China have now sent the wrong message, and one that could be destabilizing both to Taiwan and to the entire Asian theater.

I think the United States should pursue our own ''three-no's'' policy on the question of Taiwan, and they are: We will not accept any nonpeaceful resolution of the Taiwan question; we will not force Taiwan to the table with China, nor will we be an intermediary in resolving this dispute; and we will not turn our backs on democracy and the right of the Taiwanese people, or any people, to live according to free democratic principles.

So finally, Mr. President, well in advance of President Clinton's trip to China, I and a number of colleagues in the Senate sent a letter to the President urging him to press the Chinese Government on renouncing the threat of the use of force against Taiwan.

I ask unanimous consent that a copy of this letter be printed in the CONGRESSIONAL RECORD following my remarks.

The PRESIDING OFFICER. Without objection, it is so ordered.

(See Exhibit 2.)

Mr. MURKOWSKI. I, again, call on the President to insist that the Chinese Government renounce the threat of the use of force against Taiwan and take great effort to clarify that our position in support of Taiwan and our commitment to Taiwan has not changed.

Mr. President, I yield the floor, and I thank the floor manager, Senator BOND, for the courtesy extended me at this time.

Mr. BOND. Mr. President, I thank the Senator from Alaska.

I ask unanimous consent that I be added as a cosponsor to the resolution.

The PRESIDING OFFICER. Without objection, it is so ordered.

EXHIBIT 1

SIDING WITH THE DICTATORS

The outlines of a deal are beginning to emerge. China gives President Clinton air time for his speech. Mr. Clinton says what China wants to hear on Taiwan. Then, in classic Clinton fashion, the White House tries to have things both ways, denying that U.S. policy has changed when in fact it has, and not for the better.

Past administrations recognized, the Beijing government as the legitimate government of China and ''acknowledged'' China's position with regard to Taiwan. By ''acknowledge'' did not mean ''accept.'' The ultimate fate of Taiwan was something for Taiwan and China to work out, peacefully. Beyond that, the United States deliberately left its policy shrouded in ambiguity.

But recently officials of the Clinton administration have explicitly adopted a ''three no's'' formula much more pleasing to the Communist Chinese: no support for one Taiwan-one China; no support for Taiwan independence; no support for Taiwan membership in international organizations such as the United Nations. Now Mr. Clinton has given that policy a presidential stamp of approval—and on Chinese soil, to boot.

Why does it matter? Because Taiwan's 21 million people have forged a prosperous democracy over the past decades. There is no justification for the United States to oppose their right eventually to determine their own future. It would be fine for U.S. officials to reiterate that such a determination must take place peacefully and to encourage Taiwan-China dialogue. It would be fine for U.S. officials to warn Taiwan not to expect U.S. support for a unilateral declaration of independence. What's not fine is for the United States at this time to rule out independence or any other option the Taiwanese people eventually might choose.

When China threatened Taiwan militarily in 1996, Mr. Clinton responded with admirable resolve. But now he is trading away the human rights of Taiwan's 21 million people and sending an unfortunate signal to other democracies that might hope to rely on U.S. moral support.

As a practical matter, he's also significantly weakening Taiwan's bargaining power if and when Taiwan and China begin negotiations. China's main card always has been the threat of force; Taiwan's has been its campaign to establish sovereignty through membership in world organizations and other means. By explicitly and needlessly slamming the door on that campaign, Mr. Clinton has sided with the dictators against the democrats. To pretend this is no change only heightens the offense.

EXHIBIT 2

UNITED STATES SENATE,
Washington, DC, May 21, 1998.

Hon. WILLIAM J. CLINTON,
The President, The White House,
Washington, DC.

DEAR MR. PRESIDENT: As you prepare for your summit with the leaders of the People's Republic of China in Beijing, we thought it appropriate to share with you our thoughts regarding U.S. relations with the people and the government of Taiwan. We believe Taiwan has made extraordinary progress in recent years as the Republic of China has moved to establish a vibrant democracy with free elections, free press, and improved trading practices.

We believe the American people are united in their support for freedom and democracy in Taiwan. Time and again, Congress has made clear our commitment to Taiwan, beginning with the 1979 Taiwan Relations Act, and through many resolutions and bills since then.

Although we do not know what will be on the summit agenda, we do know that the PRC is often eager to try and persuade the United States to compromise our support for Taiwan and its democracy. Mr. President, we urge you to oppose any efforts at the summit by the PRC leadership to diminish American support for Taiwan. We believe it is important for the United States to make clear at the summit that while the U.S. supports a peaceful dialogue between Taipei and Beijing, the U.S. has committed not to pressure Taiwan on this issue and to not play any mediation role. You should reiterate statements made recently by members of your administration calling on the PRC to renounce the use of force or the threat of force against Taiwan.

Further, we urge you to reject any plans for a ''Fourth Communique'' on issues related to Taiwan; to not weaken our defensive arms sales commitment to Taiwan (either by agreeing to set an end date or by agreeing to hold prior consultations with the PRC); to not make any commitment to limit future visits by the elected representatives of the Republic of China; to not agree to revise the Taiwan Relations Act; and to not alter the U.S. position regarding sovereignty over Taiwan.

We in Congress are prepared to reiterate the commitment of the American people to freedom and democracy for the people and government of Taiwan. We look forward to your reassurance on these issues in advance of the summit.

Sincerely,

FRANK H. MURKOWSKI.
ROBERT G. TORRICELLI.
TRENT LOTT.
JESSE HELMS.

ALFONSE D'AMATO.
TIM JOHNSON.
TOM DASCHLE.
CRAIG THOMAS.
CHUCK HAGEL.
LARRY E. CRAIG.
CONNIE MACK.

AMENDMENTS SUBMITTED

PRODUCT LIABILITY REFORM ACT OF 1998

FEINGOLD AMENDMENT NO. 3061

(Ordered to lie on the table.)

Mr. FEINGOLD submitted an amendment intended to be proposed by him to the bill (S. 648) to establish legal standards and procedures for product liability litigation, and for other purposes; as follows:

After section 302, add the following:

TITLE IV—EQUAL ACCESS TO JUSTICE REFORM

SEC. 401. EQUAL ACCESS TO JUSTICE REFORM.

(a) SHORT TITLE.—This title may be cited as the ''Equal Access to Justice Reform Amendments of 1998''.

(b) AWARD OF COSTS AND FEES.—

(1) ADMINISTRATIVE PROCEEDINGS.—Section 504(a)(2) of title 5, United States Code, is amended by inserting after ''(2)'' the following: ''At any time after the commencement of an adversary adjudication covered by this section, the adjudicative officer may ask a party to declare whether such party intends to seek an award of fees and expenses against the agency should such party prevail.''.

(2) JUDICIAL PROCEEDINGS.—Section 2412(d)(1)(B) of title 28, United States Code, is amended by inserting after ''(B)'' the following: ''At any time after the commencement of an adversary adjudication covered by this section, the court may ask a party to declare whether such party intends to seek an award of fees and expenses against the agency should such party prevail.''.

(c) HOURLY RATE FOR ATTORNEY FEES.—

(1) ADMINISTRATIVE PROCEEDINGS.—Section 504(b)(1)(A)(ii) of title 5, United States Code, is amended by striking all beginning with ''$125 per hour'' and inserting ''$125 per hour unless the agency determines by regulation that an increase in the cost-of-living based on the date of final disposition justifies a higher fee);''.

(2) JUDICIAL PROCEEDINGS.—Section 2412(d)(2)(A)(ii) of title 28, United States Code, is amended by striking all beginning with ''$125 per hour'' and inserting ''$125 per hour unless the court determines that an increase in the cost-of-living based on the date of final disposition justifies a higher fee);''.

(d) PAYMENT FROM AGENCY APPROPRIATIONS.—

(1) ADMINISTRATIVE PROCEEDINGS.—Section 504(d) of title 5, United States Code, is amended by adding at the end the following: ''Fees and expenses awarded under this subsection may not be paid from the claims and judgments account of the Treasury from funds appropriated pursuant to section 1304 of title 31.''.

(2) JUDICIAL PROCEEDINGS.—Section 2412(d)(4) of title 28, United States Code, is amended by adding at the end the following: ''Fees and expenses awarded under this subsection may not be paid from the claims and judgments account of the Treasury from funds appropriated pursuant to section 1304 of title 31.''.

(e) OFFERS OF SETTLEMENT.—

(1) ADMINISTRATIVE PROCEEDINGS.—Section 504 of title 5, United States Code, is amended—

(A) by redesignating subsections (e) and (f) as subsections (f) and (g), respectively; and

(B) by inserting after subsection (d) the following new subsection:

''(e)(1) At any time after the filing of an application for fees and other expenses under this section, an agency from which a fee award is sought may serve upon the applicant an offer of settlement of the claims made in the application. If within 10 days after service of the offer the applicant serves written notice that the offer is accepted, either party may then file the offer and notice of acceptance together with proof of service thereof.

''(2) An offer not accepted shall be deemed withdrawn. The fact that an offer is made but not accepted shall not preclude a subsequent offer. If any award of fees and expenses for the merits of the proceeding finally obtained by the applicant is not more favorable than the offer, the applicant shall not be entitled to receive an award for attorneys' fees or other expenses incurred in relation to the application for fees and expenses after the date of the offer.''.

(2) JUDICIAL PROCEEDINGS.—Section 2412 of title 28, United States Code, is amended—

(A) by redesignating subsections (e) and (f) as subsections (f) and (g), respectively; and

(B) by inserting after subsection (d) the following new subsection:

''(e)(1) At any time after the filing of an application for fees and other expenses under this section, an agency of the United States from which a fee award is sought may serve upon the applicant an offer of settlement of the claims made in the application. If within 10 days after service of the offer the applicant serves written notice that the offer is accepted, either party may then file the offer and notice of acceptance together with proof of service thereof.

''(2) An offer not accepted shall be deemed withdrawn. The fact that an offer is made but not accepted shall not preclude a subsequent offer. If any award of fees and expenses for the merits of the proceeding finally obtained by the applicant is not more favorable than the offer, the applicant shall not be entitled to receive an award for attorneys' fees or other expenses incurred in relation to the application for fees and expenses after the date of the offer.''.

(f) ELIMINATION OF SUBSTANTIAL JUSTIFICATION STANDARD.—

(1) ADMINISTRATIVE PROCEEDINGS.—Section 504 of title 5, United States Code, is amended—

(A) in subsection (a)(1), by striking all beginning with '', unless the adjudicative officer'' through ''expenses are sought''; and

(B) in subsection (a)(2), by striking ''The party shall also allege that the position of the agency was not substantially justified.''.

(2) JUDICIAL PROCEEDINGS.—Section 2412(d) of title 28, United States Code, is amended—

(A) in paragraph (1)(A), by striking '', unless the court finds that the position of the United States was substantially justified or that special circumstances make an award unjust'';

(B) in paragraph (1)(B), by striking ''The party shall also allege that the position of the United States was not substantially justified. Whether or not the position of the United States was substantially justified shall be determined on the basis of the record (including the record with respect to the action or failure to act by the agency upon which the civil action is based) which is made in the civil action for which fees and other expenses are sought.''; and

(C) in paragraph (3), by striking '', unless the court finds that during such adversary adjudication the position of the United States was substantially justified, or that special circumstances make an award unjust''.

(g) REPORTS TO CONGRESS.—

(1) ADMINISTRATIVE PROCEEDINGS.—No later than 180 days after the date of the enactment of this Act, the Administrative Conference of the United States shall submit a report to Congress—

(A) providing an analysis of the variations in the frequency of fee awards paid by specific Federal agencies under the provisions of section 504 of title 5, United States Code; and

(B) including recommendations for extending the application of such sections to other Federal agencies and administrative proceedings.

