 642(a)) is amended by adding after paragraph (3), the following:

“(4) ENFORCEMENT OF MEDICARE LEVELS IN THE SENATE.—After a concurrent resolution on the budget is agreed to, it shall not be in order in the Senate to consider any bill, joint resolution, amendment, motion, or conference report that would cause a decrease in surpluses or an increase in deficits of the Federal Hospital Insurance Trust Fund in any year relative to the levels set forth in the applicable resolution. This paragraph shall not apply to amounts to be expended from the Hospital Insurance Trust Fund for purposes relating to programs within part A of Medicare as provided in law on the date of enactment of this paragraph.”

(f) BASELINE TO EXCLUDE HOSPITAL INSURANCE TRUST FUND.—Section 257(b)(3) of the Balanced Budget and Emergency Deficit Control Act of 1985 is amended by striking “shall be included in all” and inserting “shall not be included in any”.

(g) MEDICARE TRUST FUND EXEMPT FROM SEQUESTERS.—Section 255(g)(1)(B) of the Balanced Budget and Emergency Deficit Control Act of 1985 is amended by adding at the end the following:

“Medicare as funded through the Federal Hospital Insurance Trust Fund.”

(h) BUDGETARY TREATMENT OF HOSPITAL INSURANCE TRUST FUND.—Section 710(a) of the Social Security Act (42 U.S.C. 911(a)) is amended—

(1) by striking “and” the second place it appears and inserting a comma; and

(2) by inserting after “Federal Disability Insurance Trust Fund” the following: “, Federal Hospital Insurance Trust Fund”.

SEC. 4. PREVENTING ON-BUDGET DEFICITS.

(a) POINTS OF ORDER TO PREVENT ON-BUDGET DEFICITS.—Section 312 of the Congressional Budget Act of 1974 (2 U.S.C. 643) is amended by adding at the end the following:

“(h) POINTS OF ORDER TO PREVENT ON-BUDGET DEFICITS.—

“(1) CONCURRENT RESOLUTIONS ON THE BUDGET.—It shall not be in order in the House of Representatives or the Senate to consider any concurrent resolution on the budget, or conference report thereon or amendment thereto, that would cause or increase an on-budget deficit for any fiscal year.

“(2) SUBSEQUENT LEGISLATION.—Except as provided by paragraph (3), it shall not be in order in the House of Representatives or the Senate to consider any bill, joint resolution, amendment, motion, or conference report if—

“(A) the enactment of that bill or resolution as reported;

“(B) the adoption and enactment of that amendment; or

“(C) the enactment of that bill or resolution in the form recommended in that conference report,

would cause or increase an on-budget deficit for any fiscal year.”

(b) SUPER MAJORITY REQUIREMENT.—

(1) POINT OF ORDER.—Section 904(c)(1) of the Congressional Budget Act of 1974 is amended by inserting “312(h),” after “312(g).”

(2) WAIVER.—Section 904(d)(2) of the Congressional Budget Act of 1974 is amended by inserting “312(h),” after “312(g).”

JEFFORDS (AND OTHERS)**AMENDMENT NO. 3691**

Mr. JEFFORDS (for himself, Mr. FRIST, Ms. SNOWE, Mr. ASHCROFT, Mr. ENZI, and Mr. MACK) proposed an amendment to amendment No. 3688 proposed by Mr. DASCHLE to the bill, H.R. 4577, supra; as follows:

At the end of the bill, add the following:

TITLE ___ GENETIC INFORMATION AND SERVICES**SEC. ___ 01. SHORT TITLE.**

This title may be cited as the “Genetic Information Nondiscrimination in Health Insurance Act of 1999”.

SEC. ___ 02. 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)”.

(2) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON PREDICTIVE GENETIC INFORMATION.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following:

“SEC. 714. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

“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 predictive genetic information concerning any individual (including a dependent) or family member of the individual (including information about a request for or receipt of genetic services).”

(3) CONFORMING AMENDMENTS.—

(A) IN GENERAL.—Section 702(b) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182(b)) is amended by adding at the end the following:

“(3) REFERENCE TO RELATED PROVISION.—

For a provision prohibiting the adjustment of premium or contribution amounts for a group under a group health plan on the basis of predictive genetic information (including information about a request for or receipt of genetic services), see section 714.”

(B) TABLE OF CONTENTS.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by inserting after the item relating to section 713 the following new item:

“Sec. 714. Prohibiting premium discrimination against groups on the basis of predictive genetic information.”

(b) LIMITATION ON COLLECTION OF PREDICTIVE GENETIC INFORMATION.—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) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

“(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), 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 predictive genetic information concerning any individual (including a dependent) or family member of the individual (including information about a request for or receipt of genetic services).

“(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

“(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

“(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (d), of such predictive genetic information.

“(d) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

“(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

“(A) PREPARATION OF WRITTEN NOTICE.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall post or provide, in writing and in a clear and conspicuous manner, notice of the plan or issuer's confidentiality practices, that shall include—

“(i) a description of an individual's rights with respect to predictive genetic information;

“(ii) the procedures established by the plan or issuer for the exercise of the individual's rights; and

“(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

“(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

“(2) ESTABLISHMENT OF SAFEGUARDS.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such plan or issuer.”

(c) 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.—The term ‘genetic information’ means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member (including information about a request for or receipt of genetic services).

“(7) GENETIC SERVICES.—The term ‘genetic services’ means health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

“(8) PREDICTIVE GENETIC INFORMATION.—

“(A) IN GENERAL.—The term ‘predictive genetic information’ means, in the absence of symptoms, clinical signs, or a diagnosis of the condition related to such information—

“(i) information about an individual's genetic tests;

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

“(iii) information about the occurrence of a disease or disorder in family members.

“(B) EXCEPTIONS.—The term ‘predictive genetic information’ shall not include—

“(i) information about the sex or age of the individual;

“(ii) information derived from physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests; and

“(iii) information about physical exams of the individual.

“(9) GENETIC TEST.—The term ‘genetic test’ means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of disease in asymptomatic or undiagnosed individuals. Such term does not include physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests, and physical exams of the individual, in order to detect symptoms, clinical signs, or a diagnosis of disease.”

(d) EFFECTIVE DATE.—Except as provided in this section, this section and the amendments made by this section shall apply with respect to group health plans for plan years beginning 1 year after the date of the enactment of this Act.

SEC. 403. 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 IN THE GROUP MARKET.—

(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)”.

(B) NO DISCRIMINATION IN PREMIUMS BASED ON PREDICTIVE GENETIC INFORMATION.—Subpart 2 of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-4 et seq.) is amended by adding at the end the following new section:

“SEC. 2707. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION IN THE GROUP MARKET.

“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 predictive genetic information concerning any individual (including a dependent) or family member of the individual (including information about a request for or receipt of genetic services).”

(C) CONFORMING AMENDMENT.—Section 2702(b) of the Public Health Service Act (42 U.S.C. 300gg-1(b)) is amended by adding at the end the following:

“(3) REFERENCE TO RELATED PROVISION.—For a provision prohibiting the adjustment of premium or contribution amounts for a group under a group health plan on the basis of predictive genetic information (including information about a request for or receipt of genetic services), see section 2707.”

(D) LIMITATION ON COLLECTION AND DISCLOSURE OF PREDICTIVE GENETIC INFORMATION.—Section 2702 of the Public Health Service Act (42 U.S.C. 300gg-1) is amended by adding at the end the following:

“(c) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

“(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), 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 predictive genetic information concerning any individual (including a dependent) or family member of the individual (including information about a request for or receipt of genetic services).

“(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

“(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

“(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (d), of such predictive genetic information.

“(d) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

“(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

“(A) PREPARATION OF WRITTEN NOTICE.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall post or provide, in writing and in a clear and conspicuous manner, notice of the plan or issuer's confidentiality practices, that shall include—

“(i) a description of an individual's rights with respect to predictive genetic information;

“(ii) the procedures established by the plan or issuer for the exercise of the individual’s rights; and

“(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

“(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

“(2) ESTABLISHMENT OF SAFEGUARDS.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such plan or issuer.”

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

“(15) FAMILY MEMBER.—The term ‘family member’ means, with respect to an individual—

“(A) the spouse of the individual;

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

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

“(16) GENETIC INFORMATION.—The term ‘genetic information’ means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member (including information about a request for or receipt of genetic services).

“(17) GENETIC SERVICES.—The term ‘genetic services’ means health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

“(18) PREDICTIVE GENETIC INFORMATION.—

“(A) IN GENERAL.—The term ‘predictive genetic information’ means, in the absence of symptoms, clinical signs, or a diagnosis of the condition related to such information—

“(i) information about an individual’s genetic tests;

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

“(iii) information about the occurrence of a disease or disorder in family members.

“(B) EXCEPTIONS.—The term ‘predictive genetic information’ shall not include—

“(i) information about the sex or age of the individual;

“(ii) information derived from physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests; and

“(iii) information about physical exams of the individual.

“(19) GENETIC TEST.—The term ‘genetic test’ means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of disease in asymptomatic or undiagnosed individuals. Such term does not include physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol

tests, and physical exams of the individual, in order to detect symptoms, clinical signs, or a diagnosis of disease.”

(e) AMENDMENTS TO PHSA RELATING TO THE INDIVIDUAL MARKET.—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) (42 U.S.C. 300gg-51 et seq.) is amended by adding at the end the following:

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

“(a) PROHIBITION ON PREDICTIVE GENETIC INFORMATION AS A CONDITION OF ELIGIBILITY.—A health insurance issuer offering health insurance coverage in the individual market may not use predictive genetic information as a condition of eligibility of an individual to enroll in individual health insurance coverage (including information about a request for or receipt of genetic services).

“(b) PROHIBITION ON PREDICTIVE GENETIC INFORMATION IN SETTING PREMIUM RATES.—A health insurance issuer offering health insurance coverage in the individual market shall not adjust premium rates for individuals on the basis of predictive genetic information concerning such an individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

“(c) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

“(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a health insurance issuer offering health insurance coverage in the individual market shall not request or require predictive genetic information concerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

“(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

“(A) IN GENERAL.—Notwithstanding paragraph (1), a health insurance issuer offering health insurance coverage in the individual market that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

“(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the health insurance issuer offering health insurance coverage in the individual market shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (d), of such predictive genetic information.

“(d) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

“(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

“(A) PREPARATION OF WRITTEN NOTICE.—A health insurance issuer offering health insurance coverage in the individual market shall post or provide, in writing and in a clear and conspicuous manner, notice of the issuer’s confidentiality practices, that shall include—

“(i) a description of an individual’s rights with respect to predictive genetic information;

“(ii) the procedures established by the issuer for the exercise of the individual’s rights; and

“(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

“(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

“(2) ESTABLISHMENT OF SAFEGUARDS.—A health insurance issuer offering health insurance coverage in the individual market shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such issuer.”

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to—

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

(2) health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after 1 year after the date of enactment of this Act.

SEC. 404. AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986.

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

(1) NO ENROLLMENT RESTRICTION FOR GENETIC SERVICES.—Section 9802(a)(1)(F) of the Internal Revenue Code of 1986 is amended by inserting before the period the following: “(including information about a request for or receipt of genetic services)”.

(2) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON PREDICTIVE GENETIC INFORMATION.—

(A) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is further amended by adding at the end the following:

“SEC. 9813. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

“A group health plan shall not adjust premium or contribution amounts for a group on the basis of predictive genetic information concerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).”

(B) CONFORMING AMENDMENT.—Section 9802(b) of the Internal Revenue Code of 1986 is amended by adding at the end the following:

“(3) REFERENCE TO RELATED PROVISION.—For a provision prohibiting the adjustment of premium or contribution amounts for a group under a group health plan on the basis of predictive genetic information (including information about a request for or the receipt of genetic services), see section 9813.”

(C) AMENDMENT TO TABLE OF SECTIONS.—The table of sections for subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following:

“Sec. 9813. Prohibiting premium discrimination against groups on the basis of predictive genetic information.”

(b) LIMITATION ON COLLECTION OF PREDICTIVE GENETIC INFORMATION.—Section 9802

of the Internal Revenue Code of 1986 is amended by adding at the end the following:

“(d) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

“(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a group health plan shall not request or require predictive genetic information concerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

“(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

“(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

“(B) NOTICE OF CONFIDENTIALITY PRACTICES; DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the group health plan shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (e), of such predictive genetic information.

“(e) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

“(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

“(A) PREPARATION OF WRITTEN NOTICE.—A group health plan shall post or provide, in writing and in a clear and conspicuous manner, notice of the plan's confidentiality practices, that shall include—

“(i) a description of an individual's rights with respect to predictive genetic information;

“(ii) the procedures established by the plan for the exercise of the individual's rights; and

“(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

“(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

“(2) ESTABLISHMENT OF SAFEGUARDS.—A group health plan shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such plan.”.

(c) DEFINITIONS.—Section 9832(d) of the Internal Revenue Code of 1986 is amended by adding at the end the following:

“(6) 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).

“(7) GENETIC INFORMATION.—The term ‘genetic information’ means information about

genes, gene products, or inherited characteristics that may derive from an individual or a family member (including information about a request for or receipt of genetic services).

“(8) GENETIC SERVICES.—The term ‘genetic services’ means health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

“(9) PREDICTIVE GENETIC INFORMATION.—“(A) IN GENERAL.—The term ‘predictive genetic information’ means, in the absence of symptoms, clinical signs, or a diagnosis of the condition related to such information—

“(i) information about an individual's genetic tests;

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

“(iii) information about the occurrence of a disease or disorder in family members.

“(B) EXCEPTIONS.—The term ‘predictive genetic information’ shall not include—

“(i) information about the sex or age of the individual;

“(ii) information derived from physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests; and

“(iii) information about physical exams of the individual.

“(10) GENETIC TEST.—The term ‘genetic test’ means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of disease in asymptomatic or undiagnosed individuals. Such term does not include physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests, and physical exams of the individual, in order to detect symptoms, clinical signs, or a diagnosis of disease.”.

(d) EFFECTIVE DATE.—Except as provided in this section, this section and the amendments made by this section shall apply with respect to group health plans for plan years beginning after 1 year after the date of the enactment of this Act.

TORRICELLI (AND REED)
AMENDMENT NO. 3692

(Ordered to lie on the table.)

Mr. TORRICELLI (for himself and Mr. REED) submitted an amendment intended to be proposed by them to the bill, H.R. 4577, *supra*; as follows:

On page 26, line 25, strike “\$3,204,496,000, of which” and insert “\$3,214,496,000, of which \$10,000,000 shall be made available to carry out section 317A of the Public Health Service Act and of which”.

On page 92, between lines 4 and 5, insert the following:

SEC. ____ . Amounts made available under this Act for the salaries and expenses of the Department of Labor, the Department of Health and Human Services, and the Department of Education shall be reduced on a pro rata basis, by a total of \$10,000,000.

DORGAN (AND OTHERS)
AMENDMENT NO. 3693

Mr. DORGAN (for himself, Mr. KENNEDY, Mr. DASCHLE, Mr. GRAHAM, Ms. MIKULSKI, Mr. LAUTENBERG, Mr. KERRY, Mr. EDWARDS, Mr. HARKIN, Mr. REID, Mr. ROCKEFELLER, and Mr. ROBB) proposed an amendment to the bill, H.R. 4577, *supra*; as follows:

On page 92, between lines 4 and 5, insert the following:

SEC. ____ . Any Act that is designed to protect patients against the abuses of managed care that is enacted after June 27, 2000, shall, at a minimum—

(1) provide a floor of Federal protection that is applicable to all individuals enrolled in private health plans or private health insurance coverage, including—

(A) individuals enrolled in self-insured and insured health plans that are regulated under the Employee Retirement Income Security Act of 1974;

(B) individuals enrolled in health insurance coverage purchased in the individual market; and

(C) individuals enrolled in health plans offered to State and local government employees;

(2) provide that States may provide patient protections that are equal to or greater than the protections provided under such Act; and

(3) provide the Federal Government with the authority to ensure that the Federal floor referred to in paragraph (1) is being guaranteed and enforced with respect to all individuals described in such paragraph, including determining whether protections provided under State law meet the standards of such Act.

NICKLES AMENDMENT NO. 3694

Mr. NICKLES proposed an amendment to the bill, H.R. 4577, *supra*; as follows:

On page 92, strike line 5, and insert the following:

DIVISION HEALTH CARE ACCESS AND PROTECTIONS FOR CONSUMERS

SEC. 1. SHORT TITLE.

This division may be cited as the “Patients’ Bill of Rights Plus Act”.

TITLE I—TAX-RELATED HEALTH CARE PROVISIONS

Subtitle A—Health Care and Long-Term Care

SEC. 101. DEDUCTION FOR HEALTH AND LONG-TERM CARE INSURANCE COSTS OF INDIVIDUALS NOT PARTICIPATING IN EMPLOYER-SUBSIDIZED HEALTH PLANS.

(a) IN GENERAL.—Part VII of subchapter B of chapter 1 of the Internal Revenue Code of 1986 is amended by redesignating section 222 as section 223 and by inserting after section 221 the following new section:

“SEC. 222. HEALTH AND LONG-TERM CARE INSURANCE COSTS.

“(a) IN GENERAL.—In the case of an individual, there shall be allowed as a deduction an amount equal to the applicable percentage of the amount paid during the taxable year for insurance which constitutes medical care for the taxpayer and the taxpayer's spouse and dependents.

“(b) APPLICABLE PERCENTAGE.—

“(1) IN GENERAL.—For purposes of subsection (a), the applicable percentage shall be determined in accordance with the following table:

“For taxable years beginning in calendar year—	The applicable percentage is—
2002 and 2003	25
2004	35
2005	65
2006 and thereafter	100.

“(2) LONG-TERM CARE INSURANCE FOR INDIVIDUALS 60 YEARS OR OLDER.—In the case of amounts paid for a qualified long-term care insurance contract for an individual who has attained age 60 before the close of the taxable year, the applicable percentage is 100.

“(c) LIMITATION BASED ON OTHER COVERAGE.—

“(1) COVERAGE UNDER CERTAIN SUBSIDIZED EMPLOYER PLANS.—

“(A) IN GENERAL.—Subsection (a) shall not apply to any taxpayer for any calendar month for which the taxpayer participates in any health plan maintained by any employer of the taxpayer or of the spouse of the taxpayer if 50 percent or more of the cost of coverage under such plan (determined under section 4980B and without regard to payments made with respect to any coverage described in subsection (e)) is paid or incurred by the employer.

“(B) EMPLOYER CONTRIBUTIONS TO CAFETERIA PLANS, FLEXIBLE SPENDING ARRANGEMENTS, AND MEDICAL SAVINGS ACCOUNTS.—Employer contributions to a cafeteria plan, a flexible spending or similar arrangement, or a medical savings account which are excluded from gross income under section 106 shall be treated for purposes of subparagraph (A) as paid by the employer.

“(C) AGGREGATION OF PLANS OF EMPLOYER.—A health plan which is not otherwise described in subparagraph (A) shall be treated as described in such subparagraph if such plan would be so described if all health plans of persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 were treated as one health plan.

“(D) SEPARATE APPLICATION TO HEALTH INSURANCE AND LONG-TERM CARE INSURANCE.—Subparagraphs (A) and (C) shall be applied separately with respect to—

“(i) plans which include primarily coverage for qualified long-term care services or are qualified long-term care insurance contracts, and

“(ii) plans which do not include such coverage and are not such contracts.

“(2) COVERAGE UNDER CERTAIN FEDERAL PROGRAMS.—

“(A) IN GENERAL.—Subsection (a) shall not apply to any amount paid for any coverage for an individual for any calendar month if, as of the first day of such month, the individual is covered under any medical care program described in—

“(i) title XVIII, XIX, or XXI of the Social Security Act,

“(ii) chapter 55 of title 10, United States Code,

“(iii) chapter 17 of title 38, United States Code,

“(iv) chapter 89 of title 5, United States Code, or

“(v) the Indian Health Care Improvement Act.

“(B) EXCEPTIONS.—

“(i) QUALIFIED LONG-TERM CARE.—Subparagraph (A) shall not apply to amounts paid for coverage under a qualified long-term care insurance contract.

“(ii) CONTINUATION COVERAGE OF FEHBP.—Subparagraph (A)(iv) shall not apply to coverage which is comparable to continuation coverage under section 4980B.

“(d) LONG-TERM CARE DEDUCTION LIMITED TO QUALIFIED LONG-TERM CARE INSURANCE CONTRACTS.—In the case of a qualified long-term care insurance contract, only eligible long-term care premiums (as defined in section 213(d)(10)) may be taken into account under subsection (a).

“(e) DEDUCTION NOT AVAILABLE FOR PAYMENT OF ANCILLARY COVERAGE PREMIUMS.—Any amount paid as a premium for insurance which provides for—

“(1) coverage for accidents, disability, dental care, vision care, or a specified illness, or

“(2) making payments of a fixed amount per day (or other period) by reason of being hospitalized,

shall not be taken into account under subsection (a).

“(f) SPECIAL RULES.—

“(1) COORDINATION WITH DEDUCTION FOR HEALTH INSURANCE COSTS OF SELF-EMPLOYED INDIVIDUALS.—The amount taken into account by the taxpayer in computing the deduction under section 162(l) shall not be taken into account under this section.

“(2) COORDINATION WITH MEDICAL EXPENSE DEDUCTION.—The amount taken into account by the taxpayer in computing the deduction under this section shall not be taken into account under section 213.

“(g) REGULATIONS.—The Secretary shall prescribe such regulations as may be appropriate to carry out this section, including regulations requiring employers to report to their employees and the Secretary such information as the Secretary determines to be appropriate.”.

(b) DEDUCTION ALLOWED WHETHER OR NOT TAXPAYER ITEMIZES OTHER DEDUCTIONS.—Subsection (a) of section 62 of such Code is amended by inserting after paragraph (17) the following new item:

“(18) HEALTH AND LONG-TERM CARE INSURANCE COSTS.—The deduction allowed by section 222.”.

(c) CLERICAL AMENDMENT.—The table of sections for part VII of subchapter B of chapter 1 of such Code is amended by striking the last item and inserting the following new items:

“Sec. 222. Health and long-term care insurance costs.

“Sec. 223. Cross reference.”.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2001.

SEC. 102. DEDUCTION FOR 100 PERCENT OF HEALTH INSURANCE COSTS OF SELF-EMPLOYED INDIVIDUALS.

(a) IN GENERAL.—Paragraph (1) of section 162(l) of the Internal Revenue Code of 1986 is amended to read as follows:

“(1) ALLOWANCE OF DEDUCTION.—In the case of an individual who is an employee within the meaning of section 401(c)(1), there shall be allowed as a deduction under this section an amount equal to 100 percent of the amount paid during the taxable year for insurance which constitutes medical care for the taxpayer and the taxpayer's spouse and dependents.”.

(b) CLARIFICATION OF LIMITATIONS ON OTHER COVERAGE.—The first sentence of section 162(l)(2)(B) of such Code is amended to read as follows: “Paragraph (1) shall not apply to any taxpayer for any calendar month for which the taxpayer participates in any subsidized health plan maintained by any employer (other than an employer described in section 401(c)(4)) of the taxpayer or the spouse of the taxpayer.”.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2001.

SEC. 103. LONG-TERM CARE INSURANCE PERMITTED TO BE OFFERED UNDER CAFETERIA PLANS AND FLEXIBLE SPENDING ARRANGEMENTS.

(a) CAFETERIA PLANS.—

(1) IN GENERAL.—Subsection (f) of section 125 of the Internal Revenue Code of 1986 (defining qualified benefits) is amended by inserting before the period at the end “; except that such term shall include the payment of premiums for any qualified long-term care insurance contract (as defined in section 7702B) to the extent the amount of such payment does not exceed the eligible long-term care premiums (as defined in section 213(d)(10)) for such contract”.

(b) FLEXIBLE SPENDING ARRANGEMENTS.—Section 106 of such Code (relating to contributions by employer to accident and health plans) is amended by striking subsection (c).

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2001.

SEC. 104. ADDITIONAL PERSONAL EXEMPTION FOR TAXPAYER CARING FOR ELDERLY FAMILY MEMBER IN TAXPAYER'S HOME.

(a) IN GENERAL.—Section 151 of the Internal Revenue Code of 1986 (relating to allowance of deductions for personal exemptions) is amended by redesignating subsection (e) as subsection (f) and by inserting after subsection (d) the following new subsection:

“(e) ADDITIONAL EXEMPTION FOR CERTAIN ELDERLY FAMILY MEMBERS RESIDING WITH TAXPAYER.—

“(1) IN GENERAL.—An exemption of the exemption amount for each qualified family member of the taxpayer.

