well the spirit of Aloha.

Mr. AKAKA. Mr. President, on behalf of Senator INOUYE and myself, I rise to submit a Senate Concurrent Resolution concerning the forthcoming tenth annual meeting of the Asia Pacific Parliamentary Forum, APFP, that will take place in Honolulu in January 2002.

The Asia Pacific Parliamentary Forum consists of 27 countries of which the United States is one of the original founders. Our former colleague, Senator Bill Roth, was one of the leaders of this organization which was created as a parliamentary counterpart to the heads of state meeting of the Asia Pacific Economic Cooperation, APEC, organization.

The first meeting was held in Singapore in 1991, and, earlier this year, Chile sponsored the ninth annual meeting. Next year, for the first time, the annual meeting will be hosted by the United States in Hawaii. The Center for Cultural and Technical Exchange Between East and West, better known as the East West Center, will provide the Secretariat for the meeting which is expected to attract approximately 270 parliamentarians from countries in the Asia-Pacific region.

Participating countries include Australia, Canada, Chile, China, Russia, Mexico, South Korea, Peru, Ecuador, Costa Rica, Mongolia, the Philippines, and New Zealand. Discussions and debates are frank and open. The meetings provide an opportunity for legislators in these countries to hear and exchange views on a diversity of topics including human rights, security, law, the economy, and the environment.

I invite my colleagues to attend next year's early January meeting in Hawaii. It is an occasion to meet with leaders on both sides of the Pacific for frank discussions and to experience as well the spirit of Aloha.

AMENDMENTS SUBMITTED AND PROPOSED

SA 850. Mr. NICKLES proposed an amendment to the bill S. 1052, to amend the Public Health Service Act and the Employee Retirement Income Security Act of 1974 to protect consumers in managed care plans and other health coverage.

SA 851. Mr. CRAIG proposed an amendment to the bill S. 1052, to amend the Public Health Service Act and the Employee Retirement Income Security Act of 1974 to protect consumers in managed care plans and other health coverage, as follows:

At the appropriate place insert the following:

SEC. 301. APPLICATION OF PATIENT PROTECTION STANDARDS TO FEDERAL HEALTH CARE PROGRAMS

SEC. 301. APPLICATION OF PATIENT PROTECTION STANDARDS TO FEDERAL HEALTH CARE PROGRAMS.

(a) APPLICATION OF STANDARDS.—

(1) IN GENERAL.—Subject to subparagraph (B), each Federal health care program shall comply with the patient protection requirements under title I, and such requirements shall be deemed to be incorporated into this section.

(2) CAUSE OF ACTION RELATING TO PROVISION OF HEALTH BENEFITS.—Any individual who receives a health care item or service under a Federal health care program shall have a cause of action against the Federal Government under sections 502(n) and 514(d) of the Employee Retirement Income Security Act of 1974, and the provisions of such sections shall be deemed to be incorporated into this section.

(3) RULES OF CONSTRUCTION.—For purposes of this subsection—

(A) each Federal health care program shall be deemed to be a group health plan; and

(B) the Federal Government shall be deemed to be the plan sponsor of each Federal health care program; and

(C) each individual eligible for benefits under a Federal health care program shall be deemed to be a participant, beneficiary, or enrollee under that program.

(b) FEDERAL HEALTH CARE PROGRAM DEFINED.—In this section, the term ‘‘Federal health care program’’ means any plan, program, or activity established by the Federal Government that provides health benefits program established under chapter 89 of title 5, United States Code.

SA 852. Mr. REID proposed an amendment to the bill S. 1052, to amend the Public Health Service Act and the Employee Retirement Income Security Act of 1974 to protect consumers in managed care plans and other health coverage, as follows:

On page 154, between lines 2 and 3, insert the following:

(11) LIMITATION ON AWARD OF ATTORNEYS’ FEES.—

(A) IN GENERAL.—Subject to subparagraph (B), with respect to a participant or beneficiary (or the estate of such participant or beneficiary), who brings a cause of action under this subsection and prevails in that action, the amount of attorneys’ contingency fees that a court may award to such participant or beneficiary, or estate of such participant or beneficiary (or the estate of such participant or beneficiary) who brings a cause of action under this subsection and prevails in that action, the amount of attorneys’ contingency fees that a court may award to such participant or beneficiary, or estate of such participant or beneficiary (or the estate of such participant or beneficiary) who brings a cause of action under this subsection and prevails in that action, the amount of attorneys’ contingency fees that a court may award to such participant or beneficiary, or estate of such participant or beneficiary is limited to the amount required to recover medical expenses, less a reasonable fee for the representation of such participant or beneficiary (or the estate of such participant or beneficiary).
SA 855. Mr. CARPER proposed an amendment to the bill S. 1052, to amend the Public Health Service Act and the Employee Retirement Income Security Act of 1974 to protect consumers in managed care plans and other health coverage; as follows:

On page 156, between lines 15 and 16, insert the following:

"(15) DAMAGES OPTIONS.—

(a) IN GENERAL.—In addition to plans or coverage that are subject to this Act, a plan or issuer may offer, and a participant or beneficiary may accept, a plan or coverage that provides for one or more of the following remedies, in which case the damages authorized by this section shall not apply:

(i) Equitable relief as provided for in subsection (a)(1)(B).

(ii) Unlimited economic damages, including reasonable attorneys fees.

(b) PROTECTION OF THE REGULATION OF QUALITY OF MEDICAL CARE UNDER STATE LAW.—Nothing in this paragraph shall be construed to preclude any action under State law against a person or entity for liability or vicarious liability with respect to the delivery of medical care. A claim that is based on or otherwise relates to a group health plan's administration or determination of a claim, or otherwise relates to a group health plan's administration or determination of a claim for benefits (notwithstanding the definition contained in section 502(n)(2)) shall not be deemed to be the delivery of medical care under any State law for purposes of this section. Any such claim shall be maintained exclusively under section 502.

SA 856. Mr. FRIST (for himself and Mr. BREAUX) proposed an amendment to the bill S. 1052, to amend the Public Health Service Act and the Employee Retirement Income Security Act of 1974 to protect consumers in managed care plans and other health coverage; as follows:

On page 158, strike line 9 and all that follows through page 154, line 2, and insert the following:

"(10) STATUTORY DAMAGES.—The remedies set forth in this subsection shall be the exclusive remedies for any cause of action brought under subsection (c). Such remedies shall include economic and non-economic damages, but shall not include any punitive damages.

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SA 854. Mr. KYL (for himself and Mr. NICKLES) proposed an amendment to the bill S. 1052, to amend the Public Health Service Act and the Employee Retirement Income Security Act of 1974 to protect consumers in managed care plans and other health coverage; as follows:

On page 156, between lines 21 and 22, insert the following:

"(9) DAMAGES OPTIONS.—

(A) IN GENERAL.—In addition to plans or coverage that are subject to this Act, a plan or issuer may offer, and a participant or beneficiary may accept, a plan or coverage that provides for one or more of the following remedies, in which case the damages authorized by this section shall not apply:

(i) Equitable relief as provided for in subsection (a)(1)(B).

(ii) Unlimited economic damages, including reasonable attorneys fees.

(B) PROTECTION OF THE REGULATION OF QUALITY OF MEDICAL CARE UNDER STATE LAW.—Nothing in this paragraph shall be construed to preclude any action under State law against a person or entity for liability or vicarious liability with respect to the delivery of medical care. A claim that is based on or otherwise relates to a group health plan's administration or determination of a claim, or otherwise relates to a group health plan's administration or determination of a claim for benefits (notwithstanding the definition contained in paragraph (2)) shall not be deemed to be the delivery of medical care under any State law for purposes of this section. Any such claim shall be maintained exclusively under this section.

On page 156, between lines 21 and 22, insert the following:

"(9) DAMAGES OPTIONS.—

(A) IN GENERAL.—In addition to plans or coverage that are subject to this Act, a plan or issuer may offer, and a participant or beneficiary may accept, a plan or coverage that provides for one or more of the following remedies, in which case the damages authorized by this section shall not apply:

(i) Equitable relief as provided for in section 502(a)(1)(B).

(ii) Unlimited economic damages, including reasonable attorneys fees.

(B) PROTECTION OF THE REGULATION OF QUALITY OF MEDICAL CARE UNDER STATE LAW.—Nothing in this paragraph shall be construed to preclude any action under State law against a person or entity for liability or vicarious liability with respect to the delivery of medical care. A claim that is based on or otherwise relates to a group health plan's administration or determination of a claim, or otherwise relates to a group health plan's administration or determination of a claim for benefits (notwithstanding the definition contained in section 502(n)(2)) shall not be deemed to be the delivery of medical care under any State law for purposes of this section. Any such claim shall be maintained exclusively under section 502.

Congressional Record—Senate 12565

June 29, 2001

SA 853. Mr. THOMPSON proposed an amendment to the bill S. 1052, to amend the Public Health Service Act and the Employee Retirement Income Security Act of 1974 to protect consumers in managed care plans and other health coverage; as follows:

On page 170, between lines 21 and 22, insert the following:

"(9) CHOICE OF LAW.—A cause of action brought under paragraph (1) shall be governed by the law (including choice of law rules) of the State in which the plaintiff resides.

TITLE IV—AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT

Sec. 101. Access to emergency medical care.
Sec. 102. Offering of choice of coverage options.
Sec. 103. Patient access to obstetric and gynecological care.
Sec. 104. Access to pediatric care.
Sec. 105. Timely access to specialists.
Sec. 106. Continuity of care.
Sec. 107. Protection of patient-provider communications.
Sec. 108. Patient's right to prescription drugs.
Sec. 109. Coverage for individuals participating in approved clinical trials.
Sec. 110. Required coverage for minimum hospital stay for mastectomies and lymph node dissections for the treatment of breast cancer and coverage for secondary consultations.
Sec. 111. Prohibition of discrimination against providers based on licensure.
Sec. 112. Generally applicable provision.

SUBTITLE A—Right to Advice and Care

Sec. 113. timeliness of services.
Sec. 114. Access to providers.
Sec. 115. Continuity of care.
Sec. 116. Protection of patient-provider communications.
Sec. 117. Prescription drugs.
Sec. 118. Clinical trials.
Sec. 119. Discrimination against providers.

SUBTITLE B—Right to Information About Providers

Sec. 120. Access to information.
Sec. 121. Health plan information.
Sec. 122. Information about providers.
Sec. 123. Study on the effect of physician compensation methods.

SUBTITLE C—Right to Hold Health Plans Accountable

Sec. 125. Enforcement.

SUBTITLE D—Remedies

Sec. 126. Availability of court remedies.
Sec. 127. State flexibility.
Sec. 128. Preemption; State flexibility; construction.
SEC. 102. OFFERING OF CHOICE OF COVERAGE OPTIONS.

(a) REQUIREMENT.—If a group health plan provides coverage for benefits only through a participating health care professional, the plan shall offer the participant the option to purchase point-of-service coverage.

(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 coverage of such benefits when provided by a non-participating health care professional.

(c) SMALL EMPLOYER EXEMPTION.—(1) IN GENERAL.—This section shall not apply to any group health plan with respect to a small employer.

(2) SMALL EMPLOYER.—For purposes of paragraph (1), the term ‘small employer’ means, in connection with a 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 25 employees on business days during the preceding calendar year and who employed at least 25 employees during any part 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 preventing a group health plan from imposing higher premiums or cost-sharing on a participant for the exercise of a point-of-service coverage option; or

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

(e) SPECIAL POINT OF SERVICE PROTECTION FOR INDIVIDUALS IN DENTAL PLANS.—For purposes of applying the requirements of this section under sections 2707 and 2733 of the Public Health Service Act and section 714 of the Employee Retirement Income Security Act of 1974, section 2716(c)(2)(A) of the Public Health Service Act and section 733(c)(2)(A) of the Employee Retirement Income Security Act of 1974, only relating to limited scope benefits, shall be applied to—

SEC. 103. PATIENT ACCESS TO OBSTETRIC AND GYNECOLOGICAL CARE.

(a) GENERAL RIGHTS.—

(1) DIRECT ACCESS.—A group health plan, and a health insurance issuer that offers health insurance coverage, 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, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care.