(2) JUDICIAL PROCEEDINGS.—No later than 180 days after the date of the enactment of this Act, the Department of Justice shall submit a report to Congress—

(A) providing an analysis of the variations in the frequency of fee awards paid by specific Federal districts under the provisions of section 2412 of title 28, United States Code; and

(B) including recommendations for extending the application of such sections to other Federal judicial proceedings.

(h) EFFECTIVE DATE.—The provisions of this title and the amendments made by this title shall take effect 30 days after the date of the enactment of this Act and shall apply only to an administrative complaint filed with a Federal agency or a civil action filed in a United States court on or after such date.

DEPARTMENTS OF VETERANS AFFAIRS AND HOUSING AND URBAN DEVELOPMENT, AND INDEPENDENT AGENCIES APPROPRIATIONS ACT, 1999

BUMPERS (AND OTHERS) AMENDMENT NO. 3062

Mr. BUMPERS (for himself, Mr. BRYAN, Mr. WELLSTONE, Mrs. HUTCHISON, Mr. LEAHY, Mr. KOHL, Mr. WYDEN, Mr. FEINGOLD, Mr. DURBIN, and Mr. HUTCHINSON) proposed an amendment to the bill (S. 2168) making appropriations for the Departments of Veterans Affairs and Housing and Urban Development, and for sundry independent agencies, commissions, corporations, and offices for the fiscal year ending September 30, 1999, and for other purposes; as follows:

Strike line 21 on page 76 through line 4 on page 77 and insert the following:

''For termination of the International Space Station project, $850,000,000. In addition to the other provisions of this Act, $1,000,000,000 shall be available for the Veterans Health Administration Medical Care account and $450,000,000 shall be available for the Housing Certificate Fund account within the Department of Housing and Urban Development's budget.''

DASCHLE AMENDMENT NO. 3063

Mr. DASCHLE proposed an amendment to the bill, S. 2168, supra; as follows:

At the appropriate place, insert the following:

TITLE ___—PATIENTS' BILL OF RIGHTS

SEC. ___001. SHORT TITLE.

This title may be cited as the ''Patients' Bill of Rights Act of 1998''.

Subtitle A—Health Insurance Bill of Rights

CHAPTER 1—ACCESS TO CARE

SEC. ___101. ACCESS TO EMERGENCY CARE.

(a) COVERAGE OF EMERGENCY SERVICES.—

(1) IN GENERAL.—If a group health plan, or health insurance coverage offered by a health insurance issuer, provides any benefits with respect to emergency services (as defined in paragraph (2)(B)), the plan or issuer shall cover emergency services furnished under the plan or coverage—

(A) without the need for any prior authorization determination;

(B) whether or not the health care provider furnishing such services is a participating provider with respect to such services;

(C) in a manner so that, if such services are provided to a participant, beneficiary, or enrollee by a nonparticipating health care provider—

(i) the participant, beneficiary, or enrollee is not liable for amounts that exceed the amounts of liability that would be incurred if the services were provided by a participating health care provider, and

(ii) the plan or issuer pays an amount that is not less than the amount paid to a participating health care provider for the same services; and

(D) without regard to any other term or condition of such coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 2701 of the Public Health Service Act, section 701 of the Employee Retirement Income Security Act of 1974, or section 9801 of the Internal Revenue Code of 1986, and other than applicable cost-sharing).

(2) DEFINITIONS.—In this section:

(A) EMERGENCY MEDICAL CONDITION BASED ON PRUDENT LAYPERSON STANDARD.—The term ''emergency medical condition'' means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

(B) EMERGENCY SERVICES.—The term ''emergency services'' means—

(i) a medical screening examination (as required under section 1867 of the Social Security Act) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate an emergency medical condition (as defined in subparagraph (A)), and

(ii) within the capabilities of the staff and facilities available at the hospital, such further medical examination and treatment as are required under section 1867 of such Act to stabilize the patient.

(b) REIMBURSEMENT FOR MAINTENANCE CARE AND POST-STABILIZATION CARE.—In the case of services (other than emergency services) for which benefits are available under a group health plan, or under health insurance coverage offered by a health insurance issuer, the plan or issuer shall provide for reimbursement with respect to such services provided to a participant, beneficiary, or enrollee other than through a participating

health care provider in a manner consistent with subsection (a)(1)(C) if the services are maintenance care or post-stabilization care covered under the guidelines established under section 1852(d)(2) of the Social Security Act (relating to promoting efficient and timely coordination of appropriate maintenance and post-stabilization care of an enrollee after an enrollee has been determined to be stable), or, in the absence of guidelines under such section, such guidelines as the Secretary shall establish to carry out this subsection.

SEC. ___102. OFFERING OF CHOICE OF COVERAGE OPTIONS UNDER GROUP HEALTH PLANS.

(a) REQUIREMENT.—

(1) OFFERING OF POINT-OF-SERVICE COVERAGE OPTION.—Except as provided in paragraph (2), if a group health plan (or health insurance coverage offered by a health insurance issuer in connection with a group health plan) provides benefits only through participating health care providers, the plan or issuer shall offer the participant the option to purchase point-of-service coverage (as defined in subsection (b)) for all such benefits for which coverage is otherwise so limited. Such option shall be made available to the participant at the time of enrollment under the plan or coverage and at such other times as the plan or issuer offers the participant a choice of coverage options.

(2) EXCEPTION.—Paragraph (1) shall not apply with respect to a participant in a group health plan if the plan offers the participant—

(A) a choice of health insurance coverage through more than one health insurance issuer; or

(B) two or more coverage options that differ significantly with respect to the use of participating health care providers or the networks of such providers that are used.

(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 or health insurance issuer, coverage of such benefits when provided by a nonparticipating health care provider. Such coverage need not include coverage of providers that the plan or issuer excludes because of fraud, quality, or similar reasons.

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

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

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

(3) as preventing a group health plan or health insurance issuer from imposing higher premiums or cost-sharing on a participant for the exercise of a point-of-service coverage option.

(d) NO REQUIREMENT FOR GUARANTEED AVAILABILITY.—If a health insurance issuer offers health insurance coverage that includes point-of-service coverage with respect to an employer solely in order to meet the requirement of subsection (a), nothing in section 2711(a)(1)(A) of the Public Health Service Act shall be construed as requiring the offering of such coverage with respect to another employer.

SEC. ___103. CHOICE OF PROVIDERS.

(a) PRIMARY CARE.—A group health plan, and a health insurance issuer that offers health insurance coverage, shall permit each participant, beneficiary, and enrollee to receive primary care from any participating primary care provider who is available to accept such individual.

(b) SPECIALISTS.—

(1) IN GENERAL.—Subject to paragraph (2), a group health plan and a health insurance issuer that offers health insurance coverage shall permit each participant, beneficiary, or enrollee to receive medically necessary or appropriate specialty care, pursuant to appropriate referral procedures, from any qualified participating health care provider who is available to accept such individual for such care.

(2) LIMITATION.—Paragraph (1) shall not apply to specialty care if the plan or issuer clearly informs participants, beneficiaries, and enrollees of the limitations on choice of participating providers with respect to such care.

SEC. ___104. ACCESS TO SPECIALTY CARE.

(a) OBSTETRICAL AND GYNECOLOGICAL CARE.—

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

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

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

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

(ii) may treat the ordering of other gynecological care by such a participating physician as the authorization of the primary care provider with respect to such care under the plan or coverage.

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

(b) SPECIALTY CARE.—

(1) SPECIALTY CARE FOR COVERED SERVICES.—

(A) IN GENERAL.—If—

(i) an individual is a participant or beneficiary under a group health plan or an enrollee who is covered under health insurance coverage offered by a health insurance issuer,

(ii) the individual has a condition or disease of sufficient seriousness and complexity to require treatment by a specialist, and

(iii) benefits for such treatment are provided under the plan or coverage,

the plan or issuer shall make or provide for a referral to a specialist who is available and accessible to provide the treatment for such condition or disease.

(B) SPECIALIST DEFINED.—For purposes of this subsection, the term ''specialist'' means, with respect to a condition, a health care practitioner, facility, or center (such as a center of excellence) that has adequate expertise through appropriate training and experience (including, in the case of a child, appropriate pediatric expertise) to provide high quality care in treating the condition.

(C) CARE UNDER REFERRAL.—A group health plan or health insurance issuer may require that the care provided to an individual pursuant to such referral under subparagraph (A) be—

(i) pursuant to a treatment plan, only if the treatment plan is developed by the specialist and approved by the plan or issuer, in consultation with the designated primary care provider or specialist and the individual (or the individual's designee), and

(ii) in accordance with applicable quality assurance and utilization review standards of the plan or issuer.

Nothing in this subsection shall be construed as preventing such a treatment plan for an individual from requiring a specialist to provide the primary care provider with regular updates on the specialty care provided, as well as all necessary medical information.

(D) REFERRALS TO PARTICIPATING PROVIDERS.—A group health plan or health insurance issuer is not required under subparagraph (A) to provide for a referral to a specialist that is not a participating provider, unless the plan or issuer does not have an appropriate specialist that is available and accessible to treat the individual's condition and that is a participating provider with respect to such treatment.

(E) TREATMENT OF NONPARTICIPATING PROVIDERS.—If a plan or issuer refers an individual to a nonparticipating specialist pursuant to subparagraph (A), services provided pursuant to the approved treatment plan (if any) shall be provided at no additional cost to the individual beyond what the individual would otherwise pay for services received by such a specialist that is a participating provider.

(2) SPECIALISTS AS PRIMARY CARE PROVIDERS.—

(A) IN GENERAL.—A group health plan, or a health insurance issuer, in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has an ongoing special condition (as defined in subparagraph (C)) may receive a referral to a specialist for such condition who shall be responsible for and capable of providing and coordinating the individual's primary and specialty care. If such an individual's care would most appropriately be coordinated by such a specialist, such plan or issuer shall refer the individual to such specialist.

(B) TREATMENT AS PRIMARY CARE PROVIDER.—Such specialist shall be permitted to treat the individual without a referral from the individual's primary care provider and may authorize such referrals, procedures, tests, and other medical services as the individual's primary care provider would otherwise be permitted to provide or authorize, subject to the terms of the treatment plan (referred to in paragraph (1)(C)(i)).

(C) ONGOING SPECIAL CONDITION DEFINED.—In this paragraph, the term ''special condition'' means a condition or disease that—

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

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

(D) TERMS OF REFERRAL.—The provisions of subparagraphs (C) through (E) of paragraph (1) apply with respect to referrals under subparagraph (A) of this paragraph in the same manner as they apply to referrals under paragraph (1)(A).

(3) STANDING REFERRALS.—

(A) IN GENERAL.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has a condition that requires ongoing care from a specialist may receive a standing referral to such specialist for treatment of such condition. If the plan or issuer, or if the primary care provider in consultation with the medical director of the plan or issuer and the specialist (if any), determines that such a standing referral is appropriate, the plan or issuer shall make such a referral to such a specialist.

(B) TERMS OF REFERRAL.—The provisions of subparagraphs (C) through (E) of paragraph (1) apply with respect to referrals under subparagraph (A) of this paragraph in the same

manner as they apply to referrals under paragraph (1)(A).

SEC. ___105. CONTINUITY OF CARE.

(a) IN GENERAL.—

(1) TERMINATION OF PROVIDER.—If a contract between a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, and a health care provider is terminated (as defined in paragraph (3)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in a group health plan, and an individual who is a participant, beneficiary, or enrollee in the plan or coverage is undergoing a course of treatment from the provider at the time of such termination, the plan or issuer shall—

(A) notify the individual on a timely basis of such termination, and

(B) subject to subsection (c), permit the individual to continue or be covered with respect to the course of treatment with the provider during a transitional period (provided under subsection (b)).

