

Public Health Service Act to provide for the establishment of a pediatric research initiative.

S. 1144

At the request of Mr. VOINOVICH, the names of the Senator from Illinois (Mr. DURBIN) and the Senator from Maine (Ms. SNOWE) were added as cosponsors of S. 1144, a bill to provide increased flexibility in use of highway funding, and for other purposes.

At the request of Mr. VOINOVICH, the name of the Senator from New York (Mr. SCHUMER) was withdrawn as a cosponsor of S. 1144, *supra*.

S. 1166

At the request of Mr. NICKLES, the name of the Senator from Texas (Mrs. HUTCHISON) was added as a cosponsor of S. 1166, a bill to amend the Internal Revenue Code of 1986 to clarify that natural gas gathering lines are 7-year property for purposes of depreciation.

S. 1216

At the request of Mr. TORRICELLI, the name of the Senator from Massachusetts (Mr. KENNEDY) was added as a cosponsor of S. 1216, a bill to amend the Marine Mammal Protection Act of 1972 to establish a Marine Mammal Rescue Grant Program, and for other purposes.

S. 1232

At the request of Mr. COCHRAN, the names of the Senator from Tennessee (Mr. THOMPSON), the Senator from Connecticut (Mr. LIEBERMAN), the Senator from Virginia (Mr. WARNER), the Senator from Maryland (Mr. SARBANES), and the Senator from Vermont (Mr. LEAHY) were added as cosponsors of S. 1232, a bill to provide for the correction of retirement coverage errors under chapters 83 and 84 of title 5, United States Code.

S. 1266

At the request of Mr. GORTON, the name of the Senator from New Mexico (Mr. DOMENICI) was added as a cosponsor of S. 1266, a bill to allow a State to combine certain funds to improve the academic achievement of all its students.

S. 1274

At the request of Mr. GRAMS, the names of the Senator from Colorado (Mr. ALLARD) and the Senator from North Carolina (Mr. HELMS) were added as cosponsors of S. 1274, a bill to amend the Internal Revenue Code of 1986 to increase the accessibility to and affordability of health care, and for other purposes.

S. 1277

At the request of Mr. GRASSLEY, the name of the Senator from Utah (Mr. HATCH) was added as a cosponsor of S. 1277, a bill to amend title XIX of the Social Security Act to establish a new prospective payment system for Federally-qualified health centers and rural health clinics.

S. 1293

At the request of Mr. COCHRAN, the name of the Senator from New York (Mr. MOYNIHAN) was added as a cosponsor of S. 1293, a bill to establish a Con-

gressional Recognition for Excellence in Arts Education Board.

S. 1296

At the request of Mr. McCONNELL, the name of the Senator from North Carolina (Mr. HELMS) was added as a cosponsor of S. 1296, a bill to designate portions of the lower Delaware River and associated tributaries as a component of the National Wild and Scenic Rivers System.

S. 1317

At the request of Mr. AKAKA, the name of the Senator from North Dakota (Mr. DORGAN) was added as a cosponsor of S. 1317, a bill to reauthorize the Welfare-To-Work program to provide additional resources and flexibility to improve the administration of the program.

S. 1332

At the request of Mr. BAYH, the names of the Senator from Oregon (Mr. SMITH), and the Senator from Maine (Ms. COLLINS) were added as cosponsors of S. 1332, a bill to authorize the President to award a gold medal on behalf of Congress to Father Theodore M. Hesburg, in recognition of his outstanding and enduring contributions to civil rights, higher education, the Catholic Church, the Nation, and the global community.

SENATE RESOLUTION 99

At the request of Mr. REID, the name of the Senator from Massachusetts (Mr. KENNEDY) was added as a cosponsor of Senate Resolution 99, a resolution designating November 20, 1999, as "National Survivors for Prevention of Suicide Day."

#### AMENDMENTS SUBMITTED

#### PATIENTS' BILL OF RIGHTS ACT

##### NICKLES (AND OTHERS) AMENDMENT NO. 1236

Mr. NICKLES (for himself, Mr. GRAMM, and Ms. COLLINS) proposed an amendment to the bill (S. 1344) to amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage; as follows:

At the appropriate place, insert the following:

##### SEC. \_\_\_\_\_. EXEMPTIONS.

(a) IN GENERAL.—Notwithstanding any other provision of this Act, the provisions of this Act shall not apply with respect to a group health plan (or health insurance coverage offered in connection with the group health plan) if the provisions of this Act for a plan year during which this Act is fully implemented result in—

(1) a greater than 1 percent increase in the cost of the group health plan's premiums for the plan year, as determined under subsection (b); or

(2) a decrease, in the plan year, of 100,000 or more in the number of individuals in the United States with private health insurance, as determined under subsection (c).

(b) EXEMPTION FOR INCREASED COST.—For purposes of subsection (a)(1), if an actuary certified in accordance with generally recognized standards of actuarial practice by a member of the American Academy of Actuaries or by another individual whom the Secretary has determined to have an equivalent level of training and expertise certifies that the application of this Act to a group health plan (or health insurance coverage offered in connection with the group health plan) will result in the increase described in subsection (a)(1) for a plan year during which this Act is fully implemented, the provisions of this Act shall not apply with respect to the group health plan (or the coverage).

(c) EXEMPTION FOR DECREASED NUMBER OF INSURED PERSONS.—For purposes of subsection (a)(2), unless the Administrator of the Health Care Financing Administration certifies, on the basis of projections by the National Association of Insurance Commissioners, that the provisions of this Act will not result in the decrease described in subsection (a)(2) for a plan year during which this Act is fully implemented, the provisions of this Act shall not apply with respect to a group health plan (or health insurance coverage offered in connection with a group health plan).

#### ROBB (AND OTHERS) AMENDMENT NO. 1237

Mr. KENNEDY (for Mr. ROBB (for himself, Mrs. MURRAY, Mrs. BOXER, Ms. MIKULSKI, Mr. KENNEDY, Mr. REID, Mr. DURBIN, Mr. FEINGOLD, Mrs. LINCOLN, Mr. DASCHLE, Mr. BYRD, Mr. LIEBERMAN, Mr. BINGAMAN, Mr. BRYAN, and Mr. HARKIN)) proposed an amendment to amendment No. 1236 proposed by Mr. NICKLES to the bill, S. 1344, *supra*; as follows:

In the amendment, strike all after the first word and insert the following:

#### STANDARDS RELATING TO BENEFITS FOR CERTAIN BREAST CANCER TREATMENT AND ACCESS TO APPROPRIATE OBSTETRICAL AND GYNECOLOGICAL CARE

##### (a) BREAST CANCER TREATMENT.

(1) INPATIENT CARE.—A group health plan, or a health insurance issuer in connection with group health insurance coverage, 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 his or her professional judgment consistent with generally accepted medical standards, and the patient, to be medically appropriate following—

(A) a mastectomy;  
(B) a lumpectomy; or  
(C) a lymph node dissection for the treatment of breast cancer.