(2) APPLICATION OF SECTION.—A group health plan, and a health insurance issuer that offers health insurance coverage, 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 in paragraph (1), by a participating health care provider who specializes in obstetrics or gynecology.

(b) OBSTETRICAL AND GYNECOLOGICAL CARE.—A group health plan, and a health insurance issuer that offers health insurance coverage, described in this subsection is a plan or issuer that—

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

(2) requires the designation by a participating health care provider other than a physician who specializes in obstetrics or gynecology.

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

(1) require that a group health plan or a health insurance issuer approve or provide coverage for—

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

(B) any items or services that are not medically necessary or 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 or health insurance issuer from requiring that the designated primary care professional or case manager of treatment decisions in
according with a process implemented by the plan, and a health insurance issuer that offers health insurance coverage, shall ensure that participants, beneficiaries, and enrollees receive timely coverage for access to appropriate medical specialty care, so that such specialty care is a covered benefit under the plan or coverage.

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

(c) TREATMENT PLANS.—

(A) IN GENERAL.—Nothing in this section shall be construed to prohibit a group health plan or a health insurance issuer that offers health insurance coverage, 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, beneficiary, or enrollee;

(B) if the plan or issuer requires such approval, approved in a timely manner by the plan or issuer consistent with the applicable quality assurance and utilization review standards of the plan or issuer.

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

(d) SPECIALIST DEFINED.—For purposes of this section, the term ‘specialist’ means, with respect to the medical condition of the participant, beneficiary, or enrollee, a health care professional who is appropriately credentialed or licensed in 1 or more States and who typically treats the diagnosis or condition of the participant, beneficiary, or enrollee.

SEC. 104. ACCESS TO PEDIATRIC CARE.

(a) PEDIATRIC CARE.—If a group health plan, and a health insurance issuer that offers health insurance coverage, requires or provides for a participant, beneficiary, or enrollee to designate a participating primary care provider of the plan or issuer beyond the date of discharge of the individual from such care or the termination of the participant, beneficiary, or enrollee, the plan or issuer shall be construed to prohibit a group health plan, or a health insurance issuer that offers health insurance coverage, from requiring, for specialty services 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, beneficiary, or enrollee; and

(B) if the plan or issuer requires such approval, approved in a timely manner by the plan or issuer consistent with the applicable quality assurance and utilization review standards of the plan or issuer.

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

(d) SPECIALIST DEFINED.—For purposes of this section, the term ‘specialist’ means, with respect to the medical condition of the participant, beneficiary, or enrollee, a health care professional who is appropriately credentialed or licensed in 1 or more States and who typically treats the diagnosis or condition of the participant, beneficiary, or enrollee.

SEC. 106. CONTINUITY OF CARE.

(a) TERMINATION OF PROVIDER.—If a contract between a group health plan, and a health insurance issuer that offers health insurance coverage, 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 or coverage, and an individual who is a participant, beneficiary, or enrollee under such plan or coverage is undergoing an active course of treatment for a serious and complex condition, in institutional care, inpatient care, or inpatient care for pregnancy, the plan or issuer shall notify the provider, and the individual at the time the plan or issuer receives or provides notice of such termination, the plan or issuer 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 or issuer 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 inpatient care for a provider shall extend until the earlier of

(i) the expiration of the 90-day period beginning on the date on which the notice described 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 institutional care.

(B) SCHEDULED CARE.—The 90-day limitation described in subparagraph (A)(i) shall...
include post-surgical follow-up care relating to the individual meeting the conditions described in paragraph (1) and requires substantial on-going specialized medical care; or

(2) TERMINAL ILLNESS.—If—

(A) a participant, beneficiary, or enrollee is 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 treatment 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) LIABILITY OF PROVIDERS.—A group health plan, and a health insurance issuer that offers health insurance coverage, may condition coverage of continued treatment pursuant to 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 or issuer and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period and in full (or at the rates applicable under the replacement plan after the date of the termination of the contract with the plan or issuer) 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 otherwise to adhere to such plan’s or issuer’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 or issuer.

(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 remained a participating provider; or

(2) with respect to the termination of a contract under subsection (a) to prevent a group health plan or health insurance issuer from requiring that the health care professional was licensed or certified by the State to engage in the delivery of such services in the State to which the plan or issuer is subject to subsections (b), (c), and (d) may not apply in the case of a group health plan, and a health insurance issuer that offers health insurance coverage, but does not include a termination of the contract by the plan or issuer for failure to meet applicable quality standards or for fraud.

107. PROTECTION OF PATIENT-PROVIDER RELATIONSHIP

(a) IN GENERAL.—Subject to subsection (b), a group health plan, and a health insurance issuer that offers health insurance coverage, may not require or otherwise restrict a health care professional from advising a participant, beneficiary, or enrollee who is a patient of the professional about the health status of the participant, beneficiary, or enrollee or medical care or treatment for the condition or disease of the participant, beneficiary, or enrollee, regardless of whether coverage for such care or treatment is 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, or a health insurance issuer that offers health insurance coverage, to provide specific benefits under the terms of such plan or coverage.

108. PATIENT’S RIGHT TO PRESCRIPTION DRUGS.

(a) IN GENERAL.—To the extent that a group health plan, and a health insurance issuer that offers health insurance coverage, provides coverage with respect to prescription drugs, and limits such coverage to drugs included in a formulary, the plan or issuer shall—

(1) ensure that the prescription of physicians and pharmacists in developing and reviewing such formulary; and

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

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a group health plan, or a health insurance issuer that offers health insurance coverage, from excluding coverage for a specific drug or class of drugs if such drugs or class of drugs is expressly excluded under the terms of the plan or coverage.

109. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

(a) COVERAGE.—

(1) IN GENERAL.—If a group health plan, and a health insurance issuer that offers health insurance coverage, provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer—

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

(B) subject to subsections (c), (d), and (e) may not (or may provide additional conditions on) the coverage of routine patient care 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 beneficiaries, or enrollee’s participation in such trial.

(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1), routine patient care costs do not include the cost of the tests or measurements conducted primarily for the purposes of the clinical trial involved.

(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 or an enrollee in health insurance coverage who meets the following conditions:

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

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

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

(c) Either—

(1) 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

(2) 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 paragraph (1).

(d) PATIENT—

(1) IN GENERAL.—Under this section a group health plan, and a health insurance issuer that offers health insurance coverage, shall
provide for payment for routine patient costs described in paragraph (i), 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) 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 and health insurance issuers 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 cost 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 of Members of Negotiated Rulemaking Committee.—Not later than December 30, 2003, the Secretary shall appoint the members of the negotiated rulemaking committee, as provided for under section 56(a)(5) 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.

(D) Comment Period.—Notwithstanding section 2004(h) 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 15, 2003, a period of 30 days for submission of written comments on the committee under this subparagraph.

(E) Appointment of Committee.—Not later than December 30, 2003, the Secretary shall appoint the members of the negotiated rulemaking committee under this subparagraph.

(F) Facilitator.—Not later than January 10, 2003, the negotiated rulemaking committee shall nominate a facilitator under section 56(a)(1) of title 5, United States Code, to carry out the activities described in subparagraph (d) of this section.

(G) Meetings.—During the period beginning on the date on which the facilitator is nominated under clause (iv) and ending on March 30, 2003, the negotiated rulemaking committee shall meet to develop the standards described in subparagraph (A).

(H) Preliminary Committee Report.—

(I) In general.—The negotiated rulemaking committee appointed under subparagraph (F) shall report to the Secretary, by not later than March 30, 2003, regarding the committee’s progress on achieving a consensus with regard to the rulemaking proce- dures under which such consensus is likely to occur before the target date described in subsection (F).

(J) Termination of Process and Publication of Rule.—(1) In general.—If the rulemaking committee reports under clause (i) that the committee has failed to make significant progress toward 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, 2003, of a rule under this paragraph through such other methods as the Secretary may provide.

(2) Final Committee Report and Publication of Rule.—(I) In general.—If the rulemaking committee is not terminated under subparagraph (D)(i), the committee shall submit to the Secretary, by not later than May 30, 2003, 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, 2003, of the proposed rule.

(III) Target Date for Rule of Publication.—(A) In general.—In this section, the term “target date for publication” means the date described in paragraph (C)(i), and for purposes of this paragraph, the “target date for publication” (referred to in section 56(a)(5) of title 5, United States Code) shall be June 30, 2003.

(IV) Effective Date.—The provisions of this paragraph shall apply to group health plans and health insurance issuers that offer health insurance coverage for a period of more than one year beginning on or after January 1, 2004.

(K) Payment Rates.—In the case of covered items and services provided by—

(A) a participating provider, the payment rate shall not exceed the rate the provider would normally pay for comparable services under subparagraph (A);

(B) a nonparticipating provider, the payment rate shall be—

(I) the rate the provider would normally pay for comparable services under subparagraph (A);

or

(II) an amount that is—

(A) determined by the Secretary, in consultation with the National Institutes of Health, to be at least equal to the rate the provider would normally pay for comparable services under subparagraph (A); and

(B) adjusted for—

(I) the average years beginning on or after January 1, 2003, the negotiated rulemaking committee received a report from the Office of the Comptroller of the Currency; and

(II) the Secretary shall provide for a period, beginning on the date on which the notice is published under clause (i), a period of 30 days for submission of written comments on the report.

(L) Appropriate Standards for Determining Routine Patient Costs.—(1) In general.—For purposes of this section, the term “appropriate standards” means—

(A) the proposed scope of the committee;

(B) the interests that may be impacted by the standards;

(C) the list of the proposed membership of the committee;

(D) the proposed meeting schedule of the committee;

(E) the solicitation for public comment on the committee; and

(F) the procedures under which an individual may apply for membership on the committee.

(2) Amendments.—In making the determination of appropriate standards, the Secretary shall take into account—

(A) the proposed scope of the committee;

(B) the interests that may be impacted by the standards;

(C) the list of the proposed membership of the committee;

(D) the proposed meeting schedule of the committee;

(E) the solicitation for public comment on the committee; and

(F) the procedures under which an individual may apply for membership on the committee.

(M) starttime 12569

(1) In general.—A group health plan, and a health insurance issuer that offers health insurance coverage, that provides medical and surgical benefits shall ensure that inpatient hospital stays and services associated with the treatment of breast cancer are provided for a period of time as determined by the attending physician, in consultation with the patient, to be medically necessary and appropriate for the patient's condition.

(2) Exception.—Nothing in this section shall be construed to require nonpayment by the plan of hospital stay and services that are necessary and appropriate for the patient's condition.

(N) Prohibition on Certain Modifications.—In implementing the requirements of this section, a group health plan, and a health insurance issuer that offers health insurance coverage, may not modify the terms and conditions of coverage based on the determination by a participant, beneficiary, or enrollee to request less than the minimum coverage required under subsection (a).

(O) Secondary Consultations.—(1) In general.—A group health plan, and a health insurance issuer that offers health insurance coverage, that provides medical and surgical services provided in relation to the diagnosis and treatment of breast cancer shall ensure that full coverage with respect to medical and surgical services is provided for secondary consultations by specialists in the appropriate medical fields (including pathology, radiology, and oncology) to confirm or refute such diagnosis and plan or implement treatment if full coverage is provided for such secondary consultation whether such consultation is based on a positive or negative initial diagnosis, or any case in which the attending physician certifies in writing that services necessary for such a secondary consultation...
are not sufficiently available from specialists of the plan or coverage with respect to whose services coverage is otherwise provided under such plan or by such issuer, such plan or issuer shall ensure that such failure 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 the request of the individual beyond that which the individual would have paid if the specialist was participating in the network of the plan or issuer:

(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed requiring the provision of secondary consultations where the patient determines not to seek such a consultation.

(d) PROHIBITION ON PENALTIES OR INCENTIVES.—A health plan, and a health insurance issuer that offers health insurance coverage, 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, beneficiary, or enrollee in accordance with this section;

(2) provide financial or other incentives to a physician or specialist to induce the physician or specialist to refrain from referring a participant, beneficiary, or enrollee for a secondary consultation that would otherwise be covered by the plan or coverage involved under subsection (c);

(3) 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

(4) provide financial or other incentives to a physician or specialist to induce the physician or specialist to refrain from referring a participant, beneficiary, or enrollee for a secondary consultation that would otherwise be covered by the plan or coverage involved under subsection (c).