(2) TREATMENT OF TERMINATION OF CONTRACT WITH HEALTH INSURANCE ISSUER.—If a contract for the provision of health insurance coverage between a group health plan and a health insurance issuer is terminated and, as a result of such termination, coverage of services of a health care provider is terminated with respect to an individual, the provisions of paragraph (1) (and the succeeding provisions of this section) shall apply under the plan in the same manner as if there had been a contract between the plan and the provider that had been terminated, but only with respect to benefits that are covered under the plan after the contract termination.

(3) TERMINATION.—In this section, the term ''terminated'' includes, with respect to a contract, the expiration or nonrenewal of the contract, but does not include a termination of the contract by the plan or issuer for failure to meet applicable quality standards or for fraud.

(b) TRANSITIONAL PERIOD.—

(1) IN GENERAL.—Except as provided in paragraphs (2) through (4), the transitional period under this subsection shall extend for at least 90 days from the date of the notice described in subsection (a)(1)(A) of the provider's termination.

(2) INSTITUTIONAL CARE.—The transitional period under this subsection for institutional or inpatient care from a provider shall extend until the discharge or termination of the period of institutionalization and also shall include institutional care provided within a reasonable time of the date of termination of the provider status if the care was scheduled before the date of the announcement of the termination of the provider status under subsection (a)(1)(A) or if the individual on such date was on an established waiting list or otherwise scheduled to have such care.

(3) PREGNANCY.—If—

(A) a participant, beneficiary, or enrollee has entered the second trimester of pregnancy at the time of a provider's termination of participation, and

(B) the provider was treating the pregnancy before date of the termination,

the transitional period under this subsection with respect to provider's treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

(4) TERMINAL ILLNESS.—If—

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

(B) the provider was treating the terminal illness before the date of termination,

the transitional period under this subsection shall extend for the remainder of the individual's life for care directly related to the treatment of the terminal illness.

(c) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan or health insurance issuer may condition coverage of continued treatment by a provider under subsection (a)(1)(B) upon the provider agreeing to the following terms and conditions:

(1) The 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 as payment in full (or, in the case described in subsection (a)(2), at the rates applicable under the replacement plan or issuer after the date of the termination of the contract with the health insurance 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 subsection (a)(1) had not been terminated.

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

(3) The 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) CONSTRUCTION.—Nothing in this section shall be construed to require the coverage of benefits which would not have been covered if the provider involved remained a participating provider.

SEC. ___106. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

(a) COVERAGE.—

(1) IN GENERAL.—If a group health plan, or health insurance issuer that is providing 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)(2);

(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

(C) may not discriminate against the individual on the basis of the enrollee's participation in such trial.

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

(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

(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 who is an enrollee under health insurance coverage, and who meets the following conditions:

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

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

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

(2) Either—

(A) the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

(B) the participant, 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).

(c) PAYMENT.—

(1) IN GENERAL.—Under this section a group health plan or health insurance issuer shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are reasonably expected (as determined by the Secretary) to be paid for by the sponsors of an approved clinical trial.

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

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

(B) a nonparticipating provider, the payment rate shall be at the rate the plan or issuer would normally pay for comparable services under subparagraph (A).

(d) APPROVED CLINICAL TRIAL DEFINED.—

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

(A) The National Institutes of Health.

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

(C) Either of the following if the conditions described in paragraph (2) are met:

(i) The Department of Veterans Affairs.

(ii) The Department of Defense.

(2) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

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

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

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

SEC. ___107. ACCESS TO NEEDED PRESCRIPTION DRUGS.

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

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

(2) disclose to providers and, disclose upon request under section ___121(c)(6) to participants, beneficiaries, and enrollees, the nature of the formulary restrictions; and

(3) consistent with the standards for a utilization review program under section

___115, provide for exceptions from the formulary limitation when a non-formulary alternative is medically indicated.

(b) COVERAGE OF APPROVED DRUGS AND MEDICAL DEVICES.—

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

(A) in the case of a prescription drug—

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

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

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

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

SEC. ___108. ADEQUACY OF PROVIDER NETWORK.

(a) IN GENERAL.—Each group health plan, and each health insurance issuer offering health insurance coverage, that provides benefits, in whole or in part, through participating health care providers shall have (in relation to the coverage) a sufficient number, distribution, and variety of qualified participating health care providers to ensure that all covered health care services, including specialty services, will be available and accessible in a timely manner to all participants, beneficiaries, and enrollees under the plan or coverage.

(b) TREATMENT OF CERTAIN PROVIDERS.—The qualified health care providers under subsection (a) may include Federally qualified health centers, rural health clinics, migrant health centers, and other essential community providers located in the service area of the plan or issuer and shall include such providers if necessary to meet the standards established to carry out such subsection.

SEC. ___109. NONDISCRIMINATION IN DELIVERY OF SERVICES.

(a) APPLICATION TO DELIVERY OF SERVICES.—Subject to subsection (b), a group health plan, and health insurance issuer in relation to health insurance coverage, may not discriminate against a participant, beneficiary, or enrollee in the delivery of health care services consistent with the benefits covered under the plan or coverage or as required by law based on race, color, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.

(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed as relating to the eligibility to be covered, or the offering (or guaranteeing the offer) of coverage, under a plan or health insurance coverage, the application of any pre-existing condition exclusion consistent with applicable law, or premiums charged under such plan or coverage.

CHAPTER 2—QUALITY ASSURANCE

SEC. ___111. INTERNAL QUALITY ASSURANCE PROGRAM.

(a) REQUIREMENT.—A group health plan, and a health insurance issuer that offers health insurance coverage, shall establish and maintain an ongoing, internal quality assurance and continuous quality improvement program that meets the requirements of subsection (b).

(b) PROGRAM REQUIREMENTS.—The requirements of this subsection for a quality improvement program of a plan or issuer are as follows:

(1) ADMINISTRATION.—The plan or issuer has a separate identifiable unit with responsibility for administration of the program.

(2) WRITTEN PLAN.—The plan or issuer has a written plan for the program that is updated annually and that specifies at least the following:

(A) The activities to be conducted.

(B) The organizational structure.

(C) The duties of the medical director.

(D) Criteria and procedures for the assessment of quality.

(3) SYSTEMATIC REVIEW.—The program provides for systematic review of the type of health services provided, consistency of services provided with good medical practice, and patient outcomes.

(4) QUALITY CRITERIA.—The program—

(A) uses criteria that are based on performance and patient outcomes where feasible and appropriate;

(B) includes criteria that are directed specifically at meeting the needs of at-risk populations and covered individuals with chronic conditions or severe illnesses, including gender-specific criteria and pediatric-specific criteria where available and appropriate;

(C) includes methods for informing covered individuals of the benefit of preventive care and what specific benefits with respect to preventive care are covered under the plan or coverage; and

(D) makes available to the public a description of the criteria used under subparagraph (A).

(5) SYSTEM FOR REPORTING.—The program has procedures for reporting of possible quality concerns by providers and enrollees and for remedial actions to correct quality problems, including written procedures for responding to concerns and taking appropriate corrective action.

(6) DATA ANALYSIS.—The program provides, using data that include the data collected under section ___112, for an analysis of the plan's or issuer's performance on quality measures.

(7) DRUG UTILIZATION REVIEW.—The program provides for a drug utilization review program in accordance with section ___114.

(c) DEEMING.—For purposes of subsection (a), the requirements of—

(1) subsection (b) (other than paragraph (5)) are deemed to be met with respect to a health insurance issuer that is a qualified health maintenance organization (as defined in section 1310(c) of the Public Health Service Act); or

(2) subsection (b) are deemed to be met with respect to a health insurance issuer that is accredited by a national accreditation organization that the Secretary certifies as applying, as a condition of certification, standards at least as stringent as those required for a quality improvement program under subsection (b).

(d) VARIATION PERMITTED.—The Secretary may provide for variations in the application of the requirements of this section to group health plans and health insurance issuers based upon differences in the delivery system among such plans and issuers as the Secretary deems appropriate.

SEC. ___112. COLLECTION OF STANDARDIZED DATA.

(a) IN GENERAL.—A group health plan and a health insurance issuer that offers health insurance coverage shall collect uniform quality data that include a minimum uniform data set described in subsection (b).

(b) MINIMUM UNIFORM DATA SET.—The Secretary shall specify (and may from time to time update) the data required to be included in the minimum uniform data set under subsection (a) and the standard format for such data. Such data shall include at least—

(1) aggregate utilization data;

(2) data on the demographic characteristics of participants, beneficiaries, and enrollees;

(3) data on disease-specific and age-specific mortality rates and (to the extent feasible) morbidity rates of such individuals;

(4) data on satisfaction of such individuals, including data on voluntary disenrollment and grievances; and

(5) data on quality indicators and health outcomes, including, to the extent feasible and appropriate, data on pediatric cases and on a gender-specific basis.

(c) AVAILABILITY.—A summary of the data collected under subsection (a) shall be disclosed under section ___121(b)(9). The Secretary shall be provided access to all the data so collected.

(d) VARIATION PERMITTED.—The Secretary may provide for variations in the application of the requirements of this section to group health plans and health insurance issuers based upon differences in the delivery system among such plans and issuers as the Secretary deems appropriate.

SEC. ___113. PROCESS FOR SELECTION OF PROVIDERS.

(a) IN GENERAL.—A group health plan and a health insurance issuer that offers health insurance coverage shall, if it provides benefits through participating health care professionals, have a written process for the selection of participating health care professionals, including minimum professional requirements.

(b) VERIFICATION OF BACKGROUND.—Such process shall include verification of a health care provider's license and a history of suspension or revocation.

(c) RESTRICTION.—Such process shall not use a high-risk patient base or location of a provider in an area with residents with poorer health status as a basis for excluding providers from participation.

(d) NONDISCRIMINATION BASED ON LICENSURE.—

(1) IN GENERAL.—Such process shall not discriminate with respect to participation or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of such license or certification.

(2) CONSTRUCTION.—Paragraph (1) shall not be construed—

(A) as requiring the coverage under a plan or coverage of particular benefits or services 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 or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan or issuer; or

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

(e) GENERAL NONDISCRIMINATION.—

(1) IN GENERAL.—Subject to paragraph (2), such process shall not discriminate with respect to selection of a health care professional to be a participating health care provider, or with respect to the terms and conditions of such participation, based on the

professional's race, color, religion, sex, national origin, age, sexual orientation, or disability (consistent with the Americans with Disabilities Act of 1990).

(2) RULES.—The appropriate Secretary may establish such definitions, rules, and exceptions as may be appropriate to carry out paragraph (1), taking into account comparable definitions, rules, and exceptions in effect under employment-based nondiscrimination laws and regulations that relate to each of the particular bases for discrimination described in such paragraph.

SEC. ___114. DRUG UTILIZATION PROGRAM.

A group health plan, and a health insurance issuer that provides health insurance coverage, that includes benefits for prescription drugs shall establish and maintain, as part of its internal quality assurance and continuous quality improvement program under section ___111, a drug utilization program which—

(1) encourages appropriate use of prescription drugs by participants, beneficiaries, and enrollees and providers, and

(2) takes appropriate action to reduce the incidence of improper drug use and adverse drug reactions and interactions.

SEC. ___115. STANDARDS FOR UTILIZATION REVIEW ACTIVITIES.

(a) COMPLIANCE WITH REQUIREMENTS.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer that provides health insurance coverage, shall conduct utilization review activities in connection with the provision of benefits under such plan or coverage only in accordance with a utilization review program that meets the requirements of this section.