(2) PROHIBITIONS.—A group health plan, or a health insurance issuer in connection with group health insurance coverage, may not—

(A) deny to a patient eligibility, or continued eligibility, to enroll or to renew coverage under the terms of the plan or coverage, solely for the purpose of avoiding the requirements of this subsection;

(B) provide monetary payments or rebates to patients to encourage such patients to accept less than the minimum protections available under this subsection;

(C) penalize or otherwise reduce or limit the reimbursement of an attending provider because such provider provided care to an individual participant, beneficiary or enrollee in accordance with this subsection;

(D) provide incentives (monetary or otherwise) to an attending provider to induce such

provider to provide care to an individual participant, beneficiary or enrollee in a manner inconsistent with this subsection; or

(E) subject to paragraph (3)(B), restrict benefits for any portion of a period within a hospital length of stay required under paragraph (1) in a manner which is less favorable than the benefits provided for any preceding portion of such stay.

(3) RULES OF CONSTRUCTION.—

(A) Nothing in this subsection shall be construed to require a patient who is a participant, beneficiary or enrollee—

(i) to undergo a mastectomy, lumpectomy or lymph node dissection in a hospital; or

(ii) to stay in the hospital for a fixed period of time following a mastectomy, lumpectomy or lymph node dissection.

(B) Nothing in this subsection shall be construed as preventing a group health plan or a health insurance issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits for hospital lengths of stay in connection with a mastectomy, lumpectomy or lymph node dissection for the treatment of breast cancer under the plan except that such coinsurance or other cost-sharing for any portion of a period within a hospital length of stay required under paragraph (1) may not be greater than such coinsurance or cost-sharing for any preceding portion of such stay.

(4) LEVEL AND TYPE OF REIMBURSEMENTS.— Nothing in this subsection shall be construed to prevent a group health plan or a health insurance issuer from negotiating the level and type of reimbursement with a provider for care provided in accordance with this subsection.

(5) DEFINITION.—In this subsection, the term "mastectomy" means the surgical removal of all or part of a breast.

(b) OBSTETRICAL AND GYNECOLOGICAL CARE.—

(1) IN GENERAL.—If a group health plan, or a health insurance issuer in connection with the provision of group health insurance coverage, requires or provides for a participant, beneficiary, or enrollee to designate a participating primary care provider—

(A) the plan or issuer shall permit such an individual who is a female to designate a participating physician who specializes in obstetrics and gynecology as the individual's primary care provider; and

(B) if such an individual has not designated such a provider as a primary care provider, the plan or issuer—

(i) shall not require authorization or a referral by the individual's primary care provider or otherwise for coverage of covered gynecological care and pregnancy-related services provided by a participating health care professional who specializes in obstetrics and gynecology to the extent such care is otherwise covered, and

(ii) shall treat the ordering of other obstetrical and gynecological care by such a participating health professional as the authorization of the primary care provider with respect to such care under the plan or coverage.

(2) CONSTRUCTION.—Nothing in paragraph (1)(B)(ii) shall waive any requirements of coverage relating to medical necessity or appropriateness with respect to coverage of obstetrical and gynecological care so ordered.

(c) SPECIAL RULE.—Nothing in subsection (b) shall be construed as preventing a plan or issuer from offering (but not requiring a participant or beneficiary to accept) a health care professional trained, credentialed, and operating within the scope of their licensure to perform gynecological and obstetric care.

(d) APPLICATION OF SECTION.—This section shall supersede the provisions of sections 104(a) and 152.

(e) REVIEW.—Failure to meet the requirements of this section shall constitute an appealable decision under section 132(a)(2).

(f) PLAN SATISFACTION OF CERTAIN REQUIREMENTS.—Pursuant to rules of the Secretary, if a health insurance issuer offers health insurance coverage in connection with a group health plan and takes an action in violation of any provision of this subchapter, the group health plan shall not be liable for such violation unless the plan caused such violation.

(g) NONAPPLICATION OF CERTAIN PROVISION.—Only for purposes of applying the requirements of this section under section 714 of the Employee Retirement Income Security Act of 1974 (as added by section 301 of this Act), sections 2707 and 2753 of the Public Health Service Act (as added by sections 201 and 202 of this Act), and section 9813 of the Internal Revenue Code of 1986 (as added by section 401 of this Act)—

(i) section 2721(b)(2) of the Public Health Service Act and section 9831(a)(1) of the Internal Revenue Code of 1986 shall not apply to the provisions of this section; and

(2) with respect to limited scope dental benefits, subparagraph (A) of section 733(c)(2) of the Employee Retirement Income Security Act of 1974, subparagraph (A) of section 2791(c)(2) of the Public Health Service Act, and subparagraph (A) of section 9832(c)(2) of the Internal Revenue Code of 1986 shall not apply to the provisions of this section.

(h) NO IMPACT ON SOCIAL SECURITY TRUST FUND.—

(1) IN GENERAL.—Nothing in this section 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 section 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 section 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 section.

(i) LIMITATION ON ACTIONS.—

(1) IN GENERAL.—Except as provided for in paragraph (2), no action may be brought under subsection (a)(1)(B), (a)(2), or (a)(3) of section 502 by a participant or beneficiary seeking relief based on the application of any provision in this section.

(2) PERMISSIBLE ACTIONS.—An action may be brought under subsection (a)(1)(B), (a)(2), or (a)(3) of section 502 by a participant or beneficiary seeking relief based on the application of this section to the individual circumstances of that participant or beneficiary; except that—

(A) such an action may not be brought or maintained as a class action; and

(B) in such an action relief may only provide for the provision of (or payment for) benefits, items, or services denied to the individual participant or beneficiary involved (and for attorney's fees and the costs of the action, at the discretion of the court) and shall not provide for any other relief to the participant or beneficiary or for any relief to any other person.

(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as affecting any action brought by the Secretary.

(j) EFFECTIVE DATE.—The provisions of this section shall apply to group health plans for plan years beginning after, and to health insurance issuers for coverage offered or sold after, October 1, 2000.

(k) INFORMATION REQUIREMENTS.—

(I) 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.

(I) LIMITATIONS ON WELFARE BENEFIT FUNDS OF 10 OR MORE EMPLOYER PLANS.—

(I) BENEFITS TO WHICH EXCEPTION APPLIES.—Section 419A(f)(6)(A) of the Internal Revenue Code of 1986 (relating to exception for 10 or more employer plans) is amended to read as follows:

"(A) IN GENERAL.—This subpart shall not apply to a welfare benefit fund which is part of a 10 or more employer plan if the only benefits provided through the fund are 1 or more of the following:

"(i) Medical benefits.

"(ii) Disability benefits.

"(iii) Group term life insurance benefits which do not provide for any cash surrender value or other money that can be paid, assigned, borrowed, or pledged for collateral for a loan.

The preceding sentence shall not apply to any plan which maintains experience-rating arrangements with respect to individual employers."