“(2) QUALIFIED FAMILY MEMBER.—For purposes of this subsection, the term ‘qualified family member’ means, with respect to any taxable year, any individual—

“(A) who is an ancestor of the taxpayer or of the taxpayer's spouse or who is the spouse of any such ancestor,

“(B) who is a member for the entire taxable year of a household maintained by the taxpayer, and

“(C) who has been certified, before the due date for filing the return of tax for the taxable year (without extensions), by a physician (as defined in section 1861(r)(1) of the Social Security Act) as being an individual with long-term care needs described in paragraph (3) for a period—

“(i) which is at least 180 consecutive days, and

“(ii) a portion of which occurs within the taxable year.

Such term shall not include any individual otherwise meeting the requirements of the preceding sentence unless within the 39½ month period ending on such due date (or such other period as the Secretary prescribes) a physician (as so defined) has certified that such individual meets such requirements.

“(3) INDIVIDUALS WITH LONG-TERM CARE NEEDS.—An individual is described in this paragraph if the individual—

“(A) is unable to perform (without substantial assistance from another individual) at least two activities of daily living (as defined in section 7702B(c)(2)(B)) due to a loss of functional capacity, or

“(B) requires substantial supervision to protect such individual from threats to health and safety due to severe cognitive impairment and is unable to perform, without reminding or cuing assistance, at least one activity of daily living (as so defined) or to the extent provided in regulations prescribed by the Secretary (in consultation with the Secretary of Health and Human Services), is unable to engage in age appropriate activities.

“(4) SPECIAL RULES.—Rules similar to the rules of paragraphs (1), (2), (3), (4), and (5) of section 21(e) shall apply for purposes of this subsection.”.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2001.

SEC. 105. STUDY OF LONG-TERM CARE NEEDS IN THE 21ST CENTURY.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall on or after October 1, 2001, provide, in accordance with this section, for a study in order to determine—

(1) future demand for long-term health care services (including institutional and home and community-based services) in the United States in order to meet the needs in the 21st century; and

(2) long-term options to finance the provision of such services.

(b) DETAILS.—The study conducted under subsection (a) shall include the following:

(1) An identification of the relevant demographic characteristics affecting demand for long-term health care services, at least through the year 2030.

(2) The viability and capacity of community-based and other long-term health care services under different federal programs, including through the medicare and medicaid programs, grants to States, housing services, and changes in tax policy.

(3) How to improve the quality of long-term health care services.

(4) The integration of long-term health care services for individuals between different classes of health care providers (such as hospitals, nursing facilities, and home care agencies) and different Federal programs (such as the medicare and medicaid programs).

(5) The possibility of expanding private sector initiatives, including long-term care insurance, to meet the need to finance such services.

(6) An examination of the effect of enactment of the Health Insurance Portability and Accountability Act of 1996 on the provision and financing of long-term health care services, including on portability and affordability of private long-term care insurance, the impact of insurance options on low-income older Americans, and the options for eligibility to improve access to such insurance.

(7) The financial impact of the provision of long-term health care services on caregivers and other family members.

(c) REPORT AND RECOMMENDATIONS.—

(1) IN GENERAL.—October 1, 2002, the Secretary shall provide for a report on the study under this section.

(2) RECOMMENDATIONS.—The report under paragraph (1) shall include findings and recommendations regarding each of the following:

(A) The most effective and efficient manner that the Federal Government may use its resources to educate the public on planning for needs for long-term health care services.

(B) The public, private, and joint public-private strategies for meeting identified needs for long-term health care services.

(C) The role of States and local communities in the financing of long-term health care services.

(3) INCLUSION OF COST ESTIMATES.—The report under paragraph (1) shall include cost estimates of the various options for which recommendations are made.

(d) CONDUCT OF STUDY.—

(1) USE OF INSTITUTE OF MEDICINE.—The Secretary of Health and Human Services shall seek to enter into an appropriate arrangement with the Institute of Medicine of the National Academy of Sciences to conduct the study under this section. If such an arrangement cannot be made, the Secretary may provide for the conduct of the study by

any other qualified non-governmental entity.

(2) CONSULTATION.—The study should be conducted under this section in consultation with experts from a wide-range of groups from the public and private sectors.

Subtitle B—Medical Savings Accounts**SEC. 111. EXPANSION OF AVAILABILITY OF MEDICAL SAVINGS ACCOUNTS.**

(a) REPEAL OF LIMITATIONS ON NUMBER OF MEDICAL SAVINGS ACCOUNTS.—

(1) IN GENERAL.—Subsections (i) and (j) of section 220 of the Internal Revenue Code of 1986 are hereby repealed.

(2) CONFORMING AMENDMENTS.—

(A) Paragraph (1) of section 220(c) of such Code is amended by striking subparagraph (D).

(B) Section 138 of such Code is amended by striking subsection (f).

(b) AVAILABILITY NOT LIMITED TO ACCOUNTS FOR EMPLOYEES OF SMALL EMPLOYERS AND SELF-EMPLOYED INDIVIDUALS.—

(1) IN GENERAL.—Section 220(c)(1)(A) of such Code (relating to eligible individual) is amended to read as follows:

“(A) IN GENERAL.—The term ‘eligible individual’ means, with respect to any month, any individual if—

“(i) such individual is covered under a high deductible health plan as of the 1st day of such month, and

“(ii) such individual is not, while covered under a high deductible health plan, covered under any health plan—

“(I) which is not a high deductible health plan, and

“(II) which provides coverage for any benefit which is covered under the high deductible health plan.”.

(2) CONFORMING AMENDMENTS.—

(A) Section 220(c)(1) of such Code is amended by striking subparagraph (C).

(B) Section 220(c) of such Code is amended by striking paragraph (4) (defining small employer) and by redesignating paragraph (5) as paragraph (4).

(C) Section 220(b) of such Code is amended by striking paragraph (4) (relating to deduction limited by compensation) and by redesignating paragraphs (5), (6), and (7) as paragraphs (4), (5), and (6), respectively.

(c) INCREASE IN AMOUNT OF DEDUCTION ALLOWED FOR CONTRIBUTIONS TO MEDICAL SAVINGS ACCOUNTS.—

(1) IN GENERAL.—Paragraph (2) of section 220(b) of such Code is amended to read as follows:

“(2) MONTHLY LIMITATION.—The monthly limitation for any month is the amount equal to 1/2 of the annual deductible (as of the first day of such month) of the individual’s coverage under the high deductible health plan.”.

(2) CONFORMING AMENDMENT.—Clause (ii) of section 220(d)(1)(A) of such Code is amended by striking “75 percent of”.

(d) BOTH EMPLOYERS AND EMPLOYEES MAY CONTRIBUTE TO MEDICAL SAVINGS ACCOUNTS.—Paragraph (4) of section 220(b) of such Code (as redesignated by subsection (b)(2)(C)) is amended to read as follows:

“(4) COORDINATION WITH EXCLUSION FOR EMPLOYER CONTRIBUTIONS.—The limitation which would (but for this paragraph) apply under this subsection to the taxpayer for any taxable year shall be reduced (but not below zero) by the amount which would (but for section 106(b)) be includible in the taxpayer’s gross income for such taxable year.”.

(e) REDUCTION OF PERMITTED DEDUCTIBLES UNDER HIGH DEDUCTIBLE HEALTH PLANS.—

(1) IN GENERAL.—Subparagraph (A) of section 220(c)(2) of such Code (defining high deductible health plan) is amended—

(A) by striking “\$1,500” in clause (i) and inserting “\$1,000”;

(B) by striking “\$3,000” in clause (ii) and inserting “\$2,000”; and

(C) by striking the matter preceding subclause (I) in clause (iii) and inserting “pursuant to which the annual out-of-pocket expenses (including deductibles and co-payments) are required to be paid under the plan (other than for premiums) for covered benefits and may not exceed—”.

(2) CONFORMING AMENDMENT.—Subsection (g) of section 220 of such Code is amended to read as follows:

“(g) COST-OF-LIVING ADJUSTMENT.—

“(1) IN GENERAL.—In the case of any taxable year beginning in a calendar year after 2002, each dollar amount in subsection (c)(2) shall be increased by an amount equal to—

“(A) such dollar amount, multiplied by

“(B) the cost-of-living adjustment determined under section 1(f)(3) for the calendar year in which such taxable year begins by substituting ‘calendar year 2001’ for ‘calendar year 1992’ in subparagraph (B) thereof.

“(2) SPECIAL RULES.—In the case of the \$1,000 amount in subsection (c)(2)(A)(i) and the \$2,000 amount in subsection (c)(2)(A)(ii), paragraph (1)(B) shall be applied by substituting ‘calendar year 2002’ for ‘calendar year 2001’.

“(3) ROUNDING.—If any increase under paragraph (1) or (2) is not a multiple of \$50, such increase shall be rounded to the nearest multiple of \$50.”.

(f) LIMITATION ON ADDITIONAL TAX ON DISTRIBUTIONS NOT USED FOR QUALIFIED MEDICAL EXPENSES.—Section 220(f)(4) of such Code (relating to additional tax on distributions not used for qualified medical expenses) is amended by adding at the end the following:

“(D) EXCEPTION IN CASE OF SUFFICIENT ACCOUNT BALANCE.—Subparagraph (A) shall not apply to any payment or distribution in any taxable year, but only to the extent such payment or distribution does not reduce the fair market value of the assets of the medical savings account to an amount less than the annual deductible for the high deductible health plan of the account holder (determined as of the earlier of January 1 of the calendar year in which the taxable year begins or January 1 of the last calendar year in which the account holder is covered under a high deductible health plan).”.

(g) TREATMENT OF NETWORK-BASED MANAGED CARE PLANS.—Section 220(c)(2)(B) of such Code (relating to special rules for high deductible health plans) is amended by adding at the end the following:

“(iii) TREATMENT OF NETWORK-BASED MANAGED CARE PLANS.—A plan which provides health care services through a network of contracted or affiliated health care providers, if the benefits provided when services are obtained through network providers meet the requirements of subparagraph (A), shall not fail to be treated as a high deductible health plan by reason of providing benefits for services rendered by providers who are not members of the network, so long as the annual deductible and annual limit on out-of-pocket expenses applicable to services received from non-network providers are not lower than those applicable to services received from the network providers.”.

(h) MEDICAL SAVINGS ACCOUNTS MAY BE OFFERED UNDER CAFETERIA PLANS.—Subsection (f) of section 125 of such Code is amended by striking “106(b).”.

(i) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided by paragraph (2), the amendments made by this

section shall apply to taxable years beginning after December 31, 2001.

(2) LIMITATION ON ADDITIONAL TAX ON DISTRIBUTIONS NOT USED FOR QUALIFIED MEDICAL EXPENSES.—The amendment made by subsection (f) shall apply to taxable years beginning after December 31, 2005.

SEC. 112. AMENDMENTS TO TITLE 5, UNITED STATES CODE, RELATING TO MEDICAL SAVINGS ACCOUNTS AND HIGH DEDUCTIBLE HEALTH PLANS UNDER FEHBP.

(a) MEDICAL SAVINGS ACCOUNTS.—

(1) CONTRIBUTIONS.—Title 5, United States Code, is amended by redesignating section 8906a as section 8906c and by inserting after section 8906 the following:

“§ 8906a. Government contributions to medical savings accounts

“(a) An employee or annuitant enrolled in a high deductible health plan is entitled, in addition to the Government contribution under section 8906(b) toward the subscription charge for such plan, to have a Government contribution made, in accordance with succeeding provisions of this section, to a medical savings account of such employee or annuitant.

“(b)(1) The biweekly Government contribution under this section shall, in the case of any such employee or annuitant, be equal to the amount (if any) by which—

“(A) the biweekly equivalent of the maximum Government contribution for the contract year involved (as defined by paragraph (2)), exceeds

“(B) the amount of the biweekly Government contribution payable on such employee's or annuitant's behalf under section 8906(b) for the period involved.

“(2) For purposes of this section, the term ‘maximum Government contribution’ means, with respect to a contract year, the maximum Government contribution that could be made for health benefits for an employee or annuitant for such contract year, as determined under section 8906(b) (disregarding paragraph (2) thereof).

“(3) Notwithstanding any other provision of this section, no contribution under this section shall be payable to any medical savings account of an employee or annuitant for any period—

“(A) if, as of the first day of the month before the month in which such period commences, such employee or annuitant (or the spouse of such employee or annuitant, if coverage is for self and family) is entitled to benefits under part A of title XVIII of the Social Security Act;

“(B) to the extent that such contribution, when added to previous contributions made under this section for that same year with respect to such employee or annuitant, would cause the total to exceed—

“(i) the limitation under paragraph (1) of section 220(b) of the Internal Revenue Code of 1986 (determined without regard to paragraph (3) thereof) which is applicable to such employee or annuitant for the calendar year in which such period commences; or

“(ii) such lower amount as the employee or annuitant may specify in accordance with regulations of the Office, including an election not to receive contributions under this section for a year or the remainder of a year; or

“(C) for which any information (or documentation) under subsection (d) that is needed in order to make such contribution has not been timely submitted.

“(4) Notwithstanding any other provision of this section, no contribution under this section shall be payable to any medical sav-

ings account of an employee for any period in a contract year unless that employee was enrolled in a health benefits plan under this chapter as an employee for not less than—

“(A) the 1 year of service immediately before the start of such contract year, or

“(B) the full period or periods of service between the last day of the first period, as prescribed by regulations of the Office of Personnel Management, in which he is eligible to enroll in the plan and the day before the start of such contract year, whichever is shorter.

“(5) The Office shall provide for the conversion of biweekly rates of contributions specified by paragraph (1) to rates for employees and annuitants whose pay or annuity is provided on other than a biweekly basis, and for this purpose may provide for the adjustment of the converted rate to the nearest cent.

“(c) A Government contribution under this section—

“(1) shall be made at the same time that, and the same frequency with which, Government contributions under section 8906(b) are made for the benefit of the employee or annuitant involved; and

“(2) shall be payable from the same appropriation, fund, account, or other source as would any Government contributions under section 8906(b) with respect to the employee or annuitant involved.

“(d) The Office shall by regulation prescribe the time, form, and manner in which an employee or annuitant shall submit any information (and supporting documentation) necessary to identify any medical savings account to which contributions under this section are requested to be made.

“(e) Nothing in this section shall be considered to entitle an employee or annuitant to any Government contribution under this section with respect to any period for which such employee or annuitant is ineligible for a Government contribution under section 8906(b).

“§ 8906b. Individual contributions to medical savings accounts

“(a) Upon the written request of an employee or annuitant enrolled in a high deductible health plan, there shall be withheld from the pay or annuity of such employee or annuitant and contributed to the medical savings account identified by such employee or annuitant in accordance with applicable regulations under subsection (c) such amount as the employee or annuitant may specify.

“(b) Notwithstanding subsection (a), no withholding under this section may be made from the pay or annuity of an employee or annuitant for any period—

“(1) if, or to the extent that, a Government contribution for such period under section 8906a would not be allowable by reason of subparagraph (A) or (B)(i) of subsection (b)(3) thereof;

“(2) for which any information (or documentation) that is needed in order to make such contribution has not been timely submitted; or

“(3) if the employee or annuitant submits a request for termination of withholdings, beginning on or after the effective date of the request and before the end of the year.

“(c) The Office of Personnel Management shall prescribe any regulations necessary to carry out this section, including provisions relating to the time, form, and manner in which any request for withholdings under this section may be made, changed, or terminated.”.

(2) RULES OF CONSTRUCTION.—Nothing in this section or in any amendment made by this section shall be considered—

(A) to permit or require that any contributions to a medical savings account (whether by the Government or through withholdings from pay or annuity) be paid into the Employees Health Benefits Fund; or

(B) to affect any authority under section 1005(f) of title 39, United States Code, to vary, add to, or substitute for any provision of chapter 89 of title 5, United States Code, as amended by this section.

(3) CONFORMING AMENDMENTS.—

(A) The table of sections at the beginning of chapter 89 of title 5, United States Code, is amended by striking the item relating to section 8906a and inserting the following:

“8906a. Government contributions to medical savings accounts.

“8906b. Individual contributions to medical savings accounts.

“8906c. Temporary employees.”.

(B) Section 8913(b)(4) of title 5, United States Code, is amended by striking “8906a(a)” and inserting “8906c(a)”.

(b) INFORMATIONAL REQUIREMENTS.—Section 8907 of title 5, United States Code, is amended by adding at the end the following:

“(c) In addition to any information otherwise required under this section, the Office shall make available to all employees and annuitants eligible to enroll in a high deductible health plan, information relating to—

“(1) the conditions under which Government contributions under section 8906a shall be made to a medical savings account;

“(2) the amount of any Government contributions under section 8906a to which an employee or annuitant may be entitled (or how such amount may be ascertained);

“(3) the conditions under which contributions to a medical savings account may be made under section 8906b through withholdings from pay or annuity; and

“(4) any other matter the Office considers appropriate in connection with medical savings accounts.”.

(c) HIGH DEDUCTIBLE HEALTH PLAN AND MEDICAL SAVINGS ACCOUNT DEFINED.—Section 8901 of title 5, United States Code, is amended—

(1) in paragraph (10) by striking “and” after the semicolon;

(2) in paragraph (11) by striking the period and inserting a semicolon; and

(3) by adding at the end the following:

“(12) the term ‘high deductible health plan’ means a plan described by section 8903(5) or section 8903a(d); and

“(13) the term ‘medical savings account’ has the meaning given such term by section 220(d) of the Internal Revenue Code of 1986.”.

(d) AUTHORITY TO CONTRACT FOR HIGH DEDUCTIBLE HEALTH PLANS, ETC.—

(1) CONTRACTS FOR HIGH DEDUCTIBLE HEALTH PLANS.—Section 8902 of title 5, United States Code, is amended by adding at the end the following:

“(p)(1) The Office shall contract under this chapter for a high deductible health plan with any qualified carrier that offers such a plan and, as of the date of enactment of this subsection, offers a health benefits plan under this chapter.

“(2) The Office may contract under this chapter for a high deductible health plan with any qualified carrier that offers such a plan, but does not, as of the date of enactment of this subsection, offer a health benefits plan under this chapter.”.

(2) COMPUTATION OF GOVERNMENT CONTRIBUTIONS TO PLANS UNDER CHAPTER 89 NOT AFFECTED BY HIGH DEDUCTIBLE HEALTH PLANS.—

Paragraph (2) of section 8906(a) of title 5, United States Code, is amended by striking “(2)” and inserting “(2)(A)”, and adding at the end the following:

“(B) Notwithstanding any other provision of this section, the subscription charges for, and the number of enrollees enrolled in, high deductible health plans shall be disregarded for purposes of determining any weighted average under paragraph (1).”

(e) DESCRIPTION OF HIGH DEDUCTIBLE HEALTH PLANS AND BENEFITS TO BE PROVIDED THEREUNDER.—

(1) IN GENERAL.—Section 8903 of title 5, United States Code, is amended by adding at the end the following:

“(5) HIGH DEDUCTIBLE HEALTH PLANS.—(A) One or more plans described by paragraph (1), (2), (3), or (4), which—

“(i) are high deductible health plans (as defined by section 220(c)(2) of the Internal Revenue Code of 1986); and

“(ii) provide benefits of the types referred to by section 8904(a)(5).

“(B) Nothing in this section shall be considered—

“(i) to prevent a carrier from simultaneously offering a plan described by subparagraph (A) and a plan described by paragraph (1) or (2); or

“(ii) to require that a high deductible health plan offer two levels of benefits.”

(2) TYPES OF BENEFITS.—Section 8904(a) of title 5, United States Code, is amended by inserting after paragraph (4) the following:

“(5) HIGH DEDUCTIBLE HEALTH PLANS.—Benefits of the types named under paragraph (1) or (2) of this subsection or both.”

(3) CONFORMING AMENDMENTS.—

(A) Section 8903a of title 5, United States Code, is amended by redesignating subsection (d) as subsection (e) and by inserting after subsection (c) the following:

“(d) The plans under this section may include one or more plans, otherwise allowable under this section, that satisfy the requirements of clauses (i) and (ii) of section 8903(5)(A).”

(B) Section 8909(d) of title 5, United States Code, is amended by striking “8903a(d)” and inserting “8903a(e)”.

(4) REFERENCES.—Section 8903 of title 5, United States Code, is amended by adding after paragraph (5) (as added by paragraph (1) of this subsection) as a flush left sentence, the following:

“The Office shall prescribe regulations in accordance with which the requirements of section 8902(c), 8902(n), 8909(e), and any other provision of this chapter that applies with respect to a plan described by paragraph (1), (2), (3), or (4) of this section shall apply with respect to the corresponding plan under paragraph (5) of this section. Similar regulations shall be prescribed with respect to any plan under section 8903a(d).”

(f) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to contract years beginning on or after October 1, 2001. The Office of Personnel Management shall take appropriate measures to ensure that coverage under a high deductible health plan under chapter 89 of title 5, United States Code (as amended by this section) shall be available as of the beginning of the first contract year described in the preceding sentence.

SEC. 113. RULE WITH RESPECT TO CERTAIN PLANS.

(a) IN GENERAL.—Notwithstanding any other provision of law, health insurance issuers may offer, and eligible individuals may purchase, high deductible health plans described in section 220(c)(2)(A) of the Inter-

nal Revenue Code of 1986. Effective for the 5-year period beginning on October 1, 2001, such health plans shall not be required to provide payment for any health care items or services that are exempt from the plan's deductible.

(b) EXISTING STATE LAWS.—A State law relating to payment for health care items and services in effect on the date of enactment of this Act that is preempted under paragraph (1), shall not apply to high deductible health plans after the expiration of the 5-year period described in such paragraph unless the State reenacts such law after such period.

Subtitle C—Other Health-Related Provisions
SEC. 121. EXPANDED HUMAN CLINICAL TRIALS QUALIFYING FOR ORPHAN DRUG CREDIT.

(a) IN GENERAL.—Subclause (I) of section 45C(b)(2)(A)(ii) of the Internal Revenue Code of 1986 is amended to read as follows:

“(I) after the date that the application is filed for designation under such section 526, and”

(b) CONFORMING AMENDMENT.—Clause (i) of section 45C(b)(2)(A) of such Code is amended by inserting “which is” before “being” and by inserting before the comma at the end “and which is designated under section 526 of such Act”.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to amounts paid or incurred after December 31, 2001.

SEC. 122. CARRYOVER OF UNUSED BENEFITS FROM CAFETERIA PLANS, FLEXIBLE SPENDING ARRANGEMENTS, AND HEALTH FLEXIBLE SPENDING ACCOUNTS.

(a) IN GENERAL.—Section 125 of the Internal Revenue Code of 1986 (relating to cafeteria plans) is amended by redesignating subsections (h) and (i) as subsections (i) and (j) and by inserting after subsection (g) the following new subsection:

“(h) ALLOWANCE OF CARRYOVERS OF UNUSED BENEFITS TO LATER TAXABLE YEARS.—

“(1) IN GENERAL.—For purposes of this title—

“(A) notwithstanding subsection (d)(2), a plan or other arrangement shall not fail to be treated as a cafeteria plan or flexible spending or similar arrangement, and

“(B) no amount shall be required to be included in gross income by reason of this section or any other provision of this chapter, solely because under such plan or other arrangement any nontaxable benefit which is unused as of the close of a taxable year may be carried forward to 1 or more succeeding taxable years.

“(2) LIMITATION.—Paragraph (1) shall not apply to amounts carried from a plan to the extent such amounts exceed \$500 (applied on an annual basis). For purposes of this paragraph, all plans and arrangements maintained by an employer or any related person shall be treated as 1 plan.

“(3) ALLOWANCE OF ROLLOVER.—

“(A) IN GENERAL.—In the case of any unused benefit described in paragraph (1) which consists of amounts in a health flexible spending account or dependent care flexible spending account, the plan or arrangement shall provide that a participant may elect, in lieu of such carryover, to have such amounts distributed to the participant.

“(B) AMOUNTS NOT INCLUDED IN INCOME.—Any distribution under subparagraph (A) shall not be included in gross income to the extent that such amount is transferred in a trustee-to-trustee transfer, or is contributed within 60 days of the date of the distribution, to—

“(i) a qualified cash or deferred arrangement described in section 401(k),

“(ii) a plan under which amounts are contributed by an individual's employer for an annuity contract described in section 403(b),

“(iii) an eligible deferred compensation plan described in section 457, or

“(iv) a medical savings account (within the meaning of section 220).

Any amount rolled over under this subparagraph shall be treated as a rollover contribution for the taxable year from which the unused amount would otherwise be carried.

(C) TREATMENT OF ROLLOVER.—Any amount rolled over under subparagraph (B) shall be treated as an eligible rollover under section 220, 401(k), 403(b), or 457, whichever is applicable, and shall be taken into account in applying any limitation (or participation requirement) on employer or employee contributions under such section or any other provision of this chapter for the taxable year of the rollover.

(4) COST-OF-LIVING ADJUSTMENT.—In the case of any taxable year beginning in a calendar year after 2002, the \$500 amount under paragraph (2) shall be adjusted at the same time and in the same manner as under section 415(d)(2), except that the base period taken into account shall be the calendar quarter beginning October 1, 2001, and any increase which is not a multiple of \$50 shall be rounded to the next lowest multiple of \$50.