SEC. 111. PROHIBITION OF DISCRIMINATION AGAINST PROVIDERS BASED ON LICENSE, CERTIFICATION, OR CREDENTIALING.

(a) In General.—A group health plan, and a health insurance issuer that offers health insurance coverage, 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 or the 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 or health insurance coverage, of a particular benefit or service or to prohibit a plan or issuer from including, providers only to the extent necessary to meet the needs of the plan's or issuer's participants, beneficiaries, or enrollees from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan or issuer;

(2) to override any State licensure or scope-of-practice law; or

(3) as requiring a plan or issuer that offers network coverage to include for participation every willing provider who meets the terms and conditions of the plan or coverage.

SEC. 112. GENERALLY APPLICABLE PROVISION.

Notwithstanding section 102, in the case of a group health plan, and a health insurance issuer that offers health insurance coverage, that provides benefits under 2 or more coverage options, the requirements of this part shall apply separately with respect to each coverage option.

Subtitle B—Right to Information About Plans and Providers

SEC. 121. HEALTH PLAN INFORMATION.

(a) REQUIREMENT.—

(1) In general.—A group health plan, and a health insurance plan that offers health insurance coverage, shall provide for the disclosure of the information described in subsection (b) to participants, beneficiaries, and enrollees—

(A) at the time of the initial enrollment of the participant, beneficiary, or enrollee under the plan or coverage;

(B) on an annual basis after enrollment—

(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

(ii) 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, BENEFICIARIES, OR ENROLLEES.—The information described in subsection (A) shall be provided—

(i) jointly to each participant and beneficiary who reside at the same address; and

(ii) to each enrollee.

(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 noncompliance.

(3) PROVISION OF INFORMATION.—Information shall be provided to participants, beneficiaries, and enrollees under this section at the last known address maintained by the plan or issuer with respect to such participants, beneficiaries, or enrollees, to the extent that such information is provided to participants, beneficiaries, or enrollees via the United States Postal Service or other private delivery service.

(b) REQUIRED INFORMATION.—The information 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 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 percentage, coinsurance, copayment amounts, and liability for balance billing above any reasonable and customary charges, for which the participant, beneficiary, or enrollee will be responsible under each option available under the plan;

(B) any maximum out-of-pocket expense for which the participant, beneficiary, or enrollee may be liable;

(C) any cost-sharing requirements for out-of-network benefits or services received from nonparticipating providers; and

(D) any restriction on cost-sharing or charges for benefits and services that are furnished without meeting applicable plan or coverage requirements, such as prior authorization or pre-certification.

(3) SERVICE AREA.—A description of the plan's 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, telephone number, and specialty 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, beneficiaries, and enrollees in selecting a 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 104 for a participant, beneficiary, or enrollee 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, beneficiaries, and enrollees in accessing specialty care and obtaining referrals, including the right to timely access to specialists operating under the plan or coverage if the plan or 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, beneficiaries, and enrollees in obtaining access to prescription drugs under section 107 if such section applies.

(9) EMERGENCY SERVICES.—A summary of the rules and procedures for accessing emergency services, including the right of a participant, beneficiary, or enrollee to obtain emergency services under the prudent layperson standard under section 101, if such section applies, and any educational information regarding the appropriate use of emergency services.

June 29, 2001
(12) CLAIMS AND APPEALS.—A description of the procedures and processes pertaining to claims and appeals, a description of the rights of participants, beneficiaries, or enrollees under sections 503, 503A and 503B of the Employee Retirement Income Security Act of 1974, a description of procedures under sections 2706 and 2758 of the Public Health Service with respect to non-Federal governmental plans and individual health insurance coverage in obtaining covered benefits, filing a claim for benefits, and appealing coverage decisions internally and externally (including telephone numbers and addresses of claim review and, if available, Internet websites), and a description of any additional legal rights and remedies available under section 502 of the Employee Retirement Income Security Act of 1974.

(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, telephone numbers, and, if available, email address of the plan administrator and the issuer to be used by participants, beneficiaries, and enrollees seeking information about plan or coverage benefits and a description of how to access these informational materials to be provided upon the written determination of an independent medical reviewer under section 503B of such Act. Notice of whether the benefits under the plan are provided under a contract or policy of one or more issuers, 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) to be provided for non-English speakers and participants, beneficiaries, and enrollees with communication disabilities and a description of how to access these 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 are calculated to be understood by the average participant.

(17) NOTICE OF REQUIREMENTS.—A description of any rights of participants, beneficiaries, and enrollees that are established by this Act (excluding those described in paragraphs (1) through (16)) if such rights apply. The description required under this paragraph may be combined with the notices required under sections 711(d), 713(b), or 606(a)(1) of the Employee Retirement Income Security Act of 1974, and with any other notice provided that the Secretary determines may be combined.

(18) COMPENSATION METHODS.—A summary description of the methods (including capita tion, salary, wage, tip, benefit, bonus, bundled payments, per diem, or a combination thereof) used for compensating participating health care professionals (including providers and, if applicable, facilities) and facilities in connection with the provision of health care services to participants, beneficiaries, or enrollees, and a description of the plan or issuer's proprietary payment methodology.

(19) DISENROLLMENT.—Information relating to the disenrollment of a participant, beneficiary, or enrollee, if the plan or issuer uses a disenrollment mechanism, or a description of any additional legal rights and remedies available under section 502 of the Employee Retirement Income Security Act of 1974.

(20) 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.

(21) ADDITIONAL INFORMATION.—The information materials to be provided upon the request of a participant, beneficiary, or enrollee, if the plan or issuer uses a defined formulary.

(22) CLAIMS AND APPEALS INFORMATION.—A description of the action that is calculated to be understood by the average participant.

(23) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a group health plan, or a health insurance issuer that offers health insurance coverage, from—

(1) distributing any other additional information determined by the plan or issuer to be important or necessary in assisting participants, beneficiaries, and enrollees in the selection of a health plan; and

(2) complying with the provisions of this section by providing information in brochures, pamphlets, or other written, electronic, or audio-visual media, or through other similar means, so long as participants, beneficiaries, and enrollees are provided with an opportunity to request that informational materials be provided in printed form.

(24) 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 of Health and Human Services or the Secretary of Labor (as appropriate) may assess a civil money 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, beneficiary, or enrollee if the plan or issuer failed to comply with the requirements of the plan or issuer, if the plan or issuer uses a disenrollment mechanism, or a description of any additional legal rights and remedies available under section 502 of the Employee Retirement Income Security Act of 1974.

(B) INCREASE IN AMOUNT.—The amount prescribed 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.

(3) FAILURE DEFINED.—For purposes of this subsection, a plan or issuer shall be deemed to have failed to comply with the requirements of this section with respect to a participant, beneficiary, or enrollee if the plan or issuer failed to comply with the requirements of this section within 30 days—

(A) of the date described in subsection (a)(1)(A) or (B); or

(B) of the date described in subsection (a)(1)(A)(I); or

(C) of the date on which additional information was requested under subsection (c).

(h) CONFORMING AMENDMENTS.—

(1) Section 732(a)(3) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(a)(3)) is amended by striking ‘‘732(a)(3)’’ and inserting ‘‘732(a)(1)’’; and


SEC. 122. 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 barriers to the sharing of information concerning health care professionals; and

(2) an evaluation of the legal and other barriers to the sharing of information concerning health care professionals; and

(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 section (a).

SEC. 123. STUDY ON THE EFFECT OF PHYSICIAN COMPENSATION METHODS.

(a) STUDY AND REPORT.—

(1) IN GENERAL.—The Secretary shall enter into a contract with the Institute of Medicine for the conduct of a study in accordance with this section, to be submitted to the Secretary of Health and Human Services for providing information to the Secretary of Labor as provided for in paragraph (4).

(2) MATTERS TO BE STUDIED.—The study under paragraph (1) shall include—

(A) a survey if necessary, of physician compensation arrangements that are utilized in employer-sponsored group health plans (including group health plans sponsored by government and non-government employers) and commercial health insurance products, including—
GROUP HEALTH PLANS.—

after the date of enactment of this Act, the

ing health care professional involved regard-

(B) an analysis of the effect of such dif-

differences on physician behavior with respect to the provision of medical care

to patients, including whether and how such

arrangements affect the quality of patient care and the ability of physicians to provide care

that is medically necessary and appro-

priate.

(3) STUDY DESIGN.—The Secretary shall

consult with the Director of the Agency for

Healthcare Research and Quality, shall con-

duct and support research to develop sci-

entific evidence regarding the effects of dif-

fering physician compensation methods on physician behavior with respect to the provi-

sion of medical care to patients, particularly issues relating to the quality of patient care

and whether patients receive medically nec-

essary and appropriate care.

(2) AUTHORIZATION OF APPROPRIATIONS.—

For purposes of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

Subtitle C—Right to Hold Health Plans Accountable

SEC. 131. AMENDMENTS TO EMPLOYEE RETIRE-

MENT 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 501 (29 U.S.C. 1133) the fol-

lowing:

"SEC. 501A. CLAIMS AND INTERNAL APPEALS

PROCEDURES FOR GROUP HEALTH PLANS.

(a) INITIAL CLAIM FOR BENEFITS UNDER

GROUP HEALTH PLANS.—

(ii) the provision of medical care to patients

and the treating health care professional involved regard-

ing a determination on an initial claim for

benefits made under the terms and condi-

tions of the plan or issuer to make a determination on the claim, in no case shall such deter-

mination be made later than 60 business days after the determination (or applicable time-

frame, as applicable).

(b) ACCESS TO INFORMATION.—With respect to

an initial claim for benefits, the partici-

pant or beneficiary (or authorized representa-

tive) and the treating health care profes-

sional (if any) shall provide the plan or issuer with access to information requested on the date of the request or

within the 72-hour or 24-hour period referred to in clauses (i) and (ii) of paragraph (2)(A) if applicable.

(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 that offers 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 DETERMINA-

TIONS.—

"(i) IN GENERAL.—A group health plan, or

health insurance issuer that offers health in-

surance coverage in connection with a group health plan, shall maintain procedures to en-

sure that a prior authorization determina-

tion is made by a participant or beneficiary (or authorized representative) and the treating health care professional involved regard-

ing a determination on an initial claim for

benefits made under the terms and condi-

tions of the plan or issuer to make a determina-

tion on the claim, 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.—Notwith-

standing clause (i), a group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, shall maintain procedures for expediting a prior authorization determina-

tion 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 de-

termination and the treating health care professional substantiates, with the request, that a determination under the procedures described in clause (i) would seriously jeop-

ardize 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 that offers health insurance coverage in connection with a group health plan, shall maintain procedures to ensure that: a determination under the procedures described in clause (i) would seriously jeop-

ardize 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.

"(B) RETROSPECTIVE DETERMINATION.—A group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, shall maintain procedures to ensure that: a determination under the procedures described in clause (i) would seriously jeop-

ardize 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.
CONGRESSIONAL RECORD—SENATE

June 29, 2001

12573

“(B) ACCESS TO INFORMATION.—With respect to a denial of a claim for benefits under this section, a group health plan, or health insurance issuer that offers 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 such appeal, but in no case shall such determination be made later than 28 business days after the receipt of the request for the appeal.

“(C) PRIOR AUTHORIZATION DETERMINATIONS.—

“(1) IN GENERAL.—A group health plan, or health insurance issuer that offers 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 such appeal, but in no case shall such determination be made later than 28 business days after the receipt of the request for the appeal.

“(2) EXPEDITED DETERMINATION.—Notwithstanding clause (i), a group health plan, or health insurance issuer that offers 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 receipt of such appeal as received by the plan or issuer under this subsection.

“(iii) CONCURRENT DETERMINATIONS.—A group health plan, or health insurance issuer that offers 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.