(2) LIMITATION ON USE OF AMOUNTS FOR OTHER PURPOSES.—Section 4976(b) of such Act (defining disqualified benefit) is amended by adding at the end the following new paragraph:

(5) SPECIAL RULE FOR 10 OR MORE EMPLOYER PLANS EXEMPTED FROM PREFUNDING LIMITS.—For purposes of paragraph (1)(C), if—

"(A) subpart D of part I of subchapter D of chapter 1 does not apply by reason of section 419A(f)(6) to contributions to provide 1 or more welfare benefits through a welfare benefit fund under a 10 or more employer plan, and

"(B) any portion of the welfare benefit fund attributable to such contributions is used for a purpose other than that for which the contributions were made,

then such portion shall be treated as reverting to the benefit of the employers maintaining the fund."

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to contributions paid or accrued after the date of the enactment of this Act, in taxable years ending after such date.

(d) DEDUCTION FOR HEALTH INSURANCE COSTS OF SELF-EMPLOYED INDIVIDUALS INCREASED.—

(1) IN GENERAL.—Section 162(l)(1) of the Internal Revenue Code of 1986 (relating to special rules for health insurance costs of self-employed individuals) 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(e)(1), there shall be allowed as a deduction under this section an amount equal to the amount paid during the taxable year for insurance which constitutes medical care for the taxpayer, the taxpayer's spouse, and dependents."

(2) CERTIFICATION OF LIMITATIONS ON OTHER COVERAGE.—The first sentence of section

162(l)(2)(B) of the Internal Revenue Code of 1986 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(e)(4)) of the taxpayer or the spouse of the taxpayer."

(3) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 1998.

(e) EXTENSION OF TAXES.—

(I) ENVIRONMENTAL TAX.—Section 59A(e) of the Internal Revenue Code of 1986 is amended to read as follows:

"(e) APPLICATION OF TAX.—The tax imposed by this section shall apply to taxable years beginning after December 31, 1986, and before January 1, 1996, and to taxable years beginning after December 31, 1999, and before January 1, 2009."

(2) EFFECTIVE DATES.—The amendment made by subsection (e)(1) shall apply to taxable years beginning after December 31, 1999.

#### FRIST (AND JEFFORDS) AMENDMENT NO. 1238

Mr. NICKLES (for Mr. FRIST (for himself and Mr. JEFFORDS)) proposed an amendment to amendment No. 1236 proposed by Mr. NICKLES to the bill, S. 1344, supra; as follows:

At the end add the following:

Notwithstanding any other provision of this Act, subtitle D of title I and all that follows through section 151 is null, void, and shall have no effect.

#### Subtitle E—Protecting the Doctor-Patient Relationship

##### SEC. 141. PROHIBITION OF INTERFERENCE WITH CERTAIN MEDICAL COMMUNICATIONS.

(a) PROHIBITION.—

(1) GENERAL RULE.—The provisions of any contract or agreement, or the operation of any contract or agreement, between a group health plan or health insurance issuer in relation to health insurance coverage (including any partnership, association, or other organization that enters into or administers such a contract or agreement) and a health care provider (or group of health care providers) shall not prohibit or restrict the provider from engaging in medical communications with the provider's patient.

(2) NULLIFICATION.—Any contract provision or agreement that restricts or prohibits medical communications in violation of paragraph (1) shall be null and void.

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

(1) to prohibit the enforcement, as part of a contract or agreement to which a health care provider is a party, of any mutually agreed upon terms and conditions, including terms and conditions requiring a health care provider to participate in, and cooperate with, all programs, policies, and procedures developed or operated by a group health plan or health insurance issuer to assure, review, or improve the quality and effective utilization of health care services (if such utilization is according to guidelines or protocols that are based on clinical or scientific evidence and the professional judgment of the provider) but only if the guidelines or protocols under such utilization do not prohibit or restrict medical communications between providers and their patients; or

(2) to permit a health care provider to misrepresent the scope of benefits covered under the group health plan or health insurance coverage or to otherwise require a group health plan health insurance issuer to reimburse providers for benefits not covered under the plan or coverage.

(c) MEDICAL COMMUNICATION DEFINED.—In this section:

(1) IN GENERAL.—The term "medical communication" means any communication made by a health care provider with a patient of the health care provider (or the guardian or legal representative of such patient) with respect to—

(A) the patient's health status, medical care, or treatment options;

(B) any utilization review requirements that may affect treatment options for the patient; or

(C) any financial incentives that may affect the treatment of the patient.

(2) MISREPRESENTATION.—The term "medical communication" does not include a communication by a health care provider with a patient of the health care provider (or the guardian or legal representative of such patient) if the communication involves a knowing or willful misrepresentation by such provider.

##### SEC. 142. PROHIBITION AGAINST TRANSFER OF INDEMNIFICATION OR IMPROPER INCENTIVE ARRANGEMENTS.

(a) PROHIBITION OF TRANSFER OF INDEMNIFICATION.—

(1) IN GENERAL.—No contract or agreement between a group health plan or health insurance issuer (or any agent acting on behalf of such a plan or issuer) and a health care provider shall contain any provision purporting to transfer to the health care provider by indemnification or otherwise any liability relating to activities, actions, or omissions of the plan, issuer, or agent (as opposed to the provider).

(2) NULLIFICATION.—Any contract or agreement provision described in paragraph (1) shall be null and void.

(b) PROHIBITION OF IMPROPER PHYSICIAN INCENTIVE PLANS.—

(1) IN GENERAL.—A group health plan and a health insurance issuer offering health insurance coverage may not operate any physician incentive plan (as defined in subparagraph (B) of section 1876(i)(8) of the Social Security Act) unless the requirements described in subparagraph (A) of such section are met with respect to such a plan.

(2) APPLICATION.—For purposes of carrying out paragraph (1), any reference in section 1876(i)(8) of the Social Security Act to the Secretary, an eligible organization, or an individual enrolled with the organization shall be treated as a reference to the applicable authority, a group health plan or health insurance issuer, respectively, and a participant, beneficiary, or enrollee with the plan or organization, respectively.

##### SEC. 143. ADDITIONAL RULES REGARDING PARTICIPATION OF HEALTH CARE PROFESSIONALS.

(a) PROCEDURES.—Insofar as a group health plan, or health insurance issuer that offers health insurance coverage, provides benefits through participating health care professionals, the plan or issuer shall establish reasonable procedures relating to the participation (under an agreement between a professional and the plan or issuer) of such professionals under the plan or coverage. Such procedures shall include—

(1) providing notice of the rules regarding participation;

(2) providing written notice of participation decisions that are adverse to professionals; and

(3) providing a process within the plan or issuer for appealing such adverse decisions, including the presentation of information and views of the professional regarding such decision.

(b) CONSULTATION IN MEDICAL POLICIES.—A group health plan, and health insurance issuer that offers health insurance coverage, shall consult with participating physicians

(if any) regarding the plan's or issuer's medical policy, quality, and medical management procedures.