(5) APPLICABILITY.—This subsection shall apply to taxable years beginning after December 31, 2001.”

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2001.

SEC. 123. REDUCTION IN TAX ON VACCINES.

(a) IN GENERAL.—Paragraph (1) of section 4131(b) of the Internal Revenue Code of 1986 (relating to amount of tax) is amended by striking “75 cents” and inserting “50 cents”.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on January 1, 2002.

Subtitle D—Miscellaneous Provisions

SEC. 131. NO IMPACT ON SOCIAL SECURITY TRUST FUND.

(a) IN GENERAL.—Nothing in this division (or an amendment made by this division) shall be construed to alter or amend the Social Security Act (or any regulation promulgated under that Act).

(b) TRANSFERS.—

(1) ESTIMATE OF SECRETARY.—The Secretary of the Treasury shall annually estimate the impact that the enactment of this division has on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401).

(2) TRANSFER OF FUNDS.—If, under paragraph (1), the Secretary of the Treasury estimates that the enactment of this division has a negative impact on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401), the Secretary shall transfer, not less frequently than quarterly, from the general revenues of the Federal Government an amount sufficient so as to ensure that the income and balances of such trust funds are not reduced as a result of the enactment of this division.

SEC. 132. CUSTOMS USER FEES.

Section 13031(j)(3) of the Consolidated Omnibus Budget Reconciliation Act of 1985 (19 U.S.C. 58c(j)(3)) is amended by striking “2003” and inserting “2010”.

SEC. 133. ESTABLISHMENT OF MEDICARE ADMINISTRATIVE FEE FOR SUBMISSION OF PAPER CLAIMS.

(a) IMPOSITION OF FEE.—Notwithstanding any other provision of law and subject to

subsection (b), the Secretary of Health and Human Services shall establish (in the form of a separate fee or reduction of payment otherwise made under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.)) an administrative fee of \$1 for the submission of a claim in a paper or non-electronic form for items or services for which payment is sought under such title.

(b) EXCEPTION AUTHORITY.—The Secretary of Health and Human Services shall waive the imposition of the fee under subsection (a)—

(1) in cases in which there is no method available for the submission of claims other than in a paper or non-electronic form; and

(2) for rural providers and small providers that the Secretary determines, under procedures established by the Secretary, are unable to purchase the necessary hardware in order to submit claims electronically.

(c) TREATMENT OF FEES FOR PURPOSES OF COST REPORTS.—An entity may not include a fee assessed pursuant to this section as an allowable item on a cost report under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) or title XIX of such Act (42 U.S.C. 1396 et seq.).

(d) EFFECTIVE DATE.—The provisions of this section apply to claims submitted on or after January 1, 2002.

SEC. 134. ESTABLISHMENT OF MEDICARE ADMINISTRATIVE FEE FOR SUBMISSION OF DUPLICATE AND UNPROCESSABLE CLAIMS.

(a) IMPOSITION OF FEE.—Notwithstanding any other provision of law, the Secretary of Health and Human Services shall establish (in the form of a separate fee or reduction of payment otherwise made under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.)) an administrative fee of \$2 for the submission of a claim described in subsection (b).

(b) CLAIMS SUBJECT TO FEE.—A claim described in this subsection is a claim that—

(1) is submitted by an individual or entity for items or services for which payment is sought under title XVIII of the Social Security Act; and

(2) either—

(A) duplicates, in whole or in part, another claim submitted by the same individual or entity; or

(B) is a claim that cannot be processed and must, in accordance with the Secretary of Health and Human Service's instructions, be returned by the fiscal intermediary or carrier to the individual or entity for completion.

(c) TREATMENT OF FEES FOR PURPOSES OF COST REPORTS.—An entity may not include a fee assessed pursuant to this section as an allowable item on a cost report under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) or title XIX of such Act (42 U.S.C. 1396 et seq.).

(d) EFFECTIVE DATE.—The provisions of this section apply to claims submitted on or after January 1, 2002.

TITLE II—PATIENTS' BILL OF RIGHTS

Subtitle A—Right to Advice and Care

SEC. 201. PATIENT RIGHT TO MEDICAL ADVICE AND CARE.

(a) IN GENERAL.—Part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1181 et seq.) is amended—

(1) by redesignating subpart C as subpart D; and

(2) by inserting after subpart B the following:

“Subpart C—Patient Right to Medical Advice and Care

“SEC. 721. ACCESS TO EMERGENCY MEDICAL CARE.

“(a) COVERAGE OF EMERGENCY SERVICES.—If a group health plan (other than a fully insured group health plan) provides coverage for any benefits consisting of emergency medical care, except for items or services specifically excluded from coverage, the plan shall, without regard to prior authorization or provider participation—

“(1) provide coverage for emergency medical screening examinations to the extent that a prudent layperson, who possesses an average knowledge of health and medicine, would determine such examinations to be necessary; and

“(2) provide coverage for additional emergency medical care to stabilize an emergency medical condition following an emergency medical screening examination (if determined necessary), pursuant to the definition of stabilize under section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

“(b) COVERAGE OF EMERGENCY AMBULANCE SERVICES.—If a group health plan (other than a fully insured group health plan) provides coverage for any benefits consisting of emergency ambulance services, except for items or services specifically excluded from coverage, the plan shall, without regard to prior authorization or provider participation, provide coverage for emergency ambulance services to the extent that a prudent layperson, who possesses an average knowledge of health and medicine, would determine such emergency ambulance services to be necessary.

“(c) CARE AFTER STABILIZATION.—

“(1) IN GENERAL.—In the case of medically necessary and appropriate items or services related to the emergency medical condition that may be provided to a participant or beneficiary by a nonparticipating provider after the participant or beneficiary is stabilized, the nonparticipating provider shall contact the plan as soon as practicable, but not later than 2 hours after stabilization occurs, with respect to whether—

“(A) the provision of items or services is approved;

“(B) the participant or beneficiary will be transferred; or

“(C) other arrangements will be made concerning the care and treatment of the participant or beneficiary.

“(2) FAILURE TO RESPOND AND MAKE ARRANGEMENTS.—If a group health plan fails to respond and make arrangements within 2 hours of being contacted in accordance with paragraph (1), then the plan shall be responsible for the cost of any additional items or services provided by the nonparticipating provider if—

“(A) coverage for items or services of the type furnished by the nonparticipating provider is available under the plan;

“(B) the items or services are medically necessary and appropriate and related to the emergency medical condition involved; and

“(C) the timely provision of the items or services is medically necessary and appropriate.

“(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to apply to a group health plan that does not require prior authorization for items or services provided to a participant or beneficiary after the participant or beneficiary is stabilized.

“(d) REIMBURSEMENT TO A NON-PARTICIPATING PROVIDER.—The responsibility of a group health plan to provide reimbursement

to a nonparticipating provider under this section shall cease accruing upon the earlier of—

“(1) the transfer or discharge of the participant or beneficiary; or

“(2) the completion of other arrangements made by the plan and the nonparticipating provider.

“(e) RESPONSIBILITY OF PARTICIPANT.—With respect to items or services provided by a nonparticipating provider under this section, the participant or beneficiary shall not be responsible for amounts that exceed the amounts (including co-insurance, co-payments, deductibles or any other form of cost-sharing) that would be incurred if the care was provided by a participating health care provider with prior authorization.

“(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a group health plan from negotiating reimbursement rates with a nonparticipating provider for items or services provided under this section.

“(g) DEFINITIONS.—In this section:

“(1) EMERGENCY AMBULANCE SERVICES.—The term ‘emergency ambulance services’ means, with respect to a participant or beneficiary under a group health plan (other than a fully insured group health plan), ambulance services furnished to transport an individual who has an emergency medical condition to a treating facility for receipt of emergency medical care if—

“(A) the emergency services are covered under the group health plan (other than a fully insured group health plan) involved; and

“(B) a prudent layperson who possesses an average knowledge of health and medicine could reasonably expect the absence of such transport to result in placing the health of the participant or beneficiary (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.

“(2) EMERGENCY MEDICAL CARE.—The term ‘emergency medical care’ means, with respect to a participant or beneficiary under a group health plan (other than a fully insured group health plan), covered inpatient and outpatient items or services that—

“(A) are furnished by any provider, including a nonparticipating provider, that is qualified to furnish such items or services; and

“(B) are needed to evaluate or stabilize (as such term is defined in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3))) an emergency medical condition.

“(3) EMERGENCY MEDICAL CONDITION.—The term ‘emergency medical condition’ means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in placing the health of the participant or beneficiary (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.

“SEC. 722. OFFERING OF CHOICE OF COVERAGE OPTIONS.

“(a) REQUIREMENT.—If a group health plan (other than a fully insured group health plan) provides coverage for benefits only through a defined set of participating health

care professionals, the plan shall offer the participant the option to purchase point-of-service coverage (as defined in subsection (b)) for all such benefits for which coverage is otherwise so limited. Such option shall be made available to the participant at the time of enrollment under the plan and at such other times as the plan offers the participant a choice of coverage options.

“(b) POINT-OF-SERVICE COVERAGE DEFINED.—In this section, the term ‘point-of-service coverage’ means, with respect to benefits covered under a group health plan (other than a fully insured group health plan), coverage of such benefits when provided by a nonparticipating health care professional.

“(c) SMALL EMPLOYER EXEMPTION.—

“(1) IN GENERAL.—This section shall not apply to any group health plan (other than a fully insured group health plan) of a small employer.

“(2) SMALL EMPLOYER.—For purposes of paragraph (1), the term ‘small employer’ means, in connection with a group health plan (other than a fully insured group health plan) with respect to a calendar year and a plan year, an employer who employed an average of at least 2 but not more than 50 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year. For purposes of this paragraph, the provisions of subparagraph (C) of section 712(c)(1) shall apply in determining employer size.

“(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

“(1) as requiring coverage for benefits for a particular type of health care professional;

“(2) as requiring an employer to pay any costs as a result of this section or to make equal contributions with respect to different health coverage options;

“(3) as preventing a group health plan (other than a fully insured group health plan) from imposing higher premiums or cost-sharing on a participant for the exercise of a point-of-service coverage option; or

“(4) to require that a group health plan (other than a fully insured group health plan) include coverage of health care professionals that the plan excludes because of fraud, quality of care, or other similar reasons with respect to such professionals.

“SEC. 723. PATIENT ACCESS TO OBSTETRIC AND GYNECOLOGICAL CARE.

“(a) GENERAL RIGHTS.—

“(1) DIRECT ACCESS.—A group health plan described in subsection (b) may not require authorization or referral by the primary care provider described in subsection (b)(2) in the case of a female participant or beneficiary who seeks coverage for obstetrical or gynecological care provided by a participating physician who specializes in obstetrics or gynecology.

“(2) OBSTETRICAL AND GYNECOLOGICAL CARE.—A group health plan described in subsection (b) shall treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (1), by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

“(b) APPLICATION OF SECTION.—A group health plan described in this subsection is a group health plan (other than a fully insured group health plan), that—

“(1) provides coverage for obstetric or gynecologic care; and

“(2) requires the designation by a participant or beneficiary of a participating primary care provider other than a physician who specializes in obstetrics or gynecology.

“(c) RULES OF CONSTRUCTION.—Nothing in this section shall be construed—

“(1) to require that a group health plan approve or provide coverage for—

“(A) any items or services that are not covered under the terms and conditions of the group health plan;

“(B) any items or services that are not medically necessary and appropriate; or

“(C) any items or services that are provided, ordered, or otherwise authorized under subsection (a)(2) by a physician unless such items or services are related to obstetric or gynecologic care;

“(2) to preclude a group health plan from requiring that the physician described in subsection (a) notify the designated primary care professional or case manager of treatment decisions in accordance with a process implemented by the plan, except that the group health plan shall not impose such a notification requirement on the participant or beneficiary involved in the treatment decision;

“(3) to preclude a group health plan from requiring authorization, including prior authorization, for certain items and services from the physician described in subsection (a) who specializes in obstetrics and gynecology if the designated primary care provider of the participant or beneficiary would otherwise be required to obtain authorization for such items or services;

“(4) to require that the participant or beneficiary described in subsection (a)(1) obtain authorization or a referral from a primary care provider in order to obtain obstetrical or gynecological care from a health care professional other than a physician if the provision of obstetrical or gynecological care by such professional is permitted by the group health plan and consistent with State licensure, credentialing, and scope of practice laws and regulations; or

“(5) to preclude the participant or beneficiary described in subsection (a)(1) from designating a health care professional other than a physician as a primary care provider if such designation is permitted by the group health plan and the treatment by such professional is consistent with State licensure, credentialing, and scope of practice laws and regulations.

“SEC. 724. ACCESS TO PEDIATRIC CARE.

“(a) PEDIATRIC CARE.—If a group health plan (other than a fully insured group health plan) requires or provides for a participant or beneficiary to designate a participating primary care provider for a child of such participant or beneficiary, the plan shall permit the participant or beneficiary to designate a physician who specializes in pediatrics as the child’s primary care provider if such provider participates in the network of the plan.

“(b) RULES OF CONSTRUCTION.—With respect to the child of a participant or beneficiary, nothing in subsection (a) shall be construed to—

“(1) require that the participant or beneficiary obtain prior authorization or a referral from a primary care provider in order to obtain pediatric care from a health care professional other than a physician if the provision of pediatric care by such professional is permitted by the plan and consistent with State licensure, credentialing, and scope of practice laws and regulations; or

“(2) preclude the participant or beneficiary from designating a health care professional other than a physician as a primary care

provider for the child if such designation is permitted by the plan and the treatment by such professional is consistent with State licensure, credentialing, and scope of practice laws.

“SEC. 725. TIMELY ACCESS TO SPECIALISTS.

“(a) TIMELY ACCESS.—

“(1) IN GENERAL.—A group health plan (other than a fully insured group health plan) shall ensure that participants and beneficiaries receive timely coverage for access to specialists who are appropriate to the medical condition of the participant or beneficiary, when such specialty care is a covered benefit under the plan.

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

“(A) to require the coverage under a group health plan (other than a fully insured group health plan) of benefits or services;

“(B) to prohibit a plan from including providers in the network only to the extent necessary to meet the needs of the plan’s participants and beneficiaries;

“(C) to prohibit a plan from establishing measures designed to maintain quality and control costs consistent with the responsibilities of the plan; or

“(D) to override any State licensure or scope-of-practice law.

“(3) ACCESS TO CERTAIN PROVIDERS.—

“(A) PARTICIPATING PROVIDERS.—Nothing in this section shall be construed to prohibit a group health plan (other than a fully insured group health plan) from requiring that a participant or beneficiary obtain specialty care from a participating specialist.

“(B) NONPARTICIPATING PROVIDERS.—

“(i) IN GENERAL.—With respect to specialty care under this section, if a group health plan (other than a fully insured group health plan) determines that a participating specialist is not available to provide such care to the participant or beneficiary, the plan shall provide for coverage of such care by a nonparticipating specialist.

“(ii) TREATMENT OF NONPARTICIPATING PROVIDERS.—If a group health plan (other than a fully insured group health plan) refers a participant or beneficiary to a nonparticipating specialist pursuant to clause (i), such specialty care shall be provided at no additional cost to the participant or beneficiary beyond what the participant or beneficiary would otherwise pay for such specialty care if provided by a participating specialist.

“(b) REFERRALS.—

“(1) AUTHORIZATION.—Nothing in this section shall be construed to prohibit a group health plan (other than a fully insured group health plan) from requiring an authorization in order to obtain coverage for specialty services so long as such authorization is for an appropriate duration or number of referrals.

“(2) REFERRALS FOR ONGOING SPECIAL CONDITIONS.—

“(A) IN GENERAL.—A group health plan (other than a fully insured group health plan) shall permit a participant or beneficiary who has an ongoing special condition (as defined in subparagraph (B)) to receive a referral to a specialist for the treatment of such condition and such specialist may authorize such referrals, procedures, tests, and other medical services with respect to such condition, or coordinate the care for such condition, subject to the terms of a treatment plan referred to in subsection (c) with respect to the condition.

“(B) ONGOING SPECIAL CONDITION DEFINED.—In this subsection, the term ‘ongoing special condition’ means a condition or disease that—

“(i) is life-threatening, degenerative, or disabling; and

“(ii) requires specialized medical care over a prolonged period of time.

“(c) TREATMENT PLANS.—

“(1) IN GENERAL.—Nothing in this section shall be construed to prohibit a group health plan (other than a fully insured group health plan) from requiring that specialty care be provided pursuant to a treatment plan so long as the treatment plan is—

“(A) developed by the specialist, in consultation with the case manager or primary care provider, and the participant or beneficiary;

“(B) approved by the plan in a timely manner if the plan requires such approval; and

“(C) in accordance with the applicable quality assurance and utilization review standards of the plan.

“(2) NOTIFICATION.—Nothing in paragraph (1) shall be construed as prohibiting a plan from requiring the specialist to provide the plan with regular updates on the specialty care provided, as well as all other necessary medical information.

“(d) SPECIALIST DEFINED.—For purposes of this section, the term ‘specialist’ means, with respect to the medical condition of the participant or beneficiary, a health care professional, facility, or center (such as a center of excellence) that has adequate expertise (including age-appropriate expertise) through appropriate training and experience.

“(e) RIGHT TO EXTERNAL REVIEW.—Pursuant to the requirements of section 503B, a participant or beneficiary shall have the right to an independent external review if the denial of an item or service or condition that is required to be covered under this section is eligible for such review.

“SEC. 726. CONTINUITY OF CARE.

“(a) TERMINATION OF PROVIDER.—If a contract between a group health plan (other than a fully insured group health plan) and a treating health care provider is terminated (as defined in paragraph (e)(4)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in such plan, and an individual who is a participant or beneficiary in the plan is undergoing an active course of treatment for a serious and complex condition, institutional care, pregnancy, or terminal illness from the provider at the time the plan receives or provides notice of such termination, the plan shall—

“(1) notify the individual, or arrange to have the individual notified pursuant to subsection (d)(2), on a timely basis of such termination;

“(2) provide the individual with an opportunity to notify the plan of the individual’s need for transitional care; and

“(3) subject to subsection (c), permit the individual to elect to continue to be covered with respect to the active course of treatment with the provider’s consent during a transitional period (as provided for under subsection (b)).

“(b) TRANSITIONAL PERIOD.—

“(1) SERIOUS AND COMPLEX CONDITIONS.—The transitional period under this section with respect to a serious and complex condition shall extend for up to 90 days from the date of the notice described in subsection (a)(1) of the provider’s termination.

“(2) INSTITUTIONAL OR INPATIENT CARE.—

“(A) IN GENERAL.—The transitional period under this section for institutional or non-elective inpatient care from a provider shall extend until the earlier of—

“(i) the expiration of the 90-day period beginning on the date on which the notice de-

scribed in subsection (a)(1) of the provider’s termination is provided; or

“(ii) the date of discharge of the individual from such care or the termination of the period of institutionalization.

“(B) SCHEDULED CARE.—The 90 day limitation described in subparagraph (A)(i) shall include post-surgical follow-up care relating to non-elective surgery that has been scheduled before the date of the notice of the termination of the provider under subsection (a)(1).

“(3) PREGNANCY.—If—

“(A) a participant or beneficiary has entered the second trimester of pregnancy at the time of a provider’s termination of participation; and

“(B) the provider was treating the pregnancy before the date of the termination; the transitional period under this subsection with respect to provider’s treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

“(4) TERMINAL ILLNESS.—If—

“(A) a participant or beneficiary was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) at the time of a provider’s termination of participation; and

“(B) the provider was treating the terminal illness before the date of termination; the transitional period under this subsection shall extend for the remainder of the individual’s life for care that is directly related to the treatment of the terminal illness.

“(c) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan (other than a fully insured group health plan) may condition coverage of continued treatment by a provider under this section upon the provider agreeing to the following terms and conditions:

“(1) The treating health care provider agrees to accept reimbursement from the plan and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or at the rates applicable under the replacement plan after the date of the termination of the contract with the group health plan) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in this section had not been terminated.

“(2) The treating health care provider agrees to adhere to the quality assurance standards of the plan responsible for payment under paragraph (1) and to provide to such plan necessary medical information related to the care provided.

“(3) The treating health care provider agrees otherwise to adhere to such plan’s policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan.

“(d) RULES OF CONSTRUCTION.—Nothing in this section shall be construed—

“(1) to require the coverage of benefits which would not have been covered if the provider involved remained a participating provider; or

“(2) with respect to the termination of a contract under subsection (a) to prevent a group health plan from requiring that the health care provider—

“(A) notify participants or beneficiaries of their rights under this section; or

“(B) provide the plan with the name of each participant or beneficiary who the provider believes is eligible for transitional care under this section.

“(e) DEFINITIONS.—In this section:

“(1) CONTRACT.—The term ‘contract between a plan and a treating health care provider’ shall include a contract between such a plan and an organized network of providers.

“(2) HEALTH CARE PROVIDER.—The term ‘health care provider’ or ‘provider’ means—

“(A) any individual who is engaged in the delivery of health care services in a State and who is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State; and

“(B) any entity that is engaged in the delivery of health care services in a State and that, if it is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State, is so licensed.

“(3) SERIOUS AND COMPLEX CONDITION.—The term ‘serious and complex condition’ means, with respect to a participant or beneficiary under the plan, a condition that is medically determinable and—

“(A) in the case of an acute illness, is a condition serious enough to require specialized medical treatment to avoid the reasonable possibility of death or permanent harm; or

“(B) in the case of a chronic illness or condition, is an illness or condition that—

“(i) is complex and difficult to manage;

“(ii) is disabling or life-threatening; and

“(iii) requires—

“(I) frequent monitoring over a prolonged period of time and requires substantial ongoing specialized medical care; or

“(II) frequent ongoing specialized medical care across a variety of domains of care.

“(4) TERMINATED.—The term ‘terminated’ includes, with respect to a contract (as defined in paragraph (1)), the expiration or nonrenewal of the contract by the group health plan, but does not include a termination of the contract by the plan for failure to meet applicable quality standards or for fraud.

“(f) RIGHT TO EXTERNAL REVIEW.—Pursuant to the requirements of section 503B, a participant or beneficiary shall have the right to an independent external review if the denial of an item or service or condition that is required to be covered under this section is eligible for such review.

“SEC. 727. PROTECTION OF PATIENT-PROVIDER COMMUNICATIONS.

“(a) IN GENERAL.—Subject to subsection (b), a group health plan (other than a fully insured group health plan and in relation to a participant or beneficiary) shall not prohibit or otherwise restrict a health care professional from advising such a participant or beneficiary who is a patient of the professional about the health status of the participant or beneficiary or medical care or treatment for the condition or disease of the participant or beneficiary, regardless of whether coverage for such care or treatment are provided under the contract, if the professional is acting within the lawful scope of practice.

“(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as requiring a group health plan (other than a fully insured group health plan) to provide specific benefits under the terms of such plan.

“SEC. 728. PATIENT’S RIGHT TO PRESCRIPTION DRUGS.

“(a) IN GENERAL.—To the extent that a group health plan (other than a fully insured group health plan) provides coverage for benefits with respect to prescription drugs, and limits such coverage to drugs included in a formulary, the plan shall—

“(1) ensure the participation of physicians and pharmacists in developing and reviewing such formulary; and

“(2) in accordance with the applicable quality assurance and utilization review standards of the plan, provide for exceptions from the formulary limitation when a non-formulary alternative is medically necessary and appropriate.

“(b) RIGHT TO EXTERNAL REVIEW.—Pursuant to the requirements of section 503B, a participant or beneficiary shall have the right to an independent external review if the denial of an item or service or condition that is required to be covered under this section is eligible for such review.

“SEC. 729. SELF-PAYMENT FOR BEHAVIORAL HEALTH CARE SERVICES.

“(a) IN GENERAL.—A group health plan (other than a fully insured group health plan) may not—

“(1) prohibit or otherwise discourage a participant or beneficiary from self-paying for behavioral health care services once the plan has denied coverage for such services; or

“(2) terminate a health care provider because such provider permits participants or beneficiaries to self-pay for behavioral health care services—

“(A) that are not otherwise covered under the plan; or

“(B) for which the group health plan provides limited coverage, to the extent that the group health plan denies coverage of the services.

“(b) RULE OF CONSTRUCTION.—Nothing in subsection (a)(2)(B) shall be construed as prohibiting a group health plan from terminating a contract with a health care provider for failure to meet applicable quality standards or for fraud.

“SEC. 730. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CANCER CLINICAL TRIALS.

“(a) COVERAGE.—

“(1) IN GENERAL.—If a group health plan (other than a fully insured group health plan) provides coverage to a qualified individual (as defined in subsection (b)), the plan—

“(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

“(B) subject to subsections (b), (c), and (d) may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

“(C) may not discriminate against the individual on the basis of the participant's or beneficiary's participation in such trial.