“(3) RETROSPECTIVE DETERMINATION.—A group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, shall maintain procedures to ensure that a retrospective determination on an appeal of a denial 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 in accordance with such procedures established by the plan or issuer, and the treating health care professional not later than 2 business days after the completion of the review.

“(B) REVIEW OF MEDICAL DECISIONS BY PHYSICIANS.—In connection with a group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, may—

“(1) LIMIT THE FILING OF SUCH A REQUEST TO A FINAL DETERMINATION ON AN APPEAL OF A DENIAL OF A CLAIM FOR BENEFITS UNDER THIS SUBSECTION; AND

“(2) REQUIRE A FINAL DETERMINATION ON AN APPEAL OF A DENIAL OF A CLAIM FOR BENEFITS UNDER THIS SUBSECTION WITHIN 90 DAYS AFTER THE DATE ON WHICH THE PLAN OR ISSUER RECEIVES THE REQUEST FOR THE APPEAL.

“(3) 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.

“(4) EXPEDITED OR CONCURRENT CASES.—In the case of an expedited or concurrent review conducted 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.

“(5) ACCESS TO PLAN OR ISSUER AND HEALTH CARE PROFESSIONAL.—With respect to an independent external review conducted 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.

“(6) ACCESS TO PLAN OR ISSUER AND HEALTH CARE PROFESSIONAL.—With respect to an independent external review conducted 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.

“(1) IN GENERAL.—A group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, and a health insurance issuer that offers health insurance coverage under a group health plan, or health insurance issuer that offers health insurance coverage under a group health plan, shall—

“(A) 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 UNDER THIS SUBSECTION; AND

“(B) REQUIRE A FINAL DETERMINATION ON AN APPEAL OF A DENIAL OF A CLAIM FOR BENEFITS UNDER THIS SUBSECTION WITHIN 90 DAYS AFTER THE DATE ON WHICH THE PLAN OR ISSUER RECEIVES THE REQUEST FOR THE APPEAL.

“(C) 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 UNDER THIS SUBSECTION; AND

“(D) REQUIRE A FINAL DETERMINATION ON AN APPEAL OF A DENIAL OF A CLAIM FOR BENEFITS UNDER THIS SUBSECTION WITHIN 90 DAYS AFTER THE DATE ON WHICH THE PLAN OR ISSUER RECEIVES THE REQUEST FOR THE APPEAL.

“(2) ACCESS TO PLAN OR ISSUER AND HEALTH CARE PROFESSIONAL.—With respect to an independent external review conducted 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.

“(3) REQUIREMENT FOR FILING 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.

“(4) INCREASE IN AMOUNT.—The amount referred to in clause (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 2002.

“(5) REFERRAL TO QUALIFIED EXTERNAL REVIEW ENTITY UPON REQUEST.—

“(A) IN GENERAL.—Upon the filing of a request for independent external review conducted in connection with a group health plan, or health insurance issuer that offers health insurance 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.

“(B) ACCESS TO PLAN OR ISSUER AND HEALTH CARE PROFESSIONAL.—With respect to an independent external review conducted 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.

“(C) REQUIREMENT FOR FILING 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.

“(D) INCREASE IN AMOUNT.—The amount referred to in clause (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 2002.

“(E) REFERRAL TO QUALIFIED EXTERNAL REVIEW ENTITY UPON REQUEST.—

“(A) IN GENERAL.—Upon the filing of a request for independent external review conducted in connection with a group health plan, or health insurance issuer that offers health insurance 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.

“(B) ACCESS TO PLAN OR ISSUER AND HEALTH CARE PROFESSIONAL.—With respect to an independent external review conducted 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.
section, as determined by the entity, not later than 30 calendar 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 chronically ill individual that is referred to the reviewer under subsection (d)(2); 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—

(A) the total amount payable under the plan or coverage for the item or service that was the subject of such denial exceeds $100; or

(B) 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) NO DEFEANCE TO PRIOR DETERMINATIONS.—In making determinations under subparagraph (A), there shall be no deference to any determinations made by the plan or issuer under section 503A or the recommendation of a treating health care professional (if any). The entity shall refer such request for the conduct of an independent medical review unless the entity determines that—

(i) whether the item or service or condition is necessary and appropriate, or the experimental or investigational nature of the treatment.

(ii) based upon an affirmative determination under clause (i), whether or not the denial of a claim for benefits that is the subject of the review should be upheld or reversed.

(2) STANDARD FOR DETERMINATION.—The independent medical reviewer’s determination relating to the medical necessity and appropriateness, or the experimental or investigational nature of the treatment, is affirmed, reversed, or upheld as the reviewer deems appropriate.

(3) IN GENERAL.—An independent medical reviewer under this paragraph shall make a new independent determination with respect to—

(A) whether the item or service or condition is necessary and appropriate, or the experimental or investigational nature of the treatment; and

(B) whether the determination is affirmed, reversed, or upheld as the reviewer deems appropriate.

(4) TIMELINES AND NOTIFICATIONS.—

(i) IN GENERAL.—The independent medical reviewer (or reviewers) shall make a determination relating to the medical necessity and appropriateness, or the experimental or investigational nature of the treatment, 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.

(ii) USE OF APPROPRIATE PERSONNEL.—A qualified external review entity referred to under clause (i) of 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.

(iii) ADDITIONAL EVIDENCE OR 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:

(A) The determination made by the plan or issuer with respect to the denial of a claim for benefits described in this paragraph is one for which the requirements of this paragraph do not apply. Such determination is affirmed, reversed, or upheld as the reviewer deems appropriate, or the experimental or investigational nature of the treatment.

(B) The plan or coverage document.

(C) EVIDENCE AND INFORMATION TO BE USED IN MEDICAL REVIEWS.—In making a determination under this paragraph, the independent medical reviewer shall—

(i) consider the claim under review with respect to the determination made by the plan or issuer under section 503A or the recommendation of the treating health care professional (if any); and

(ii) consider, but not be bound by the definition of the term or issuer of ‘medically necessary and appropriate’, ‘experimental or investigational’, or ‘other equivalent terms that are used by the plan or issuer to describe medical necessity and appropriateness’.

(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.

(ii) EVIDENTIARY DETERMINATION.—In making the determination, the independent medical reviewer shall—

(A) consider the claim under review with respect to the determination made by the plan or issuer under section 503A or the recommendation of the treating health care professional (if any); and

(B) consider, but not be bound by the definition of the term or issuer of ‘medically necessary and appropriate’. The determination of the reviewer or submitted by the plan, issuer, participant or beneficiary (or an authorized representative), or treating health care professional.

(iii) THRESHOLDS.—

(A) IN GENERAL.—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 and, in the case of a reversal, the timeframe within which the plan or issuer shall authorize coverage to comply with the determination. Such written determination shall include the specific reasons of the reviewer for such determinations, and a summary of the medical or scientific evidence used or relied on in 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.

(B) DENIALS BASED ON MEDICAL Necessity AND Appropriateness.—The basis of the determination is that the item or service is not medically necessary and appropriate.

(C) DENIALS BASED ON EXPERIMENTAL OR INVESTIGATIONAL TREATMENT.—The basis of the determination is that the item or service is experimental or investigational.

(D) EVIDENCE AND INFORMATION TO BE USED IN MEDICAL REVIEWS.—In making a determination under this subsection, the independent medical reviewer shall—

(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 is necessary and appropriate, or the experimental or investigational nature of the treatment;

(B) STANDARD FOR DETERMINATION.—The independent medical reviewer’s determination relating to the medical necessity and appropriateness, or the experimental or investigational nature of the treatment, is affirmed, reversed, or upheld as the reviewer deems appropriate.

(1) TIMELINES AND NOTIFICATIONS.—

(A) IN GENERAL.—The independent medical reviewer (or reviewers) shall make a determination relating to the medical necessity and appropriateness, or the experimental or investigational nature of the treatment, within the overall timeline that is applicable to the case under review as described in subsection (e)(3) not later than 14 business days.
after the receipt of information under subsection (c) of paragraph (7); and

(ii) not have a material familial, financial, or professional relationship with such a party (as determined under regulations).

(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—

(A) a non-affiliated individual is not reasonably available; or

(B) the affiliated individual is not involved in the provision of items or services in the case under review;

(ii) 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; or

(iii) the affiliated individual or the plan or issuer fails to provide reimbursement to a professional, participant or beneficiary (or authorized representative) for the professional medical services provided under paragraph (7); and

(iv) the affiliated individual is not an employee of the plan or issuer and does not provide services exclusively or primarily to or on behalf of the plan or issuer;

(iv) 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 affiliated individual is not in a professional medical services arrangement with the plan or issuer; and

(v) 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 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 professional of the same specialty as a professional who typically treats a 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—

CONGRESSIONAL RECORD—SENATE
June 29, 2001

12576

(A) not exceed a reasonable level; and
(B) not create any incentives for external review entities to make decisions in a biased manner.

(B) STATE AUTHORITY WITH RESPECT TO QUALIFIED EXTERNAL REVIEW ENTITIES FOR HEALTH CARE SERVICES.—With respect to health insurance issuers offering health insurance coverage in a State, the State may 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, the entity designated by the State to conduct unbiased determinations in connection with reviews under this section shall make a decision in a timely manner uninterested.

(C) The health care professional that provides the 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 decisions in a biased manner.

(B) STATE AUTHORITY WITH RESPECT TO QUALIFIED EXTERNAL REVIEW ENTITIES FOR HEALTH CARE SERVICES.—With respect to health insurance issuers offering health insurance coverage in a State, the State may 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, the entity designated by the State to conduct unbiased determinations in connection with reviews under this section shall make a decision in a timely manner uninterested.

(ii) INFORMATION TO BE INCLUDED.—The information to be included under this paragraph shall include:

(I) the entity has (directly or through consultants) 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 as set forth in subsection (b)(3)(A) and providing for independent medical reviews under subsection (d);

(III) 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 (including an organization of such plans or issuers), and does not create any incentives for external review entities under this section if the compensation is provided consistent with clause (iv).

(iv) CONSIDERATIONS IN RECERTIFICATION.—In conducting recertification of a qualified external review entity under this section, 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 (by the entity and independent medical reviewers it refers to cases to).

(III) Compliance with limitations on compensation (with respect to both the entity and independent medical reviewers it refers to cases).

(IV) Compliance with applicable independence requirements.

(i) PERIOD OF CERTIFICATION OR RECERTIFICATION.—A certification or recertification provided under this paragraph shall extend for a period not to exceed 5 years.

(ii) 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.

(i) 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 (related to the denials which have been referred to the entity for the conduct of external review activities under this section) as the Secretary determines appropriate to assure compliance with the independence and other requirements of this section, including 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 an 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) INFORMATION TO BE PROVIDED TO CERTIFICATION OR RECERTIFICATION ORGANIZATION.—

(I) In general.—In the case of a qualified external review entity which is certified
(ii) ADDITIONAL INFORMATION.—Nothing in this subparagraph shall be construed as precluding such an organization from requiring additional information as a condition of certification or recertification of an entity.

(iv) USE OF INFORMATION.—

(I) IN GENERAL.—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.

(II) REPORT TO CONGRESS.—Not later than 2 years after the date on which the Bipartisan Patients' Bill of Rights Act of 2001 takes effect under section 501 of such Act, and every 2 years thereafter, the Secretary, in consultation with the Secretary of Health and Human Services, shall prepare and submit to the appropriate committees of Congress, a report that contains:

(a) a description of the information provided to the Secretary under clause (ii);

(b) a description of the effect that the appeals process established under this section and section 503A had on the access of individuals to health insurance and health care;

(cc) a description of the effect on health care costs associated with the implementation and section 503A had on the access of individuals to health insurance and health care;

(dd) a description of the effect that the appeals process established under this section and section 503A had on the access of individuals to health insurance and health care.

(III) RECOMMENDATIONS.—The Secretary may from time to time submit recommendations to Congress with respect to proposed modifications to the appeals process based on the reports submitted under subclause (II).

(2) 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 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:

(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;

(C) a family member of the participant or beneficiary (or the estate of the participant or beneficiary) or the participant's or beneficiary's health care professional when the participant or beneficiary is unable to provide consent.