**SEC. 144. PROTECTION FOR PATIENT ADVOCACY.**

(a) PROTECTION FOR USE OF UTILIZATION REVIEW AND GRIEVANCE PROCESS.—In accordance with section 510 of the Employee Retirement Income Security Act, a group health plan, and a health insurance issuer with respect to the provision of health insurance coverage, may not retaliate against a participant, beneficiary, enrollee, or health care provider based on the participant's beneficiary's, enrollee's or provider's use of, or participation in, a utilization review process or a grievance process of the plan or issuer (including an internal or external review or appeal process) under this title.

(b) PROTECTION FOR QUALITY ADVOCACY BY HEALTH CARE PROFESSIONALS.—

(1) IN GENERAL.—A group health plan or health insurance issuer may not retaliate or discriminate against a protected health care professional because the professional in good faith—

(A) discloses information relating to the care, services, or conditions affecting one or more participants, beneficiaries, or enrollees of the plan or issuer to an appropriate public regulatory agency, an appropriate private accreditation body, or appropriate management personnel of the plan or issuer; or

(B) initiates, cooperates, or otherwise participates in an investigation or proceeding by such an agency with respect to such care, services, or conditions.

If an institutional health care provider is a participating provider with such a plan or issuer or otherwise receives payments for benefits provided by such a plan or issuer, the provisions of the previous sentence shall apply to the provider in relation to care, services, or conditions affecting one or more patients within an institutional health care provider in the same manner as they apply to the plan or issuer in relation to care, services, or conditions provided to one or more participants, beneficiaries, or enrollees; and for purposes of applying this sentence, any reference to a plan or issuer is deemed a reference to the institutional health care provider.

(2) GOOD FAITH ACTION.—For purposes of paragraph (1), a protected health care professional is considered to be acting in good faith with respect to disclosure of information or participation if, with respect to the information disclosed as part of the action—

(A) the disclosure is made on the basis of personal knowledge and is consistent with that degree of learning and skill ordinarily possessed by health care professionals with the same licensure or certification and the same experience;

(B) the professional reasonably believes the information to be true;

(C) the information evidences either a violation of a law, rule, or regulation, of an applicable accreditation standard, or of a generally recognized professional or clinical standard or that a patient is in imminent hazard of loss of life or serious injury; and

(D) subject to subparagraphs (B) and (C) of paragraph (3), the professional has followed reasonable internal procedures of the plan, issuer, or institutional health care provider established for the purpose of addressing quality concerns before making the disclosure.

(3) EXCEPTION AND SPECIAL RULE.—

(A) GENERAL EXCEPTION.—Paragraph (1) does not protect disclosures that would violate Federal or State law or diminish or impair the rights of any person to the continued protection of confidentiality of communications provided by such law.

(B) NOTICE OF INTERNAL PROCEDURES.—Subparagraph (D) of paragraph (2) shall not

apply unless the internal procedures involved are reasonably expected to be known to the health care professional involved. For purposes of this subparagraph, a health care professional is reasonably expected to know of internal procedures if those procedures have been made available to the professional through distribution or posting.

(C) INTERNAL PROCEDURE EXCEPTION.—Subparagraph (D) of paragraph (2) also shall not apply if—

(i) the disclosure relates to an imminent hazard of loss of life or serious injury to a patient;

(ii) the disclosure is made to an appropriate private accreditation body pursuant to disclosure procedures established by the body; or

(iii) the disclosure is in response to an inquiry made in an investigation or proceeding of an appropriate public regulatory agency and the information disclosed is limited to the scope of the investigation or proceeding.

(4) ADDITIONAL CONSIDERATIONS.—It shall not be a violation of paragraph (1) to take an adverse action against a protected health care professional if the plan, issuer, or provider taking the adverse action involved demonstrates that it would have taken the same adverse action even in the absence of the activities protected under such paragraph.

(5) NOTICE.—A group health plan, health insurance issuer, and institutional health care provider shall post a notice, to be provided or approved by the Secretary of Labor, setting forth excerpts from, or summaries of, the pertinent provisions of this subsection and information pertaining to enforcement of such provisions.

(6) CONSTRUCTIONS.—

(A) DETERMINATIONS OF COVERAGE.—Nothing in this subsection shall be construed to prohibit a plan or issuer from making a determination not to pay for a particular medical treatment or service or the services of a type of health care professional.

(B) ENFORCEMENT OF PEER REVIEW PROTOCOLS AND INTERNAL PROCEDURES.—Nothing in this subsection shall be construed to prohibit a plan, issuer, or provider from establishing and enforcing reasonable peer review or utilization review protocols or determining whether a protected health care professional has complied with those protocols or from establishing and enforcing internal procedures for the purpose of addressing quality concerns.

(C) RELATION TO OTHER RIGHTS.—Nothing in this subsection shall be construed to abridge rights of participants, beneficiaries, enrollees, and protected health care professionals under other applicable Federal or State laws.

(7) PROTECTED HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this subsection, the term "protected health care professional" means an individual who is a licensed or certified health care professional and who—

(A) with respect to a group health plan or health insurance issuer, is an employee of the plan or issuer or has a contract with the plan or issuer for provision of services for which benefits are available under the plan or issuer; or

(B) with respect to an institutional health care provider, is an employee of the provider or has a contract or other arrangement with the provider respecting the provision of health care services.

**SEC. 145. AMENDMENT TO EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.**

(a) IN GENERAL.—Notwithstanding section 301(b), section 503 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1133) is amended to read as follows:

**"SEC. 503. CLAIMS PROCEDURE, COVERAGE DETERMINATION, GRIEVANCES AND APPEALS.**

"(a) CLAIMS PROCEDURE.—In accordance with regulations of the Secretary, every employee benefit plan shall—

"(1) provide adequate notice in writing to any participant or beneficiary whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant; and

"(2) afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claim.

**"(b) COVERAGE DETERMINATIONS UNDER GROUP HEALTH PLANS.**

**"(I) PROCEDURES.**

"(A) IN GENERAL.—A group health plan or health insurance issuer conducting utilization review shall ensure that procedures are in place for—

"(i) making determinations regarding whether a participant or beneficiary is eligible to receive a payment or coverage for health services under the plan or coverage involved and any cost-sharing amount that the participant or beneficiary is required to pay with respect to such service;

"(ii) notifying a covered participant or beneficiary (or the authorized representative of such participant or beneficiary) and the treating health care professionals involved regarding determinations made under the plan or issuer and any additional payments that the participant or beneficiary may be required to make with respect to such service; and

"(iii) responding to requests, either written or oral, for coverage determinations or for internal appeals from a participant or beneficiary (or the authorized representative of such participant or beneficiary) or the treating health care professional with the consent of the participant or beneficiary.

"(B) ORAL REQUESTS.—With respect to an oral request described in subparagraph (A)(iii), a group health plan or health insurance issuer may require that the requesting individual provide written evidence of such request.