(2) USE OF OUTSIDE AGENTS.—Nothing in this section shall be construed as preventing a group health plan or health insurance issuer from arranging through a contract or otherwise for persons or entities to conduct utilization review activities on behalf of the plan or issuer, so long as such activities are conducted in accordance with a utilization review program that meets the requirements of this section.

(3) UTILIZATION REVIEW DEFINED.—For purposes of this section, the terms ''utilization review'' and ''utilization review activities'' mean procedures used to monitor or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of health care services, procedures or settings, and includes prospective review, concurrent review, second opinions, case management, discharge planning, or retrospective review.

(b) WRITTEN POLICIES AND CRITERIA.—

(1) WRITTEN POLICIES.—A utilization review program shall be conducted consistent with written policies and procedures that govern all aspects of the program.

(2) USE OF WRITTEN CRITERIA.—

(A) IN GENERAL.—Such a program shall utilize written clinical review criteria developed pursuant to the program with the input of appropriate physicians. Such criteria shall include written clinical review criteria described in section ___111(b)(4)(B).

(B) CONTINUING USE OF STANDARDS IN RETROSPECTIVE REVIEW.—If a health care service has been specifically pre-authorized or approved for an enrollee under such a program, the program shall not, pursuant to retrospective review, revise or modify the specific standards, criteria, or procedures used for the utilization review for procedures, treatment, and services delivered to the enrollee during the same course of treatment.

(c) CONDUCT OF PROGRAM ACTIVITIES.—

(1) ADMINISTRATION BY HEALTH CARE PROFESSIONALS.—A utilization review program shall be administered by qualified health care professionals who shall oversee review decisions. In this subsection, the term ''health care professional'' means a physician or other health care practitioner licensed, accredited, or certified to perform specified health services consistent with State law.

(2) USE OF QUALIFIED, INDEPENDENT PERSONNEL.—

(A) IN GENERAL.—A utilization review program shall provide for the conduct of utilization review activities only through personnel who are qualified and, to the extent required, who have received appropriate training in the conduct of such activities under the program.

(B) PEER REVIEW OF SAMPLE OF ADVERSE CLINICAL DETERMINATIONS.—Such a program shall provide that clinical peers (as defined in section ___191(c)(2)) shall evaluate the clinical appropriateness of at least a sample of adverse clinical determinations.

(C) PROHIBITION OF CONTINGENT COMPENSATION ARRANGEMENTS.—Such a program shall not, with respect to utilization review activities, permit or provide compensation or anything of value to its employees, agents, or contractors in a manner that—

(i) provides incentives, direct or indirect, for such persons to make inappropriate review decisions, or

(ii) is based, directly or indirectly, on the quantity or type of adverse determinations rendered.

(D) PROHIBITION OF CONFLICTS.—Such a program shall not permit a health care professional who provides health care services to an individual to perform utilization review activities in connection with the health care services being provided to the individual.

(3) ACCESSIBILITY OF REVIEW.—Such a program shall provide that appropriate personnel performing utilization review activities under the program are reasonably accessible by toll-free telephone during normal business hours to discuss patient care and allow response to telephone requests, and that appropriate provision is made to receive and respond promptly to calls received during other hours.

(4) LIMITS ON FREQUENCY.—Such a program shall not provide for the performance of utilization review activities with respect to a class of services furnished to an individual more frequently than is reasonably required to assess whether the services under review are medically necessary or appropriate.

(5) LIMITATION ON INFORMATION REQUESTS.—Under such a program, information shall be required to be provided by health care providers only to the extent it is necessary to perform the utilization review activity involved.

(d) DEADLINE FOR DETERMINATIONS.—

(1) PRIOR AUTHORIZATION SERVICES.—Except as provided in paragraph (2), in the case of a utilization review activity involving the prior authorization of health care items and services for an individual, the utilization review program shall make a determination concerning such authorization, and provide notice of the determination to the individual or the individual's designee and the individual's health care provider by telephone and in printed form, as soon as possible in accordance with the medical exigencies of the cases, and in no event later than 3 business days after the date of receipt of information that is reasonably necessary to make such determination.

(2) CONTINUED CARE.—In the case of a utilization review activity involving authorization for continued or extended health care services for an individual, or additional services for an individual undergoing a course of continued treatment prescribed by a health care provider, the utilization review program shall make a determination concerning such authorization, and provide notice of the determination to the individual or the individual's designee and the individual's health care provider by telephone and in printed form, as soon as possible in accordance with the medical exigencies of the cases, and in no event later than 1 business day after the date of receipt of information that is reasonably necessary to make such determination. Such notice shall include, with respect to continued or extended health care services, the number of extended services approved, the new total of approved services, the date of onset of services, and the next review date, if any.

(3) PREVIOUSLY PROVIDED SERVICES.—In the case of a utilization review activity involving retrospective review of health care services previously provided for an individual, the utilization review program shall make a determination concerning such services, and provide notice of the determination to the individual or the individual's designee and the individual's health care provider by telephone and in printed form, within 30 days of the date of receipt of information that is reasonably necessary to make such determination.

(4) REFERENCE TO SPECIAL RULES FOR EMERGENCY SERVICES, MAINTENANCE CARE, AND POST-STABILIZATION CARE.—For waiver of prior authorization requirements in certain cases involving emergency services and maintenance care and post-stabilization care, see subsections (a)(1) and (b) of section ___101, respectively.

(e) NOTICE OF ADVERSE DETERMINATIONS.—

(1) IN GENERAL.—Notice of an adverse determination under a utilization review program shall be provided in printed form and shall include—

(A) the reasons for the determination (including the clinical rationale);

(B) instructions on how to initiate an appeal under section ___132; and

(C) notice of the availability, upon request of the individual (or the individual's designee) of the clinical review criteria relied upon to make such determination.

(2) SPECIFICATION OF ANY ADDITIONAL INFORMATION.—Such a notice shall also specify what (if any) additional necessary information must be provided to, or obtained by, the person making the determination in order to make a decision on such an appeal.

SEC. ___116. HEALTH CARE QUALITY ADVISORY BOARD.

(a) ESTABLISHMENT.—The President shall establish an advisory board to provide information to Congress and the administration on issues relating to quality monitoring and improvement in the health care provided under group health plans and health insurance coverage.

(b) NUMBER AND APPOINTMENT.—The advisory board shall be composed of the Secretary of Health and Human Services (or the Secretary's designee), the Secretary of Labor (or the Secretary's designee), and 20 additional members appointed by the President, in consultation with the Majority and Minority Leaders of the Senate and House of Representatives. The members so appointed shall include individuals with expertise in—

(1) consumer needs;

(2) education and training of health professionals;

(3) health care services;

(4) health plan management;

(5) health care accreditation, quality assurance, improvement, measurement, and oversight;

(6) medical practice, including practicing physicians;

(7) prevention and public health; and

(8) public and private group purchasing for small and large employers or groups.

(c) DUTIES.—The advisory board shall—

(1) identify, update, and disseminate measures of health care quality for group health

plans and health insurance issuers, including network and non-network plans;

(2) advise the Secretary on the development and maintenance of the minimum data set in section ___112(b); and

(3) advise the Secretary on standardized formats for information on group health plans and health insurance coverage.

The measures identified under paragraph (1) may be used on a voluntary basis by such plans and issuers. In carrying out paragraph (1), the advisory board shall consult and cooperate with national health care standard setting bodies which define quality indicators, the Agency for Health Care Policy and Research, the Institute of Medicine, and other public and private entities that have expertise in health care quality.

(d) REPORT.—The advisory board shall provide an annual report to Congress and the President on the quality of the health care in the United States and national and regional trends in health care quality. Such report shall include a description of determinants of health care quality and measurements of practice and quality variability within the United States.

(e) SECRETARIAL CONSULTATION.—In serving on the advisory board, the Secretaries of Health and Human Services and Labor (or their designees) shall consult with the Secretaries responsible for other Federal health insurance and health care programs.

(f) VACANCIES.—Any vacancy on the board shall be filled in such manner as the original appointment. Members of the board shall serve without compensation but shall be reimbursed for travel, subsistence, and other necessary expenses incurred by them in the performance of their duties. Administrative support, scientific support, and technical assistance for the advisory board shall be provided by the Secretary of Health and Human Services.

(g) CONTINUATION.—Section 14(a)(2)(B) of the Federal Advisory Committee Act (5 U.S.C. App.; relating to the termination of advisory committees) shall not apply to the advisory board.

CHAPTER 3—Patient Information

SEC. ___121. PATIENT INFORMATION.

(a) DISCLOSURE REQUIREMENT.—

(1) GROUP HEALTH PLANS.—A group health plan shall—

(A) provide to participants and beneficiaries at the time of initial coverage under the plan (or the effective date of this section, in the case of individuals who are participants or beneficiaries as of such date), and at least annually thereafter, the information described in subsection (b) in printed form;

(B) provide to participants and beneficiaries, within a reasonable period (as specified by the appropriate Secretary) before or after the date of significant changes in the information described in subsection (b), information in printed form on such significant changes; and

(C) upon request, make available to participants and beneficiaries, the applicable authority, and prospective participants and beneficiaries, the information described in subsection (b) or (c) in printed form.

(2) HEALTH INSURANCE ISSUERS.—A health insurance issuer in connection with the provision of health insurance coverage shall—

(A) provide to individuals enrolled under such coverage at the time of enrollment, and at least annually thereafter, the information described in subsection (b) in printed form;

(B) provide to enrollees, within a reasonable period (as specified by the appropriate Secretary) before or after the date of significant changes in the information described in subsection (b), information in printed form on such significant changes; and

(C) upon request, make available to the applicable authority, to individuals who are prospective enrollees, and to the public the information described in subsection (b) or (c) in printed form.

(b) INFORMATION PROVIDED.—The information described in this subsection with respect to a group health plan or health insurance coverage offered by a health insurance issuer includes the following:

(1) SERVICE AREA.—The service area of the plan or issuer.

(2) BENEFITS.—Benefits offered under the plan or coverage, including—

(A) covered benefits, including benefit limits and coverage exclusions;

(B) cost sharing, such as deductibles, coinsurance, and copayment amounts, including any liability for balance billing, any maximum limitations on out of pocket expenses, and the maximum out of pocket costs for services that are provided by non participating providers or that are furnished without meeting the applicable utilization review requirements;

(C) the extent to which benefits may be obtained from nonparticipating providers;

(D) the extent to which a participant, beneficiary, or enrollee may select from among participating providers and the types of providers participating in the plan or issuer network;

(E) process for determining experimental coverage; and

(F) use of a prescription drug formulary.

(3) ACCESS.—A description of the following:

(A) The number, mix, and distribution of providers under the plan or coverage.

(B) Out-of-network coverage (if any) provided by the plan or coverage.

(C) Any point-of-service option (including any supplemental premium or cost-sharing for such option).

(D) The procedures for participants, beneficiaries, and enrollees to select, access, and change participating primary and specialty providers.

(E) The rights and procedures for obtaining referrals (including standing referrals) to participating and nonparticipating providers.

(F) The name, address, and telephone number of participating health care providers and an indication of whether each such provider is available to accept new patients.

(G) Any limitations imposed on the selection of qualifying participating health care providers, including any limitations imposed under section ___103(b)(2).

(H) How the plan or issuer addresses the needs of participants, beneficiaries, and enrollees and others who do not speak English or who have other special communications needs in accessing providers under the plan or coverage, including the provision of information described in this subsection and subsection (c) to such individuals and including the provision of information in a language other than English if 5 percent of the number of participants, beneficiaries, and enrollees communicate in that language instead of English.