(2) CLAIM FOR BENEFITS.—The term 'claim for benefits' includes 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 of any health care 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(b)(1). 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)(2).

(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 plan, sponsor, or group health plan issuer that a plan, health insurance issuer or provider sponsored organization means a physician 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.

(7) TREATING HEALTH CARE PROFESSIONAL.—The term 'treated health care professional' with respect to a group health plan, health insurance issuer or provider sponsored organization means a physician (medical doctor, osteopathic physician), 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, health insurance issuer or provider sponsored organization means a physician 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) HEALTH PLAN.—The term 'health plan' includes a group health plan, health insurance issuer or provider sponsored organization.

(10) GROUP HEALTH PLAN.—The term 'group health plan' includes a health plan offered by an employer or other plan sponsor.

(11) PLAN.—The term 'plan' means a health plan.

(12) HEALTH PLAN.—The term 'health plan' includes a group health plan.

(13) HEALTH INSURANCE ISSUER.—The term 'health insurance issuer' includes an issuer of health insurance.

SEC. 132. 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:

(5) The Secretary may assess a civil penalty against the plan and the plan sponsor in an amount of at least $10,000 for a violation by the plan and the plan sponsor in an amount of at least $10,000 for a violation.

(6) The Secretary may assess a civil penalty against the plan and the plan sponsor in an amount of at least $10,000 for a violation.

(C) RELIEF FROM LIABILITY FOR EMPLOYER OR OTHER PLAN SPONSOR BY MEANS OF DESIGNATED DECISION-MAKER.—

(1) IN GENERAL.—Notwithstanding the direct participation (as defined in paragraph (3)(C)(i)) of an employer or plan sponsor, in any case in which there is deemed to be a designated decision-maker, any action taken by the designated decision-maker shall be deemed to be an action taken by the employer or plan sponsor.

(2) RELIEF FROM LIABILITY FOR EMPLOYER OR OTHER PLAN SPONSOR.—In all cases in which there is deemed to be a designated decision-maker, any action taken by the designated decision-maker shall be deemed to be an action taken by the employer or plan sponsor.

(3) PLAN.—The term 'plan' includes a group health plan.

(4) HEALTH PLAN.—The term 'health plan' includes a group health plan.
(II) with respect to such liability, the designated decisionmaker shall be substituted for the employer or plan sponsor (or employee) in the action and may not raise any defense that the employer or plan sponsor (or employee) could not raise if such a defense were available to the designated decisionmaker.

(ii) AUTOMATIC DESIGNATION.—A health insurance issuer shall be deemed to be a designated decisionmaker for purposes of clause (i) with respect to the participants and beneficiaries of an employer or plan sponsor, whether or not the employer or plan sponsor makes such designation, and nothing in this subsection is intended to have assumed unconditionally all liability of the employer or plan sponsor under such designation in accordance with paragraph (2), unless the employer or plan sponsor affirmatively enters into a contract to prevent the service of the designated decisionmaker.

The deeming of a designated decisionmaker under this clause shall not affect the liability of the appointing employer or plan sponsor for the failure of the employer or plan sponsor to comply with any other provision of this title.

(D) PREVENTION OF DUPLICATION OF ACTION WITH ACTION UNDER STATE LAW.—No action may be brought under this subsection based upon facts and circumstances if a cause of action under State law is brought based upon the same facts and circumstances.

(E) APPLICATION TO CERTAIN PLANS.—

(i) IN GENERAL.—Notwithstanding any other provision of this subsection, no group health plan described in clause (ii) shall be liable for any amount of liability assumed under this subsection or arising in a cause of action by a participant or beneficiary, and

(ii) DEFINITION.—A group health plan described in this clause is—

(I) a group health plan that is self-insured and self-administered by an employer (including an employee of such an employer acting within the scope of employment); or

(II) a multiemployer plan as defined in section 3(3)(A) (including an employee of a contributing employer or of the plan, or a fiduciary of the plan, acting within the scope of employment except as a fiduciary responsibility) that is self-insured and self-administered.

(2) REQUIREMENTS FOR DESIGNATED DECISIONMAKERS OF GROUP HEALTH PLANS.—

(A) For purposes of this subsection and section 514(c)(3), a designated decisionmaker meets the requirements of this subparagraph with respect to any participant or beneficiary if—

(i) such designation is in such form as may be prescribed in regulations of the Secretary;

(ii) the designated decisionmaker—

(1) meets the requirements of subparagraph (B); and

(2) assumes unconditionally all liability of the employer or plan sponsor involved (and any employee thereof acting within the scope of employment) either arising under this subsection or arising in a cause of action in connection with any action permitted under section 514(c) in connection with any action taken under subparagraph (B)(ii), the requirements relating to the financial obligation of an entity for liability described in paragraph (1), or any engagement by the employer or other plan sponsor (or employee) in the service of a designated decisionmaker under this paragraph; or

(iii) evidence of minimum capital and surplus levels that are maintained by such entity to cover any losses as a result of liability arising from its service as a designated decisionmaker under this paragraph.

The appropriate amounts of liability insured and minimum capital and surplus levels for purposes of clauses (i) and (ii) shall be determined in an actuarial analysis applying sound actuarial principles and accounting practices pursuant to established guidelines of the American Academy of Actuaries and in accordance with such regulations as the Secretary may prescribe and shall be maintained throughout the term for which the designation is in effect. The provisions of this subparagraph shall apply only to the case of a designated decisionmaker that is a group health plan, plan sponsor, or health insurance issuer and that is regulated under Federal law.

(3) LIMITATION ON APPOINTMENT OF TREATING PHYSICIANS.—A treating physician who directly delivered the care, treatment, or services that are the subject of a cause of action by a participant or beneficiary under this subsection or section 514(c) may not be designated as a designated decisionmaker under this subsection with respect to such participant or beneficiary.

(3) EXCLUSION OF EMPLOYERS AND OTHER PLAN SPONSORS.—

(A) CAUSES OF ACTION AGAINST EMPLOYERS AND PLAN SPONSORS PRECLUDED.—Subject to subparagraph (B), paragraph (1) does not authorize a cause of action against an employer or other plan sponsor (or employee) in the plan (or against an employee of such an employer or other plan sponsor acting within the scope of employment).

(B) CONSEQUENCES OF CERTAIN ACTIONS PERMITTED.—Notwithstanding subparagraph (A), a cause of action may arise, subject to the requirements and limitations of paragraph (1), against an employer or other plan sponsor (or against an employee of such an employer or other plan sponsor acting within the scope of employment) in the plan (or against an employee of such an employer or other plan sponsor acting within the scope of employment).

(C) DIRECT PARTICIPATION.—

(I) IN GENERAL.—For purposes of subparagraph (B), the term ‘direct participation’ means, in connection with a decision described in paragraph (1), the actual making of a decision or the actual exercise of control in making such decision.

(ii) RULES OF CONSTRUCTION.—For purposes of clause (i), the employer or plan sponsor (or employee) shall be directly engaged in direct participation because of any form of decisionmaking or other conduct that is merely collateral or precedent to the decision described in paragraph (1) on a particular claim for benefits of a participant or beneficiary, including (but not limited to) any participation by the employer or other plan sponsor (or employee) in the process of creating, continuing, modifying, or terminating the plan or any benefit under the plan, if such process was not substantially focused solely on the particular situation of the participant or beneficiary referred to in paragraph (1); and

(iii) any participation by the employer or other plan sponsor (or employee) in the design of any benefit under the plan, including the amount of copayment and limits connected with such benefit.

(D) IRRELAVANCE OF CERTAIN COLLABORATIVE EFFORTS MADE BY EMPLOYER OR PLAN SPONSOR.—For purposes of this subparagraph, an employer or other plan sponsor (or employee) shall not be treated as engaged in direct participation in a decision with respect to any claim for benefits or denial thereof in the case of any participant or beneficiary so treated under section 5013(a) of title 5, United States Code.

(E) EXCLUSION OF EMPLOYERS AND OTHER PLAN SPONSORS.—

(A) CAUSES OF ACTION AGAINST EMPLOYERS AND PLAN SPONSORS PRECLUDED.—Subject to subparagraph (B), paragraph (1) does not authorize a cause of action against an employer or other plan sponsor (or employee) in the plan (or against an employee of such an employer or other plan sponsor acting within the scope of employment).

(B) CONSEQUENCES OF CERTAIN ACTIONS PERMITTED.—Notwithstanding subparagraph (A), a cause of action may arise, subject to the requirements and limitations of paragraph (1), against an employer or other plan sponsor (or against an employee of such an employer or other plan sponsor acting within the scope of employment) in the plan (or against an employee of such an employer or other plan sponsor acting within the scope of employment).

(C) DIRECT PARTICIPATION.—

(I) IN GENERAL.—For purposes of subparagraph (B), the term ‘direct participation’ means, in connection with a decision described in paragraph (1), the actual making of a decision or the actual exercise of control in making such decision.

(ii) RULES OF CONSTRUCTION.—For purposes of clause (i), the employer or plan sponsor (or employee) shall be directly engaged in direct participation because of any form of decisionmaking or other conduct that is merely collateral or precedent to the decision described in paragraph (1) on a particular claim for benefits of a participant or beneficiary, including (but not limited to) any participation by the employer or other plan sponsor (or employee) in the process of creating, continuing, modifying, or terminating the plan or any benefit under the plan, if such process was not substantially focused solely on the particular situation of the participant or beneficiary referred to in paragraph (1); and

(iii) any participation by the employer or other plan sponsor (or employee) in the design of any benefit under the plan, including the amount of copayment and limits connected with such benefit.

(D) IRRELAVANCE OF CERTAIN COLLABORATIVE EFFORTS MADE BY EMPLOYER OR PLAN SPONSOR.—For purposes of this subparagraph, an employer or other plan sponsor (or employee) shall not be treated as engaged in direct participation in a decision with respect to any claim for benefits or denial thereof in the case of any participant or beneficiary so treated under section 5013(a) of title 5, United States Code.

(E) EXCLUSION OF EMPLOYERS AND OTHER PLAN SPONSORS.—

(A) CAUSES OF ACTION AGAINST EMPLOYERS AND PLAN SPONSORS PRECLUDED.—Subject to subparagraph (B), paragraph (1) does not authorize a cause of action against an employer or other plan sponsor (or employee) in the plan (or against an employee of such an employer or other plan sponsor acting within the scope of employment).

(B) CONSEQUENCES OF CERTAIN ACTIONS PERMITTED.—Notwithstanding subparagraph (A), a cause of action may arise, subject to the requirements and limitations of paragraph (1), against an employer or other plan sponsor (or against an employee of such an employer or other plan sponsor acting within the scope of employment) in the plan (or against an employee of such an employer or other plan sponsor acting within the scope of employment).

(C) DIRECT PARTICIPATION.—

(I) IN GENERAL.—For purposes of subparagraph (B), the term ‘direct participation’ means, in connection with a decision described in paragraph (1), the actual making of a decision or the actual exercise of control in making such decision.

(ii) RULES OF CONSTRUCTION.—For purposes of clause (i), the employer or plan sponsor (or employee) shall be directly engaged in direct participation because of any form of decisionmaking or other conduct that is merely collateral or precedent to the decision described in paragraph (1) on a particular claim for benefits of a participant or beneficiary, including (but not limited to) any participation by the employer or other plan sponsor (or employee) in the process of creating, continuing, modifying, or terminating the plan or any benefit under the plan, if such process was not substantially focused solely on the particular situation of the participant or beneficiary referred to in paragraph (1); and

(iii) any participation by the employer or other plan sponsor (or employee) in the design of any benefit under the plan, including the amount of copayment and limits connected with such benefit.

(D) IRRELAVANCE OF CERTAIN COLLABORATIVE EFFORTS MADE BY EMPLOYER OR PLAN SPONSOR.—For purposes of this subparagraph, an employer or other plan sponsor (or employee) shall not be treated as engaged in direct participation in a decision with respect to any claim for benefits or denial thereof in the case of any participant or beneficiary so treated under section 5013(a) of title 5, United States Code.