“(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

“(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

“(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term ‘qualified individual’ means an individual who is a participant or beneficiary in a group health plan and who meets the following conditions:

“(1)(A) The individual has been diagnosed with cancer for which no standard treatment is effective.

“(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

“(C) The individual's participation in the trial offers meaningful potential for significant clinical benefit for the individual.

“(2) Either—

“(A) the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

“(B) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

“(c) PAYMENT.—

“(1) IN GENERAL.—Under this section a group health plan (other than a fully insured group health plan) shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are reasonably expected to be paid for by the sponsors of an approved clinical trial.

“(2) STANDARDS FOR DETERMINING ROUTINE PATIENT COSTS ASSOCIATED WITH CLINICAL TRIAL PARTICIPATION.—

“(A) IN GENERAL.—The Secretary shall, in accordance with this paragraph, establish standards relating to the coverage of routine patient costs for individuals participating in clinical trials that group health plans must meet under this section.

“(B) FACTORS.—In establishing routine patient cost standards under subparagraph (A), the Secretary shall consult with interested parties and take into account—

“(i) quality of patient care;

“(ii) routine patient care costs versus costs associated with the conduct of clinical trials, including unanticipated patient care costs as a result of participation in clinical trials; and

“(iii) previous and on-going studies relating to patient care costs associated with participation in clinical trials.

“(C) APPOINTMENT AND MEETINGS OF NEGOTIATED RULEMAKING COMMITTEE.—

“(i) PUBLICATION OF NOTICE.—Not later than November 15, 2000, the Secretary shall publish notice of the establishment of a negotiated rulemaking committee, as provided for under section 564(a) of title 5, United States Code, to develop the standards described in subparagraph (A), which shall include—

“(I) the proposed scope of the committee;

“(II) the interests that may be impacted by the standards;

“(iii) a list of the proposed membership of the committee;

“(iv) the proposed meeting schedule of the committee;

“(v) a solicitation for public comment on the committee; and

“(vi) the procedures under which an individual may apply for membership on the committee.

“(ii) COMMENT PERIOD.—Notwithstanding section 564(c) of title 5, United States Code, the Secretary shall provide for a period, beginning on the date on which the notice is published under clause (i) and ending on November 30, 2000, for the submission of public comments on the committee under this subparagraph.

“(iii) APPOINTMENT OF COMMITTEE.—Not later than December 30, 2000, the Secretary shall appoint the members of the negotiated

rulemaking committee under this subparagraph.

“(iv) FACILITATOR.—Not later than January 10, 2001, the negotiated rulemaking committee shall nominate a facilitator under section 566(c) of title 5, United States Code, to carry out the activities described in subsection (d) of such section.

“(v) MEETINGS.—During the period beginning on the date on which the facilitator is nominated under clause (iv) and ending on March 30, 2001, the negotiated rulemaking committee shall meet to develop the standards described in subparagraph (A).

“(D) PRELIMINARY COMMITTEE REPORT.—

“(i) IN GENERAL.—The negotiated rulemaking committee appointed under subparagraph (C) shall report to the Secretary, by not later than March 30, 2001, regarding the committee's progress on achieving a consensus with regard to the rulemaking proceedings and whether such consensus is likely to occur before the target date described in subsection (F).

“(ii) TERMINATION OF PROCESS AND PUBLICATION OF RULE BY SECRETARY.—If the committee reports under clause (i) that the committee has failed to make significant progress towards such consensus or is unlikely to reach such consensus by the target date described in subsection (F), the Secretary shall terminate such process and provide for the publication in the Federal Register, by not later than June 30, 2001, of a rule under this paragraph through such other methods as the Secretary may provide.

“(E) FINAL COMMITTEE REPORT AND PUBLICATION OR RULE BY SECRETARY.—

“(i) IN GENERAL.—If the rulemaking committee is not terminated under subparagraph (D)(ii), the committee shall submit to the Secretary, by not later than May 30, 2001, a report containing a proposed rule.

“(ii) PUBLICATION OF RULE.—If the Secretary receives a report under clause (i), the Secretary shall provide for the publication in the Federal Register, by not later than June 30, 2001, of the proposed rule.

“(F) TARGET DATE FOR PUBLICATION OF RULE.—As part of the notice under subparagraph (C)(i), and for purposes of this paragraph, the ‘target date for publication’ (referred to in section 564(a)(5) of title 5, United States Code) shall be June 30, 2001.

“(G) EFFECTIVE DATE.—The provisions of this paragraph shall apply to group health plans (other than a fully insured group health plan) for plan years beginning on or after January 1, 2002.

“(3) PAYMENT RATE.—In the case of covered items and services provided by—

“(A) a participating provider, the payment rate shall be at the agreed upon rate, or

“(B) a nonparticipating provider, the payment rate shall be at the rate the plan would normally pay for comparable services under subparagraph (A).

“(d) APPROVED CLINICAL TRIAL DEFINED.—

“(1) IN GENERAL.—In this section, the term ‘approved clinical trial’ means a cancer clinical research study or cancer clinical investigation approved or funded (which may include funding through in-kind contributions) by one or more of the following:

“(A) The National Institutes of Health.

“(B) A cooperative group or center of the National Institutes of Health.

“(C) The Food and Drug Administration.

“(D) Either of the following if the conditions described in paragraph (2) are met:

“(i) The Department of Veterans Affairs.

“(ii) The Department of Defense.

“(2) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a

study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

“(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

“(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

“(e) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan's coverage with respect to clinical trials.

“(f) PLAN SATISFACTION OF CERTAIN REQUIREMENTS; RESPONSIBILITIES OF FIDUCIARIES.—

“(1) IN GENERAL.—For purposes of this section, insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the requirements of this section with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer.

“(2) CONSTRUCTION.—Nothing in this section shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B.

“(g) STUDY AND REPORT.—

“(1) STUDY.—The Secretary shall study the impact on group health plans for covering routine patient care costs for individuals who are entitled to benefits under this section and who are enrolled in an approved cancer clinical trial program.

“(2) REPORT TO CONGRESS.—Not later than January 1, 2005, the Secretary shall submit a report to Congress that contains an assessment of—

“(A) any incremental cost to group health plans resulting from the provisions of this section;

“(B) a projection of expenditures to such plans resulting from this section; and

“(C) any impact on premiums resulting from this section.

“(h) RIGHT TO EXTERNAL REVIEW.—Pursuant to the requirements of section 503B, a participant or beneficiary shall have the right to an independent external review if the denial of an item or service or condition that is required to be covered under this section is eligible for such review.

“SEC. 730A. PROHIBITION OF DISCRIMINATION AGAINST PROVIDERS BASED ON LICENSURE.

“(a) IN GENERAL.—A group health plan (other than a fully insured group health plan) shall not discriminate with respect to participation or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of such license or certification.

“(b) CONSTRUCTION.—Subsection (a) shall not be construed—

“(1) as requiring the coverage under a group health plan of a particular benefit or service or to prohibit a plan from including providers only to the extent necessary to meet the needs of the plan's participants or beneficiaries or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan;

“(2) to override any State licensure or scope-of-practice law; or

“(3) as requiring a plan that offers network coverage to include for participation every

willing provider who meets the terms and conditions of the plan.

“SEC. 730B. GENERALLY APPLICABLE PROVISION.

“In the case of a group health plan that provides benefits under 2 or more coverage options, the requirements of this subpart shall apply separately with respect to each coverage option.”.

(b) RULE WITH RESPECT TO CERTAIN PLANS.—

(1) IN GENERAL.—Notwithstanding any other provision of law, health insurance issuers may offer, and eligible individuals may purchase, high deductible health plans described in section 220(c)(2)(A) of the Internal Revenue Code of 1986. Effective for the 5-year period beginning on the date of the enactment of this Act, such health plans shall not be required to provide payment for any health care items or services that are exempt from the plan's deductible.

(2) EXISTING STATE LAWS.—A State law relating to payment for health care items and services in effect on the date of enactment of this Act that is preempted under paragraph (1), shall not apply to high deductible health plans after the expiration of the 5-year period described in such paragraph unless the State reenacts such law after such period.

(c) DEFINITION.—Section 733(a) of the Employee Retirement Income Security Act of 1974 (42 U.S.C. 1191(a)) is amended by adding at the end the following:

“(3) FULLY INSURED GROUP HEALTH PLAN.—The term ‘fully insured group health plan’ means a group health plan where benefits under the plan are provided pursuant to the terms of an arrangement between a group health plan and a health insurance issuer and are guaranteed by the health insurance issuer under a contract or policy of insurance.”.

(d) CONFORMING AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended—

(1) in the item relating to subpart C of part 7 of subtitle B of title I, by striking “Subpart C” and inserting “Subpart D”; and

(2) by adding at the end of the items relating to subpart B of part 7 of subtitle B of title I, the following:

“SUBPART C—PATIENT RIGHT TO MEDICAL ADVICE AND CARE

“Sec. 721. Access to emergency medical care.

“Sec. 722. Offering of choice of coverage options.

“Sec. 723. Patient access to obstetric and gynecological care.

“Sec. 724. Access to pediatric care.

“Sec. 725. Timely access to specialists.

“Sec. 726. Continuity of care.

“Sec. 727. Protection of patient-provider communications.

“Sec. 728. Patient's right to prescription drugs.

“Sec. 729. Self-payment for behavioral health care services.

“Sec. 730. Coverage for individuals participating in approved cancer clinical trials.

“Sec. 730A. Prohibition of discrimination against providers based on licensure.

“Sec. 730C. Generally applicable provision.”.

SEC. 202. CONFORMING AMENDMENT TO THE INTERNAL REVENUE CODE OF 1986.

Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended—

(1) in the table of sections, by inserting after the item relating to section 9812 the following new item:

“Sec. 9813. Standard relating to patient's bill of rights.”;

and

(2) by inserting after section 9812 the following:

“SEC. 9813. STANDARD RELATING TO PATIENTS' BILL OF RIGHTS.

“A group health plan (other than a fully insured group health plan) shall comply with the requirements of subpart C of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, as added by section 201 of the Patients' Bill of Rights Plus Act, and such requirements shall be deemed to be incorporated into this section.”.

SEC. 203. EFFECTIVE DATE AND RELATED RULES.

(a) IN GENERAL.—The amendments made by this subtitle shall apply with respect to plan years beginning on or after January 1 of the second calendar year following the date of the enactment of this Act. The Secretary shall issue all regulations necessary to carry out the amendments made by this section before the effective date thereof.

(b) LIMITATION ON ENFORCEMENT ACTIONS.—No enforcement action shall be taken, pursuant to the amendments made by this subtitle, against a group health plan with respect to a violation of a requirement imposed by such amendments before the date of issuance of regulations issued in connection with such requirement, if the plan has sought to comply in good faith with such requirement.

Subtitle B—Right to Information About Plans and Providers

SEC. 211. INFORMATION ABOUT PLANS.

(a) EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185 et seq.) is amended by adding at the end the following:

“SEC. 714. HEALTH PLAN INFORMATION.

“(a) REQUIREMENT—

“(1) DISCLOSURE.—

“(A) IN GENERAL.—A group health plan, and a health insurance issuer that provides coverage in connection with group health insurance coverage, shall provide for the disclosure of the information described in subsection (b) to participants and beneficiaries—

“(i) at the time of the initial enrollment of the participant or beneficiary under the plan or coverage;

“(ii) on an annual basis after enrollment—

“(I) in conjunction with the election period of the plan or coverage if the plan or coverage has such an election period; or

“(II) in the case of a plan or coverage that does not have an election period, in conjunction with the beginning of the plan or coverage year; and

“(iii) in the case of any material reduction to the benefits or information described in paragraphs (1), (2) and (3) of subsection (b), in the form of a summary notice provided not later than the date on which the reduction takes effect.

“(B) PARTICIPANTS AND BENEFICIARIES.—The disclosure required under subparagraph (A) shall be provided—

“(i) jointly to each participant and beneficiary who reside at the same address; or

“(ii) in the case of a beneficiary who does not reside at the same address as the participant, separately to the participant and such beneficiary.

“(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prevent a group health plan sponsor and health insurance issuer from entering into an agreement under which either the plan sponsor or the

issuer agrees to assume responsibility for compliance with the requirements of this section, in whole or in part, and the party delegating such responsibility is released from liability for compliance with the requirements that are assumed by the other party, to the extent the party delegating such responsibility did not cause such non-compliance.

“(3) PROVISION OF INFORMATION.—Information shall be provided to participants and beneficiaries under this section at the last known address maintained by the plan or issuer with respect to such participants or beneficiaries, to the extent that such information is provided to participants or beneficiaries via the United States Postal Service or other private delivery service.

“(b) REQUIRED INFORMATION.—The informational materials to be distributed under this section shall include for each option available under the group health plan or health insurance coverage the following:

“(1) BENEFITS.—A description of the covered benefits, including—

“(A) any in- and out-of-network benefits;

“(B) specific preventative services covered under the plan or coverage if such services are covered;

“(C) any benefit limitations, including any annual or lifetime benefit limits and any monetary limits or limits on the number of visits, days, or services, and any specific coverage exclusions; and

“(D) any definition of medical necessity used in making coverage determinations by the plan, issuer, or claims administrator.

“(2) COST SHARING.—A description of any cost-sharing requirements, including—

“(A) any premiums, deductibles, coinsurance, copayment amounts, and liability for balance billing above any reasonable and customary charges, for which the participant or beneficiary will be responsible under each option available under the plan;

“(B) any maximum out-of-pocket expense for which the participant or beneficiary may be liable;

“(C) any cost-sharing requirements for out-of-network benefits or services received from nonparticipating providers; and

“(D) any additional cost-sharing or charges for benefits and services that are furnished without meeting applicable plan or coverage requirements, such as prior authorization or precertification.

“(3) SERVICE AREA.—A description of the plan or issuer's service area, including the provision of any out-of-area coverage.

“(4) PARTICIPATING PROVIDERS.—A directory of participating providers (to the extent a plan or issuer provides coverage through a network of providers) that includes, at a minimum, the name, address, and telephone number of each participating provider, and information about how to inquire whether a participating provider is currently accepting new patients.

“(5) CHOICE OF PRIMARY CARE PROVIDER.—A description of any requirements and procedures to be used by participants and beneficiaries in selecting, accessing, or changing their primary care provider, including providers both within and outside of the network (if the plan or issuer permits out-of-network services), and the right to select a pediatrician as a primary care provider under section 724 for a participant or beneficiary who is a child if such section applies.

“(6) PREAUTHORIZATION REQUIREMENTS.—A description of the requirements and procedures to be used to obtain preauthorization for health services, if such preauthorization is required.

“(7) EXPERIMENTAL AND INVESTIGATIONAL TREATMENTS.—A description of the process for determining whether a particular item, service, or treatment is considered experimental or investigational, and the circumstances under which such treatments are covered by the plan or issuer.

“(8) SPECIALTY CARE.—A description of the requirements and procedures to be used by participants and beneficiaries in accessing specialty care and obtaining referrals to participating and nonparticipating specialists, including the right to timely coverage for access to specialists care under section 725 if such section applies.

“(9) CLINICAL TRIALS.—A description the circumstances and conditions under which participation in clinical trials is covered under the terms and conditions of the plan or coverage, and the right to obtain coverage for approved cancer clinical trials under section 729 if such section applies.

“(10) PRESCRIPTION DRUGS.—To the extent the plan or issuer provides coverage for prescription drugs, a statement of whether such coverage is limited to drugs included in a formulary, a description of any provisions and cost-sharing required for obtaining on- and off-formulary medications, and a description of the rights of participants and beneficiaries in obtaining access to access to prescription drugs under section 727 if such section applies.

“(11) EMERGENCY SERVICES.—A summary of the rules and procedures for accessing emergency services, including the right of a participant or beneficiary to obtain emergency services under the prudent layperson standard under section 721, if such section applies, and any educational information that the plan or issuer may provide regarding the appropriate use of emergency services.

“(12) CLAIMS AND APPEALS.—A description of the plan or issuer's rules and procedures pertaining to claims and appeals, a description of the rights of participants and beneficiaries under sections 503, 503A and 503B in obtaining covered benefits, filing a claim for benefits, and appealing coverage decisions internally and externally (including telephone numbers and mailing addresses of the appropriate authority), and a description of any additional legal rights and remedies available under section 502.

“(13) ADVANCE DIRECTIVES AND ORGAN DONATION.—A description of procedures for advance directives and organ donation decisions if the plan or issuer maintains such procedures.

“(14) INFORMATION ON PLANS AND ISSUERS.—The name, mailing address, and telephone number or numbers of the plan administrator and the issuer to be used by participants and beneficiaries seeking information about plan or coverage benefits and services, payment of a claim, or authorization for services and treatment. The name of the designated decision-maker (or decision-makers) appointed under section 502(n)(2) for purposes of making final determinations under section 503A and approving coverage pursuant to the written determination of an independent medical reviewer under section 503B. Notice of whether the benefits under the plan are provided under a contract or policy of insurance issued by an issuer, or whether benefits are provided directly by the plan sponsor who bears the insurance risk.

“(15) TRANSLATION SERVICES.—A summary description of any translation or interpretation services (including the availability of printed information in languages other than English, audio tapes, or information in Braille) that are available for non-English

speakers and participants and beneficiaries with communication disabilities and a description of how to access these items or services.

“(16) ACCREDITATION INFORMATION.—Any information that is made public by accrediting organizations in the process of accreditation if the plan or issuer is accredited, or any additional quality indicators (such as the results of enrollee satisfaction surveys) that the plan or issuer makes public or makes available to participants and beneficiaries.

“(17) NOTICE OF REQUIREMENTS.—A description of any rights of participants and beneficiaries that are established by the Patients' Bill of Rights Plus Act (excluding those described in paragraphs (1) through (16)) if such sections apply. The description required under this paragraph may be combined with the notices required under sections 711(d), 713(b), or 606(a)(1), and with any other notice provision that the Secretary determines may be combined.

“(18) AVAILABILITY OF ADDITIONAL INFORMATION.—A statement that the information described in subsection (c), and instructions on obtaining such information (including telephone numbers and, if available, Internet websites), shall be made available upon request.

“(c) ADDITIONAL INFORMATION.—The informational materials to be provided upon the request of a participant or beneficiary shall include for each option available under a group health plan or health insurance coverage the following:

“(1) STATUS OF PROVIDERS.—The State licensure status of the plan or issuer's participating health care professionals and participating health care facilities, and, if available, the education, training, specialty qualifications or certifications of such professionals.

“(2) COMPENSATION METHODS.—A summary description of the methods (such as capitation, fee-for-service, salary, bundled payments, per diem, or a combination thereof) used for compensating participating health care professionals (including primary care providers and specialists) and facilities in connection with the provision of health care under the plan or coverage. The requirement of this paragraph shall not be construed as requiring plans or issuers to provide information concerning proprietary payment methodology.

“(3) PRESCRIPTION DRUGS.—Information about whether a specific prescription medication is included in the formulary of the plan or issuer, if the plan or issuer uses a defined formulary.

“(4) EXTERNAL APPEALS INFORMATION.—Aggregate information on the number and outcomes of external medical reviews, relative to the sample size (such as the number of covered lives) determined for the plan or issuer's book of business.

“(d) MANNER OF DISCLOSURE.—The information described in this section shall be disclosed in an accessible medium and format that is calculated to be understood by the average participant.

“(e) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a group health plan, or a health insurance issuer in connection with group health insurance coverage, from—

“(1) distributing any other additional information determined by the plan or issuer to be important or necessary in assisting participants and beneficiaries in the selection of a health plan; and

“(2) complying with the provisions of this section by providing information in brochures, through the Internet or other electronic media, or through other similar means, so long as participants and beneficiaries are provided with an opportunity to request that informational materials be provided in printed form.

“(f) CONFORMING REGULATIONS.—The Secretary shall issue regulations to coordinate the requirements on group health plans and health insurance issuers under this section with the requirements imposed under part 1, to reduce duplication with respect to any information that is required to be provided under any such requirements.

“(g) SECRETARIAL ENFORCEMENT AUTHORITY.—

“(1) IN GENERAL.—The Secretary may assess a civil monetary penalty against the administrator of a plan or issuer in connection with the failure of the plan or issuer to comply with the requirements of this section.

“(2) AMOUNT OF PENALTY.—

“(A) IN GENERAL.—The amount of the penalty to be imposed under paragraph (1) shall not exceed \$100 for each day for each participant and beneficiary with respect to which the failure to comply with the requirements of this section occurs.

“(B) INCREASE IN AMOUNT.—The amount referred to in subparagraph (A) shall be increased or decreased, for each calendar year that ends after December 31, 2000, by the same percentage as the percentage by which the medical care expenditure category of the Consumer Price Index for All Urban Consumers (United States city average), published by the Bureau of Labor Statistics, for September of the preceding calendar year has increased or decreased from the such Index for September of 2000.

“(3) FAILURE DEFINED.—For purposes of this subsection, a plan or issuer shall have failed to comply with the requirements of this section with respect to a participant or beneficiary if the plan or issuer failed or refused to comply with the requirements of this section within 30 days—

“(A) of the date described in subsection (a)(1)(A)(i);

“(B) of the date described in subsection (a)(1)(A)(ii); or

“(C) of the date on which additional information was requested under subsection (c).”.

(b) CONFORMING AMENDMENTS.—

(1) Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191a(a)) is amended by striking “section 711” and inserting “sections 711 and 714”.

(2) The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001) is amended by inserting after the item relating to section 713, the following:

“Sec 714. Health plan comparative information.”.

(3) Section 502(b)(3) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(b)(3)) is amended by striking “733(a)(1)” and inserting “733(a)(1), except with respect to the requirements of section 714”.

SEC. 212. INFORMATION ABOUT PROVIDERS.

(a) STUDY.—The Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine for the conduct of a study, and the submission to the Secretary of a report, that includes—

(1) an analysis of information concerning health care professionals that is currently available to patients, consumers, States, and professional societies, nationally and on a State-by-State basis, including patient preferences with respect to information about such professionals and their competencies;

(2) an evaluation of the legal and other barriers to the sharing of information concerning health care professionals; and

(3) recommendations for the disclosure of information on health care professionals, including the competencies and professional qualifications of such practitioners, to better facilitate patient choice, quality improvement, and market competition.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall forward to the appropriate committees of Congress a copy of the report and study conducted under subsection (a).

Subtitle C—Right to Hold Health Plans Accountable

SEC. 221. AMENDMENTS TO EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

(a) IN GENERAL.—Part 5 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by inserting after section 503 (29 U.S.C. 1133) the following:

“SEC. 503A. CLAIMS AND INTERNAL APPEALS PROCEDURES FOR GROUP HEALTH PLANS.

“(a) INITIAL CLAIM FOR BENEFITS UNDER GROUP HEALTH PLANS.—

“(1) PROCEDURES.—

“(A) IN GENERAL.—A group health plan, or health insurance issuer offering health insurance coverage in connection with a group health plan, shall ensure that procedures are in place for—

“(i) making a determination on an initial claim for benefits by a participant or beneficiary (or authorized representative) regarding payment or coverage for items or services under the terms and conditions of the plan or coverage involved, including any cost-sharing amount that the participant or beneficiary is required to pay with respect to such claim for benefits; and

“(ii) notifying a participant or beneficiary (or authorized representative) and the treating health care professional involved regarding a determination on an initial claim for benefits made under the terms and conditions of the plan or coverage, including any cost-sharing amounts that the participant or beneficiary may be required to make with respect to such claim for benefits, and of the right of the participant or beneficiary to an internal appeal under subsection (b).

“(B) ACCESS TO INFORMATION.—With respect to an initial claim for benefits, the participant or beneficiary (or authorized representative) and the treating health care professional (if any) shall provide the plan or issuer with access to information necessary to make a determination relating to the claim, not later than 5 business days after the date on which the claim is filed or to meet the applicable timelines under clauses (ii) and (iii) of paragraph (2)(A).

“(C) ORAL REQUESTS.—In the case of a claim for benefits involving an expedited or concurrent determination, a participant or beneficiary (or authorized representative) may make an initial claim for benefits orally, but a group health plan, or health insurance issuer offering health insurance coverage in connection with a group health plan, may require that the participant or beneficiary (or authorized representative) provide written confirmation of such request in a timely manner.

“(2) TIMELINE FOR MAKING DETERMINATIONS.—

“(A) PRIOR AUTHORIZATION DETERMINATION.—

“(i) IN GENERAL.—A group health plan, or health insurance issuer offering health insurance coverage in connection with a group health plan, shall maintain procedures to ensure that a prior authorization determination on a claim for benefits is made within 14 business days from the date on which the plan or issuer receives information that is reasonably necessary to enable the plan or issuer to make a determination on the request for prior authorization, but in no case shall such determination be made later than 28 business days after the receipt of the claim for benefits.