(4) OUT-OF-AREA COVERAGE.—Out-of-area coverage provided by the plan or issuer.

(5) EMERGENCY COVERAGE.—Coverage of emergency services, including—

(A) the appropriate use of emergency services, including use of the 911 telephone system or its local equivalent in emergency situations and an explanation of what constitutes an emergency situation;

(B) the process and procedures of the plan or issuer for obtaining emergency services; and

(C) the locations of (i) emergency departments, and (ii) other settings, in which plan physicians and hospitals provide emergency services and post-stabilization care.

(6) PERCENTAGE OF PREMIUMS USED FOR BENEFITS (LOSS-RATIOS).—In the case of health insurance coverage only (and not with respect to group health plans that do not provide coverage through health insurance coverage), a description of the overall loss-ratio for the coverage (as defined in accordance with rules established or recognized by the Secretary of Health and Human Services).

(7) PRIOR AUTHORIZATION RULES.—Rules regarding prior authorization or other review requirements that could result in noncoverage or nonpayment.

(8) GRIEVANCE AND APPEALS PROCEDURES.—All appeal or grievance rights and procedures under the plan or coverage, including the method for filing grievances and the time frames and circumstances for acting on grievances and appeals, who is the applicable authority with respect to the plan or issuer, and the availability of assistance through an ombudsman to individuals in relation to group health plans and health insurance coverage.

(9) QUALITY ASSURANCE.—A summary description of the data on quality collected under section ___112(a), including a summary description of the data on satisfaction of participants, beneficiaries, and enrollees (including data on individual voluntary disenrollment and grievances and appeals) described in section ___112(b)(4).

(10) SUMMARY OF PROVIDER FINANCIAL INCENTIVES.—A summary description of the information on the types of financial payment incentives (described in section 1852(j)(4) of the Social Security Act) provided by the plan or issuer under the coverage.

(11) INFORMATION ON ISSUER.—Notice of appropriate mailing addresses and telephone numbers to be used by participants, beneficiaries, and enrollees in seeking information or authorization for treatment.

(12) AVAILABILITY OF INFORMATION ON REQUEST.—Notice that the information described in subsection (c) is available upon request.

(c) INFORMATION MADE AVAILABLE UPON REQUEST.—The information described in this subsection is the following:

(1) UTILIZATION REVIEW ACTIVITIES.—A description of procedures used and requirements (including circumstances, time frames, and appeal rights) under any utilization review program under section ___115, including under any drug formulary program under section ___107.

(2) GRIEVANCE AND APPEALS INFORMATION.—Information on the number of grievances and appeals and on the disposition in the aggregate of such matters.

(3) METHOD OF PHYSICIAN COMPENSATION.—An overall summary description as to the method of compensation of participating physicians, including information on the types of financial payment incentives (described in section 1852(j)(4) of the Social Security Act) provided by the plan or issuer under the coverage.

(4) SPECIFIC INFORMATION ON CREDENTIALS OF PARTICIPATING PROVIDERS.—In the case of each participating provider, a description of the credentials of the provider.

(5) CONFIDENTIALITY POLICIES AND PROCEDURES.—A description of the policies and procedures established to carry out section ___122.

(6) FORMULARY RESTRICTIONS.—A description of the nature of any drug formula restrictions.

(7) PARTICIPATING PROVIDER LIST.—A list of current participating health care providers.

(d) FORM OF DISCLOSURE.—

(1) UNIFORMITY.—Information required to be disclosed under this section shall be provided in accordance with uniform, national reporting standards specified by the Secretary, after consultation with applicable

State authorities, so that prospective enrollees may compare the attributes of different issuers and coverage offered within an area.

(2) INFORMATION INTO HANDBOOK.—Nothing in this section shall be construed as preventing a group health plan or health insurance issuer from making the information under subsections (b) and (c) available to participants, beneficiaries, and enrollees through an enrollee handbook or similar publication.

(3) UPDATING PARTICIPATING PROVIDER INFORMATION.—The information on participating health care providers described in subsection (b)(3)(C) shall be updated within such reasonable period as determined appropriate by the Secretary. Nothing in this section shall prevent an issuer from changing or updating other information made available under this section.

(e) CONSTRUCTION.—Nothing in this section shall be construed as requiring public disclosure of individual contracts or financial arrangements between a group health plan or health insurance issuer and any provider.

SEC. ___122. PROTECTION OF PATIENT CONFIDENTIALITY.

Insofar as a group health plan, or a health insurance issuer that offers health insurance coverage, maintains medical records or other health information regarding participants, beneficiaries, and enrollees, the plan or issuer shall establish procedures—

(1) to safeguard the privacy of any individually identifiable enrollee information;

(2) to maintain such records and information in a manner that is accurate and timely, and

(3) to assure timely access of such individuals to such records and information.

SEC. ___123. HEALTH INSURANCE OMBUDSMEN.

(a) IN GENERAL.—Each State that obtains a grant under subsection (c) shall provide for creation and operation of a Health Insurance Ombudsman through a contract with a not-for-profit organization that operates independent of group health plans and health insurance issuers. Such Ombudsman shall be responsible for at least the following:

(1) To assist consumers in the State in choosing among health insurance coverage or among coverage options offered within group health plans.

(2) To provide counseling and assistance to enrollees dissatisfied with their treatment by health insurance issuers and group health plans in regard to such coverage or plans and with respect to grievances and appeals regarding determinations under such coverage or plans.

(b) FEDERAL ROLE.—In the case of any State that does not provide for such an Ombudsman under subsection (a), the Secretary shall provide for the creation and operation of a Health Insurance Ombudsman through a contract with a not-for-profit organization that operates independent of group health plans and health insurance issuers and that is responsible for carrying out with respect to that State the functions otherwise provided under subsection (a) by a Health Insurance Ombudsman.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary of Health and Human Services such amounts as may be necessary to provide for grants to States for contracts for Health Insurance Ombudsmen under subsection (a) or contracts for such Ombudsmen under subsection (b).

(d) CONSTRUCTION.—Nothing in this section shall be construed to prevent the use of other forms of enrollee assistance.

CHAPTER 4—GRIEVANCE AND APPEALS PROCEDURES

SEC. ___131. ESTABLISHMENT OF GRIEVANCE PROCESS.

(a) ESTABLISHMENT OF GRIEVANCE SYSTEM.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, shall establish and maintain a system to provide for the presentation and resolution of oral and written grievances brought by individuals who are participants, beneficiaries, or enrollees, or health care providers or other individuals acting on behalf of an individual and with the individual's consent, regarding any aspect of the plan's or issuer's services.

(2) SCOPE.—The system shall include grievances regarding access to and availability of services, quality of care, choice and accessibility of providers, network adequacy, and compliance with the requirements of this subtitle.

(b) GRIEVANCE SYSTEM.—Such system shall include the following components with respect to individuals who are participants, beneficiaries, or enrollees:

(1) Written notification to all such individuals and providers of the telephone numbers and business addresses of the plan or issuer personnel responsible for resolution of grievances and appeals.

(2) A system to record and document, over a period of at least 3 previous years, all grievances and appeals made and their status.

(3) A process providing for timely processing and resolution of grievances.

(4) Procedures for follow-up action, including the methods to inform the person making the grievance of the resolution of the grievance.

(5) Notification to the continuous quality improvement program under section ___111(a) of all grievances and appeals relating to quality of care.

SEC. ___132. INTERNAL APPEALS OF ADVERSE DETERMINATIONS.

(a) RIGHT OF APPEAL.—

(1) IN GENERAL.—A participant or beneficiary in a group health plan, and an enrollee in health insurance coverage offered by a health insurance issuer, and any provider or other person acting on behalf of such an individual with the individual's consent, may appeal any appealable decision (as defined in paragraph (2)) under the procedures described in this section and (to the extent applicable) section ___133. Such individuals and providers shall be provided with a written explanation of the appeal process and the determination upon the conclusion of the appeals process and as provided in section ___121(b)(8).

(2) APPEALABLE DECISION DEFINED.—In this section, the term ''appealable decision'' means any of the following:

(A) Denial, reduction, or termination of, or failure to provide or make payment (in whole or in part) for, a benefit, including a failure to cover an item or service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate.

(B) Failure to provide coverage of emergency services or reimbursement of maintenance care or post-stabilization care under section ___101.

(C) Failure to provide a choice of provider under section ___103.

(D) Failure to provide qualified health care providers under section ___103.

(E) Failure to provide access to specialty and other care under section ___104.

(F) Failure to provide continuation of care under section ___105.

(G) Failure to provide coverage of routine patient costs in connection with an approval clinical trial under section ___106.

(H) Failure to provide access to needed drugs under section ___107(a)(3) or ___107(b).

(I) Discrimination in delivery of services in violation of section ___109.

(J) An adverse determination under a utilization review program under section ___115.

(K) The imposition of a limitation that is prohibited under section ___151.

(b) INTERNAL APPEAL PROCESS.—

(1) IN GENERAL.—Each group health plan and health insurance issuer shall establish and maintain an internal appeal process under which any participant, beneficiary, enrollee, or provider acting on behalf of such an individual with the individual's consent, who is dissatisfied with any appealable decision has the opportunity to appeal the decision through an internal appeal process. The appeal may be communicated orally.

(2) CONDUCT OF REVIEW.—

(A) IN GENERAL.—The process shall include a review of the decision by a physician or other health care professional (or professionals) who has been selected by the plan or issuer and who has not been involved in the appealable decision at issue in the appeal.

(B) AVAILABILITY AND PARTICIPATION OF CLINICAL PEERS.—The individuals conducting such review shall include one or more clinical peers (as defined in section ___191(c)(2)) who have not been involved in the appealable decision at issue in the appeal.

(3) DEADLINE.—

(A) IN GENERAL.—Subject to subsection (c), the plan or issuer shall conclude each appeal as soon as possible after the time of the receipt of the appeal in accordance with medical exigencies of the case involved, but in no event later than—

(i) 72 hours after the time of receipt of an expedited appeal, and

(ii) except as provided in subparagraph (B), 30 business days after such time (or, if the participant, beneficiary, or enrollee supplies additional information that was not available to the plan or issuer at the time of the receipt of the appeal, after the date of supplying such additional information) in the case of all other appeals.

(B) EXTENSION.—In the case of an appeal that does not relate to a decision regarding an expedited appeal and that does not involve medical exigencies, if a group health plan or health insurance issuer is unable to conclude the appeal within the time period provided under subparagraph (A)(ii) due to circumstances beyond the control of the plan or issuer, the deadline shall be extended for up to an additional 10 business days if the plan or issuer provides, on or before 10 days before the deadline otherwise applicable, written notice to the participant, beneficiary, or enrollee and the provider involved of the extension and the reasons for the extension.

(4) NOTICE.—If a plan or issuer denies an appeal, the plan or issuer shall provide the participant, beneficiary, or enrollee and provider involved with notice in printed form of the denial and the reasons therefore, together with a notice in printed form of rights to any further appeal.

(c) EXPEDITED REVIEW PROCESS.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer, shall establish procedures in writing for the expedited consideration of appeals under subsection (b) in situations in which the application of the normal timeframe for making a determination could seriously jeopardize the life or health of the participant, beneficiary, or enrollee or such an individual's ability to regain maximum function.

(2) PROCESS.—Under such procedures—

(A) the request for expedited appeal may be submitted orally or in writing by an individual or provider who is otherwise entitled to request the appeal;

(B) all necessary information, including the plan's or issuer's decision, shall be transmitted between the plan or issuer and the requester by telephone, facsimile, or other similarly expeditious available method; and

(C) the plan or issuer shall expedite the appeal if the request for an expedited appeal is submitted under subparagraph (A) by a physician and the request indicates that the situation described in paragraph (1) exists.