(E) EXCLUSION OF EMPLOYERS AND OTHER PLAN SPONSORS.—

(A) CAUSES OF ACTION AGAINST EMPLOYERS AND PLAN SPONSORS PRECLUDED.—Subject to subparagraph (B), paragraph (1) does not authorize a cause of action against an employer or other plan sponsor (or employee) in the plan (or against an employee of such an employer or other plan sponsor acting within the scope of employment).

(B) CONSEQUENCES OF CERTAIN ACTIONS PERMITTED.—Notwithstanding subparagraph (A), a cause of action may arise, subject to the requirements and limitations of paragraph (1), against an employer or other plan sponsor (or against an employee of such an employer or other plan sponsor acting within the scope of employment) in the plan (or against an employee of such an employer or other plan sponsor acting within the scope of employment).

(C) DIRECT PARTICIPATION.—

(I) IN GENERAL.—For purposes of subparagraph (B), the term ‘direct participation’ means, in connection with a decision described in paragraph (1), the actual making of a decision or the actual exercise of control in making such decision.

(ii) RULES OF CONSTRUCTION.—For purposes of clause (i), the employer or plan sponsor (or employee) shall be directly engaged in direct participation because of any form of decisionmaking or other conduct that is merely collateral or precedent to the decision described in paragraph (1) on a particular claim for benefits of a participant or beneficiary, including (but not limited to) any participation by the employer or other plan sponsor (or employee) in the process of creating, continuing, modifying, or terminating the plan or any benefit under the plan, if such process was not substantially focused solely on the particular situation of the participant or beneficiary referred to in paragraph (1); and

(iii) any participation by the employer or other plan sponsor (or employee) in the design of any benefit under the plan, including the amount of copayment and limits connected with such benefit.

(D) IRRELAVANCE OF CERTAIN COLLABORATIVE EFFORTS MADE BY EMPLOYER OR PLAN SPONSOR.—For purposes of this subparagraph, an employer or other plan sponsor (or employee) shall not be treated as engaged in direct participation in a decision with respect to any claim for benefits or denial thereof in the case of any participant or beneficiary so treated under section 5013(a) of title 5, United States Code.
(II) any provision that may have been made by law for plan or plan administrator to deny benefits which are not covered under the terms and conditions of the plan for that or any other participant or beneficiary (or any group health plan or health insurance issuer that offers health insurance coverage in connection with a group health plan). Any determination made under section 503B, or a period of time elapsing after coverage has increased or decreased from the such index for September of the preceding calendar year. The amount awarded for economic loss.

(B) INCREASE IN AMOUNT.—The amount referred to in subparagraph (A)(i) shall be increased (or decreased, for each calendar year that ends after December 31, 2002, 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 2002.

(C) SEVERAL LIABILITY.—In the case of any action commenced pursuant to paragraph (1), the designated decision-maker shall be responsible to the extent that, in the judgment of the court, the amount of damages attributable to such designated decision-maker in direct proportion to such decision-maker's share of fault or responsibility for the injury suffered by the participant or beneficiary. In all such cases, the liability of a designated decision-maker 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 under clause (ii), by any other amount that has been, or will be, made to such participant or beneficiary, pursuant to an order or judgment of another court, to compensate such participant or beneficiary for an 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—

(1) 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

(2) 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 (1).

(E) ADMISSIBILITY.—Any determination made under See paragraph (1) of this subparagraph shall be excluded ex-clusively under section 503B.

(II) Construction.—Nothing in this subsection shall be construed to preclude any action under State law against a person or entity for liability or vicarious liability with respect to the delivery of medical care. A claim that is based on, or otherwise relates to a group health plan's administration or determination of a claim for benefits (as such term is defined in section 503A and notwithstanding the definition contained in 1128, shall be an affirmative defense that—

(1) a participant or beneficiary that was necessary to determine liability.

(2) any cause of action under paragraph (1), it shall not be used in any action under section 503A; or a period of time elapsing after coverage has been authorized.

(10) CONSTRUCTION.—Nothing in this subsection shall be construed to preclude any action under State law against a person or entity for liability or vicarious liability with respect to the delivery of medical care. A claim that is based on, or otherwise relates to a group health plan's administration or determination of a claim for benefits (as such term is defined in section 503A and notwithstanding the definition contained in 1128, shall be an affirmative defense that—

(1) a participant or beneficiary that was necessary to determine liability.

(2) any cause of action under paragraph (1), it shall not be used in any action under section 503A; or a period of time elapsing after coverage has been authorized.

(10) CONSTRUCTION.—Nothing in this subsection shall be construed to preclude any action under State law against a person or entity for liability or vicarious liability with respect to the delivery of medical care. A claim that is based on, or otherwise relates to a group health plan's administration or determination of a claim for benefits (as such term is defined in section 503A and notwithstanding the definition contained in 1128, shall be an affirmative defense that—

(1) a participant or beneficiary that was necessary to determine liability.

(2) any cause of action under paragraph (1), it shall not be used in any action under section 503A; or a period of time elapsing after coverage has been authorized.

(10) CONSTRUCTION.—Nothing in this subsection shall be construed to preclude any action under State law against a person or entity for liability or vicarious liability with respect to the delivery of medical care. A claim that is based on, or otherwise relates to a group health plan's administration or determination of a claim for benefits (as such term is defined in section 503A and notwithstanding the definition contained in 1128, shall be an affirmative defense that—

(1) a participant or beneficiary that was necessary to determine liability.

(2) any cause of action under paragraph (1), it shall not be used in any action under section 503A; or a period of time elapsing after coverage has been authorized.

(10) CONSTRUCTION.—Nothing in this subsection shall be construed to preclude any action under State law against a person or entity for liability or vicarious liability with respect to the delivery of medical care. A claim that is based on, or otherwise relates to a group health plan's administration or determination of a claim for benefits (as such term is defined in section 503A and notwithstanding the definition contained in 1128, shall be an affirmative defense that—

(1) a participant or beneficiary that was necessary to determine liability.

(2) any cause of action under paragraph (1), it shall not be used in any action under section 503A; or a period of time elapsing after coverage has been authorized.

(10) CONSTRUCTION.—Nothing in this subsection shall be construed to preclude any action under State law against a person or entity for liability or vicarious liability with respect to the delivery of medical care. A claim that is based on, or otherwise relates to a group health plan's administration or determination of a claim for benefits (as such term is defined in section 503A and notwithstanding the definition contained in 1128, shall be an affirmative defense that—

(1) a participant or beneficiary that was necessary to determine liability.

(2) any cause of action under paragraph (1), it shall not be used in any action under section 503A; or a period of time elapsing after coverage has been authorized.
(b) AUTHORITY TO IMPOSE CIVIL PENALTIES FOR FRAUDULENT A PLAN BENEFIT.—Section 503 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:—

"(2) the participant or beneficiary has appealed such determination under section 503B and such determination is not subject to independent medical review as determined by a qualified external review entity under section 503B;"
CONGRESSIONAL RECORD—SENATE

June 29, 2001

6862

(B) State Law Described.—A State law described in this subparagraph (as defined in paragraph (3)).

(2) Limitation.—In the case of a group health plan covered under title I of the Employed Retirement Income Security Act of 1974, paragraph (1) shall be construed to apply only with respect to the health insurance coverage (if any) offered in connection with the plan.

(3) Patient Protection Requirement Defined.—For purposes of this section, the term ‘patient protection requirement’ means any one or more requirements under the following:

(A) Section 101 (relating to access to emergency care).

(B) Section 102 (relating to consumer choice option) with respect to non-Federal governmental plans only.

(C) Section 103 (relating to patient access to obstetrical care).

(D) Section 104 (relating to access to pediatric care).

(E) Section 105 (relating to timely access to specialists).

(F) Section 106 (relating to continuity of care), but only insofar as a replacement issuer assumes the obligation for continuity of care.

(G) Section 108 (relating to access to needed prescription drugs).

(H) Section 109 (relating to coverage for individuals participating in approved clinical trials).

(I) Section 110 (relating to required coverage for minimum hospital stay for mastectomies and lymph node dissections for the treatment of breast cancer and coverage for secondary consultations).

(J) A prohibition under—

(i) Section 111 (prohibiting to prohibition of interference with certain medical communications); and

(ii) Section 111 (relating to prohibition of discrimination against providers based on licensure).

(K) An informational requirement under section 121.

(3) Determinations With Respect to Certifications.—

(I) Notify the State involved that specified additional information is needed to make the determination described in paragraph (3); or

(II) Submit a recommendation to the Secretary that a certification be disapproved (and the reasons therefore) of the certification.

(4) Review by Secretary.—

(A) In General.—The recommendation by the Board to approve or disapprove a certification submitted under paragraph (1) shall be considered to be approved by the Secretary unless the Secretary notifies the State in writing, within 30 days after the date on which the Board submits its recommendation to the Secretary under paragraph (2) concerning such certification, that the certification is approved or disapproved (and the reasons for the approval or disapproval).

(B) Reference to States.—The recommendation of the Board to approve a certification submitted under paragraph (1) shall be approved by the Secretary unless the Secretary finds that there is no reasonable basis or there is insufficient evidence for approving the certification.

(C) Notice.—

(I) State Notification.—The Secretary shall provide a State with written notice of the determination of the Secretary to approve or disapprove a certification submitted by the State under paragraph (1) within 30 days after the date on which the Board submits its recommendation to the Secretary under paragraph (2) concerning such certification.

(II) Public Notification.—The Secretary shall publish each notice provided under clause (i) in the Federal Register and as otherwise determined appropriate by the Secretary (including the Internet) to inform the general public. The Secretary shall annually publish (in accordance with the preceding sentence) the status of all States with respect to certifications.

(5) State Challenge.—A State that has a certification disapproved by the Secretary under paragraph (4) may challenge such disapproval in the appropriate United States district court. The court shall make a de novo determination with respect to a challenge brought under this paragraph.

(6) Termination of Certification.—

(A) In General.—The Secretary, not more frequently than once every 5 years, may review (in accordance with the procedures set forth in paragraphs (3) and (4)) a certification to determine whether the State law involved has not been—

(i) Repealed; or

(ii) Modified to such an extent that such law is no longer consistent with a patient protection requirement under this title.

(B) Termination.—If a State fails to submit an assurance to the Secretary under paragraph (A) within the 60-day period beginning on the date on which the Secretary makes a request for such an assurance, the certification applicable to the State under this section shall terminate.

(7) Rule of Construction.—Nothing in this section shall be construed to prohibit a State from submitting more than one certification under paragraph (1).

(8) Petitions by Plans or Issuers.—

(A) Petition Process.—Effective on the date on which the provisions of this Act become effective, as provided for in section 501, a group health plan or health insurance issuer may submit to the Secretary for a determination as to whether or not a standard or requirement under a State law applicable to the plan or issuer, that is not the subject of a certification under subsection (c), is superseded under subsection (a)(1) because such standard or requirement prevents the application of a requirement of this title.

(B) Approval.—The Secretary shall issue a determination with respect to a petition submitted under subparagraph (A) within the 60-day period beginning on the date on which such petition is submitted.

(d) Patients’ Protection Board.—

(1) Establishment of Board.—

(A) In General.—There is hereby established in the Department of Health and Human Services a Patients’ Protection Board. Consistent with the requirements of sections 5 and 10 of the Federal Advisory Committee Act, the Board shall carry out the duties described in paragraph (2).

(B) Composition.—The Board shall be composed of 13 members appointed by the Secretary, in consultation with the Secretary of Health and Human Services, and officials of State governments. Members shall first be appointed to the Board not later than May 1, 2002.

(C) Terms.—The terms of the members of the Board shall be for 3 years except that for those members first appointed the Secretary shall designate staggered terms of 3 years for 2 members, 2 years for 2 members, and 1 year for 1 member. A vacancy occurring before the expiration of the term for which a member was appointed shall be filled in the same manner in which the original appointment was made and a member appointed to fill a vacancy occurring before the expiration of the term for which the member was appointed shall be appointed only for the remainder of that term.

(2) Duties.—

(A) Review of Certifications Submitted.—The Board shall review certifications submitted under subsection (c) and make recommendations to the Secretary of Health and Human Services as provided for in such subsection.