“(ii) EXPEDITED DETERMINATION.—Notwithstanding clause (i), a group health plan, or health insurance issuer offering health insurance coverage in connection with a group health plan, shall maintain procedures for expediting a prior authorization determination on a claim for benefits described in such clause when a request for such an expedited determination is made by a participant or beneficiary (or authorized representative) at any time during the process for making a determination and the treating health care professional substantiates, with the request, that a determination under the procedures described in clause (i) would seriously jeopardize the life or health of the participant or beneficiary. Such determination shall be made within 72 hours after a request is received by the plan or issuer under this clause.

“(iii) CONCURRENT DETERMINATIONS.—A group health plan, or health insurance issuer offering health insurance coverage in connection with a group health plan, shall maintain procedures to ensure that a concurrent determination on a claim for benefits that results in a discontinuation of inpatient care is made within 24 hours after the receipt of the claim for benefits.

“(B) RETROSPECTIVE DETERMINATION.—A group health plan, or health insurance issuer offering health insurance coverage in connection with a group health plan, shall maintain procedures to ensure that a retrospective determination on a claim for benefits is made within 30 business days of the date on which the plan or issuer receives information that is reasonably necessary to enable the plan or issuer to make a determination on the claim, but in no case shall such determination be made later than 60 business days after the receipt of the claim for benefits.

“(3) NOTICE OF A DENIAL OF A CLAIM FOR BENEFITS.—Written notice of a denial made under an initial claim for benefits shall be issued to the participant or beneficiary (or authorized representative) and the treating health care professional not later than 2 business days after the determination (or within the 72-hour or 24-hour period referred to in clauses (ii) and (iii) of paragraph (2)(A) if applicable).

“(4) REQUIREMENTS OF NOTICE OF DETERMINATIONS.—The written notice of a denial of a claim for benefits determination under paragraph (3) shall include—

“(A) the reasons for the determination (including a summary of the clinical or scientific-evidence based rationale used in making the determination and instruction on obtaining a more complete description written in a manner calculated to be understood by the average participant);

“(B) the procedures for obtaining additional information concerning the determination; and

“(C) notification of the right to appeal the determination and instructions on how to initiate an appeal in accordance with subsection (b).

“(b) INTERNAL APPEAL OF A DENIAL OF A CLAIM FOR BENEFITS.—

“(1) RIGHT TO INTERNAL APPEAL.—

“(A) IN GENERAL.—A participant or beneficiary (or authorized representative) may appeal any denial of a claim for benefits under subsection (a) under the procedures described in this subsection.

“(B) TIME FOR APPEAL.—A group health plan, or health insurance issuer offering health insurance coverage in connection with a group health plan, shall ensure that a participant or beneficiary (or authorized representative) has a period of not less than 60 days beginning on the date of a denial of a claim for benefits under subsection (a) in which to appeal such denial under this subsection.

“(C) FAILURE TO ACT.—The failure of a plan or issuer to issue a determination on a claim for benefits under subsection (a) within the applicable timeline established for such a determination under such subsection shall be treated as a denial of a claim for benefits for purposes of proceeding to internal review under this subsection.

“(D) PLAN WAIVER OF INTERNAL REVIEW.—A group health plan, or health insurance issuer offering health insurance coverage in connection with a group health plan, may waive the internal review process under this subsection and permit a participant or beneficiary (or authorized representative) to proceed directly to external review under section 503B.

“(2) TIMELINES FOR MAKING DETERMINATIONS.—

“(A) ORAL REQUESTS.—In the case of an appeal of a denial of a claim for benefits under this subsection that involves an expedited or concurrent determination, a participant or beneficiary (or authorized representative) may request such appeal orally, but a group health plan, or health insurance issuer offering health insurance coverage in connection with a group health plan, may require that the participant or beneficiary (or authorized representative) provide written confirmation of such request in a timely manner.

“(B) ACCESS TO INFORMATION.—With respect to an appeal of a denial of a claim for benefits, the participant or beneficiary (or authorized representative) and the treating health care professional (if any) shall provide the plan or issuer with access to information necessary to make a determination relating to the appeal, not later than 5 business days after the date on which the request for the appeal is filed or to meet the applicable timelines under clauses (ii) and (iii) of subparagraph (C).

“(C) PRIOR AUTHORIZATION DETERMINATIONS.—

“(i) IN GENERAL.—A group health plan, or health insurance issuer offering health insurance coverage in connection with a group health plan, shall maintain procedures to ensure that a determination on an appeal of a denial of a claim for benefits under this subsection is made within 14 business days after the date on which the plan or issuer receives information that is reasonably necessary to enable the plan or issuer to make a determination on the appeal, but in no case shall such determination be made later than 28 business days after the receipt of the request for the appeal.

“(ii) EXPEDITED DETERMINATION.—Notwithstanding clause (i), a group health plan, or health insurance issuer offering health insurance coverage in connection with a group health plan, shall maintain procedures for expediting a prior authorization determination on an appeal of a denial of a claim for

benefits described in clause (i), when a request for such an expedited determination is made by a participant or beneficiary (or authorized representative) at any time during the process for making a determination and the treating health care professional substantiates, with the request, that a determination under the procedures described in clause (i) would seriously jeopardize the life or health of the participant or beneficiary. Such determination shall be made not later than 72 hours after the request for such appeal is received by the plan or issuer under this clause.

“(iii) CONCURRENT DETERMINATIONS.—A group health plan, or health insurance issuer offering health insurance coverage in connection with a group health plan, shall maintain procedures to ensure that a concurrent determination on an appeal of a denial of a claim for benefits that results in a discontinuation of inpatient care is made within 24 hours after the receipt of the request for appeal.

“(B) RETROSPECTIVE DETERMINATION.—A group health plan, or health insurance issuer offering health insurance coverage in connection with a group health plan, shall maintain procedures to ensure that a retrospective determination on an appeal of a claim for benefits is made within 30 business days of the date on which the plan or issuer receives necessary information that is reasonably required by the plan or issuer to make a determination on the appeal, but in no case shall such determination be made later than 60 business days after the receipt of the request for the appeal.

“(3) CONDUCT OF REVIEW.—

“(A) IN GENERAL.—A review of a denial of a claim for benefits under this subsection shall be conducted by an individual with appropriate expertise who was not directly involved in the initial determination.

“(B) REVIEW OF MEDICAL DECISIONS BY PHYSICIANS.—A review of an appeal of a denial of a claim for benefits that is based on a lack of medical necessity and appropriateness, or based on an experimental or investigational treatment, or requires an evaluation of medical facts, shall be made by a physician with appropriate expertise, including age-appropriate expertise, who was not involved in the initial determination.

“(4) NOTICE OF DETERMINATION.—

“(A) IN GENERAL.—Written notice of a determination made under an internal appeal of a denial of a claim for benefits shall be issued to the participant or beneficiary (or authorized representative) and the treating health care professional not later than 2 business days after the completion of the review (or within the 72-hour or 24-hour period referred to in paragraph (2) if applicable).

“(B) FINAL DETERMINATION.—The decision by a plan or issuer under this subsection shall be treated as the final determination of the plan or issuer on a denial of a claim for benefits. The failure of a plan or issuer to issue a determination on an appeal of a denial of a claim for benefits under this subsection within the applicable timeline established for such a determination shall be treated as a final determination on an appeal of a denial of a claim for benefits for purposes of proceeding to external review under section 503B.

“(C) REQUIREMENTS OF NOTICE.—With respect to a determination made under this subsection, the notice described in subparagraph (A) shall include—

“(i) the reasons for the determination (including a summary of the clinical or scientific-evidence based rationale used in mak-

ing the determination and instruction on obtaining a more complete description written in a manner calculated to be understood by the average participant);

“(ii) the procedures for obtaining additional information concerning the determination; and

“(iii) notification of the right to an independent external review under section 503B and instructions on how to initiate such a review.

“(c) DEFINITIONS.—The definitions contained in section 503B(i) shall apply for purposes of this section.

“SEC. 503B. INDEPENDENT EXTERNAL APPEALS PROCEDURES FOR GROUP HEALTH PLANS.

“(a) RIGHT TO EXTERNAL APPEAL.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall provide in accordance with this section participants and beneficiaries (or authorized representatives) with access to an independent external review for any denial of a claim for benefits.

“(b) INITIATION OF THE INDEPENDENT EXTERNAL REVIEW PROCESS.—

“(1) TIME TO FILE.—A request for an independent external review under this section shall be filed with the plan or issuer not later than 60 business days after the date on which the participant or beneficiary receives notice of the denial under section 503A(b)(4) or the date on which the internal review is waived by the plan or issuer under section 503A(b)(1)(D).

“(2) FILING OF REQUEST.—

“(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, a group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may—

“(i) except as provided in subparagraph (B)(i), require that a request for review be in writing;

“(ii) limit the filing of such a request to the participant or beneficiary involved (or an authorized representative);

“(iii) except if waived by the plan or issuer under section 503A(b)(1)(D), condition access to an independent external review under this section upon a final determination of a denial of a claim for benefits under the internal review procedure under section 503A;

“(iv) except as provided in subparagraph (B)(ii), require payment of a filing fee to the plan or issuer of a sum that does not exceed \$50; and

“(v) require that a request for review include the consent of the participant or beneficiary (or authorized representative) for the release of medical information or records of the participant or beneficiary to the qualified external review entity for purposes of conducting external review activities.

“(B) REQUIREMENTS AND EXCEPTION RELATING TO GENERAL RULE.—

“(i) ORAL REQUESTS PERMITTED IN EXPEDITED OR CONCURRENT CASES.—In the case of an expedited or concurrent external review as provided for under subsection (e), the request may be made orally. In such case a written confirmation of such request shall be made in a timely manner. Such written confirmation shall be treated as a consent for purposes of subparagraph (A)(v).

“(ii) EXCEPTION TO FILING FEE REQUIREMENT.—

“(I) INDIGENCY.—Payment of a filing fee shall not be required under subparagraph (A)(iv) where there is a certification (in a form and manner specified in guidelines established by the Secretary) that the participant or beneficiary is indigent (as defined in

such guidelines). In establishing guidelines under this subclause, the Secretary shall ensure that the guidelines relating to indigency are consistent with the poverty guidelines used by the Secretary of Health and Human Services under title XIX of the Social Security Act.

“(II) FEE NOT REQUIRED.—Payment of a filing fee shall not be required under subparagraph (A)(iv) if the plan or issuer waives the internal appeals process under section 503A(b)(1)(D).

“(III) REFUNDING OF FEE.—The filing fee paid under subparagraph (A)(iv) shall be refunded if the determination under the independent external review is to reverse the denial which is the subject of the review.

“(IV) INCREASE IN AMOUNT.—The amount referred to in subclause (I) shall be increased or decreased, for each calendar year that ends after December 31, 2001, by the same percentage as the percentage by which the Consumer Price Index for All Urban Consumers (United States city average), published by the Bureau of Labor Statistics, for September of the preceding calendar year has increased or decreased from the such Index for September of 2001.

“(c) REFERRAL TO QUALIFIED EXTERNAL REVIEW ENTITY UPON REQUEST.—

“(1) IN GENERAL.—Upon the filing of a request for independent external review with the group health plan, or health insurance issuer offering coverage in connection with a group health plan, the plan or issuer shall refer such request to a qualified external review entity selected in accordance with this section.

“(2) ACCESS TO PLAN OR ISSUER AND HEALTH PROFESSIONAL INFORMATION.—With respect to an independent external review conducted under this section, the participant or beneficiary (or authorized representative), the plan or issuer, and the treating health care professional (if any) shall provide the external review entity with access to information that is necessary to conduct a review under this section, as determined by the entity, not later than 5 business days after the date on which a request is referred to the qualified external review entity under paragraph (1), or earlier as determined appropriate by the entity to meet the applicable timelines under clauses (ii) and (iii) of subsection (e)(1)(A).

“(3) SCREENING OF REQUESTS BY QUALIFIED EXTERNAL REVIEW ENTITIES.—

“(A) IN GENERAL.—With respect to a request referred to a qualified external review entity under paragraph (1) relating to a denial of a claim for benefits, the entity shall refer such request for the conduct of an independent medical review unless the entity determines that—

“(i) any of the conditions described in subsection (b)(2)(A) have not been met;

“(ii) the thresholds described in subparagraph (B) have not been met;

“(iii) the denial of the claim for benefits does not involve a medically reviewable decision under subsection (d)(2);

“(iv) the denial of the claim for benefits relates to a decision regarding whether an individual is a participant or beneficiary who is enrolled under the terms of the plan or coverage (including the applicability of any waiting period under the plan or coverage); or

“(v) the denial of the claim for benefits is a decision as to the application of cost-sharing requirements or the application of a specific exclusion or express limitation on the amount, duration, or scope of coverage of items or services under the terms and condi-

tions of the plan or coverage unless the decision is a denial described in subsection (d)(2)(C);

Upon making a determination that any of clauses (i) through (v) applies with respect to the request, the entity shall determine that the denial of a claim for benefits involved is not eligible for independent medical review under subsection (d), and shall provide notice in accordance with subparagraph (D).

“(B) THRESHOLDS.—

“(i) IN GENERAL.—The thresholds described in this subparagraph are that—

“(I) the total amount payable under the plan or coverage for the item or service that was the subject of such denial exceeds a significant financial threshold (as determined under guidelines established by the Secretary); or

“(II) a physician has asserted in writing that there is a significant risk of placing the life, health, or development of the participant or beneficiary in jeopardy if the denial of the claim for benefits is sustained.

“(ii) THRESHOLDS NOT APPLIED.—The thresholds described in this subparagraph shall not apply if the plan or issuer involved waives the internal appeals process with respect to the denial of a claim for benefits involved under section 503A(b)(1)(D).

“(C) PROCESS FOR MAKING DETERMINATIONS.—

“(i) NO DEFERENCE TO PRIOR DETERMINATIONS.—In making determinations under subparagraph (A), there shall be no deference given to determinations made by the plan or issuer under section 503A or the recommendation of a treating health care professional (if any).

“(ii) USE OF APPROPRIATE PERSONNEL.—A qualified external review entity shall use appropriately qualified personnel to make determinations under this section.

“(D) NOTICES AND GENERAL TIMELINES FOR DETERMINATION.—

“(i) NOTICE IN CASE OF DENIAL OF REFERRAL.—If the entity under this paragraph does not make a referral to an independent medical reviewer, the entity shall provide notice to the plan or issuer, the participant or beneficiary (or authorized representative) filing the request, and the treating health care professional (if any) that the denial is not subject to independent medical review. Such notice—

“(I) shall be written (and, in addition, may be provided orally) in a manner calculated to be understood by an average participant;

“(II) shall include the reasons for the determination; and

“(III) include any relevant terms and conditions of the plan or coverage.

“(ii) GENERAL TIMELINE FOR DETERMINATIONS.—Upon receipt of information under paragraph (2), the qualified external review entity, and if required the independent medical reviewer, shall make a determination within the overall timeline that is applicable to the case under review as described in subsection (e), except that if the entity determines that a referral to an independent medical reviewer is not required, the entity shall provide notice of such determination to the participant or beneficiary (or authorized representative) within 2 business days of such determination.

“(d) INDEPENDENT MEDICAL REVIEW.—

“(1) IN GENERAL.—If a qualified external review entity determines under subsection (c) that a denial of a claim for benefits is eligible for independent medical review, the entity shall refer the denial involved to an independent medical reviewer for the conduct of an independent medical review under this subsection.

“(2) MEDICALLY REVIEWABLE DECISIONS.—A denial described in this paragraph is one for which the item or service that is the subject of the denial would be a covered benefit under the terms and conditions of the plan or coverage but for one (or more) of the following determinations:

“(A) DENIALS BASED ON MEDICAL NECESSITY AND APPROPRIATENESS.—The basis of the determination is that the item or service is not medically necessary and appropriate.

“(B) DENIALS BASED ON EXPERIMENTAL OR INVESTIGATIONAL TREATMENT.—The basis of the determination is that the item or service is experimental or investigational.

“(C) DENIALS OTHERWISE BASED ON AN EVALUATION OF MEDICAL FACTS.—A determination that the item or service or condition is not covered but an evaluation of the medical facts by a health care professional in the specific case involved is necessary to determine whether the item or service or condition is required to be provided under the terms and conditions of the plan or coverage.

“(3) INDEPENDENT MEDICAL REVIEW DETERMINATION.—

“(A) IN GENERAL.—An independent medical reviewer under this section shall make a new independent determination with respect to—

“(i) whether the item or service or condition that is the subject of the denial is covered under the terms and conditions of the plan or coverage; and

“(ii) based upon an affirmative determination under clause (i), whether or not the denial of a claim for a benefit that is the subject of the review should be upheld or reversed.

“(B) STANDARD FOR DETERMINATION.—The independent medical reviewer's determination relating to the medical necessity and appropriateness, or the experimental or investigation nature, or the evaluation of the medical facts of the item, service, or condition shall be based on the medical condition of the participant or beneficiary (including the medical records of the participant or beneficiary) and the valid, relevant scientific evidence and clinical evidence, including peer-reviewed medical literature or findings and including expert consensus.

“(C) NO COVERAGE FOR EXCLUDED BENEFITS.—Nothing in this subsection shall be construed to permit an independent medical reviewer to require that a group health plan, or health insurance issuer offering health insurance coverage in connection with a group health plan, provide coverage for items or services that are specifically excluded or expressly limited under the plan or coverage and that are not covered regardless of any determination relating to medical necessity and appropriateness, experimental or investigational nature of the treatment, or an evaluation of the medical facts in the case involved.

“(D) EVIDENCE AND INFORMATION TO BE USED IN MEDICAL REVIEWS.—In making a determination under this subsection, the independent medical reviewer shall also consider appropriate and available evidence and information, including the following:

“(i) The determination made by the plan or issuer with respect to the claim upon internal review and the evidence or guidelines used by the plan or issuer in reaching such determination.

“(ii) The recommendation of the treating health care professional and the evidence, guidelines, and rationale used by the treating health care professional in reaching such recommendation.

“(iii) Additional evidence or information obtained by the reviewer or submitted by the

plan, issuer, participant or beneficiary (or an authorized representative), or treating health care professional.

“(iv) The plan or coverage document.

“(E) INDEPENDENT DETERMINATION.—In making the determination, the independent medical reviewer shall—

“(i) consider the claim under review without deference to the determinations made by the plan or issuer under section 503A or the recommendation of the treating health care professional (if any);

“(ii) consider, but not be bound by the definition used by the plan or issuer of ‘medically necessary and appropriate’, or ‘experimental or investigational’, or other equivalent terms that are used by the plan or issuer to describe medical necessity and appropriateness or experimental or investigational nature of the treatment; and

“(iii) notwithstanding clause (ii), adhere to the definition used by the plan or issuer of ‘medically necessary and appropriate’, or ‘experimental or investigational’ if such definition is the same as the definition of such term—

“(I) that has been adopted pursuant to a State statute or regulation; or

“(II) that is used for purposes of the program established under titles XVIII or XIX of the Social Security Act or under chapter 89 of title 5, United States Code.

“(F) DETERMINATION OF INDEPENDENT MEDICAL REVIEWER.—An independent medical reviewer shall, in accordance with the deadlines described in subsection (e), prepare a written determination to uphold or reverse the denial under review. Such written determination shall include the specific reasons of the reviewer for such determination, including a summary of the clinical or scientific-evidence based rationale used in making the determination. The reviewer may provide the plan or issuer and the treating health care professional with additional recommendations in connection with such a determination, but any such recommendations shall not be treated as part of the determination.

“(e) TIMELINES AND NOTIFICATIONS.—

“(1) TIMELINES FOR INDEPENDENT MEDICAL REVIEW.—

“(A) PRIOR AUTHORIZATION DETERMINATION.—

“(i) IN GENERAL.—The independent medical reviewer (or reviewers) shall make a determination on a denial of a claim for benefits that is referred to the reviewer under subsection (c)(3) not later than 14 business days after the receipt of information under subsection (c)(2) if the review involves a prior authorization of items or services.

“(ii) EXPEDITED DETERMINATION.—Notwithstanding clause (i), the independent medical reviewer (or reviewers) shall make an expedited determination on a denial of a claim for benefits described in clause (i), when a request for such an expedited determination is made by a participant or beneficiary (or authorized representative) at any time during the process for making a determination, and the treating health care professional substantiates, with the request, that a determination under the timeline described in clause (i) would seriously jeopardize the life or health of the participant or beneficiary. Such determination shall be made not later than 72 hours after the receipt of information under subsection (c)(2).

“(iii) CONCURRENT DETERMINATION.—Notwithstanding clause (i), a review described in such subclause shall be completed not later than 24 hours after the receipt of information under subsection (c)(2) if the review involves a discontinuation of inpatient care.

“(B) RETROSPECTIVE DETERMINATION.—The independent medical reviewer (or reviewers) shall complete a review in the case of a retrospective determination on an appeal of a denial of a claim for benefits that is referred to the reviewer under subsection (c)(3) not later than 30 business days after the receipt of information under subsection (c)(2).

“(2) NOTIFICATION OF DETERMINATION.—The external review entity shall ensure that the plan or issuer, the participant or beneficiary (or authorized representative) and the treating health care professional (if any) receives a copy of the written determination of the independent medical reviewer prepared under subsection (d)(3)(F). Nothing in this paragraph shall be construed as preventing an entity or reviewer from providing an initial oral notice of the reviewer’s determination.

“(3) FORM OF NOTICES.—Determinations and notices under this subsection shall be written in a manner calculated to be understood by an average participant.

“(4) TERMINATION OF EXTERNAL REVIEW PROCESS IF APPROVAL OF A CLAIM FOR BENEFITS DURING PROCESS.—

“(A) IN GENERAL.—If a plan or issuer—

“(i) reverses a determination on a denial of a claim for benefits that is the subject of an external review under this section and authorizes coverage for the claim or provides payment of the claim; and

“(ii) provides notice of such reversal to the participant or beneficiary (or authorized representative) and the treating health care professional (if any), and the external review entity responsible for such review, the external review process shall be terminated with respect to such denial and any filing fee paid under subsection (b)(2)(A)(iv) shall be refunded.

“(B) TREATMENT OF TERMINATION.—An authorization of coverage under subparagraph (A) by the plan or issuer shall be treated as a written determination to reverse a denial under section (d)(3)(F) for purposes of liability under section 502(n)(1)(B).

“(f) COMPLIANCE.—

“(1) APPLICATION OF DETERMINATIONS.—

“(A) EXTERNAL REVIEW DETERMINATIONS BINDING ON PLAN.—The determinations of an external review entity and an independent medical reviewer under this section shall be binding upon the plan or issuer involved.

“(B) COMPLIANCE WITH DETERMINATION.—If the determination of an independent medical reviewer is to reverse the denial, the plan or issuer, upon the receipt of such determination, shall authorize coverage to comply with the medical reviewer’s determination in accordance with the timeframe established by the medical reviewer.

“(2) FAILURE TO COMPLY.—If a plan or issuer fails to comply with the timeframe established under paragraph (1)(B)(i) with respect to a participant or beneficiary, where such failure to comply is caused by the plan or issuer, the participant or beneficiary may obtain the items or services involved (in a manner consistent with the determination of the independent external reviewer) from any provider regardless of whether such provider is a participating provider under the plan or coverage.

“(3) REIMBURSEMENT.—

“(A) IN GENERAL.—Where a participant or beneficiary obtains items or services in accordance with paragraph (2), the plan or issuer involved shall provide for reimbursement of the costs of such items or services. Such reimbursement shall be made to the treating health care professional or to the participant or beneficiary (in the case of a

participant or beneficiary who pays for the costs of such items or services).

“(B) AMOUNT.—The plan or issuer shall fully reimburse a professional, participant or beneficiary under subparagraph (A) for the total costs of the items or services provided (regardless of any plan limitations that may apply to the coverage of such items of services) so long as—

“(i) the items or services would have been covered under the terms of the plan or coverage if provided by the plan or issuer; and

“(ii) the items or services were provided in a manner consistent with the determination of the independent medical reviewer.

“(4) FAILURE TO REIMBURSE.—Where a plan or issuer fails to provide reimbursement to a professional, participant or beneficiary in accordance with this subsection, the professional, participant or beneficiary may commence a civil action (or utilize other remedies available under law) to recover only the amount of any such reimbursement that is unpaid and any necessary legal costs or expenses (including attorneys’ fees) incurred in recovering such reimbursement.

“(g) QUALIFICATIONS OF INDEPENDENT MEDICAL REVIEWERS.—

“(1) IN GENERAL.—In referring a denial to 1 or more individuals to conduct independent medical review under subsection (c), the qualified external review entity shall ensure that—

“(A) each independent medical reviewer meets the qualifications described in paragraphs (2) and (3);

“(B) with respect to each review at least 1 such reviewer meets the requirements described in paragraphs (4) and (5); and

“(C) compensation provided by the entity to the reviewer is consistent with paragraph (6).

“(2) LICENSURE AND EXPERTISE.—Each independent medical reviewer shall be a physician or health care professional who—

“(A) is appropriately credentialed or licensed in 1 or more States to deliver health care services; and

“(B) typically treats the diagnosis or condition or provides the type or treatment under review.