(d) DIRECT USE OF FURTHER APPEALS.—In the event that the plan or issuer fails to comply with any of the deadlines for completion of appeals under this section or in the event that the plan or issuer for any reason expressly waives its rights to an internal review of an appeal under subsection (b), the participant, beneficiary, or enrollee involved and the provider involved shall be relieved of any obligation to complete the appeal involved and may, at such an individual's or provider's option, proceed directly to seek further appeal through any applicable external appeals process.

SEC. ___133. EXTERNAL APPEALS OF ADVERSE DETERMINATIONS.

(a) RIGHT TO EXTERNAL APPEAL.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage, shall provide for an external appeals process that meets the requirements of this section in the case of an externally appealable decision described in paragraph (2). The appropriate Secretary shall establish standards to carry out such requirements.

(2) EXTERNALLY APPEALABLE DECISION DEFINED.—For purposes of this section, the term ''externally appealable decision'' means an appealable decision (as defined in section ___132(a)(2)) if—

(A) the amount involved exceeds a significant threshold; or

(B) the patient's life or health is jeopardized as a consequence of the decision.

Such term does not include a denial of coverage for services that are specifically listed in plan or coverage documents as excluded from coverage.

(3) EXHAUSTION OF INTERNAL APPEALS PROCESS.—A plan or issuer may condition the use of an external appeal process in the case of an externally appealable decision upon completion of the internal review process provided under section ___132, but only if the decision is made in a timely basis consistent with the deadlines provided under this chapter.

(b) GENERAL ELEMENTS OF EXTERNAL APPEALS PROCESS.—

(1) CONTRACT WITH QUALIFIED EXTERNAL APPEAL ENTITY.—

(A) CONTRACT REQUIREMENT.—Subject to subparagraph (B), the external appeal process under this section of a plan or issuer shall be conducted under a contract between the plan or issuer and one or more qualified external appeal entities (as defined in subsection (c)).

(B) RESTRICTIONS ON QUALIFIED EXTERNAL APPEAL ENTITY.—

(i) BY STATE FOR HEALTH INSURANCE ISSUERS.—With respect to health insurance issuers in a State, the State may provide for external review activities to be conducted by a qualified external appeal entity that is designated by the State or that is selected by the State in such a manner as to assure an unbiased determination.

(ii) BY FEDERAL GOVERNMENT FOR GROUP HEALTH PLANS.—With respect to group health plans, the appropriate Secretary may exercise the same authority as a State may exercise with respect to health insurance issuers under clause (i). Such authority may include requiring the use of the qualified external appeal entity designated or selected under such clause.

(iii) LIMITATION ON PLAN OR ISSUER SELECTION.—If an applicable authority permits more than one entity to qualify as a qualified external appeal entity with respect to a group health plan or health insurance issuer and the plan or issuer may select among such qualified entities, the applicable authority—

(I) shall assure that the selection process will not create any incentives for external appeal entities to make a decision in a biased manner, and

(II) shall implement a procedures for auditing a sample of decisions by such entities to assure that no such decisions are made in a biased manner.

(C) OTHER TERMS AND CONDITIONS.—The terms and conditions of a contract under this paragraph shall be consistent with the standards the appropriate Secretary shall establish to assure there is no real or apparent conflict of interest in the conduct of external appeal activities. Such contract shall provide that the direct costs of the process (not including costs of representation of a participant, beneficiary, or enrollee) shall be paid by the plan or issuer, and not by the participant, beneficiary, or enrollee.

(2) ELEMENTS OF PROCESS.—An external appeal process shall be conducted consistent with standards established by the appropriate Secretary that include at least the following:

(A) FAIR PROCESS; DE NOVO DETERMINATION.—The process shall provide for a fair, de novo determination.

(B) DETERMINATION CONCERNING EXTERNALLY APPEALABLE DECISIONS.—A qualified external appeal entity shall determine whether a decision is an externally appealable decision and related decisions, including—

(i) whether such a decision involves an expedited appeal;

(ii) the appropriate deadlines for internal review process required due to medical exigencies in a case; and

(iii) whether such a process has been completed.

(C) OPPORTUNITY TO SUBMIT EVIDENCE, HAVE REPRESENTATION, AND MAKE ORAL PRESENTATION.—Each party to an externally appealable decision—

(i) may submit and review evidence related to the issues in dispute,

(ii) may use the assistance or representation of one or more individuals (any of whom may be an attorney), and

(iii) may make an oral presentation.

(D) PROVISION OF INFORMATION.—The plan or issuer involved shall provide timely access to all its records relating to the matter of the externally appealable decision and to all provisions of the plan or health insurance coverage (including any coverage manual) relating to the matter.

(E) TIMELY DECISIONS.—A determination by the external appeal entity on the decision shall—

(i) be made orally or in writing and, if it is made orally, shall be supplied to the parties in writing as soon as possible;

(ii) be binding on the plan or issuer;

(iii) be made in accordance with the medical exigencies of the case involved, but in no event later than 60 days (or 72 hours in the case of an expedited appeal) from the date of completion of the filing of notice of external appeal of the decision;

(iv) state, in layperson's language, the basis for the determination, including, if relevant, any basis in the terms or conditions of the plan or coverage; and

(v) inform the participant, beneficiary, or enrollee of the individual's rights to seek further review by the courts (or other process) of the external appeal determination.

(c) QUALIFICATIONS OF EXTERNAL APPEAL ENTITIES.—

(1) IN GENERAL.—For purposes of this section, the term ''qualified external appeal entity'' means, in relation to a plan or issuer, an entity (which may be a governmental entity) that is certified under paragraph (2) as meeting the following requirements:

(A) There is no real or apparent conflict of interest that would impede the entity conducting external appeal activities independent of the plan or issuer.

(B) The entity conducts external appeal activities through clinical peers.

(C) The entity has sufficient medical, legal, and other expertise and sufficient staffing to conduct external appeal activities for the plan or issuer on a timely basis consistent with subsection (b)(3)(E).

(D) The entity meets such other requirements as the appropriate Secretary may impose.

(2) CERTIFICATION OF EXTERNAL APPEAL ENTITIES.—

(A) IN GENERAL.—In order to be treated as a qualified external appeal entity with respect to—

(i) a group health plan, the entity must be certified (and, in accordance with subparagraph (B), periodically recertified) as meeting the requirements of paragraph (1) by the Secretary of Labor (or under a process recognized or approved by the Secretary of Labor); or

(ii) a health insurance issuer operating in a State, the entity must be certified (and, in accordance with subparagraph (B), periodically recertified) as meeting such requirements by the applicable State authority (or, if the States has not established an adequate certification and recertification process, by the Secretary of Health and Human Services, or under a process recognized or approved by such Secretary).

(B) RECERTIFICATION PROCESS.—The appropriate Secretary shall develop standards for the recertification of external appeal entities. Such standards shall include a specification of—

(i) the information required to be submitted as a condition of recertification on the entity's performance of external appeal activities, which information shall include the number of cases reviewed, a summary of the disposition of those cases, the length of time in making determinations on those cases, and such information as may be necessary to assure the independence of the entity from the plans or issuers for which external appeal activities are being conducted; and

(ii) the periodicity which recertification will be required.

(d) CONTINUING LEGAL RIGHTS OF ENROLLEES.—Nothing in this subtitle shall be construed as removing any legal rights of participants, beneficiaries, enrollees, and others under State or Federal law, including the right to file judicial actions to enforce rights.

CHAPTER 5—PROTECTING THE DOCTOR-PATIENT RELATIONSHIP

SEC. ___141. PROHIBITION OF INTERFERENCE WITH CERTAIN MEDICAL COMMUNICATIONS.

(a) PROHIBITION.—

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

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

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

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

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

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

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

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

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

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

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

SEC. ___142. PROHIBITION AGAINST TRANSFER OF INDEMNIFICATION OR IMPROPER INCENTIVE ARRANGEMENTS.

(a) PROHIBITION OF TRANSFER OF INDEMNIFICATION.—

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

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

(b) PROHIBITION OF IMPROPER PHYSICIAN INCENTIVE PLANS.—

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

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

SEC. ___143. ADDITIONAL RULES REGARDING PARTICIPATION OF HEALTH CARE PROFESSIONALS.

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

(1) providing notice of the rules regarding participation;

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

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

(b) CONSULTATION IN MEDICAL POLICIES.—A group health plan, and health insurance issuer that offers health insurance coverage, shall consult with participating physicians (if any) regarding the plan's or issuer's medical policy, quality, and medical management procedures.

SEC. ___144. PROTECTION FOR PATIENT ADVOCACY.

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

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

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

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

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

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

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

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

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

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

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

(3) EXCEPTION AND SPECIAL RULE.—

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

(B) NOTICE OF INTERNAL PROCEDURES.—Subparagraph (D) of paragraph (2) shall not apply unless the internal procedures involved are reasonably expected to be known to the health care professional involved. For purposes of this subparagraph, a health care professional is reasonably expected to know of internal procedures if those procedures have been made available to the professional through distribution or posting.

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

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

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

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

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

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

(6) CONSTRUCTIONS.—

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

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

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

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

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

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

CHAPTER 6—PROMOTING GOOD MEDICAL PRACTICE

SEC. ___151. PROMOTING GOOD MEDICAL PRACTICE.

(a) PROHIBITING ARBITRARY LIMITATIONS OR CONDITIONS FOR THE PROVISION OF SERVICES.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, may not arbitrarily interfere with or alter the decision of the treating physician regarding the manner or setting in which particular services are delivered if the services are medically necessary or appropriate for treatment or diagnosis to the extent that such treatment or diagnosis is otherwise a covered benefit.

(2) CONSTRUCTION.—Paragraph (1) shall not be construed as prohibiting a plan or issuer from limiting the delivery of services to one or more health care providers within a network of such providers.

(3) MANNER OR SETTING DEFINED.—In paragraph (1), the term ''manner or setting'' means the location of treatment, such as whether treatment is provided on an inpatient or outpatient basis, and the duration of treatment, such as the number of days in a hospital, Such term does not include the coverage of a particular service or treatment.

(b) NO CHANGE IN COVERAGE.—Subsection (a) shall not be construed as requiring coverage of particular services the coverage of which is otherwise not covered under the terms of the plan or coverage or from conducting utilization review activities consistent with this subsection.

(c) MEDICAL NECESSITY OR APPROPRIATENESS DEFINED.—In subsection (a), the term ''medically necessary or appropriate'' means, with respect to a service or benefit, a service or benefit which is consistent with generally accepted principles of professional medical practice.

SEC. ___152. STANDARDS RELATING TO BENEFITS FOR CERTAIN BREAST CANCER TREATMENT.

(a) INPATIENT CARE.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage, that provides medical and surgical benefits shall ensure that inpatient coverage with respect to the treatment of breast cancer is provided for a period of time as is determined by the attending physician, in his or her professional judgment consistent with generally accepted medical standards, in consultation with the patient, to be medically appropriate following—

(A) a mastectomy;

(B) a lumpectomy; or

(C) a lymph node dissection for the treatment of breast cancer.

(2) EXCEPTION.—Nothing in this section shall be construed as requiring the provision of inpatient coverage if the attending physician and patient determine that a shorter period of hospital stay is medically appropriate.