(B) Annual Congressional Reports.—

(1) In General.—The Board shall submit to Congress an annual report on its activities. Each such report shall include the findings of the Board as to—

(I) the States that have failed to obtain a certification under subsection (c); and

(II) whether the enforcement role of the Federal Government with respect to health insurance has substantially expanded.

(ii) Initial Report.—The first annual report under clause (i) shall focus specifically on the development by the Board of criteria for certification and for the evaluation of State laws and any other activities of the Board during its first year of operation.

(e) Definitions.—For purposes of this section:
TITLE II—AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT

SECTION 201. APPLICATION TO CERTAIN HEALTH INSURANCE COVERAGE.

(a) IN GENERAL.—Subpart 2 of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-21 et seq.) is amended by adding at the end the following:

"SEC. 2707. PATIENT PROTECTION STANDARDS AND ACCOUNTABILITY.

"(a) IN GENERAL.—Each health insurance issuer shall comply with the patient protection requirements under titles I and IV of the Bipartisan Patients' Bill of Rights Act of 2001 with respect to individual health insurance coverage offered by health insurers, and such requirements shall be deemed to be incorporated into this section.

"(b) ACCOUNTABILITY.—The provisions of sections 503 through 503B of the Employee Retirement Income Security Act of 1974 (in effect as of the date of the enactment of such Act), and such requirements shall be deemed to be incorporated into this section.

SECTION 202. APPLICATION TO INDIVIDUAL HEALTH INSURANCE COVERAGE.

Part B of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-21 et seq.) is amended by adding at the end the following:

"SEC. 2753. PATIENT PROTECTION STANDARDS AND ACCOUNTABILITY.

"(a) IN GENERAL.—Each health insurance issuer shall comply with the patient protection requirements under titles A and B of title I of the Bipartisan Patients' Bill of Rights Act of 2001 with respect to individual health insurance coverage offered by health insurers, and such requirements shall be deemed to be incorporated into this section.

"(b) ACCOUNTABILITY.—The provisions of sections 503 through 503B of the Employee Retirement Income Security Act of 1974 (in effect as of the date of the enactment of such Act), and such requirements shall be deemed to be incorporated into this section.

SECTION 203. LIMITATION ON AUTHORITY OF THE SECRETARY AND HUMAN SERVICES WITH RESPECT TO NON-FEDERAL GOVERNMENTAL PLANS.

Section 2722(b) of the Public Health Service Act (42 U.S.C. 300gg-22(b)) is amended—

(1) in paragraph (1), by striking "only"—

and all that follows through the period and inserting "only as provided under subsection (a)(2)"; and

(2) in paragraph (2)—

(A) in subparagraph (A), by striking "any non-Federal governmental plan that is a group health plan and";

and

(B) in subparagraph (B), by striking "by—

all that follows through the period and inserting "by a health insurance issuer, the issuer is liable for such penalty.".

SECTION 204. COOPERATION BETWEEN FEDERAL AND STATE AUTHORITIES.

Part C of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-91 et seq.) is amended by adding at the end the following:

"SEC. 2783. COOPERATION BETWEEN FEDERAL AND STATE AUTHORITIES.

"(a) AGREEMENT WITH STATES.—A State may enter into an agreement with the Secretary for the delegation to the State of some or all of the Secretary's authority under this title to enforce the requirements applicable under title I of the Bipartisan Patients' Bill of Rights Act of 2001 to health insurance issuers in connection with non-Federal governmental plans and individual health insurance coverage.

"(b) DELEGATIONS.—Any department, agency, or instrumentality of a State to which authority is delegated pursuant to an agreement entered into under this section may, if authorized under State law and to the extent consistent with such agreement, exercise the powers of the Secretary under this title which relate to such authority.

TITLE III—AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

SECTION 201. APPLICATION OF PATIENT PROTECTION STANDARDS TO GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE.

Subpart B of part 7 of subpart B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185 et seq.) is further amended by adding at the end the following new section:

"SEC. 714. PATIENT PROTECTION STANDARDS.

"(a) IN GENERAL.—Subject to subsection (b), a group health plan (and a health insurance issuer offering health insurance coverage in connection with a group health plan) shall comply with the requirements of title I of the Bipartisan Patients' Bill of Rights Act of 2001 (as in effect as of the date of the enactment of such Act), and such requirements shall be deemed to be incorporated into this subsection.

"(b) PLAN SATISFACTION OF CERTAIN REQUIREMENTS.

"(1) SATISFACTION OF CERTAIN REQUIREMENTS THROUGH INSURANCE.—For purposes of subsection (a), in so far as a group health plan (and a health insurance issuer offering health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the following requirements of title I of the Bipartisan Patients' Bill of Rights Act of 2001 with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to comply with an undue delay long as the plan sponsor or its representatives did not cause such failure by the issuer.

CONGRESSIONAL RECORD—SENATE

June 29, 2001

12582

(1) BOARD.—The term "Board" means the Patients Protection Board established under subsection (d).

(2) STATE, STATE LAW.—The terms "State" and "State law" shall have the meanings given such terms in section 2722(d) of the Public Health Service Act (42 U.S.C. 300gg-23(d)).
June 29, 2001

CONGRESSIONAL RECORD—SENATE

"(A) Section 101 (relating to access to emergency services)."

"(B) Section 102 (relating to consumer choice option)."

"(C) Section 103 (relating to patient access to obstetrical and gynecological care)."

"(D) Section 104 (relating to access to pediatric care)."

"(E) Section 105 (relating to timely access to specialists)."

"(F) Section 106 (relating to continuity of care), but only insofar as a replacement issuer assumes the obligation for continuity of care.

"(G) Section 108 (relating to access to needed prescription drugs)."

"(H) Section 109 (relating to coverage for individuals participating in approved clinical trials)."

"(I) Section 110 (relating to required coverage for minimum hospital stay for mastectomies and lymph node dissections for the treatment of breast cancer and coverage for secondary consultations)."

"(J) Section 121 (relating to the provision of information)."

"(2) APPLICATION TO PROHIBITIONS.—Pursuant to rules of the Secretary, if a health insurance issuer offering health insurance coverage with a group health plan shall not be liable for such violation unless the plan caused such violation:

"(A) Section 107 (relating to prohibition of interference with certain medical communications)."

"(B) Section 111 (relating to prohibition of discrimination against providers based on licensure)."

"(3) CONSTRUCTION.—Nothing in this subsection shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B.

"(4) TREATMENT OF CONSISTENT STATE LAWS.—For purposes of applying this subsection, a health insurance issuer offering coverage in connection with a group health plan shall be deemed to be in compliance with one or more of the patient protection requirements of the Bipartisan Patients’ Bill of Rights Act of 2001 if the group health plan is covered by a State law, with respect to the patient protection requirements involved, that has been certified in accordance with section 151(c) of such Act:

"(A) the issuer (or plan) is in compliance with a State law, with respect to the patient protection requirements involved, that has been certified in accordance with section 151(c) of such Act; or

"(B) the issuer (or plan) is in compliance with a State law, with respect to the patient protection requirements involved, that has been determined by the Secretary as not preventing the application of the patient protection requirements involved, in accordance with section 151(c)(8)(B) of such Act.

"(c) 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 the other provisions of this title.

"(b) SATISFACTION OF ERISA CLAIMS PROCEDURE REQUIREMENT.—Section 503 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(b)(3)) is amended—

"(1) by inserting "(a)" after "Sec. 503.;" and

"(2) by adding at the end the following:

"(b) The claims denial shall be deemed compliance with subsection (a) with respect to such claims denial.

"(c) ENFORCEMENT.—Section 502(b)(3) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(b)(3)) is amended—

"(1) by striking "The Secretary" and inserting "(A) The Secretary; and"

"(2) by adding at the end the following:

"(B) A participant, beneficiary, plan fiduciary, or the Secretary may not bring an action to enforce the requirements of section 714 against a health insurance issuer (or plan) offering coverage in connection with a group health plan (or such group health plan where the patient protection requirements of the Bipartisan Patients’ Bill of Rights Act of 2001 (as defined in section 151(b)(3) of such Act) otherwise applicable to such issuer (or plan) under section 714 do not apply because the issuer (or plan) is in compliance with a State law, with respect to the patient protection requirements involved, that has been certified in accordance with section 151(c) of such Act; or

"(2) by adding after section 714 the following:

"Sec. 9813. Standard relating to patients’ Bill of Rights.

"A group health plan shall comply with the requirements of title I of the Bipartisan Patients’ Bill of Rights Act of 2001 (as in effect as of the date of the enactment of such Act), and such requirements shall be deemed to be incorporated into this section.

"SEC. 402. CONFORMING ENFORCEMENT FOR WOMEN’S HEALTH AND CANCER RIGHTS.

Subchapter B of chapter 100 of the Internal Revenue Code of 1986, as amended by section 401, is further amended—

"(1) in the tables of sections, by inserting after the item relating to section 9813 the following new item:

"Sec. 9814. Standard relating to women’s health and cancer rights.

"(d) CONFORMING AMENDMENTS.—

"(1) Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(a)) is amended—

"(1) by striking "section 711" and inserting "sections 711 and 714.

"(2) by adding after section 714 the following:

"Sec. 9814. Standard relating to women’s health and cancer rights.

"The provisions of section 713 of the Employee Retirement Income Security Act of 1974 (as in effect as of the date of the enactment of this section) shall apply to group health plans as if included in this subchapter.

"TITLE V—EFFECTIVE DATE; SEVERABILITY

SEC. 501. EFFECTIVE DATE AND RELATED RULES.

Except as otherwise provided in this Act, the provisions of this Act, including the amendments made by title I, shall apply on the later of—

"(1) plan years beginning on or after January 1, 2003; or

"(2) plan years beginning on or after 18 months after the date on which the Secretary of Health and Human Services and the Secretary of Labor issue final regulations, subject to the notice and comment period required under subchapter 2 of chapter 5 of title 5, United States Code, necessary to carry out the amendments made by this Act.

"SEC. 502. SEVERABILITY.

"(a) IN GENERAL.—Except as provided in subsections (b) and (c), if any provision of this Act or any amendment made by this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, the amendments made by such section, and the application of the provisions of such Act to any person or circumstance shall not be affected thereby.

"(b) DEPENDENCE OF REMEDIES ON APPEALS.—If any provision of section 131, or the amendments made by such section, or the application of such section or amendments to any person or circumstance is held to be unconstitutional, sections 141 and 143, and the amendments made by such sections, shall be deemed to be null and void and shall be given no force or effect.

"(c) REMEDIES.—If any provision of section 141, or the amendments made by such section, or the application of such section or amendments to any person or circumstance is held to be unconstitutional, the remainder of such section, and the amendments made by such section shall be deemed to be null and void and shall be given no force or effect.

"SEC. 503. ANNUAL REVIEW.

"(a) IN GENERAL.—Not later than 21 months after the effective date referred to in section 501, and annually thereafter for each of the succeeding 4 calendar years, the Secretary shall make such review of the provisions of this Act as the Secretary determines appropriate, and the findings of such review shall be included in the annual report required by such section.
request that the Institute of Medicine of the National Academy of Sciences prepare and submit to the appropriate committees of Congress a report concerning the impact of this Act, and the amendments made by this Act, on the number of individuals in the United States with health insurance coverage.

(b) Limitation With Respect to Certain Plans.—If the Secretary, in any report submitted under subsection (a), determines that more than 1,000,000 individuals in the United States have lost their health insurance coverage as a result of the enactment of this Act, as compared to the number of individuals with health insurance coverage in the 12-month period preceding the date of enactment of this Act, section 141 and the amendments made by such section shall be repealed effective on the date that is 12 month after the date on which the report is submitted, and the submission of any further reports under subsection (a) shall not be required.

(c) Funding.—From funds appropriated to the Department of Health and Human Services for fiscal years 2003 and 2004, the Secretary of Health and Human Services shall provide for such funding as the Secretary determines necessary for the conduct of the study under this Act, as compared to the number of individuals with health insurance coverage in the 12-month period preceding the date of enactment of this Act, as determined by the Secretary.