“(3) INDEPENDENCE.—

“(A) IN GENERAL.—Subject to subparagraph (B), each independent medical reviewer in a case shall—

“(i) not be a related party (as defined in paragraph (7));

“(ii) not have a material familial, financial, or professional relationship with such a party; and

“(iii) not otherwise have a conflict of interest with such a party (as determined under regulations).

“(B) EXCEPTION.—Nothing in this subparagraph (A) shall be construed to—

“(i) prohibit an individual, solely on the basis of affiliation with the plan or issuer, from serving as an independent medical reviewer if—

“(I) a non-affiliated individual is not reasonably available;

“(II) the affiliated individual is not involved in the provision of items or services in the case under review; and

“(III) the fact of such an affiliation is disclosed to the plan or issuer and the participant or beneficiary (or authorized representative) and neither party objects;

“(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as an independent medical reviewer if the affiliation is disclosed to the plan or issuer and the participant or beneficiary (or authorized representative), and neither party objects;

“(iii) permit an employee of a plan or issuer, or an individual who provides services exclusively or primarily to or on behalf of a plan or issuer, from serving as an independent medical reviewer; or

“(iv) prohibit receipt of compensation by an independent medical reviewer from an entity if the compensation is provided consistent with paragraph (6).

“(4) PRACTICING HEALTH CARE PROFESSIONAL IN SAME FIELD.—

“(A) IN GENERAL.—The requirement of this paragraph with respect to a reviewer in a case involving treatment, or the provision of items or services, by—

“(i) a physician, is that the reviewer be a practicing physician of the same or similar specialty, when reasonably available, as a physician who typically treats the diagnosis or condition or provides such treatment in the case under review; or

“(ii) a health care professional (other than a physician), is that the reviewer be a practicing physician or, if determined appropriate by the qualified external review entity, a health care professional (other than a physician), of the same or similar specialty as the health care professional who typically treats the diagnosis or condition or provides the treatment in the case under review.

“(B) PRACTICING DEFINED.—For purposes of this paragraph, the term ‘practicing’ means, with respect to an individual who is a physician or other health care professional that the individual provides health care services to individual patients on average at least 1 day per week.

“(5) AGE-APPROPRIATE EXPERTISE.—The independent medical reviewer shall have expertise under paragraph (2) that is age-appropriate to the participant or beneficiary involved.

“(6) LIMITATIONS ON REVIEWER COMPENSATION.—Compensation provided by a qualified external review entity to an independent medical reviewer in connection with a review under this section shall—

“(A) not exceed a reasonable level; and

“(B) not be contingent on the decision rendered by the reviewer.

“(7) RELATED PARTY DEFINED.—For purposes of this section, the term ‘related party’ means, with respect to a denial of a claim under a plan or coverage relating to a participant or beneficiary, any of the following:

“(A) The plan, plan sponsor, or issuer involved, or any fiduciary, officer, director, or employee of such plan, plan sponsor, or issuer.

“(B) The participant or beneficiary (or authorized representative).

“(C) The health care professional that provides the items of services involved in the denial.

“(D) The institution at which the items or services (or treatment) involved in the denial are provided.

“(E) The manufacturer of any drug or other item that is included in the items or services involved in the denial.

“(F) Any other party determined under any regulations to have a substantial interest in the denial involved.

“(h) QUALIFIED EXTERNAL REVIEW ENTITIES.—

“(1) SELECTION OF QUALIFIED EXTERNAL REVIEW ENTITIES.—

“(A) LIMITATION ON PLAN OR ISSUER SELECTION.—The Secretary shall implement procedures with respect to the selection of qualified external review entities by a plan or issuer to assure that the selection process among qualified external review entities will not create any incentives for external review

entities to make a decision in a biased manner.

“(B) STATE AUTHORITY WITH RESPECT TO QUALIFIED EXTERNAL REVIEW ENTITIES FOR HEALTH INSURANCE ISSUERS.—With respect to health insurance issuers offering health insurance coverage in connection with a group health plan in a State, the State may, pursuant to a State law that is enacted after the date of enactment of the Patients’ Bill of Rights Plus Act, provide for the designation or selection of qualified external review entities in a manner determined by the State to assure an unbiased determination in conducting external review activities. In conducting reviews under this section, an entity designated or selected under this subparagraph shall comply with the provision of this section.

“(2) CONTRACT WITH QUALIFIED EXTERNAL REVIEW ENTITY.—Except as provided in paragraph (1)(B), the external review process of a plan or issuer under this section shall be conducted under a contract between the plan or issuer and 1 or more qualified external review entities (as defined in paragraph (4)(A)).

“(3) TERMS AND CONDITIONS OF CONTRACT.—The terms and conditions of a contract under paragraph (2) shall—

“(A) be consistent with the standards the Secretary shall establish to assure there is no real or apparent conflict of interest in the conduct of external review activities; and

“(B) provide that the costs of the external review process shall be borne by the plan or issuer.

Subparagraph (B) shall not be construed as applying to the imposition of a filing fee under subsection (b)(2)(A)(iv) or costs incurred by the participant or beneficiary (or authorized representative) or treating health care professional (if any) in support of the review, including the provision of additional evidence or information.

“(4) QUALIFICATIONS.—

“(A) IN GENERAL.—In this section, the term ‘qualified external review entity’ means, in relation to a plan or issuer, an entity that is initially certified (and periodically recertified) under subparagraph (C) as meeting the following requirements:

“(i) The entity has (directly or through contracts or other arrangements) sufficient medical, legal, and other expertise and sufficient staffing to carry out duties of a qualified external review entity under this section on a timely basis, including making determinations under subsection (b)(2)(A) and providing for independent medical reviews under subsection (d).

“(ii) The entity is not a plan or issuer or an affiliate or a subsidiary of a plan or issuer, and is not an affiliate or subsidiary of a professional or trade association of plans or issuers or of health care providers.

“(iii) The entity has provided assurances that it will conduct external review activities consistent with the applicable requirements of this section and standards specified in subparagraph (C), including that it will not conduct any external review activities in a case unless the independence requirements of subparagraph (B) are met with respect to the case.

“(iv) The entity has provided assurances that it will provide information in a timely manner under subparagraph (D).

“(v) The entity meets such other requirements as the Secretary provides by regulation.

“(B) INDEPENDENCE REQUIREMENTS.—

“(i) IN GENERAL.—Subject to clause (ii), an entity meets the independence requirements of this subparagraph with respect to any case if the entity—

“(I) is not a related party (as defined in subsection (g)(7));

“(II) does not have a material familial, financial, or professional relationship with such a party; and

“(III) does not otherwise have a conflict of interest with such a party (as determined under regulations).

“(ii) EXCEPTION FOR REASONABLE COMPENSATION.—Nothing in clause (i) shall be construed to prohibit receipt by a qualified external review entity of compensation from a plan or issuer for the conduct of external review activities under this section if the compensation is provided consistent with clause (iii).

“(iii) LIMITATIONS ON ENTITY COMPENSATION.—Compensation provided by a plan or issuer to a qualified external review entity in connection with reviews under this section shall—

“(I) not exceed a reasonable level; and

“(II) not be contingent on the decision rendered by the entity or by any independent medical reviewer.

“(C) CERTIFICATION AND RECERTIFICATION PROCESS.—

“(i) IN GENERAL.—The initial certification and recertification of a qualified external review entity shall be made—

“(I) under a process that is recognized or approved by the Secretary; or

“(II) by a qualified private standard-setting organization that is approved by the Secretary under clause (iii).

“(ii) PROCESS.—The Secretary shall not recognize or approve a process under clause (i)(I) unless the process applies standards (as promulgated in regulations) that ensure that a qualified external review entity—

“(I) will carry out (and has carried out, in the case of recertification) the responsibilities of such an entity in accordance with this section, including meeting applicable deadlines;

“(II) will meet (and has met, in the case of recertification) appropriate indicators of fiscal integrity;

“(III) will maintain (and has maintained, in the case of recertification) appropriate confidentiality with respect to individually identifiable health information obtained in the course of conducting external review activities; and

“(IV) in the case recertification, shall review the matters described in clause (iv).

“(iii) APPROVAL OF QUALIFIED PRIVATE STANDARD-SETTING ORGANIZATIONS.—For purposes of clause (i)(II), the Secretary may approve a qualified private standard-setting organization if the Secretary finds that the organization only certifies (or recertifies) external review entities that meet at least the standards required for the certification (or recertification) of external review entities under clause (ii).

“(iv) CONSIDERATIONS IN RECERTIFICATIONS.—In conducting recertifications of a qualified external review entity under this paragraph, the Secretary or organization conducting the recertification shall review compliance of the entity with the requirements for conducting external review activities under this section, including the following:

“(I) Provision of information under subparagraph (D).

“(II) Adherence to applicable deadlines (both by the entity and by independent medical reviewers it refers cases to).

“(III) Compliance with limitations on compensation (with respect to both the entity and independent medical reviewers it refers cases to).

“(IV) Compliance with applicable independence requirements.

“(V) PERIOD OF CERTIFICATION OR RECERTIFICATION.—A certification or recertification provided under this paragraph shall extend for a period not to exceed 5 years.

“(vi) REVOCATION.—A certification or recertification under this paragraph may be revoked by the Secretary or by the organization providing such certification upon a showing of cause.

“(D) PROVISION OF INFORMATION.—

“(i) IN GENERAL.—A qualified external review entity shall provide to the Secretary, in such manner and at such times as the Secretary may require, such information (relating to the denials which have been referred to the entity for the conduct of external review under this section) as the Secretary determines appropriate to assure compliance with the independence and other requirements of this section to monitor and assess the quality of its external review activities and lack of bias in making determinations. Such information shall include information described in clause (ii) but shall not include individually identifiable medical information.

“(ii) INFORMATION TO BE INCLUDED.—The information described in this subclause with respect to an entity is as follows:

“(I) The number and types of denials for which a request for review has been received by the entity.

“(II) The disposition by the entity of such denials, including the number referred to a independent medical reviewer and the reasons for such dispositions (including the application of exclusions), on a plan or issuer-specific basis and on a health care specialty-specific basis.

“(III) The length of time in making determinations with respect to such denials.

“(IV) Updated information on the information required to be submitted as a condition of certification with respect to the entity's performance of external review activities.

“(iii) INFORMATION TO BE PROVIDED TO CERTIFYING ORGANIZATION.—

“(I) IN GENERAL.—In the case of a qualified external review entity which is certified (or recertified) under this subsection by a qualified private standard-setting organization, at the request of the organization, the entity shall provide the organization with the information provided to the Secretary under clause (i).

“(II) ADDITIONAL INFORMATION.—Nothing in this subparagraph shall be construed as preventing such an organization from requiring additional information as a condition of certification or recertification of an entity.

“(iv) USE OF INFORMATION.—Information provided under this subparagraph may be used by the Secretary and qualified private standard-setting organizations to conduct oversight of qualified external review entities, including recertification of such entities, and shall be made available to the public in an appropriate manner.

“(E) LIMITATION ON LIABILITY.—No qualified external review entity having a contract with a plan or issuer, and no person who is employed by any such entity or who furnishes professional services to such entity (including as an independent medical reviewer), shall be held by reason of the performance of any duty, function, or activity required or authorized pursuant to this section, to be civilly liable under any law of the United States or of any State (or political subdivision thereof) if there was no actual malice or gross misconduct in the performance of such duty, function, or activity.

“(i) DEFINITIONS.—In this section:

“(1) AUTHORIZED REPRESENTATIVE.—The term ‘authorized representative’ means, with respect to a participant or beneficiary—

“(A) a person to whom a participant or beneficiary has given express written consent to represent the participant or beneficiary in any proceeding under this section;

“(B) a person authorized by law to provide substituted consent for the participant or beneficiary; or

“(C) a family member of the participant or beneficiary (or the estate of the participant or beneficiary) or the participant's or beneficiary's treating health care professional when the participant or beneficiary is unable to provide consent.

“(2) CLAIM FOR BENEFITS.—The term ‘claim for benefits’ means any request by a participant or beneficiary (or authorized representative) for benefits (including requests that are subject to authorization of coverage or utilization review), for eligibility, or for payment in whole or in part, for an item or service under a group health plan or health insurance coverage offered by a health insurance issuer in connection with a group health plan.

“(3) GROUP HEALTH PLAN.—The term ‘group health plan’ shall have the meaning given such term in section 733(a). In applying this paragraph, excepted benefits described in section 733(c) shall not be treated as benefits consisting of medical care.

“(4) HEALTH INSURANCE COVERAGE.—The term ‘health insurance coverage’ has the meaning given such term in section 733(b)(1). In applying this paragraph, excepted benefits described in section 733(c) shall not be treated as benefits consisting of medical care.

“(5) HEALTH INSURANCE ISSUER.—The term ‘health insurance issuer’ has the meaning given such term in section 733(b)(2).

“(6) PRIOR AUTHORIZATION DETERMINATION.—The term ‘prior authorization determination’ means a determination by the group health plan or health insurance issuer offering health insurance coverage in connection with a group health plan prior to the provision of the items and services as a condition of coverage of the items and services under the terms and conditions of the plan or coverage.

“(7) TREATING HEALTH CARE PROFESSIONAL.—The term ‘treating health care professional’ with respect to a group health plan, health insurance issuer or provider sponsored organization means a physician (medical doctor or doctor of osteopathy) or other health care practitioner who is acting within the scope of his or her State licensure or certification for the delivery of health care services and who is primarily responsible for delivering those services to the participant or beneficiary.

“(8) UTILIZATION REVIEW.—The term ‘utilization review’ with respect to a group health plan or health insurance coverage means procedures used in the determination of coverage for a participant or beneficiary, such as procedures to evaluate the medical necessity, appropriateness, efficacy, quality, or efficiency of health care services, procedures or settings, and includes prospective review, concurrent review, second opinions, case management, discharge planning, or retrospective review.”

(b) CONFORMING AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by inserting after the item relating to section 503 the following:

“Sec. 503A. Claims and internal appeals procedures for group health plans.

“Sec. 503B. Independent external appeals procedures for group health plans.”

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan years beginning on or after 2 years after the date of enactment of this Act. The Secretary shall issue all regulations necessary to carry out the amendments made by this section before the effective date thereof.

SEC. 222. ENFORCEMENT.

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

“(8) The Secretary may assess a civil penalty against any plan of up to \$10,000 for the plan's failure or refusal to comply with any deadline applicable under section 503B or any determination under such section, except that in any case in which treatment was not commenced by the plan in accordance with the determination of an independent external reviewer, the Secretary shall assess a civil penalty of \$10,000 against the plan and the plan shall pay such penalty to the participant or beneficiary involved.”

Subtitle D—Remedies

SEC. 231. AVAILABILITY OF COURT REMEDIES.

(a) IN GENERAL.—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) CAUSE OF ACTION RELATING TO DENIAL OF A CLAIM FOR HEALTH BENEFITS.—

“(1) IN GENERAL.—

“(A) FAILURE TO COMPLY WITH EXTERNAL MEDICAL REVIEW.—In any case in which—

“(i) a designated decision-maker described in paragraph (2) fails to exercise ordinary care in approving coverage pursuant to the written determination of an independent medical reviewer under section 503B(d)(3)(F) that reverses a denial of a claim for benefits; and

“(ii) the failure described in clause (i) is the proximate cause of substantial harm to, or the wrongful death of, the participant or beneficiary;

such designated decision-maker shall be liable to the participant or beneficiary (or the estate of such participant or beneficiary) for economic and noneconomic damages in connection with such failure and such injury or death (subject to paragraph (4)).

“(B) WRONGFUL DETERMINATION RESULTING IN DELAY IN PROVIDING BENEFITS.—In any case in which—

“(i) a designated decision-maker described in paragraph (2) acts in bad faith in making a final determination denying a claim for benefits under section 503A(b);

“(ii) the denial described in clause (i) is reversed by an independent medical reviewer under section 503B(d); and

“(iii) the delay attributable to the failure described in clause (i) is the proximate cause of substantial harm to, or the wrongful death of, the participant or beneficiary;

such designated decision-maker shall be liable to the participant or beneficiary (or the estate of such participant or beneficiary) for economic and noneconomic damages in connection with such failure and such injury or death (subject to paragraph (4)).

“(2) DESIGNATED DECISION-MAKERS FOR PURPOSES OF LIABILITY.—An employer or plan sponsor shall not be liable under any cause of action described in paragraph (1) if the employer or plan sponsor complies with the following provisions:

“(A) APPOINTMENT.—A group health plan may designate one or more persons to serve

as the designated decision-maker for purposes of paragraph (1). Such designated decision-makers shall have the exclusive authority under the group health plan (or under the health insurance coverage in the case of a health insurance issuer offering coverage in connection with a group health plan) to make determinations described in section 503A with respect to claims for benefits and determination to approve coverage pursuant to written determination of independent medical reviewers under section 503B, except that the plan documents may expressly provide that the designated decision-maker is subject to the direction of a named fiduciary.

“(B) PROCEDURES.—A designated decision-maker shall—

“(i) be a person who is named in the plan or coverage documents, or who, pursuant to procedures specified in the plan or coverage documents, is identified as the designated decision-maker by—

“(I) a person who is an employer or employee organization with respect to the plan or issuer;

“(II) a person who is such an employer and such an employee organization acting jointly; or

“(III) a person who is a named fiduciary;

“(ii) agree to accept appointment as a designated decision-maker; and

“(iii) be identified in the plan or coverage documents as required under section 714(b)(14).

“(C) QUALIFICATIONS.—To be appointed as a designated decision-maker under this paragraph, a person shall be—

“(i) a plan sponsor;

“(ii) a group health plan;

“(iii) a health insurance issuer; or

“(iv) any other person who can provide adequate evidence, in accordance with regulations promulgated by the Secretary, of the ability of the person to—

“(I) carry out the responsibilities set forth in the plan or coverage documents;

“(II) carry out the applicable requirements of this subsection; and

“(III) meet other applicable requirements under this Act, including any financial obligation for liability under this subsection.

“(D) FLEXIBILITY IN ADMINISTRATION.—A group health plan, or health insurance issuer offering coverage in connection with a group health plan, may provide—

“(i) that any person or group of persons may serve in more than one capacity with respect to the plan or coverage (including service as a designated decision-maker, administrator, and named fiduciary); or

“(ii) that a designated decision-maker may employ one or more persons to provide advice with respect to any responsibility of such decision-maker under the plan or coverage.

“(E) FAILURE TO DESIGNATE.—In any case in which a designated decision-maker is not appointed under this paragraph, the group health plan (or health insurance issuer offering coverage in connection with the group health plan), the administrator, or the party or parties that bears the sole responsibility for making the final determination under section 503A(b) (with respect to an internal review), or for approving coverage pursuant to the written determination of an independent medical reviewer under section 503B, with respect to a denial of a claim for benefits shall be treated as the designated decision-maker for purposes of liability under this section.

“(3) REQUIREMENT OF EXHAUSTION OF INDEPENDENT MEDICAL REVIEW.—Paragraph (1) shall apply only if a final determination de-

termining a claim for benefits under section 503A(b) has been referred for independent medical review under section 503B(d) and a written determination by an independent medical reviewer to reverse such final determination has been issued with respect to such review.

“(4) LIMITATIONS ON RECOVERY OF DAMAGES.—

“(A) MAXIMUM AWARD OF NONECONOMIC DAMAGES.—The aggregate amount of liability for noneconomic loss in an action under paragraph (1) may not exceed \$350,000.

“(B) INCREASE IN AMOUNT.—The amount referred to in subparagraph (A) shall be increased or decreased, for each calendar year that ends after December 31, 2001, by the same percentage as the percentage by which the Consumer Price Index for All Urban Consumers (United States city average), published by the Bureau of Labor Statistics, for September of the preceding calendar year has increased or decreased from the such Index for September of 2001.

“(C) JOINT AND SEVERAL LIABILITY.—In the case of any action commenced pursuant to paragraph (1), the defendant shall be liable only for the amount of noneconomic damages attributable to such defendant in direct proportion to such defendant's share of fault or responsibility for the injury suffered by the participant or beneficiary. In all such cases, the liability of a defendant for noneconomic damages shall be several and not joint.

“(D) TREATMENT OF COLLATERAL SOURCE PAYMENTS.—

“(i) IN GENERAL.—In the case of any action commenced pursuant to paragraph (1), the total amount of damages received by a participant or beneficiary under such action shall be reduced, in accordance with clause (ii), by any other payment that has been, or will be, made to such participant or beneficiary to compensate such participant or beneficiary for the injury that was the subject of such action.

“(ii) AMOUNT OF REDUCTION.—The amount by which an award of damages to a participant or beneficiary for an injury shall be reduced under clause (i) shall be—

“(I) the total amount of any payments (other than such award) that have been made or that will be made to such participant or beneficiary to pay costs of or compensate such participant or beneficiary for the injury that was the subject of the action; less

“(II) the amount paid by such participant or beneficiary (or by the spouse, parent, or legal guardian of such participant or beneficiary) to secure the payments described in subclause (I).

“(iii) DETERMINATION OF AMOUNTS FROM COLLATERAL SOURCES.—The reduction required under clause (ii) shall be determined by the court in a pretrial proceeding. At the subsequent trial no evidence shall be admitted as to the amount of any charge, payments, or damage for which a participant or beneficiary—

“(I) has received payment from a collateral source or the obligation for which has been assured by a third party; or

“(II) is, or with reasonable certainty, will be eligible to receive from a collateral source which will, with reasonable certainty, be assumed by a third party.

“(5) AFFIRMATIVE DEFENSES.—In the case of any cause of action under paragraph (1), it shall be an affirmative defense that—

“(A) the group health plan, or health insurance issuer offering health insurance coverage in connection with a group health plan, involved did not receive from the par-

ticipant or beneficiary (or authorized representative) or the treating health care professional (if any), sufficient information regarding the medical condition of the participant or beneficiary that was necessary to make a final determination on a claim for benefits under section 503A(b);

“(B) the participant or beneficiary (or authorized representative)—

“(i) was in possession of facts that were sufficient to enable the participant or beneficiary (or authorized representative) to know that an expedited review under section 503A or 503B would have prevented the harm that is the subject of the action; and

“(ii) failed to notify the plan or issuer of the need for such an expedited review; or

“(C) the cause of action is based solely on the failure of a qualified external review entity or an independent medical reviewer to meet the timelines applicable under section 503B.

Nothing in this paragraph shall be construed to limit the application of any other affirmative defense that may be applicable to the cause of action involved.

“(6) WAIVER OF INTERNAL REVIEW.—In the case of any cause of action under paragraph (1), the waiver or nonwaiver of internal review under section 503A(b)(1)(D) by the group health plan, or health insurance issuer offering health insurance coverage in connection with a group health plan, shall not be used in determining liability.

“(7) LIMITATIONS ON ACTIONS.—Paragraph (1) shall not apply in connection with any action that is commenced more than 1 year after—

“(A) the date on which the last act occurred which constituted a part of the failure referred to in such paragraph; or

“(B) in the case of an omission, the last date on which the decision-maker could have cured the failure.

“(8) LIMITATION ON RELIEF WHERE DEFENDANT'S POSITION PREVIOUSLY SUPPORTED UPON EXTERNAL REVIEW.—In any case in which the court finds the defendant to be liable in an action under this subsection, to the extent that such liability is based on a finding by the court of a particular failure described in paragraph (1) and such finding is contrary to a previous determination by an independent medical reviewer under section 503B(d) with respect to such defendant, no relief shall be available under this subsection in addition to the relief otherwise available under subsection (a)(1)(B).

“(9) CONSTRUCTION.—Nothing in this subsection shall be construed as authorizing a cause of action under paragraph (1) for—

“(A) the failure of a group health plan or health insurance issuer to provide an item or service that is specifically excluded under the plan or coverage; or

“(B) any denial of a claim for benefits that was not eligible for independent medical review under section 503B(d).

“(10) FEDERAL JURISDICTION.—In the case of any action commenced pursuant to paragraph (1) the district courts of the United States shall have exclusive jurisdiction.

“(11) DEFINITIONS.—In this subsection:

“(A) AUTHORIZED REPRESENTATIVE.—The term ‘authorized representative’ has the meaning given such term in section 503B(i).

“(B) CLAIM FOR BENEFITS.—The term ‘claim for benefits’ shall have the meaning given such term in section 503B(i), except that such term shall only include claims for prior authorization determinations (as such term is defined in section 503B(i)).

“(C) GROUP HEALTH PLAN.—The term ‘group health plan’ shall have the meaning given such term in section 733(a).

“(D) HEALTH INSURANCE COVERAGE.—The term ‘health insurance coverage’ has the meaning given such term in section 733(b)(1).

“(E) HEALTH INSURANCE ISSUER.—The term ‘health insurance issuer’ has the meaning given such term in section 733(b)(2) (including health maintenance organizations as defined in section 733(b)(3)).