(b) PROHIBITIONS.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not—

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

(2) provide monetary payments or rebates to women to encourage such women to accept less than the minimum protections available under this section;

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

(4) provide incentives (monetary or otherwise) to an attending provider to induce such provider to provide care to an individual participant or beneficiary in a manner inconsistent with this section; or

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

(c) RULES OF CONSTRUCTION.—

(1) Nothing in this section shall be construed to require a woman who is a participant or beneficiary—

(A) to undergo a mastectomy or lymph node dissection in a hospital; or

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

(2) This section shall not apply with respect to any group health plan, or any group health insurance coverage offered by a health insurance issuer, which does not provide benefits for hospital lengths of stay in connection with a mastectomy or lymph node dissection for the treatment of breast cancer.

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

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

(e) EXCEPTION FOR HEALTH INSURANCE COVERAGE IN CERTAIN STATES.—

(1) IN GENERAL.—The requirements of this section shall not apply with respect to health insurance coverage if there is a State law (as defined in section 2723(d)(1) of the Public Health Service Act) for a State that regulates such coverage that is described in any of the following subparagraphs:

(A) Such State law requires such coverage to provide for at least a 48-hour hospital length of stay following a mastectomy performed for treatment of breast cancer and at least a 24-hour hospital length of stay following a lymph node dissection for treatment of breast cancer.

(B) Such State law requires, in connection with such coverage for surgical treatment of breast cancer, that the hospital length of stay for such care is left to the decision of (or required to be made by) the attending provider in consultation with the woman involved.

(2) CONSTRUCTION.—Section 2723(a)(1) of the Public Health Service Act and section 731(a)(1) of the Employee Retirement Income Security Act of 1974 shall not be construed as superseding a State law described in paragraph (1).

SEC. ___153. STANDARDS RELATING TO BENEFITS FOR RECONSTRUCTIVE BREAST SURGERY.

(a) REQUIREMENTS FOR RECONSTRUCTIVE BREAST SURGERY.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage, that provides coverage for breast surgery in connection with a mastectomy shall provide coverage for reconstructive breast surgery resulting from the mastectomy. Such coverage shall include coverage for all stages of reconstructive breast surgery performed on a nondiseased breast to establish symmetry with the diseased when reconstruction on the diseased breast is performed and coverage of prostheses and complications of mastectomy including lymphedema.

(2) RECONSTRUCTIVE BREAST SURGERY DEFINED.—In this section, the term ''reconstructive breast surgery'' means surgery performed as a result of a mastectomy to reestablish symmetry between two breasts, and includes augmentation mammoplasty, reduction mammoplasty, and mastopexy.

(3) MASTECTOMY DEFINED.—In this section, the term ''mastectomy'' means the surgical removal of all or part of a breast.

(b) PROHIBITIONS.—

(1) DENIAL OF COVERAGE BASED ON COSMETIC SURGERY.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not deny coverage described in subsection (a)(1) on the basis that the coverage is for cosmetic surgery.

(2) APPLICATION OF SIMILAR PROHIBITIONS.—Paragraphs (2) through (5) of section ___152 shall apply under this section in the same manner as they apply with respect to section ___152.

(c) RULES OF CONSTRUCTION.—

(1) Nothing in this section shall be construed to require a woman who is a participant or beneficiary to undergo reconstructive breast surgery.

(2) This section shall not apply with respect to any group health plan, or any group health insurance coverage offered by a health insurance issuer, which does not provide benefits for mastectomies.

(3) Nothing in this section shall be construed as preventing a group health plan or issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits for reconstructive breast surgery under the plan (or under health insurance coverage offered in connection with a group health plan), except that such coinsurance or other cost-sharing for any portion may not be greater than such coinsurance or cost-sharing that is otherwise applicable with respect to benefits for mastectomies.

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

(f) EXCEPTION FOR HEALTH INSURANCE COVERAGE IN CERTAIN STATES.—

(1) IN GENERAL.—The requirements of this section shall not apply with respect to health insurance coverage if there is a State law (as defined in section 2723(d)(1) of the Public Health Service Act) for a State that regulates such coverage and that requires coverage of at least the coverage of reconstructive breast surgery otherwise required under this section.

(2) CONSTRUCTION.—Section 2723(a)(1) of the Public Health Service Act and section 731(a)(1) of the Employee Retirement Income Security Act of 1974 shall not be construed as superseding a State law described in paragraph (1).

CHAPTER 7—DEFINITIONS

SEC. ___191. DEFINITIONS.

(a) INCORPORATION OF GENERAL DEFINITIONS.—The provisions of section 2971 of the Public Health Service Act shall apply for purposes of this subtitle in the same manner as they apply for purposes of title XXVII of such Act.

(b) SECRETARY.—Except as otherwise provided, the term ''Secretary'' means the Secretary of Health and Human Services, in consultation with the Secretary of Labor and the Secretary of the Treasury and the term ''appropriate Secretary'' means the Secretary of Health and Human Services in relation to carrying out this subtitle under sections 2706 and 2751 of the Public Health Service Act, the Secretary of Labor in relation to carrying out this subtitle under section 713 of the Employee Retirement Income Security Act of 1974, and the Secretary of the Treasury in relation to carrying out this subtitle under chapter 100 and section 4980D of the Internal Revenue Code of 1986.

(c) ADDITIONAL DEFINITIONS.—For purposes of this subtitle:

(1) APPLICABLE AUTHORITY.—The term ''applicable authority'' means—

(A) in the case of a group health plan, the Secretary of Health and Human Services and the Secretary of Labor; and

(B) in the case of a health insurance issuer with respect to a specific provision of this subtitle, the applicable State authority (as defined in section 2791(d) of the Public Health Service Act), or the Secretary of Health and Human Services, if such Secretary is enforcing such provision under section 2722(a)(2) or 2761(a)(2) of the Public Health Service Act.

(2) CLINICAL PEER.—The term ''clinical peer'' means, with respect to a review or appeal, a physician (allopathic or osteopathic) or other health care professional who holds a non-restricted license in a State and who is appropriately credentialed in the same or similar specialty as typically manages the medical condition, procedure, or treatment under review or appeal and includes a pediatric specialist where appropriate; except that only a physician may be a clinical peer with respect to the review or appeal of treatment rendered by a physician.

(3) HEALTH CARE PROVIDER.—The term ''health care provider'' includes a physician or other health care professional, as well as an institutional provider of health care services.

(4) NONPARTICIPATING.—The term ''nonparticipating'' means, with respect to a health care provider that provides health care items and services to a participant, beneficiary, or enrollee under group health plan or health insurance coverage, a health care provider that is not a participating health care provider with respect to such items and services.

(5) PARTICIPATING.—The term ''participating'' mean, with respect to a health care provider that provides health care items and services to a participant, beneficiary, or enrollee under group health plan or health insurance coverage offered by a health insurance issuer, a health care provider that furnishes such items and services under a contract or other arrangement with the plan or issuer.

SEC. ___192. PREEMPTION; STATE FLEXIBILITY; CONSTRUCTION.

(a) CONTINUED APPLICABILITY OF STATE LAW WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

(1) IN GENERAL.—Subject to paragraph (2), this subtitle shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement of this subtitle.

(2) CONTINUED PREEMPTION WITH RESPECT TO GROUP HEALTH PLANS.—Nothing in this subtitle shall be construed to affect or modify the provisions of section 514 of the Employee Retirement Income Security Act of 1974 with respect to group health plans.

(b) RULES OF CONSTRUCTION.—Except as provided in sections ___152 and ___153, nothing in this subtitle shall be construed as requiring a group health plan or health insurance coverage to provide specific benefits under the terms of such plan or coverage.

(c) DEFINITIONS.—For purposes of this section:

(1) STATE LAW.—The term ''State law'' includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.

(2) STATE.—The term ''State'' includes a State, the Northern Mariana Islands, any political subdivisions of a State or such Islands, or any agency or instrumentality of either.

SEC. ___193. REGULATIONS.

The Secretaries of Health and Human Services, Labor, and the Treasury shall issue such regulations as may be necessary or appropriate to carry out this subtitle. Such regulations shall be issued consistent with section 104 of Health Insurance Portability and Accountability Act of 1996. Such Secretaries may promulgate any interim final rules as the Secretaries determine are appropriate to carry out this subtitle.

Subtitle B—Application of Patient Protection Standards to Group Health Plans and Health Insurance Coverage Under Public Health Service Act

SEC. ___201. APPLICATION TO GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE.

(a) IN GENERAL.—Subpart 2 of part A of title XXVII of the Public Health Service Act is amended by adding at the end the following new section:

''SEC. 2706. PATIENT PROTECTION STANDARDS.

''(a) IN GENERAL.—Each group health plan shall comply with patient protection requirements under subtitle A of the Patients' Bill of Rights Act of 1998, and each health insurance issuer shall comply with patient protection requirements under such subtitle with respect to group health insurance coverage it offers, and such requirements shall be deemed to be incorporated into this subsection.

''(b) NOTICE.—A group health plan shall comply with the notice requirement under section 711(d) of the Employee Retirement Income Security Act of 1974 with respect to the requirements referred to in subsection (a) and a health insurance issuer shall comply with such notice requirement as if such section applied to such issuer and such issuer were a group health plan.''.

(b) CONFORMING AMENDMENT.—Section 2721(b)(1)(A) of such Act (42 U.S.C. 300gg–21(b)(1)(A)) is amended by inserting ''(other than section 2706)'' after ''requirements of such subparts''.

SEC. ___202. APPLICATION TO INDIVIDUAL HEALTH INSURANCE COVERAGE.

Part B of title XXVII of the Public Health Service Act is amended by inserting after section 2751 the following new section:

''SEC. 2752. PATIENT PROTECTION STANDARDS.

''(a) IN GENERAL.—Each health insurance issuer shall comply with patient protection requirements under subtitle A of the Patients' Bill of Rights Act of 1998 with respect to individual health insurance coverage it offers, and such requirements shall be deemed to be incorporated into this subsection.

''(b) NOTICE.—A health insurance issuer under this part shall comply with the notice requirement under section 711(d) of the Employee Retirement Income Security Act of 1974 with respect to the requirements of such subtitle as if such section applied to such issuer and such issuer were a group health plan.''.

Subtitle C—Amendments to the Employee Retirement Income Security Act of 1974

SEC. ___301. APPLICATION OF PATIENT PROTECTION STANDARDS TO GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

(a) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following new section:

''SEC. 713. PATIENT PROTECTION STANDARDS.

''(a) IN GENERAL.—Subject to subsection (b), a group health plan (and a health insurance issuer offering group health insurance coverage in connection with such a plan) shall comply with the requirements of subtitle A of the Patients' Bill of Rights Act of 1998 (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), insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the following requirements of subtitle A of the Patients' Bill of Rights Act of 1998 with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer:

''(A) section ___101 (relating to access to emergency care).

''(B) Section ___102(a)(1) (relating to offering option to purchase point-of-service coverage), but only insofar as the plan is meeting such requirement through an agreement with the issuer to offer the option to purchase point-of-service coverage under such section.

''(C) Section ___103 (relating to choice of providers).

''(D) Section ___104 (relating to access to specialty care).

''(E) Section ___105(a)(1) (relating to continuity in case of termination of provider contract) and section ___105(a)(2) (relating to continuity in case of termination of issuer contract), but only insofar as a replacement

issuer assumes the obligation for continuity of care.

''(F) section ___106 (relating to coverage for individuals participating in approved clinical trials.)

''(G) section ___107 (relating to access to needed prescription drugs).

''(H) Section ___108 (relating to adequacy of provider network).

''(I) Chapter 2 (relating to quality assurance).

''(J) Section ___143 (relating to additional rules regarding participation of health care professionals).

''(K) Section ___152 (relating to standards relating to benefits for certain breast cancer treatment).

''(L) Section ___153 (relating to standards relating to benefits for reconstructive breast surgery).