SEC. 857. Mrs. BOXER submitted an amendment intended to be proposed by her to the bill S. 976, to provide for such funding as the Secretary determines necessary for the conduct of the study under this Act, as compared to the number of individuals with health insurance coverage in the 12-month period preceding the date of enactment of this Act, as determined by the Secretary.

SEC. 858. Mrs. BOXER submitted an amendment intended to be proposed by her to the bill S. 976, to provide for such funding as the Secretary determines necessary for the conduct of the study under this Act, as compared to the number of individuals with health insurance coverage in the 12-month period preceding the date of enactment of this Act, as determined by the Secretary.

SA 858. Mrs. BOXER submitted an amendment intended to be proposed by her to the bill S. 976, to provide for such funding as the Secretary determines necessary for the conduct of the study under this Act, as compared to the number of individuals with health insurance coverage in the 12-month period preceding the date of enactment of this Act, as determined by the Secretary.

SA 859. Mrs. BOXER submitted an amendment intended to be proposed by her to the bill S. 976, to provide for such funding as the Secretary determines necessary for the conduct of the study under this Act, as compared to the number of individuals with health insurance coverage in the 12-month period preceding the date of enactment of this Act, as determined by the Secretary.

SA 860. Mr. REID (for Mr. KENNEDY) submitted an amendment to the bill S. 1052, to amend the Public Health Service Act and the Employee Retirement Income Security Act of 1974 to protect consumers in managed care plans and other health coverage.

On page 117, after line 14, add the following:

SEC. 6. IMMUNITY FOR HEALTH CARE PROFESSIONALS.

SA 857. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill S. 1052, to amend the Public Health Service Act and the Employee Retirement Income Security Act of 1974 to protect consumers in managed care plans and other health coverage.

On page 179, after line 14, add the following:

On page 15, line 5, strike “(4)” and insert “(3)”.

SA 859. Mrs. BOXER submitted an amendment intended to be proposed by her to the bill S. 976, to provide for such funding as the Secretary determines necessary for the conduct of the study under this Act, as compared to the number of individuals with health insurance coverage in the 12-month period preceding the date of enactment of this Act, as determined by the Secretary.

SA 860. Mr. REID (for Mr. KENNEDY) submitted an amendment to the bill S. 1052, to amend the Public Health Service Act and the Employee Retirement Income Security Act of 1974 to protect consumers in managed care plans and other health coverage.

On page 22, lines 13 and 14, strike “Review of Medical Decisions by Physicians” and insert “Peer Review of Medical Decision by Health Care Professionals”.

On page 22, strike lines 18 through 22, and insert the following: “evaluation of medical decision: “(A) shall be made by a physician (allopathic or osteopathic); or “(B) in a claim for benefits provided by a non-medical professional health care professional, shall be made by reviewer (or reviewers) including at least one practicing non-physician health professional of the same or similar specialty; “with appropriate expertise (including, in the case of a child, appropriate pediatric expertise) and acting within the appropriate scope of practice within the State in which the service is provided or rendered, who was not involved in the initial determination.”.

On page 52, line 4, after “who” insert the following: “, acting within the appropriate scope of practice within the State in which the service is provided or rendered.”.

On page 52, strike lines 7 through 17, and insert the following: “(ii) by a non-physician health care professional, a reviewer (or reviewers) shall include at least one practicing non-physician health care professional of the same or similar specialty as the non-physician health care professional who, acting within the appropriate scope of practice within the State in which the service is provided or rendered, typically treats the condition, makes the diagnosis, or provides the type of treatment under review.”.

On page 93, line 18, insert the following: “, such as a qualified nongovernmental research entity to which the National Cancer Institute has awarded a center support grant.”.

On page 94, line 13, strike “scientific” and insert “ethical”.

On page 100, line 13, strike “104(b)(3)(C)” and insert “104(d)(3)(C)”.

On page 142, line 1, strike “person” and insert “plan, plan sponsor or issuer”.

On page 154, line 11, strike “(5)” and insert “(9)”.

On page 174, line 5, strike “determined without regard to” and insert “excluding”.

On page 174, line 8, strike the period and insert a semicolon.

On page 174, line 9, strike “For” and insert “but shall apply not later than 1 year after the general effective date for “. “
SEC. 304. SENSE OF THE SENATE CONCERNING
the following:

such amounts as the number of individuals
appropriated under subsection (b) for a fiscal year,

At the end of subsection A of title I, insert the following:

(a) Grants.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall establish a fund, to be known as the "Health Care Consumer Assistance Fund", to be used to award grants to eligible States to carry out consumer assistance activities (including programs established by States prior to the enactment of this Act) designed to provide information, assistance, and referrals to consumer assistance products.

(2) STATE ELIGIBILITY.—To be eligible to receive a grant under this subsection a State shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a plan that describes:

(A) the manner in which the State will ensure that the health care consumer assistance office (established under paragraph (4)) will educate and assist health care consumers in obtaining necessary health care;

(B) the manner in which the State will coordinate and distinguish the services provided by the health care consumer assistance office with the services provided by Federal, State, and local health-related ombudsman, information, protection and advocacy, insurance, and fraud and abuse programs;

(C) the manner in which the State will provide information, outreach, and services to underserved, minority populations with limited English proficiency and populations residing in rural areas;

(D) the manner in which the State will oversee the health care consumer assistance office, its activities, product materials and evaluate program effectiveness;

(E) the manner in which the State will ensure that funds made available under this section will be used to supplement, and not supplant, any other Federal, State, or local funds expended to provide services for programs described under this section and those described in subparagraphs (C) and (D); and

(F) the manner in which the State will ensure that health care consumer office personnel have the professional background and training to carry out the activities of the office;

(3) AMOUNT OF GRANT.—

(A) IN GENERAL.—From amounts appropriated under subsection (b) for a fiscal year, the Secretary shall award a grant to a State in an amount that bears the same ratio to such amounts as the number of individuals within the State covered under a group health plan or under health insurance coverage offered by a health insurance issuer bears to the total number of individuals so covered in all States (as determined by the Secretary). Amounts awarded under this subsection that are not used by the State shall be remitted to the Secretary and reallocated in accordance with this subparagraph.

(B) MINIMUM AMOUNT.—In no case shall the amount provided to a State under a grant provided under this subsection for a fiscal year be less than an amount equal to 0.5 percent of the amount appropriated for such fiscal year to carry out this section.

(4) PROVISION OF FUNDS FOR ESTABLISHMENT OF OFFICE.—

(A) IN GENERAL.—From amounts provided under a grant awarded under this subsection, a State shall, directly or through a contract with an independent, nonprofit entity with demonstrated experience in serving the needs of health care consumers, provide for the establishment and operation of a State health care consumer assistance office.

(B) ELIGIBILITY OF ENTITY.—To be eligible to enter into a contract with the Secretary in accordance with paragraph (A), an entity shall demonstrate that it has the technical, organizational, and professional capacity to deliver the services described in subsection (b) to all public and private health insurance participants, beneficiaries, enrollees, or prospective enrollees.

(C) EXISTING STATE ENTITY.—Nothing in this section shall preclude the funding of an existing health care consumer assistance program that otherwise meets the requirements of this section.

(b) USE OF FUNDS.—

(1) BY STATE.—A State shall use amounts provided under a grant awarded under this section to carry out consumer assistance activities directly or by contract with an independent, nonprofit organization. An eligible entity may use any reasonable amount of such grant to ensure the adequate training of the personnel carrying out such activities. To the extent that funds received under this subsection, an eligible entity may use or disclose to State agencies, or released or disclosed to State agencies or outside persons or entities without the prior written authorization (in accordance with section 164.508 of title 45, Code of Federal Regulations) of the individual or personal representative of the entity that enters into a contract with the Secretary, any health information that is not used by or disclosed to carry out consumer assistance activities.

(2) AVAILABILITY OF SERVICES.—The health care consumer assistance office of a State shall not discriminate in the provision of information, referrals, and services regardless of the source of the individual's health insurance coverage or prospective coverage, including individuals covered under a group health plan or health insurance coverage offered by a health insurance issuer, the Medicare or Medicaid programs under title XVIII and title XIX of the Social Security Act (42 U.S.C. 1395 and 1396 et seq.), or under any other Federal or State health care program.

(3) DESIGNATION OF RESPONSIBILITIES.—

(A) WITHIN EXISTING STATE ENTITY.—If the health care consumer assistance office of a State is located within an existing State regulatory agency or office of an elected State official, the State shall ensure that—

(i) there is a separate delineation of the funding, activities, and responsibilities of the office as compared to the other funding, activities, and responsibilities of the agency; and

(ii) the office establishes and implements procedures and protocols to ensure the confidentiality of all information shared by a participant, beneficiary, enrollee, or their personal representative and their health care providers, group health plans, or health insurance issuers with the office, and to ensure that no such information is used by the office, or released or disclosed to State agencies or outside persons or entities without the prior written authorization (in accordance with section 164.508 of title 45, Code of Federal Regulations) of the individual or personal representative of the entity that enters into a contract with the Secretary.

(B) CONTRACT ENTITY.—In the case of an entity that enters into a contract with a State, the contract shall provide that the entity will provide assurances that the entity has no conflict of interest in carrying out the activities of the office and that the entity is independent of group health care providers, group health insurance issuers, providers, payers, and regulators of health care.
NOTICES OF HEARINGS

COMMITTEE ON ENERGY AND NATURAL RESOURCES

Mr. BINGAMAN. Mr. President, I would like to announce for the information of the Senate and the public that the Committee on Energy and Natural Resources has scheduled a hearing to receive testimony on S. 1006, the Renewable Fuels for Energy Security Act of 2001.

The hearing, chaired by Senator Tim Johnson, will take place on Friday, July 6, at 9:30 a.m., at the Minnehaha County Administration Building, 415 N. Dakota Avenue, 2nd Floor, County Commission Meeting Room, Sioux Falls, SD.

Those wishing to submit written statements on the legislation should address them to the Committee on Energy and Natural Resources, Attn: Shirley Neff, U.S. Senate, Washington, DC 20510.

For further information, please call Shirley Neff at 202-224-6689.

COMMITTEE ON ENERGY AND NATURAL RESOURCES

Mr. BINGAMAN. Mr. President, I would like to announce for the information of the Senate and the public that the Committee on Energy and Natural Resources has scheduled a hearing to receive testimony on legislative proposals related to energy efficiency, including S. 352, the Energy Emergency Response Act of 2001; title XIII of S. 597, the Comprehensive and Balanced Energy Policy Act of 2001; sections 602–606 of S. 388, the National Energy Security Act of 2001; S. 95, the Federal Energy Bank Act; S.J. Res. 15, providing for congressional disapproval of the rule submitted by the Department of Energy relating to the postponement of the effective date of energy conservation standards for central air conditioners.

The hearing will take place on Friday, July 13, at 9:30 a.m. in room 366 of the Dirksen Senate Office Building.

Those wishing to submit written statements on the legislation should address them to the Committee on Energy and Natural Resources, Attn: Deborah Estes, U.S. Senate, Washington, DC 20510.

For further information, please call Deborah Estes at 202-224-5360.

COMMITTEE ON ENERGY AND NATURAL RESOURCES

Mr. BINGAMAN. Mr. President, I would like to announce for the information of the Senate and the public that the Committee on Energy and Natural Resources has scheduled a hearing to receive testimony on legislative proposals related to energy efficiency, including S. 352, the Energy Emergency Response Act of 2001; title XIII of S. 597, the Comprehensive and Balanced Energy Policy Act of 2001; sections 602–606 of S. 388, the National Energy Security Act of 2001; S. 95, the Federal Energy Bank Act; S.J. Res. 15, providing for congressional disapproval of the rule submitted by the Department of Energy relating to the postponement of the effective date of energy conservation standards for central air conditioners.

The hearing will take place on Thursday, July 12, at 9:30 a.m., in room 366 of the Dirksen Senate Office Building.

Those wishing to submit written statements on the legislation should address them to the Committee on Energy and Natural Resources, Attn: Shirley Neff, U.S. Senate, Washington, DC 20510.

For further information, please call Shirley Neff at 202-224-6689.