“(F) ORDINARY CARE.—The term ‘ordinary care’ means the care, skill, prudence, and diligence under the circumstances prevailing at the time the care is provided that a prudent individual acting in a like capacity and familiar with the care being provided would use in providing care of a similar character.

“(G) SUBSTANTIAL HARM.—The term ‘substantial harm’ means the loss of life, loss or significant impairment of limb or bodily function, significant disfigurement, or severe and chronic physical pain.

“(12) EFFECTIVE DATE.—The provisions of this subsection shall apply to acts and omissions occurring on or after the date of enactment of this subsection.”.

(b) IMMUNITY FROM LIABILITY FOR PROVISION OF INSURANCE OPTIONS.—

(1) IN GENERAL.—Section 502 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132), as amended by subsection (a), is further amended by adding at the end the following:

“(o) IMMUNITY FROM LIABILITY FOR PROVISION OF INSURANCE OPTIONS.—

“(1) IN GENERAL.—No liability shall arise under subsection (n) with respect to a participant or beneficiary against a group health plan (other than a fully insured group health plan) if such plan offers the participant or beneficiary the coverage option described in paragraph (2).

“(2) COVERAGE OPTION.—The coverage option described in this paragraph is one under which the group health plan (other than a fully insured group health plan), at the time of enrollment or as provided for in paragraph (3), provides the participant or beneficiary with the option to—

“(A) enroll for coverage under a fully insured health plan; or

“(B) receive an individual benefit payment, in an amount equal to the amount that would be contributed on behalf of the participant or beneficiary by the plan sponsor for enrollment in the group health plan, for use by the participant or beneficiary in obtaining health insurance coverage in the individual market.

“(3) TIME OF OFFERING OF OPTION.—The coverage option described in paragraph (2) shall be offered to a participant or beneficiary—

“(A) during the first period in which the individual is eligible to enroll under the group health plan; or

“(B) during any special enrollment period provided by the group health plan after the date of enactment of the Patients’ Bill of Rights Plus Act for purposes of offering such coverage option.”.

(2) AMENDMENTS TO INTERNAL REVENUE CODE.—

(A) EXCLUSION FROM INCOME.—Section 106 of the Internal Revenue Code of 1986 (relating to contributions by employer to accident and health plans) is amended by adding at the end the following:

“(d) TREATMENT OF CERTAIN COVERAGE OPTION UNDER SELF-INSURED PLANS.—No amount shall be included in the gross income of an individual by reason of—

“(1) the individual’s right to elect a coverage option described in section 502(o)(2) of the Employee Retirement Income Security Act of 1974, or

“(2) the receipt by the individual of an individual benefit payment described in section 502(o)(2)(A) of such Act.”

(B) NONDISCRIMINATION RULES.—Section 105(h) of such Code (relating to self-insured medical expense reimbursement plans) is amended by adding at the end the following:

“(1) TREATMENT OF CERTAIN COVERAGE OPTIONS.—If a self-insured medical reimbursement plan offers the coverage option described in section 502(o)(2) of the Employee Retirement Income Security Act of 1974, employees who elect such option shall be treated as eligible to benefit under the plan and the plan shall be treated as benefiting such employees.”

(c) CONFORMING AMENDMENT.—Section 502(a)(1)(A) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(a)(1)(A)) is amended by inserting “or (n)” after “subsection (c)”.

SEC. 232. LIMITATION ON CERTAIN CLASS ACTION LITIGATION.

(a) ERISA.—Section 502 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132), as amended by section 231, is further amended by adding at the end the following:

“(p) LIMITATION ON CLASS ACTION LITIGATION.—A claim or cause of action under section 502(n) may not be maintained as a class action.”.

(b) RICO.—Section 1964(c) of title 18, United States Code, is amended—

(1) by inserting “(1)” after the subsection designation; and

(2) by adding at the end the following: “(2) No action may be brought under this subsection, or alleging any violation of section 1962, against any person where the action seeks relief for which a remedy may be provided under section 502 of the Employee Retirement Income Security Act of 1974.”.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by this section shall apply to all civil actions that are filed on or after the date of enactment of this Act.

(2) PENDING CIVIL ACTIONS.—Notwithstanding section 502(p) of the Employee Retirement Income Security Act of 1974 and section 1964(c)(2) of title 18, United States Code, such sections 502(p) and 1964(c)(2) shall apply to civil actions that are pending and have not been finally determined by judgment or settlement prior to the date of enactment of this Act if such actions are substantially similar in nature to the claims or causes of actions referred to in such sections 502(p) and 1964(c)(2).

SEC. 233. SEVERABILITY.

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

TITLE III—WOMEN’S HEALTH AND CANCER RIGHTS

SEC. 301. WOMEN’S HEALTH AND CANCER RIGHTS.

(a) SHORT TITLE.—This section may be cited as the “Women’s Health and Cancer Rights Act of 2000”.

(b) FINDINGS.—Congress finds that—

(1) the offering and operation of health plans affect commerce among the States;

(2) health care providers located in a State serve patients who reside in the State and patients who reside in other States; and

(3) in order to provide for uniform treatment of health care providers and patients

among the States, it is necessary to cover health plans operating in 1 State as well as health plans operating among the several States.

(c) AMENDMENTS TO ERISA.—

(1) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, as amended by section 211(a), is further amended by adding at the end the following:

“SEC. 715. REQUIRED COVERAGE FOR MINIMUM HOSPITAL STAY FOR MASTECTOMIES AND LYMPH NODE DISSECTIONS FOR THE TREATMENT OF BREAST CANCER AND COVERAGE FOR SECONDARY CONSULTATIONS.

“(a) INPATIENT CARE.—

“(1) IN GENERAL.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, that provides medical and surgical benefits shall ensure that inpatient coverage with respect to the treatment of breast cancer is provided for a period of time as is determined by the attending physician, in consultation with the patient, to be medically necessary and appropriate following—

“(A) a mastectomy;

“(B) a lumpectomy; or

“(C) a lymph node dissection for the treatment of breast cancer.

“(2) EXCEPTION.—Nothing in this section shall be construed as requiring the provision of inpatient coverage if the attending physician and patient determine that a shorter period of hospital stay is medically appropriate.

“(b) PROHIBITION ON CERTAIN MODIFICATIONS.—In implementing the requirements of this section, a group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, may not modify the terms and conditions of coverage based on the determination by a participant or beneficiary to request less than the minimum coverage required under subsection (a).

“(c) NOTICE.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan shall provide notice to each participant and beneficiary under such plan regarding the coverage required by this section in accordance with regulations promulgated by the Secretary. Such notice shall be in writing and prominently positioned in any literature or correspondence made available or distributed by the plan or issuer and shall be transmitted—

“(1) in the next mailing made by the plan or issuer to the participant or beneficiary;

“(2) as part of any yearly informational packet sent to the participant or beneficiary; or

“(3) not later than January 1, 2001; whichever is earlier.

“(d) SECONDARY CONSULTATIONS.—

“(1) IN GENERAL.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, that provides coverage with respect to medical and surgical services provided in relation to the diagnosis and treatment of cancer shall ensure that full coverage is provided for secondary consultations by specialists in the appropriate medical fields (including pathology, radiology, and oncology) to confirm or refute such diagnosis. Such plan or issuer shall ensure that full coverage is provided for such secondary consultation whether such consultation is based on a positive or negative initial diagnosis. In any case in which the attending physician certifies in writing that services necessary for such a secondary consultation

are not sufficiently available from specialists operating under the plan with respect to whose services coverage is otherwise provided under such plan or by such issuer, such plan or issuer shall ensure that coverage is provided with respect to the services necessary for the secondary consultation with any other specialist selected by the attending physician for such purpose at no additional cost to the individual beyond that which the individual would have paid if the specialist was participating in the network of the plan.

“(2) EXCEPTION.—Nothing in paragraph (1) shall be construed as requiring the provision of secondary consultations where the patient determines not to seek such a consultation.

“(e) PROHIBITION ON PENALTIES OR INCENTIVES.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, may not—

“(1) penalize or otherwise reduce or limit the reimbursement of a provider or specialist because the provider or specialist provided care to a participant or beneficiary in accordance with this section;

“(2) provide financial or other incentives to a physician or specialist to induce the physician or specialist to keep the length of inpatient stays of patients following a mastectomy, lumpectomy, or a lymph node dissection for the treatment of breast cancer below certain limits or to limit referrals for secondary consultations; or

“(3) provide financial or other incentives to a physician or specialist to induce the physician or specialist to refrain from referring a participant or beneficiary for a secondary consultation that would otherwise be covered by the plan or coverage involved under subsection (d).”.

(2) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by inserting after the item relating to section 714 the following new item:

“Sec. 715. Required coverage for minimum hospital stay for mastectomies and lymph node dissections for the treatment of breast cancer and coverage for secondary consultations.”.

(d) AMENDMENTS TO PHSA RELATING TO THE GROUP MARKET.—Subpart 2 of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-4 et seq.) is amended by adding at the end the following new section:

“SEC. 2707. REQUIRED COVERAGE FOR MINIMUM HOSPITAL STAY FOR MASTECTOMIES AND LYMPH NODE DISSECTIONS FOR THE TREATMENT OF BREAST CANCER AND COVERAGE FOR SECONDARY CONSULTATIONS.

“(a) INPATIENT CARE.—

“(1) IN GENERAL.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, that provides medical and surgical benefits shall ensure that inpatient coverage with respect to the treatment of breast cancer is provided for a period of time as is determined by the attending physician, in consultation with the patient, to be medically necessary and appropriate following—

“(A) a mastectomy;

“(B) a lumpectomy; or

“(C) a lymph node dissection for the treatment of breast cancer.

“(2) EXCEPTION.—Nothing in this section shall be construed as requiring the provision of inpatient coverage if the attending physician and patient determine that a shorter period of hospital stay is medically appropriate.

“(b) PROHIBITION ON CERTAIN MODIFICATIONS.—In implementing the requirements of this section, a group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, may not modify the terms and conditions of coverage based on the determination by a participant or beneficiary to request less than the minimum coverage required under subsection (a).

“(c) NOTICE.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan shall provide notice to each participant and beneficiary under such plan regarding the coverage required by this section in accordance with regulations promulgated by the Secretary. Such notice shall be in writing and prominently positioned in any literature or correspondence made available or distributed by the plan or issuer and shall be transmitted—

“(1) in the next mailing made by the plan or issuer to the participant or beneficiary;

“(2) as part of any yearly informational packet sent to the participant or beneficiary; or

“(3) not later than January 1, 2001; whichever is earlier.

“(d) SECONDARY CONSULTATIONS.—

“(1) IN GENERAL.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan that provides coverage with respect to medical and surgical services provided in relation to the diagnosis and treatment of cancer shall ensure that full coverage is provided for secondary consultations by specialists in the appropriate medical fields (including pathology, radiology, and oncology) to confirm or refute such diagnosis. Such plan or issuer shall ensure that full coverage is provided for such secondary consultation whether such consultation is based on a positive or negative initial diagnosis. In any case in which the attending physician certifies in writing that services necessary for such a secondary consultation are not sufficiently available from specialists operating under the plan with respect to whose services coverage is otherwise provided under such plan or by such issuer, such plan or issuer shall ensure that coverage is provided with respect to the services necessary for the secondary consultation with any other specialist selected by the attending physician for such purpose at no additional cost to the individual beyond that which the individual would have paid if the specialist was participating in the network of the plan.

“(2) EXCEPTION.—Nothing in paragraph (1) shall be construed as requiring the provision of secondary consultations where the patient determines not to seek such a consultation.

“(e) PROHIBITION ON PENALTIES OR INCENTIVES.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, may not—

“(1) penalize or otherwise reduce or limit the reimbursement of a provider or specialist because the provider or specialist provided care to a participant or beneficiary in accordance with this section;

“(2) provide financial or other incentives to a physician or specialist to induce the physician or specialist to keep the length of inpatient stays of patients following a mastectomy, lumpectomy, or a lymph node dissection for the treatment of breast cancer below certain limits or to limit referrals for secondary consultations; or

“(3) provide financial or other incentives to a physician or specialist to induce the

physician or specialist to refrain from referring a participant or beneficiary for a secondary consultation that would otherwise be covered by the plan or coverage involved under subsection (d).”.

(e) AMENDMENTS TO PHSA RELATING TO THE INDIVIDUAL MARKET.—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) (42 U.S.C. 300gg-51 et seq.) is amended—

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

(2) by adding at the end the following:

“SEC. 2753. REQUIRED COVERAGE FOR MINIMUM HOSPITAL STAY FOR MASTECTOMIES AND LYMPH NODE DISSECTIONS FOR THE TREATMENT OF BREAST CANCER AND SECONDARY CONSULTATIONS.

“The provisions of section 2707 shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as they apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market.”.

(f) AMENDMENTS TO THE IRC.—

(1) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986, as amended by section 202, is further amended by inserting after section 9813 the following:

“SEC. 9814. REQUIRED COVERAGE FOR MINIMUM HOSPITAL STAY FOR MASTECTOMIES AND LYMPH NODE DISSECTIONS FOR THE TREATMENT OF BREAST CANCER AND COVERAGE FOR SECONDARY CONSULTATIONS.

“(a) INPATIENT CARE.—

“(1) IN GENERAL.—A group health plan that provides medical and surgical benefits shall ensure that inpatient coverage with respect to the treatment of breast cancer is provided for a period of time as is determined by the attending physician, in consultation with the patient, to be medically necessary and appropriate following—

“(A) a mastectomy;

“(B) a lumpectomy; or

“(C) a lymph node dissection for the treatment of breast cancer.

“(2) EXCEPTION.—Nothing in this section shall be construed as requiring the provision of inpatient coverage if the attending physician and patient determine that a shorter period of hospital stay is medically appropriate.

“(b) PROHIBITION ON CERTAIN MODIFICATIONS.—In implementing the requirements of this section, a group health plan may not modify the terms and conditions of coverage based on the determination by a participant or beneficiary to request less than the minimum coverage required under subsection (a).

“(c) NOTICE.—A group health plan shall provide notice to each participant and beneficiary under such plan regarding the coverage required by this section in accordance with regulations promulgated by the Secretary. Such notice shall be in writing and prominently positioned in any literature or correspondence made available or distributed by the plan and shall be transmitted—

“(1) in the next mailing made by the plan to the participant or beneficiary;

“(2) as part of any yearly informational packet sent to the participant or beneficiary; or

“(3) not later than January 1, 2000; whichever is earlier.

“(d) SECONDARY CONSULTATIONS.—

“(1) IN GENERAL.—A group health plan that provides coverage with respect to medical

and surgical services provided in relation to the diagnosis and treatment of cancer shall ensure that full coverage is provided for secondary consultations by specialists in the appropriate medical fields (including pathology, radiology, and oncology) to confirm or refute such diagnosis. Such plan or issuer shall ensure that full coverage is provided for such secondary consultation whether such consultation is based on a positive or negative initial diagnosis. In any case in which the attending physician certifies in writing that services necessary for such a secondary consultation are not sufficiently available from specialists operating under the plan with respect to whose services coverage is otherwise provided under such plan or by such issuer, such plan or issuer shall ensure that coverage is provided with respect to the services necessary for the secondary consultation with any other specialist selected by the attending physician for such purpose at no additional cost to the individual beyond that which the individual would have paid if the specialist was participating in the network of the plan.

“(2) EXCEPTION.—Nothing in paragraph (1) shall be construed as requiring the provision of secondary consultations where the patient determines not to seek such a consultation.

“(e) PROHIBITION ON PENALTIES.—A group health plan may not—

“(1) penalize or otherwise reduce or limit the reimbursement of a provider or specialist because the provider or specialist provided care to a participant or beneficiary in accordance with this section;

“(2) provide financial or other incentives to a physician or specialist to induce the physician or specialist to keep the length of inpatient stays of patients following a mastectomy, lumpectomy, or a lymph node dissection for the treatment of breast cancer below certain limits or to limit referrals for secondary consultations; or

“(3) provide financial or other incentives to a physician or specialist to induce the physician or specialist to refrain from referring a participant or beneficiary for a secondary consultation that would otherwise be covered by the plan involved under subsection (d).”.

(2) CLERICAL AMENDMENT.—The table of contents for chapter 100 of such Code is amended by inserting after the item relating to section 9813 the following new item:

“Sec. 9814. Required coverage for minimum hospital stay for mastectomies and lymph node dissections for the treatment of breast cancer and coverage for secondary consultations.”.

TITLE IV—GENETIC INFORMATION AND SERVICES

SEC. 401. SHORT TITLE.

This title may be cited as the “Genetic Information Nondiscrimination in Health Insurance Act of 1999”.

SEC. 402. 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)”.

(2) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON PREDICTIVE GENETIC INFORMATION.—Subpart B of part 7 of subtitle B of title I of

the Employee Retirement Income Security Act of 1974, as amended by section 301(c), is further amended by adding at the end the following:

“SEC. 716. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

“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 predictive genetic information concerning any individual (including a dependent) or family member of the individual (including information about a request for or receipt of genetic services).”.

(3) CONFORMING AMENDMENTS.—

(A) IN GENERAL.—Section 702(b) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182(b)) is amended by adding at the end the following:

“(3) REFERENCE TO RELATED PROVISION.—For a provision prohibiting the adjustment of premium or contribution amounts for a group under a group health plan on the basis of predictive genetic information (including information about a request for or receipt of genetic services), see section 716.”.

(B) TABLE OF CONTENTS.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974, as amended by section 301, is further amended by inserting after the item relating to section 715 the following new item:

“Sec. 716. Prohibiting premium discrimination against groups on the basis of predictive genetic information.”.

(b) LIMITATION ON COLLECTION OF PREDICTIVE GENETIC INFORMATION.—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) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

“(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), 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 predictive genetic information concerning any individual (including a dependent) or family member of the individual (including information about a request for or receipt of genetic services).

“(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

“(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

“(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (d), of such predictive genetic information.

“(d) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

“(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

“(A) PREPARATION OF WRITTEN NOTICE.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall post or provide, in writing and in a clear and conspicuous manner, notice of the plan or issuer’s confidentiality practices, that shall include—

“(i) a description of an individual’s rights with respect to predictive genetic information;

“(ii) the procedures established by the plan or issuer for the exercise of the individual’s rights; and

“(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

“(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

“(2) ESTABLISHMENT OF SAFEGUARDS.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such plan or issuer.”.

(c) 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.—The term ‘genetic information’ means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member (including information about a request for or receipt of genetic services).

“(7) GENETIC SERVICES.—The term ‘genetic services’ means health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

“(8) PREDICTIVE GENETIC INFORMATION.—

“(A) IN GENERAL.—The term ‘predictive genetic information’ means, in the absence of symptoms, clinical signs, or a diagnosis of the condition related to such information—

“(i) information about an individual’s genetic tests;

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

“(iii) information about the occurrence of a disease or disorder in family members.

“(B) EXCEPTIONS.—The term ‘predictive genetic information’ shall not include—

“(i) information about the sex or age of the individual;

“(ii) information derived from physical tests, such as the chemical, blood, or urine

analyses of the individual including cholesterol tests; and

“(iii) information about physical exams of the individual.

“(9) GENETIC TEST.—The term ‘genetic test’ means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of disease in asymptomatic or undiagnosed individuals. Such term does not include physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests, and physical exams of the individual, in order to detect symptoms, clinical signs, or a diagnosis of disease.”

(d) EFFECTIVE DATE.—Except as provided in this section, this section and the amendments made by this section shall apply with respect to group health plans for plan years beginning 1 year after the date of the enactment of this Act.

SEC. 403. 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 IN THE GROUP MARKET.—

(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)”.

(B) NO DISCRIMINATION IN PREMIUMS BASED ON PREDICTIVE GENETIC INFORMATION.—Subpart 2 of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-4 et seq.), as amended by section 301(d), is amended by adding at the end the following new section: “**SEC. 2708. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION IN THE GROUP MARKET.**

“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 predictive genetic information concerning any individual (including a dependent) or family member of the individual (including information about a request for or receipt of genetic services).”.

(C) CONFORMING AMENDMENT.—Section 2702(b) of the Public Health Service Act (42 U.S.C. 300gg-1(b)) is amended by adding at the end the following:

“(3) REFERENCE TO RELATED PROVISION.—For a provision prohibiting the adjustment of premium or contribution amounts for a group under a group health plan on the basis of predictive genetic information (including information about a request for or receipt of genetic services), see section 2708.”.

(D) LIMITATION ON COLLECTION AND DISCLOSURE OF PREDICTIVE GENETIC INFORMATION.—Section 2702 of the Public Health Service Act (42 U.S.C. 300gg-1) is amended by adding at the end the following:

“(c) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

“(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), 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 predictive genetic information concerning any individual (including a dependent) or a family member of the indi-

vidual (including information about a request for or receipt of genetic services).

“(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

“(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

“(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (d), of such predictive genetic information.

“(d) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

“(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

“(A) PREPARATION OF WRITTEN NOTICE.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall post or provide, in writing and in a clear and conspicuous manner, notice of the plan or issuer’s confidentiality practices, that shall include—

“(i) a description of an individual’s rights with respect to predictive genetic information;

“(ii) the procedures established by the plan or issuer for the exercise of the individual’s rights; and

“(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

“(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

“(2) ESTABLISHMENT OF SAFEGUARDS.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such plan or issuer.”.

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

“(15) FAMILY MEMBER.—The term ‘family member’ means, with respect to an individual—

“(A) the spouse of the individual;

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

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

“(16) GENETIC INFORMATION.—The term ‘genetic information’ means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member (including information about a request for or receipt of genetic services).

“(17) GENETIC SERVICES.—The term ‘genetic services’ means health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

“(18) PREDICTIVE GENETIC INFORMATION.—

“(A) IN GENERAL.—The term ‘predictive genetic information’ means, in the absence of symptoms, clinical signs, or a diagnosis of the condition related to such information—

“(i) information about an individual’s genetic tests;

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

“(iii) information about the occurrence of a disease or disorder in family members.

“(B) EXCEPTIONS.—The term ‘predictive genetic information’ shall not include—

“(i) information about the sex or age of the individual;

“(ii) information derived from physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests; and

“(iii) information about physical exams of the individual.

“(19) GENETIC TEST.—The term ‘genetic test’ means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of disease in asymptomatic or undiagnosed individuals. Such term does not include physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests, and physical exams of the individual, in order to detect symptoms, clinical signs, or a diagnosis of disease.”.

(e) AMENDMENTS TO PHSA RELATING TO THE INDIVIDUAL MARKET.—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) (42 U.S.C. 300gg-51 et seq.), as amended by section 301(e), is further amended by adding at the end the following:

“SEC. 2754. PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

“(a) PROHIBITION ON PREDICTIVE GENETIC INFORMATION AS A CONDITION OF ELIGIBILITY.—A health insurance issuer offering health insurance coverage in the individual market may not use predictive genetic information as a condition of eligibility of an individual to enroll in individual health insurance coverage (including information about a request for or receipt of genetic services).

“(b) PROHIBITION ON PREDICTIVE GENETIC INFORMATION IN SETTING PREMIUM RATES.—A health insurance issuer offering health insurance coverage in the individual market shall not adjust premium rates for individuals on the basis of predictive genetic information concerning such an individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

“(c) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

“(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a health insurance issuer offering health insurance coverage in the individual market shall not request or require predictive genetic information concerning any individual (including

a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

“(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

“(A) IN GENERAL.—Notwithstanding paragraph (1), a health insurance issuer offering health insurance coverage in the individual market that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

“(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the health insurance issuer offering health insurance coverage in the individual market shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (d), of such predictive genetic information.

“(d) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

“(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

“(A) PREPARATION OF WRITTEN NOTICE.—A health insurance issuer offering health insurance coverage in the individual market shall post or provide, in writing and in a clear and conspicuous manner, notice of the issuer's confidentiality practices, that shall include—

“(i) a description of an individual's rights with respect to predictive genetic information;

“(ii) the procedures established by the issuer for the exercise of the individual's rights; and

“(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

“(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

“(2) ESTABLISHMENT OF SAFEGUARDS.—A health insurance issuer offering health insurance coverage in the individual market shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such issuer.”

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to—

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

(2) health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after 1 year after the date of enactment of this Act.

SEC. 404. AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986.

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

(1) NO ENROLLMENT RESTRICTION FOR GENETIC SERVICES.—Section 9802(a)(1)(F) of the Internal Revenue Code of 1986 is amended by inserting before the period the following: “(including information about a request for or receipt of genetic services)”.

(2) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON PREDICTIVE GENETIC INFORMATION.—

(A) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986, as amended by section 301(f), is further amended by adding at the end the following:

“SEC. 9815. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

“A group health plan shall not adjust premium or contribution amounts for a group on the basis of predictive genetic information concerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).”

(B) CONFORMING AMENDMENT.—Section 9802(b) of the Internal Revenue Code of 1986 is amended by adding at the end the following:

“(3) REFERENCE TO RELATED PROVISION.—For a provision prohibiting the adjustment of premium or contribution amounts for a group under a group health plan on the basis of predictive genetic information (including information about a request for or the receipt of genetic services), see section 9815.”