**"(2) TIMELINE FOR MAKING DETERMINATIONS.**

"(A) ROUTINE DETERMINATION.—A group health plan or a health insurance issuer shall maintain procedures to ensure that prior authorization determinations concerning the provision of non-emergency items or services are made within 30 days from the date on which the request for a determination is submitted, except that such period may be extended where certain circumstances exist that are determined by the Secretary to be beyond control of the plan or issuer.

**"(B) EXPEDITED DETERMINATION.**

"(i) IN GENERAL.—A prior authorization determination under this subsection shall be made within 72 hours, in accordance with the medical exigencies of the case, after a request is received by the plan or issuer under clause (ii) or (iii).

"(ii) REQUEST BY PARTICIPANT OR BENEFICIARY.—A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection upon the request of a participant or beneficiary if, based on such a request, the plan or issuer determines that the normal time for making such a determination could seriously jeopardize the life or health of the participant or beneficiary.

"(iii) DOCUMENTATION BY HEALTH CARE PROFESSIONAL.—A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection if

the request involved indicates that the treating health care professional has reasonably documented, based on the medical exigencies, that a determination under the procedures described in subparagraph (A) could seriously jeopardize the life or health of the participant or beneficiary.

“(C) CONCURRENT DETERMINATIONS.—A plan or issuer shall maintain procedures to certify or deny coverage of an extended stay or additional services.

“(D) RETROSPECTIVE DETERMINATION.—A plan or issuer shall maintain procedures to ensure that, with respect to the retrospective review of a determination made under paragraph (I), the determination shall be made within 30 working days of the date on which the plan or issuer receives necessary information.

“(3) NOTICE OF DETERMINATIONS.—

““(A) ROUTINE DETERMINATION.—With respect to a coverage determination of a plan or issuer under paragraph (2)(A), the plan or issuer shall issue notice of such determination to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and, consistent with the medical exigencies of the case, to the treating health care professional involved not later than 2 working days after the date on which the determination is made.

“(B) EXPEDITED DETERMINATION.—With respect to a coverage determination of a plan or issuer under paragraph (2)(B), the plan or issuer shall issue notice of such determination to the participant or beneficiary (or the authorized representative of the participant or beneficiary), and consistent with the medical exigencies of the case, to the treating health care professional involved within the 72 hour period described in paragraph (2)(B).

“(C) CONCURRENT REVIEWS.—With respect to the determination under a plan or issuer under paragraph (2)(C) to certify or deny coverage of an extended stay or additional services, the plan or issuer shall issue notice of such determination to the treating health care professional and to the participant or beneficiary involved (or the authorized representative of the participant or beneficiary) within 1 working day of the determination.

“(D) RETROSPECTIVE REVIEWS.—With respect to the retrospective review under a plan or issuer of a determination made under paragraph (2)(D), the plan or issuer shall issue written notice of an approval or disapproval of a determination under this subparagraph to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and health care provider involved within 5 working days of the date on which such determination is made.

“(E) REQUIREMENTS OF NOTICE OF ADVERSE COVERAGE DETERMINATIONS.—A written notice of an adverse coverage determination under this subsection, or of an expedited adverse coverage determination under paragraph (2)(B), shall be provided to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and treating health care professional (if any) involved and shall include—

“(i) the reasons for the determination (including the clinical or scientific-evidence based rationale used in making the determination) written in a manner to be understandable to the average participant or beneficiary;

“(ii) the procedures for obtaining additional information concerning the determination; and

“(iii) notification of the right to appeal the determination and instructions on how to initiate an appeal in accordance with subsection (d).

“(c) GRIEVANCES.—A group health plan or a health insurance issuer shall have written procedures for addressing grievances be-

tween the plan or issuer offering health insurance coverage in connection with a group health plan and a participant or beneficiary. Determinations under such procedures shall be non-appealable.

“(d) INTERNAL APPEAL OF COVERAGE DETERMINATIONS.—

“(i) RIGHT TO APPEAL.—

“(A) IN GENERAL.—A participant or beneficiary (or the authorized representative of the participant or beneficiary) or the treating health care professional with the consent of the participant or beneficiary (or the authorized representative of the participant or beneficiary), may appeal any adverse coverage determination under subsection (b) under the procedures described in this subsection.

“(B) TIME FOR APPEAL.—A plan or issuer shall ensure that a participant or beneficiary has a period of not less than 180 days beginning on the date of an adverse coverage determination under subsection (b) in which to appeal such determination under this subsection.

“(C) FAILURE TO ACT.—The failure of a plan or issuer to issue a determination under subsection (b) within the applicable timeline established for such a determination under such subsection shall be treated as an adverse coverage determination for purposes of proceeding to internal review under this subsection.

“(2) RECORDS.—A group health plan and a health insurance issuer shall maintain written records, for at least 6 years, with respect to any appeal under this subsection for purposes of internal quality assurance and improvement. Nothing in the preceding sentence shall be construed as preventing a plan and issuer from entering into an agreement under which the issuer agrees to assume responsibility for compliance with the requirements of this section and the plan is released from liability for such compliance.

“(3) ROUTINE DETERMINATIONS.—A group health plan or a health insurance issuer shall complete the consideration of an appeal of an adverse routine determination under this subsection not later than 30 working days after the date on which a request for such appeal is received.

“(4) EXPEDITED DETERMINATION.—

“(A) IN GENERAL.—An expedited determination with respect to an appeal under this subsection shall be made in accordance with the medical exigencies of the case, but in no case more than 72 hours after the request for such appeal is received by the plan or issuer under subparagraph (B) or (C).

“(B) REQUEST BY PARTICIPANT OR BENEFICIARY.—A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection upon the request of a participant or beneficiary if, based on such a request, the plan or issuer determines that the normal time for making such a determination could seriously jeopardize the life or health of the participant or beneficiary.

“(C) DOCUMENTATION BY HEALTH CARE PROFESSIONAL.—A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection if the request involved indicates that the treating health care professional has reasonably documented, based on the medical exigencies of the case that a determination under the procedures described in paragraph (2) could seriously jeopardize the life or health of the participant or beneficiary.

“(5) CONDUCT OF REVIEW.—A review of an adverse coverage determination under this subsection shall be conducted by an individual with appropriate expertise who was not directly involved in the initial determination.

“(6) LACK OF MEDICAL NECESSITY.—A review of an appeal under this subsection relating to a determination to deny coverage based on a lack of medical necessity and appropriateness, or based on an experimental or investigational treatment, shall be made only by a physician with appropriate expertise, including age-appropriate expertise, who was not involved in the initial determination.

“(7) NOTICE.—

“(A) IN GENERAL.—Written notice of a determination made under an internal review process shall be issued to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and the treating health care professional not later than 2 working days after the completion of the review (or within the 72-hour period referred to in paragraph (4) if applicable).

“(B) ADVERSE COVERAGE DETERMINATIONS.—With respect to an adverse coverage determination made under this subsection, the notice described in subparagraph (A) shall include—

“(i) the reasons for the determination (including the clinical or scientific-evidence based rationale used in making the determination) written in a manner to be understandable to the average participant or beneficiary;

“(ii) the procedures for obtaining additional information concerning the determination; and

“(iii) notification of the right to an independent external review under subsection (e) and instructions on how to initiate such a review.