(C) AMENDMENT TO TABLE OF SECTIONS.—The table of sections for subchapter B of chapter 100 of the Internal Revenue Code of 1986, as amended by section 301(f), is further amended by adding at the end the following:

“Sec. 9815. Prohibiting premium discrimination against groups on the basis of predictive genetic information.”

(b) LIMITATION ON COLLECTION OF PREDICTIVE GENETIC INFORMATION.—Section 9802 of the Internal Revenue Code of 1986 is amended by adding at the end the following:

“(d) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

“(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a group health plan shall not request or require predictive genetic information concerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

“(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

“(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

“(B) NOTICE OF CONFIDENTIALITY PRACTICES; DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the group health plan shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (e), of such predictive genetic information.

“(e) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

“(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

“(A) PREPARATION OF WRITTEN NOTICE.—A group health plan shall post or provide, in

writing and in a clear and conspicuous manner, notice of the plan's confidentiality practices, that shall include—

“(i) a description of an individual's rights with respect to predictive genetic information;

“(ii) the procedures established by the plan for the exercise of the individual's rights; and

“(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

“(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

“(2) ESTABLISHMENT OF SAFEGUARDS.—A group health plan shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such plan.”

(c) DEFINITIONS.—Section 9832(d) of the Internal Revenue Code of 1986 is amended by adding at the end the following:

“(6) 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).

“(7) GENETIC INFORMATION.—The term ‘genetic information’ means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member (including information about a request for or receipt of genetic services).

“(8) GENETIC SERVICES.—The term ‘genetic services’ means health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

“(9) PREDICTIVE GENETIC INFORMATION.—

“(A) IN GENERAL.—The term ‘predictive genetic information’ means, in the absence of symptoms, clinical signs, or a diagnosis of the condition related to such information—

“(i) information about an individual's genetic tests;

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

“(iii) information about the occurrence of a disease or disorder in family members.

“(B) EXCEPTIONS.—The term ‘predictive genetic information’ shall not include—

“(i) information about the sex or age of the individual;

“(ii) information derived from physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests; and

“(iii) information about physical exams of the individual.

“(10) GENETIC TEST.—The term ‘genetic test’ means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of disease in asymptomatic or undiagnosed individuals. Such term does not include physical tests,

such as the chemical, blood, or urine analyses of the individual including cholesterol tests, and physical exams of the individual, in order to detect symptoms, clinical signs, or a diagnosis of disease.”

(d) **EFFECTIVE DATE.**—Except as provided in this section, this section and the amendments made by this section shall apply with respect to group health plans for plan years beginning after 1 year after the date of the enactment of this Act.

TITLE V—PATIENT SAFETY AND ERRORS REDUCTION

SEC. 501. SHORT TITLE.

This title may be cited as the “Patient Safety and Errors Reduction Act”.

SEC. 502. PURPOSES.

It is the purpose of this title to—

(1) promote the identification, evaluation, and reporting of medical errors;

(2) raise standards and expectations for improvements in patient safety;

(3) reduce deaths, serious injuries, and other medical errors through the implementation of safe practices at the delivery level;

(4) develop error reduction systems with legal protections to support the collection of information under such systems;

(5) extend existing confidentiality and peer review protections to the reports relating to medical errors that are reported under such systems that are developed for safety and quality improvement purposes; and

(6) provide for the establishment of systems of information collection, analysis, and dissemination to enhance the knowledge base concerning patient safety.

SEC. 503. AMENDMENT TO PUBLIC HEALTH SERVICE ACT.

Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended—

(1) by redesignating part C as part D;

(2) by redesignating sections 921 through 928, as sections 931 through 938, respectively;

(3) in section 938(1) (as so redesignated), by striking “921” and inserting “931”; and

(4) by inserting after part B the following:

“PART C—REDUCING ERRORS IN HEALTH CARE

“SEC. 921. DEFINITIONS.

“In this part:

“(1) **ADVERSE EVENT.**—The term ‘adverse event’ means, with respect to the patient of a provider of services, an untoward incident, therapeutic misadventure, or iatrogenic injury directly associated with the provision of health care items and services by a health care provider or provider of services.

“(2) **CENTER.**—The term ‘Center’ means the Center for Quality Improvement and Patient Safety established under section 922(b).

“(3) **CLOSE CALL.**—The term ‘close call’ means, with respect to the patient of a provider of services, any event or situation that—

“(A) but for chance or a timely intervention, could have resulted in an accident, injury, or illness; and

“(B) is directly associated with the provision of health care items and services by a provider of services.

“(4) **EXPERT ORGANIZATION.**—The term ‘expert organization’ means a third party acting on behalf of, or in conjunction with, a provider of services to collect information about, or evaluate, a medical event.

“(5) **HEALTH CARE OVERSIGHT AGENCY.**—The term ‘health care oversight agency’ means an agency, entity, or person, including the employees and agents thereof, that performs or oversees the performance of any activities necessary to ensure the safety of the health care system.

“(6) **HEALTH CARE PROVIDER.**—The term ‘health care provider’ means—

“(A) any provider of services (as defined in section 1861(u) of the Social Security Act); and

“(B) any person furnishing any medical or other health care services as defined in section 1861(s)(1) and (2) of such Act through, or under the authority of, a provider of services described in subparagraph (A).

“(7) **PROVIDER OF SERVICES.**—The term ‘provider of services’ means a hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, renal dialysis facility, ambulatory surgical center, or hospice program, and any other entity specified in regulations promulgated by the Secretary after public notice and comment.

“(8) **PUBLIC HEALTH AUTHORITY.**—The term ‘public health authority’ means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, and an Indian tribe that is responsible for public health matters as part of its official mandate.

“(9) **MEDICAL EVENT.**—The term ‘medical event’ means, with respect to the patient of a provider of services, any sentinel event, adverse event, or close call.

“(10) **MEDICAL EVENT ANALYSIS ENTITY.**—The term ‘medical event analysis entity’ means an entity certified under section 923(a).

“(11) **ROOT CAUSE ANALYSIS.**—

“(A) **IN GENERAL.**—The term ‘root cause analysis’ means a process for identifying the basic or contributing causal factors that underlie variation in performance associated with medical events that—

“(i) has the characteristics described in subparagraph (B);

“(ii) includes participation by the leadership of the provider of services and individuals most closely involved in the processes and systems under review;

“(iii) is internally consistent; and

“(iv) includes the consideration of relevant literature.

“(B) **CHARACTERISTICS.**—The characteristics described in this subparagraph include the following:

“(i) The analysis is interdisciplinary in nature and involves those individuals who are responsible for administering the reporting systems.

“(ii) The analysis focuses primarily on systems and processes rather than individual performance.

“(iii) The analysis involves a thorough review of all aspects of the process and all contributing factors involved.

“(iv) The analysis identifies changes that could be made in systems and processes, through either redesign or development of new processes or systems, that would improve performance and reduce the risk of medical events.

“(12) **SENTINEL EVENT.**—The term ‘sentinel event’ means, with respect to the patient of a provider of services, an unexpected occurrence that—

“(A) involves death or serious physical or psychological injury (including loss of a limb); and

“(B) is directly associated with the provision of health care items and services by a health care provider or provider of services.

“SEC. 922. RESEARCH TO IMPROVE THE QUALITY AND SAFETY OF PATIENT CARE.

“(a) **IN GENERAL.**—To improve the quality and safety of patient care, the Director shall—

“(1) conduct and support research, evaluations and training, support demonstration

projects, provide technical assistance, and develop and support partnerships that will identify and determine the causes of medical errors and other threats to the quality and safety of patient care;

“(2) identify and evaluate interventions and strategies for preventing or reducing medical errors and threats to the quality and safety of patient care;

“(3) identify, in collaboration with experts from the public and private sector, reporting parameters to provide consistency throughout the errors reporting system;

“(4) identify approaches for the clinical management of complications from medical errors; and

“(5) establish mechanisms for the rapid dissemination of interventions and strategies identified under this section for which there is scientific evidence of effectiveness.

“(b) **CENTER FOR QUALITY IMPROVEMENT AND PATIENT SAFETY.**—

“(1) **ESTABLISHMENT.**—The Director shall establish a center to be known as the Center for Quality Improvement and Patient Safety to assist the Director in carrying out the requirements of subsection (a).

“(2) **MISSION.**—The Center shall—

“(A) provide national leadership for research and other initiatives to improve the quality and safety of patient care;

“(B) build public-private sector partnerships to improve the quality and safety of patient care; and

“(C) serve as a national resource for research and learning from medical errors.

“(3) **DUTIES.**—

“(A) **IN GENERAL.**—In carrying out this section, the Director, acting through the Center, shall consult and build partnerships, as appropriate, with all segments of the health care industry, including health care practitioners and patients, those who manage health care facilities, systems and plans, peer review organizations, health care purchasers and policymakers, and other users of health care research.

“(B) **REQUIRED DUTIES.**—In addition to the broad responsibilities that the Director may assign to the Center for research and related activities that are designed to improve the quality of health care, the Director shall ensure that the Center—

“(i) builds scientific knowledge and understanding of the causes of medical errors in all health care settings and identifies or develops and validates effective interventions and strategies to reduce errors and improve the safety and quality of patient care;

“(ii) promotes public and private sector research on patient safety by—

“(I) developing a national patient safety research agenda;

“(II) identifying promising opportunities for preventing or reducing medical errors; and

“(III) tracking the progress made in addressing the highest priority research questions with respect to patient safety;

“(iii) facilitates the development of voluntary national patient safety goals by convening all segments of the health care industry and tracks the progress made in meeting those goals;

“(iv) analyzes national patient safety data for inclusion in the annual report on the quality of health care required under section 913(b)(2);

“(v) strengthens the ability of the United States to learn from medical errors by—

“(I) developing the necessary tools and advancing the scientific techniques for analysis of errors;

“(II) providing technical assistance as appropriate to reporting systems; and

“(III) entering into contracts to receive and analyze aggregate data from public and private sector reporting systems;

“(vi) supports dissemination and communication activities to improve patient safety, including the development of tools and methods for educating consumers about patient safety; and

“(vii) undertakes related activities that the Director determines are necessary to enable the Center to fulfill its mission.

“(C) LIMITATION.—Aggregate data gathered for the purposes described in this section shall not include specific patient, health care provider, or provider of service identifiers.

“(c) LEARNING FROM MEDICAL ERRORS.—

“(1) IN GENERAL.—To enhance the ability of the health care community in the United States to learn from medical events, the Director shall—

“(A) carry out activities to increase scientific knowledge and understanding regarding medical error reporting systems;

“(B) carry out activities to advance the scientific knowledge regarding the tools and techniques for analyzing medical events and determining their root causes;

“(C) carry out activities in partnership with experts in the field to increase the capacity of the health care community in the United States to analyze patient safety data;

“(D) develop a confidential national safety database of medical event reports;

“(E) conduct and support research, using the database developed under subparagraph (D), into the causes and potential interventions to decrease the incidence of medical errors and close calls; and

“(F) ensure that information contained in the national database developed under subparagraph (D) does not include specific patient, health care provider, or provider of service identifiers.

“(2) NATIONAL PATIENT SAFETY DATABASE.—The Director shall, in accordance with paragraph (1)(D), establish a confidential national safety database (to be known as the National Patient Safety Database) of reports of medical events that can be used only for research to improve the quality and safety of patient care. In developing and managing the National Patient Safety Database, the Director shall—

“(A) ensure that the database is only used for its intended purpose;

“(B) ensure that the database is only used by the Agency, medical event analysis entities, and other qualified entities or individuals as determined appropriate by the Director and in accordance with paragraph (3) or other criteria applied by the Director;

“(C) ensure that the database is as comprehensive as possible by aggregating data from Federal, State, and private sector patient safety reporting systems;

“(D) conduct and support research on the most common medical errors and close calls, their causes, and potential interventions to reduce medical errors and improve the quality and safety of patient care;

“(E) disseminate findings made by the Director, based on the data in the database, to clinicians, individuals who manage health care facilities, systems, and plans, patients, and other individuals who can act appropriately to improve patient safety; and

“(F) develop a rapid response capacity to provide alerts when specific health care practices pose an imminent threat to patients or health care practitioners, or other providers of health care items or services.

“(3) CONFIDENTIALITY AND PEER REVIEW PROTECTIONS.—Notwithstanding any other

provision of law any information (including any data, reports, records, memoranda, analyses, statements, and other communications) developed by or on behalf of a health care provider or provider of services with respect to a medical event, that is contained in the National Patient Safety Database shall be confidential in accordance with section 925.

“(4) PATIENT SAFETY REPORTING SYSTEMS.—The Director shall identify public and private sector patient safety reporting systems and build scientific knowledge and understanding regarding the most effective—

“(A) components of patient safety reporting systems;

“(B) incentives intended to increase the rate of error reporting;

“(C) approaches for undertaking root cause analyses;

“(D) ways to provide feedback to those filing error reports;

“(E) techniques and tools for collecting, integrating, and analyzing patient safety data; and

“(F) ways to provide meaningful information to patients, consumers, and purchasers that will enhance their understanding of patient safety issues.

“(5) TRAINING.—The Director shall support training initiatives to build the capacity of the health care community in the United States to analyze patient safety data and to act on that data to improve patient safety.

“(d) EVALUATION.—The Director shall recommend strategies for measuring and evaluating the national progress made in implementing safe practices identified by the Center through the research and analysis required under subsection (b) and through the voluntary reporting system established under subsection (c).

“(e) IMPLEMENTATION.—In implementing strategies to carry out the functions described in subsections (b), (c), and (d), the Director may contract with public or private entities on a national or local level with appropriate expertise.

“SEC. 923. MEDICAL EVENT ANALYSIS ENTITIES.

“(a) IN GENERAL.—The Director, based on information collected under section 922(c), shall provide for the certification of entities to collect and analyze information on medical errors, and to collaborate with health care providers or providers of services in collecting information about, or evaluating, certain medical events.

“(b) COMPATIBILITY OF COLLECTED DATA.—To ensure that data reported to the National Patient Safety Database under section 922(c)(2) concerning medical errors and close calls are comparable and useful on an analytic basis, the Director shall require that the entities described in subsection (c) follow the recommendations regarding a common set of core measures for reporting that are developed by the National Forum for Health Care Quality Measurement and Reporting, or other voluntary private standard-setting organization that is designated by the Director taking into account existing measurement systems and in collaboration with experts from the public and private sector.

“(c) DUTIES OF CERTIFIED ENTITIES.—

“(1) IN GENERAL.—An entity that is certified under subsection (a) shall collect and analyze information, consistent with the requirement of subsection (b), provided to the entity under section 924(a)(4) to improve patient safety.

“(2) INFORMATION TO BE REPORTED TO THE ENTITY.—A medical event analysis entity shall, on a periodic basis and in a format that is specified by the Director, submit to the Director a report that contains—

“(A) a description of the medical events that were reported to the entity during the period covered under the report;

“(B) a description of any corrective action taken by providers of services with respect to such medical events or any other measures that are necessary to prevent similar events from occurring in the future; and

“(C) a description of the systemic changes that entities have identified, through an analysis of the medical events included in the report, as being needed to improve patient safety.

“(3) COLLABORATION.—A medical event analysis entity that is collaborating with a health care provider or provider of services to address close calls and adverse events may, at the request of the health care provider or provider of services—

“(A) provide expertise in the development of root cause analyses and corrective action plan relating to such close calls and adverse events; or

“(B) collaborate with such provider of services to identify on-going risk reduction activities that may enhance patient safety.

“(d) CONFIDENTIALITY AND PEER REVIEW PROTECTIONS.—Notwithstanding any other provision of law, any information (including any data, reports, records, memoranda, analyses, statements, and other communications) collected by a medical event analysis entity or developed by or on behalf of such an entity under this part shall be confidential in accordance with section 925.

“(e) TERMINATION AND RENEWAL.—

“(1) IN GENERAL.—The certification of an entity under this section shall terminate on the date that is 3 years after the date on which such certification was provided. Such certification may be renewed at the discretion of the Director.

“(2) NONCOMPLIANCE.—The Director may terminate the certification of a medical event analysis entity if the Director determines that such entity has failed to comply with this section.

“(f) IMPLEMENTATION.—In implementing strategies to carry out the functions described in subsection (c), the Director may contract with public or private entities on a national or local level with appropriate expertise.

“SEC. 924. PROVIDER OF SERVICES SYSTEMS FOR REPORTING MEDICAL EVENTS.

“(a) INTERNAL MEDICAL EVENT REPORTING SYSTEMS.—Each provider of services that elects to participate in a medical error reporting system under this part shall—

“(1) establish a system for—

“(A) identifying, collecting information about, and evaluating medical events that occur with respect to a patient in the care of the provider of services or a practitioner employed by the provider of services, that may include—

“(i) the provision of a medically coherent description of each event so identified;

“(ii) the provision of a clear and thorough accounting of the results of the investigation of such event under the system; and

“(iii) a description of all corrective measures taken in response to the event; and

“(B) determining appropriate follow-up actions to be taken with respect to such events;

“(2) establish policies and procedures with respect to when and to whom such events are to be reported;

“(3) take appropriate follow-up action with respect to such events; and

“(4) submit to the appropriate medical event analysis entity information that contains descriptions of the medical events identified under paragraph (1)(A).

“(b) PROMOTING IDENTIFICATION, EVALUATION, AND REPORTING OF CERTAIN MEDICAL EVENTS.—

“(1) IN GENERAL.—Notwithstanding any other provision of law any information (including any data, reports, records, memoranda, analyses, statements, and other communications) developed by or on behalf of a provider of services with respect to a medical event pursuant to a system established under subsection (a) shall be privileged in accordance with section 925.

“(2) RULES OF CONSTRUCTION.—Nothing in this subsection shall be construed as prohibiting—

“(A) disclosure of a patient’s medical record to the patient;

“(B) a provider of services from complying with the requirements of a health care oversight agency or public health authority; or

“(C) such an agency or authority from disclosing information transferred by a provider of services to the public in a form that does not identify or permit the identification of the health care provider or provider of services or patient.

“SEC. 925. CONFIDENTIALITY.

“(a) CONFIDENTIALITY AND PEER REVIEW PROTECTIONS.—Notwithstanding any other provision of law—

“(1) any information (including any data, reports, records, memoranda, analyses, statements, and other communications) developed by or on behalf of a health care provider or provider of services with respect to a medical event, that is contained in the National Patient Safety Database, collected by a medical event analysis entity, or developed by or on behalf of such an entity, or collected by a health care provider or provider of services for use under systems that are developed for safety and quality improvement purposes under this part—

“(A) shall be privileged, strictly confidential, and may not be disclosed by any other person to which such information is transferred without the authorization of the health care provider or provider of services; and

“(B) shall—

“(i) be protected from disclosure by civil, criminal, or administrative subpoena;

“(ii) not be subject to discovery or otherwise discoverable in connection with a civil, criminal, or administrative proceeding;

“(iii) not be subject to disclosure pursuant to section 552 of title 5, United States Code (the Freedom of Information Act) and any other similar Federal or State statute or regulation; and

“(iv) not be admissible as evidence in any civil, criminal, or administrative proceeding; without regard to whether such information is held by the provider or by another person to which such information was transferred;

“(2) the transfer of any such information by a provider of services to a health care oversight agency, an expert organization, a medical event analysis entity, or a public health authority, shall not be treated as a waiver of any privilege or protection established under paragraph (1) or established under State law.

“(b) PENALTY.—It shall be unlawful for any person to disclose any information described in subsection (a) other than for the purposes provided in such subsection. Any person violating the provisions of this section shall, upon conviction, be fined in accordance with title 18, United States Code, and imprisoned for not more than 6 months, or both.

“(c) APPLICATION OF PROVISIONS.—The protections provided under subsection (a) and the penalty provided for under subsection (b)

shall apply to any information (including any data, reports, memoranda, analyses, statements, and other communications) collected or developed pursuant to research, including demonstration projects, with respect to medical error reporting supported by the Director under this part.

“SEC. 926. AUTHORIZATION OF APPROPRIATIONS.

“There is authorized to be appropriated to carry out this part, \$50,000,000 for fiscal year 2001, and such sums as may be necessary for subsequent fiscal years.”

SEC. 504. EFFECTIVE DATE.

The amendments made by section 503 shall become effective on the date of the enactment of this Act.

This Act may be cited as the “Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2001.”

SCHUMER AMENDMENT NO. 3695

(Ordered to lie on the table.)

Mr. SCHUMER submitted an amendment intended to be proposed by him to the bill, H.R. 4577, supra; as follows:

On page 27, line 24, before the period insert the following: “: *Provided further*, That in addition to amounts made available under this heading for the National Program of Cancer Registries, an additional \$15,000,000 shall be made available for such Program and special emphasis in carrying out such Program shall be given to States with the highest number of the leading causes of cancer mortality: *Provided further*, That amounts made available under this Act for the administrative and related expenses of the Centers for Disease Control and Prevention shall be reduced by \$15,000,000”.

BINGAMAN AMENDMENT NO. 3696

(Ordered to lie on the table.)

Mr. BINGAMAN (for himself, Mr. DASCHLE, Mr. JOHNSON, Mr. McCAIN, Mr. CONRAD, Mrs. MURRAY, Mr. LEAHY, and Mrs. BOXER) submitted an amendment intended to be proposed by him to the bill, H.R. 4577, supra; as follows:

At the end of title III, insert the following:
SEC. . CONSTRUCTION AND RENOVATION PROJECTS.

Notwithstanding any other provision of this Act—

(1) the amount made available under this title under the heading “OFFICE OF POSTSECONDARY EDUCATION” under the heading “HIGHER EDUCATION” to carry out section 316 of the Higher Education Act of 1965 is increased by \$6,000,000, which increase shall be used for construction and renovation projects under such section; and

(2) the amount made available under this title under the heading “OFFICE OF POSTSECONDARY EDUCATION” under the heading “HIGHER EDUCATION” to carry out part B of title VII of the Higher Education Act of 1965 is decreased by \$5,000,000.

HELMS AMENDMENT NO. 3697

Mr. HELMS proposed an amendment to the bill, H.R. 4577, supra; as follows:

At the appropriate place, insert the following:

SEC. . (a) None of the funds appropriated under this Act to carry out section 330 or title X of the Public Health Service Act (42 U.S.C. 254b, 300 et seq.), title V or XIX of the Social Security Act (42 U.S.C. 701

et seq., 1396 et seq.), or any other provision of law, shall be used for the distribution or provision of postcoital emergency contraception, or the provision of a prescription for postcoital emergency contraception, to an unemancipated minor, on the premises or in the facilities of any elementary school or secondary school.

(b) This section takes effect 1 day after the date of enactment of this Act.

(c) In this section:

(1) The terms “elementary school” and “secondary school” have the meanings given the terms in section 14101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 8801).

(2) The term “unemancipated minor” means an unmarried individual who is 17 years of age or younger and is a dependent, as defined in section 152(a) of the Internal Revenue Code of 1986.

**WELLSTONE (AND JOHNSON)
AMENDMENT NO. 3698**

Mr. WELLSTONE (for himself and Mr. JOHNSON) proposed an amendment to the bill, H.R. 4577, supra; as follows:

On page 92, between lines 4 and 5, insert the following:

SEC. . (a) LIMITATION ON USE OF FUNDS FOR CERTAIN AGREEMENTS.—Except as provided in subsection (b), none of the funds made available under this Act may be used by the Secretary of Health and Human Services to enter into—

(1) an agreement on the conveyance or licensing of a patent for a drug, or on another exclusive right to a drug;

(2) an agreement on the use of information derived from animal tests or human clinical trials that are conducted by the Department of Health and Human Services with respect to a drug, including an agreement under which such information is provided by the Department to another Federal agency on an exclusive basis; or

(3) a cooperative research and development agreement under section 12 of the Stevenson-Wylder Technology Innovation Act of 1980 (15 U.S.C. 3710a) pertaining to a drug, excluding cooperative research and development agreements between the Department of Health and Human Services and a college or university.

(b) EXCEPTIONS.—Subsection (a) shall not apply to an agreement where—

(1) the sale of the drug involved is subject to a price agreement that is reasonable (as defined by the Secretary of Health and Human Services); or

(2) a reasonable price agreement with respect to the sale of the drug involved is not required by the public interest (as defined by such Secretary).

(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to apply to any agreement entered into by a college or university and any entity other than the Secretary of Health and Human Services or an entity within the Department of Health and Human Services.

**HARKIN (AND WELLSTONE)
AMENDMENT NO. 3699**

Mr. HARKIN (for himself and Mr. WELLSTONE) proposed an amendment to the bill, H.R. 4577, as follows:

On page 60, line 16, strike “\$7,352,341,000” and insert “\$15,800,000,000.”

On page 60, line 19, strike “\$4,624,000,000” and insert “\$13,071,659,000.”