“(e) INDEPENDENT EXTERNAL REVIEW.—

“(I) ACCESS TO REVIEW.—

“(A) IN GENERAL.—A group health plan or a health insurance issuer offering health insurance coverage in connection with a group health plan shall have written procedures to permit a participant or beneficiary (or the authorized representative of the participant or beneficiary) access to an independent external review with respect to an adverse coverage determination concerning a particular item or service (including a circumstance treated as an adverse coverage determination under subparagraph (B)) where—

“(i) the particular item or service involved—

“(I)(aa) would be a covered benefit, when medically necessary and appropriate under the terms and conditions of the plan, and the item or service has been determined not to be medically necessary and appropriate under the internal appeals process required under subsection (d) or there has been a failure to issue a coverage determination as described in subparagraph (B); and

“(bb)(AA) the amount of such item or service involved exceeds a significant financial threshold; or

“(BB) there is a significant risk of placing the life or health of the participant or beneficiary in jeopardy; or

“(II) would be a covered benefit, when not considered experimental or investigational under the terms and conditions of the plan, and the item or service has been determined to be experimental or investigational under the internal appeals process required under subsection (d) or there has been a failure to issue a coverage determination as described in subparagraph (B); and

“(ii) the participant or beneficiary has completed the internal appeals process under subsection (d) with respect to such determination.

“(B) FAILURE TO ACT.—The failure of a plan or issuer to issue a coverage determination under subsection (d)(6) within the applicable timeline established for such a determination under such subsection shall be treated as an adverse coverage determination for

purposes of proceeding to independent external review under this subsection.

“(2) INITIATION OF THE INDEPENDENT EXTERNAL REVIEW PROCESS.—

“(A) FILING OF REQUEST.—A participant or beneficiary (or the authorized representative of the participant or beneficiary) who desires to have an independent external review conducted under this subsection shall file a written request for such a review with the plan or issuer involved not later than 30 working days after the receipt of a final denial of a claim under subsection (d). Any such request shall include the consent of the participant or beneficiary (or the authorized representative of the participant or beneficiary) for the release of medical information and records to independent external reviewers regarding the participant or beneficiary.

“(B) INFORMATION AND NOTICE.—Not later than 5 working days after the receipt of a request under subparagraph (A), or earlier in accordance with the medical exigencies of the case, the plan or issuer involved shall select an external appeals entity under paragraph (3)(A) that shall be responsible for designating an independent external reviewer under paragraph (3)(B).

“(C) PROVISION OF INFORMATION.—The plan or issuer involved shall forward necessary information (including medical records, any relevant review criteria, the clinical rationale consistent with the terms and conditions of the contract between the plan or issuer and the participant or beneficiary for the coverage denial, and evidence of the coverage of the participant or beneficiary) to the independent external reviewer selected under paragraph (3)(B).

“(D) NOTIFICATION.—The plan or issuer involved shall send a written notification to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and the plan administrator, indicating that an independent external review has been initiated.

“(3) CONDUCT OF INDEPENDENT EXTERNAL REVIEW.—

“(A) DESIGNATION OF EXTERNAL APPEALS ENTITY BY PLAN OR ISSUER.—

“(i) IN GENERAL.—A plan or issuer that receives a request for an independent external review under paragraph (2)(A) shall designate a qualified entity described in clause (ii), in a manner designed to ensure that the entity so designated will make a decision in an unbiased manner, to serve as the external appeals entity.

“(ii) QUALIFIED ENTITIES.—A qualified entity shall be—

“(I) an independent external review entity licensed or credentialed by a State;

“(II) a State agency established for the purpose of conducting independent external reviews;

“(III) any entity under contract with the Federal Government to provide independent external review services;

“(IV) any entity accredited as an independent external review entity by an accrediting body recognized by the Secretary for such purpose; or

“(V) any other entity meeting criteria established by the Secretary for purposes of this subparagraph.

“(B) DESIGNATION OF INDEPENDENT EXTERNAL REVIEWER BY EXTERNAL APPEALS ENTITY.—The external appeals entity designated under subparagraph (A) shall, not later than 30 days after the date on which such entity is designated under subparagraph (A), or earlier in accordance with the medical exigencies of the case, designate one or more individuals to serve as independent external reviewers with respect to a request received under paragraph (2)(A). Such reviewers shall be independent medical experts who shall—

“(i) be appropriately credentialed or licensed in any State to deliver health care services;

“(ii) not have any material, professional, familial, or financial affiliation with the case under review, the participant or beneficiary involved, the treating health care professional, the institution where the treatment would take place, or the manufacturer of any drug, device, procedure, or other therapy proposed for the participant or beneficiary whose treatment is under review;

“(iii) have expertise (including age-appropriate expertise) in the diagnosis or treatment under review and, when reasonably available, be of the same specialty as the physician treating the participant or beneficiary or recommending or prescribing the treatment in question;

“(iv) receive only reasonable and customary compensation from the group health plan or health insurance issuer in connection with the independent external review that is not contingent on the decision rendered by the reviewer; and

“(v) not be held liable for decisions regarding medical determinations (but may be held liable for actions that are arbitrary and capricious).

“(4) STANDARD OF REVIEW.—

“(A) IN GENERAL.—An independent external reviewer shall—

“(i) make an independent determination based on the valid, relevant, scientific and clinical evidence to determine the medical necessity, appropriateness, experimental or investigational nature of the proposed treatment; and

“(ii) take into consideration appropriate and available information, including any evidence-based decision making or clinical practice guidelines used by the group health plan or health insurance issuer; timely evidence or information submitted by the plan, issuer, patient or patient's physician; the patient's medical record; expert consensus; and medical literature as defined in section 556(5) of the Federal Food, Drug, and Cosmetic Act.

“(B) NOTICE.—The plan or issuer involved shall ensure that the participant or beneficiary receives notice, within 30 days after the determination of the independent medical expert, regarding the actions of the plan or issuer with respect to the determination of such expert under the independent external review.

“(5) TIMEFRAME FOR REVIEW.—

“(A) IN GENERAL.—The independent external reviewer shall complete a review of an adverse coverage determination in accordance with the medical exigencies of the case.

“(B) LIMITATION.—Notwithstanding subparagraph (A), a review described in such subparagraph shall be completed not later than 30 working days after the later of—

“(i) the date on which such reviewer is designated; or

“(ii) the date on which all information necessary to completing such review is received.

“(6) BINDING DETERMINATION.—The determination of an independent external reviewer under this subsection shall be binding upon the plan or issuer if the provisions of this subsection or the procedures implemented under such provisions were complied with by the independent external reviewer.

“(7) STUDY.—Not later than 2 years after the date of enactment of this section, the General Accounting Office shall conduct a study of a statistically appropriate sample of completed independent external reviews. Such study shall include an assessment of the process involved during an independent external review and the basis of decision-making by the independent external reviewer. The results of such study shall be submitted to the appropriate committees of Congress.

“(8) EFFECT ON CERTAIN PROVISIONS.—Nothing in this section shall be construed as affecting or modifying section 514 of this Act with respect to a group health plan.

“(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a plan administrator or plan fiduciary or health plan medical director from requesting an independent external review by an independent external reviewer without first completing the internal review process.

“(g) DEFINITIONS.—In this section:

“(I) ADVERSE COVERAGE DETERMINATION.—The term 'adverse coverage determination' means a coverage determination under the plan which results in a denial of coverage or reimbursement.

“(2) COVERAGE DETERMINATION.—The term 'coverage determination' means with respect to items and services for which coverage may be provided under a health plan, a determination of whether or not such items and services are covered or reimbursable under the coverage and terms of the contract.

“(3) GRIEVANCE.—The term 'grievance' means any complaint made by a participant or beneficiary that does not involve a coverage determination.

“(4) 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.

“(5) 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.

“(6) HEALTH INSURANCE ISSUER.—The term 'health insurance issuer' has the meaning given such term in section 733(b)(2).

“(7) PRIOR AUTHORIZATION DETERMINATION.—The term 'prior authorization determination' means a coverage determination prior to the provision of the items and services as a condition of coverage of the items and services under the coverage.

“(8) 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.

“(9) UTILIZATION REVIEW.—The term 'utilization review' with respect to a group health plan or health insurance coverage means a set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings. Techniques may include ambulatory review, prospective review, second opinion, certification, concurrent review, case management, discharge planning or retrospective review."

“(b) ENFORCEMENT.—Section 502(c)(1) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(c)(1)) is amended by inserting after “or section 101(e)(1)” the following: “, or fails to comply with a coverage determination as required under section 503(e)(6),”.

“(c) CONFORMING AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by striking the item relating to section 503

and inserting the following new item:

“Sec. 503. Claims procedures, coverage determination, grievances and appeals.”.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan years beginning on or after October 1, 2000. The Secretary shall issue all regulations necessary to carry out the amendments made by this section before the effective date thereof.

**DODD (AND OTHERS) AMENDMENT  
NO. 1239**

Mr. DODD (for himself, Mrs. BOXER, Mr. HARKIN, Mr. KENNEDY, Mr. REID, Mrs. MURRAY, Mr. DURBIN, Mr. ROCKEFELLER, Mr. FEINGOLD, Mrs. FEINSTEIN, and Mr. DASCHLE) proposed an amendment to amendment No. 1232 proposed by Mr. DASCHLE to the bill, S. 1344, *supra*; as follows:

At the appropriate place in subtitle A of title I, insert the following:

**SEC. \_\_\_\_ COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS AND ACCESS TO APPROVED DRUGS AND DEVICES.**

(a) ERISA.—Subpart C of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, as added by section 101(a)(2) of this Act, is amended by adding at the end the following:

**“SEC. 730A. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS AND ACCESS TO APPROVED DRUGS AND DEVICES.**

“(a) COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.—

“(i) COVERAGE.—

“(A) IN GENERAL.—If a group health plan, or a health insurance issuer in connection with group health insurance coverage, provides coverage to a qualified individual (as defined in paragraph (2)), the plan or issuer—

“(i) may not deny the individual participation in the clinical trial referred to in paragraph (2)(B);

“(ii) subject to paragraph (3), 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

“(iii) may not discriminate against the individual on the basis of the participant’s, beneficiaries or enrollee’s participation in such trial.

“(B) EXCLUSION OF CERTAIN COSTS.—For purposes of subparagraph (A)(ii), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

“(C) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in subparagraph (A) shall be construed as preventing a plan or issuer 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.

“(2) QUALIFIED INDIVIDUAL DEFINED.—For purposes of paragraph (1), the term ‘qualified individual’ means an individual who is a participant or beneficiary in a group health plan or enrollee under health insurance coverage and who meets the following conditions:

“(A)(i) The individual has a life-threatening or serious illness for which no standard treatment is effective.

“(ii) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

“(iii) The individual’s participation in the trial offers meaningful potential for significant clinical benefit for the individual.

“(B) Either—

“(i) 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 subparagraph (A); or

“(ii) the participant, beneficiary or enrollee 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 subparagraph (A).

“(3) PAYMENT.—

“(A) IN GENERAL.—Under this subsection a group health plan, or a health insurance issuer in connection with group health insurance coverage, shall provide for payment for routine patient costs described in paragraph (1)(B) but is not required to pay for costs of items and services that are reasonably expected (as determined by the Secretary) to be paid for by the sponsors of an approved clinical trial.

“(B) PAYMENT RATE.—In the case of covered items and services provided by—

“(i) a participating provider, the payment rate shall be at the agreed upon rate, or

“(ii) a nonparticipating provider, the payment rate shall be at the rate the plan or issuer would normally pay for comparable services under clause (i).

“(4) APPROVED CLINICAL TRIAL DEFINED.—

“(A) IN GENERAL.—In this subsection, the term ‘approved clinical trial’ means a clinical research study or clinical investigation approved and funded (which may include funding through in-kind contributions) by one or more of the following:

“(i) The National Institutes of Health.

“(ii) A cooperative group or center of the National Institutes of Health.

“(iii) Either of the following if the conditions described in subparagraph (B) are met:

“(I) The Department of Veterans Affairs.

“(II) The Department of Defense.

“(B) 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—

“(i) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

“(ii) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

“(5) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan’s or issuer’s coverage with respect to clinical trials.

“(b) ACCESS TO NEEDED PRESCRIPTION DRUGS.—If a group health plan, or health insurance issuer that offers group health insurance coverage, provides benefits with respect to prescription drugs but the coverage limits such benefits to drugs included in a formulary, the plan or issuer shall—

“(i) ensure participation of participating physicians and pharmacists in the development of the formulary;

“(2) disclose to providers and, disclose upon request to participants, beneficiaries, and enrollees, the nature of the formulary restrictions; and

“(3) consistent with the standards for a utilization review program, provide for exceptions from the formulary limitation when a non-formulary alternative is medically indicated, except that—

“(A) an exception provided under this paragraph shall be provided in accordance with

cost-sharing rules in effect for drugs included in the formulary; and

“(B) nothing in this paragraph shall be construed to prevent the plan or issuer from implementing a program of differential cost-sharing for drugs included in the formulary and drugs not included in the formulary, if the drugs that are not included in the formulary do not meet the conditions described in this section.

“(c) ACCESS TO APPROVED DRUGS AND DEVICES.—

“(1) IN GENERAL.—A group health plan, or a health insurance issuer in connection with group health insurance coverage, that provides any coverage of prescription drugs or medical devices shall not deny coverage of such a drug or device on the basis that the use is investigational, if the use—

“(A) in the case of a prescription drug—

“(i) is included in the labeling authorized by the application in effect for the drug pursuant to subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act, without regard to any postmarketing requirements that may apply under such Act; or

“(ii) is included in the labeling authorized by the application in effect for the drug under section 351 of the Public Health Service Act, without regard to any postmarketing requirements that may apply pursuant to such section; or

“(B) in the case of a medical device, is included in the labeling authorized by a regulation under subsection (d) or (3) of section 513 of the Federal Food, Drug, and Cosmetic Act, an order under subsection (f) of such section, or an application approved under section 515 of such Act, without regard to any postmarketing requirements that may apply under such Act.

“(2) CONSTRUCTION.—Nothing in this subsection shall be construed as requiring a group health plan or health insurance issuer to provide any coverage of prescription drugs or medical devices.

“(d) APPLICATION OF SECTION.—This section shall supersede the provisions of section 728.

“(e) REVIEW.—Failure to meet the requirements of this section shall constitute an appealable decision under this Act.

“(f) PLAN SATISFACTION OF CERTAIN REQUIREMENTS.—Pursuant to rules of the Secretary, if a health insurance issuer offers health insurance coverage in connection with a group health plan and takes an action in violation of any provision of this subchapter, the group health plan shall not be liable for such violation unless the plan caused such violation.

“(g) APPLICABILITY.—The provisions of this section shall apply to group health plans and health insurance issuers as if included in—

“(1) subpart 2 of part A of title XXVII of the Public Health Service Act;

“(2) the first subpart 3 of part B of title XXVII of the Public Health Service Act (relating to other requirements); and

“(3) subchapter B of chapter 100 of the Internal Revenue Code of 1986.

“(h) NONAPPLICATION OF CERTAIN PROVISION.—Only for purposes of applying the requirements of this section under section 714 of the Employee Retirement Income Security Act of 1974 (as added by section 301 of this Act), sections 2707 and 2753 of the Public Health Service Act (as added by sections 201 and 202 of this Act), and section 9813 of the Internal Revenue Code of 1986 (as added by section 401 of this Act)—

“(1) section 2721(b)(2) of the Public Health Service Act and section 9831(a)(1) of the Internal Revenue Code of 1986 shall not apply to the provisions of this section; and

“(2) with respect to limited scope dental benefits, subparagraph (A) of section 733(c)(2) of the Employee Retirement Income Security Act of 1974, subparagraph (A) of section

2791(c)(2) of the Public Health Service Act, and subparagraph (A) of section 9832(c)(2) of the Internal Revenue Code of 1986 shall not apply to the provisions of this section.

“(i) NO IMPACT ON SOCIAL SECURITY TRUST FUND.—

“(I) IN GENERAL.—Nothing in this section 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 section 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 section 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 section.

“(j) LIMITATION ON ACTIONS.—

“(I) IN GENERAL.—Except as provided for in paragraph (2), no action may be brought under subsection (a)(1)(B), (a)(2), or (a)(3) of section 502 by a participant or beneficiary seeking relief based on the application of any provision in this section.

“(2) PERMISSIBLE ACTIONS.—An action may be brought under subsection (a)(1)(B), (a)(2), or (a)(3) of section 502 by a participant or beneficiary seeking relief based on the application of this section to the individual circumstances of that participant or beneficiary; except that—

“(A) such an action may not be brought or maintained as a class action; and

“(B) in such an action relief may only provide for the provision of (or payment for) benefits, items, or services denied to the individual participant or beneficiary involved (and for attorney's fees and the costs of the action, at the discretion of the court) and shall not provide for any other relief to the participant or beneficiary or for any relief to any other person.

“(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as affecting any action brought by the Secretary.

“(k) EFFECTIVE DATE.—The provisions of this section shall apply to group health plans for plan years beginning after, and to health insurance issuers for coverage offered or sold after, October 1, 2000.”.

(b) 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.

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

“(VIII) 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.

(c) MODIFICATION TO FOREIGN TAX CREDIT CARRYBACK AND CARRYOVER PERIODS.—

(1) IN GENERAL.—Section 904(c) of the Internal Revenue Code of 1986 (relating to limitation on credit) is amended—

(A) by striking “in the second preceding taxable year,”, and

(B) by striking “or fifth” and inserting “fifth, sixth, or seventh”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to credits

arising in taxable years beginning after December 31, 2001.

(d) LIMITATIONS ON WELFARE BENEFIT FUNDS OF 10 OR MORE EMPLOYER PLANS.—

(1) BENEFITS TO WHICH EXCEPTION APPLIES.—Section 419A(f)(6)(A) of the Internal Revenue Code of 1986 (relating to exception for 10 or more employer plans) is amended to read as follows:

“(A) IN GENERAL.—This subpart shall not apply to a welfare benefit fund which is part of a 10 or more employer plan if the only benefits provided through the fund are 1 or more of the following:

“(i) Medical benefits.

“(ii) Disability benefits.

“(iii) Group term life insurance benefits which do not provide for any cash surrender value or other money that can be paid, assigned, borrowed, or pledged for collateral for a loan.

The preceding sentence shall not apply to any plan which maintains experience-rating arrangements with respect to individual employers.”

(2) LIMITATION ON USE OF AMOUNTS FOR OTHER PURPOSES.—Section 4976(b) of such Act (defining disqualified benefit) is amended by adding at the end the following new paragraph:

“(5) SPECIAL RULE FOR 10 OR MORE EMPLOYER PLANS EXEMPTED FROM PREFUNDING LIMITS.—For purposes of paragraph (1)(C), if—

“(A) subpart D of part I of subchapter D of chapter 1 does not apply by reason of section 419A(f)(6) to contributions to provide 1 or more welfare benefits through a welfare benefit fund under a 10 or more employer plan, and

“(B) any portion of the welfare benefit fund attributable to such contributions is used for a purpose other than that for which the contributions were made, then such portion shall be treated as reverting to the benefit of the employers maintaining the fund.”

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to contributions paid or accrued after the date of the enactment of this Act, in taxable years ending after such date.

## TREASURY-POSTAL SERVICE APPROPRIATIONS

### CAMPBELL AMENDMENT NO. 1240

Mr. JEFFORDS (for Mr. CAMPBELL) proposed an amendment to the bill (S. 1282) making appropriations for the Treasury Department, the United States Postal Service, the Executive Office of the President, and certain Independence Agencies, for the fiscal year ending September 30, 2000, and for other purposes; as follows:

Amend page 57, line 14 by reducing the dollar figure by \$17,000,000.

On page 11, line 16 strike “\$569,225,000” and insert in lieu thereof “\$570,345,000”.

### NOTICES OF HEARINGS

#### COMMITTEE ON ENERGY AND NATURAL RESOURCES

Mr. MURKOWSKI. Mr. President, I would like to announce that on Friday, July 16, 1999, the Committee on Energy and Natural Resources will hold an oversight hearing on Damage to the National Security from Chinese Espionage at DOE Nuclear Weapons Laboratories. The hearing will be held at 9:00