''(2) INFORMATION.—With respect to information required to be provided or made available under section ___121, in the case of a group health plan that provides benefits in the form of health insurance coverage through a health insurance issuer, the Secretary shall determine the circumstances under which the plan is not required to provide or make available the information (and is not liable for the issuer's failure to provide or make available the information), if the issuer is obligated to provide and make available (or provides and makes available) such information.

''(3) GRIEVANCE AND INTERNAL APPEALS.—With respect to the grievance system and internal appeals process required to be established under sections ___131 and ___132, in the case of a group health plan that provides benefits in the form of health insurance coverage through a health insurance issuer, the Secretary shall determine the circumstances under which the plan is not required to provide for such system and process (and is not liable for the issuer's failure to provide for such system and process), if the issuer is obligated to provide for (and provides for) such system and process.

''(4) EXTERNAL APPEALS.—Pursuant to rules of the Secretary, insofar as a group health plan enters into a contract with a qualified external appeal entity for the conduct of external appeal activities in accordance with section ___133, the plan shall be treated as meeting the requirement of such section and is not liable for the entity's failure to meet any requirements under such section.

''(5) APPLICATION TO PROHIBITIONS.—Pursuant to rules of the Secretary, if a health insurance issuer offers health insurance coverage in connection with a group health plan and takes an action in violation of any of the following sections, the group health plan shall not be liable for such violation unless the plan caused such violation:

''(A) Section ___109 (relating to nondiscrimination in delivery of services).

''(B) Section ___141 (relating to prohibition of interference with certain medical communications).

''(C) Section ___142 (relating to prohibition against transfer of indemnification or improper incentive arrangements).

''(D) Section ___144 (relating to prohibition on retaliation).

''(E) Section ___151 (relating to promoting good medical practice).

''(6) 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.

''(7) APPLICATION TO CERTAIN PROHIBITIONS AGAINST RETALIATION.—With respect to compliance with the requirements of section ___144(b)(1) of the Patients' Bill of Rights Act of 1998, for purposes of this subtitle the term 'group health plan' is deemed to include a reference to an institutional health care provider.

''(c) ENFORCEMENT OF CERTAIN REQUIREMENTS.—

''(1) COMPLAINTS.—Any protected health care professional who believes that the professional has been retaliated or discriminated against in violation of section ___144(b)(1) of the Patients' Bill of Rights Act of 1998 may file with the Secretary a complaint within 180 days of the date of the alleged retaliation or discrimination.

''(2) INVESTIGATION.—The Secretary shall investigate such complaints and shall determine if a violation of such section has occurred and, if so, shall issue an order to ensure that the protected health care professional does not suffer any loss of position, pay, or benefits in relation to the plan, issuer, or provider involved, as a result of the violation found by the Secretary.

''(d) CONFORMING REGULATIONS.—The Secretary may issue regulations to coordinate the requirements on group health plans under this section with the requirements imposed under the other provisions of this title.''.

(b) SATISFACTION OF ERISA CLAIMS PROCEDURE REQUIREMENT.—Section 503 of such Act (29 U.S.C. 1133) is amended by inserting ''(a)'' after ''SEC. 503.'' and by adding at the end the following new subsection:

''(b) In the case of a group health plan (as defined in section 733) compliance with the requirements of chapter 4 (and section ___115) of subtitle A of the Patients' Bill of Rights Act of 1998 in the case of a claims denial shall be deemed compliance with subsection (a) with respect to such claims denial.''.

(c) CONFORMING AMENDMENTS.—(1) Section 732(a) of such Act (29 U.S.C. 1185(a)) is amended by striking ''section 711'' and inserting ''sections 711 and 713''.

(2) The table of contents in section 1 of such Act is amended by inserting after the item relating to section 712 the following new item:

''Sec. 713. Patient protection standards.''.

(3) Section 502(b)(3) of such Act (29 U.S.C. 1132(b)(3)) is amended by inserting ''(other than section 144(b))'' after ''part 7''.

SEC. ___302. ERISA PREEMPTION NOT TO APPLY TO CERTAIN ACTIONS INVOLVING HEALTH INSURANCE POLICYHOLDERS.

(a) IN GENERAL.—Section 514 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144) is amended by adding at the end the following subsection:

''(e) PREEMPTION NOT TO APPLY TO CERTAIN ACTIONS ARISING OUT OF PROVISION OF HEALTH BENEFITS.—

''(1) IN GENERAL.—Except as provided in this subsection, nothing in this title shall be construed to invalidate, impair, or supersede any cause of action brought by a plan participant or beneficiary (or the estate of a plan participant or beneficiary) under State law to recover damages resulting from personal injury or for wrongful death against any person—

''(A) in connection with the provision of insurance, administrative services, or medical services by such person to or for a group health plan (as defined in section 733), or

''(B) that arises out of the arrangement by such person for the provision of such insurance, administrative services, or medical services by other persons.

For purposes of this subsection, the term 'personal injury' means a physical injury and includes an injury arising out of the treatment (or failure to treat) a mental illness or disease.

''(2) EXCEPTION FOR EMPLOYERS AND OTHER PLAN SPONSORS.—

''(A) IN GENERAL.—Subject to subparagraph (B), paragraph (1) does not authorize—

''(i) any cause of action against an employer or other plan sponsor maintaining the group health plan (or against an employee of such an employer or sponsor acting within the scope of employment), or

''(ii) a right of recovery or indemnity by a person against an employer or other plan sponsor (or such an employee) for damages assessed against the person pursuant to a cause of action under paragraph (1).

''(B) SPECIAL RULE.—Subparagraph (A) shall not preclude any cause of action described in paragraph (1) against an employer or other plan sponsor (or against an employee of such an employer or sponsor acting within the scope of employment) if—

''(i) such action is based on the employer's or other plan sponsor's (or employee's) exercise of discretionary authority to make a decision on a claim for benefits covered under the plan or health insurance coverage in the case at issue; and

''(ii) the exercise by such employer or other plan sponsor (or employee) of such authority resulted in personal injury or wrongful death.

''(3) CONSTRUCTION.—Nothing in this subsection shall be construed as permitting a cause of action under State law for the failure to provide an item or service which is not covered under the group health plan involved.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to acts and omissions occurring on or after the date of the enactment of this title from which a cause of action arises.

Subtitle D—Application to Group Health Plans Under the Internal Revenue Code of 1986.

SEC. ___401. AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986.

Subchapter B of chapter 100 of the Internal Revenue Code of 1986 (as amended by section 1531(a) of the Taxpayer Relief Act of 1997) is amended—

(1) in the table of sections, by inserting after the item relating to section 9812 the following new item:

''Sec. 9813. Standard relating to patient freedom of choice.''; and

(2) by inserting after section 9812 the following:

''SEC. 9813. STANDARD RELATING TO PATIENTS' BILL OF RIGHTS.

''A group health plan shall comply with the requirements of subtitle A of the Patients' Bill of Rights Act of 1998 (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.''.

Subtitle E—Effective Dates; Coordination in Implementation

SEC. ___501. EFFECTIVE DATES.

(a) GROUP HEALTH COVERAGE.—

(1) IN GENERAL.—Subject to paragraph (2), the amendments made by sections 2201(a) and 2301 (and subtitle A insofar as it relates to such sections) shall apply with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning on or after July 1, 1999 (in this section referred to as the ''general effective date'').

(2) TREATMENT OF COLLECTIVE BARGAINING AGREEMENTS.—In the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and 1 or more employers ratified before the date of enactment of this title, the amendments made by sections 2201(a) and 2301 (and subtitle A insofar as it relates to such sections) shall not apply to plan years beginning before the later of—

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

(B) the general effective date.

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

(b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—The amendments made by section ___202 shall apply with respect to individual health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after the general effective date.

SEC. ___502. COORDINATION IN IMPLEMENTATION.

Section 104(1) of Health Insurance Portability and Accountability Act of 1996 is amended by inserting ''or under subtitle A of the Patients' Bill of Rights Act of 1998 (and the amendments made by such title)'' after ''section 401)''.

SEC. ___503. NO IMPACT ON SOCIAL SECURITY TRUST FUND.

Nothing in this title shall be construed to alter or amend the Social Security Act (or any regulation promulgated under that Act). To the extent that this title may have a negative effect on the balances of any trust fund established under the Social Security Act, such sums as may be necessary shall be transferred from the general revenues of the Federal Government to ensure that the income and balances of such trust funds are not reduced as a result of the enactment of this title.

Subtitle F—Revenue

SEC. ___601. EXTENSION OF HAZARDOUS SUBSTANCE SUPERFUND TAXES.

(a) EXTENSION OF TAXES.—

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

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

(2) EXCISE TAXES.—Section 4611(e) of such Code is amended to read as follows:

''(e) APPLICATION OF HAZARDOUS SUBSTANCE SUPERFUND FINANCING RATE.—The Hazardous Substance Superfund financing rate under this section shall apply after December 31, 1986, and before January 1, 1996, and after December 31, 1999, and before October 1, 2008.''

(b) EFFECTIVE DATES.—

(1) INCOME TAX.—The amendment made by subsection (a)(1) shall apply to taxable years beginning after December 31, 1999.

(2) EXCISE TAX.—The amendment made by subsection (a)(2) shall take effect on January 1, 2000.

SEC. ___602. CLARIFICATION OF DEFINITION OF SPECIFIED LIABILITY LOSS.

(a) IN GENERAL.—Subparagraph (B) of section 172(f)(1) of the Internal Revenue Code of 1986 (defining specified liability loss) is amended to read as follows:

''(B) Any amount (not described in subparagraph (A)) allowable as a deduction under this chapter which is attributable to a liability—

''(i) under a Federal or State law requiring the reclamation of land, decommissioning of a nuclear power plant (or any unit thereof), dismantlement of an offshore drilling platform, remediation of environmental contamination, or payment of workmen's compensation, and

''(ii) with respect to which the act (or failure to act) giving rise to such liability occurs at least 3 years before the beginning of the taxable year.''

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to net operating losses for taxable years beginning after the date of the enactment of this Act.

SEC. ___603. PROPERTY SUBJECT TO A LIABILITY TREATED IN SAME MANNER AS ASSUMPTION OF LIABILITY.

(a) REPEAL OF PROPERTY SUBJECT TO A LIABILITY TEST.—

(1) SECTION 357.—Section 357(a) of the Internal Revenue Code of 1986 (relating to assumption of liability) is amended by striking '', or acquires from the taxpayer property subject to a liability'' in paragraph (2).

(2) SECTION 358.—Section 358(d)(1) of such Code (relating to assumption of liability) is amended by striking ''or acquired from the taxpayer property subject to a liability''.

(3) SECTION 368.—

(A) Section 368(a)(1)(C) of such Code is amended by striking '', or the fact that property acquired is subject to a liability,''.

(B) The last sentence of section 368(a)(2)(B) of such Code is amended by striking '', and the amount of any liability to which any property acquired from the acquiring corporation is subject,''.

(b) CLARIFICATION OF ASSUMPTION OF LIABILITY.—Section 357(c) of the Internal Revenue Code of 1986 is amended by adding at the end the following new paragraph:

''(4) DETERMINATION OF AMOUNT OF LIABILITY ASSUMED.—For purposes of this section, section 358(d), section 368(a)(1)(C), and section 368(a)(2)(B)—

''(A) a liability shall be treated as having been assumed to the extent, as determined on the basis of facts and circumstances, the transferor is relieved of such liability or any portion thereof (including through an indemnity agreement or other similar arrangement), and

''(B) in the case of the transfer of any property subject to a nonrecourse liability, unless the facts and circumstances indicate otherwise, the transferee shall be treated as assuming with respect to such property a ratable portion of such liability determined on the basis of the relative fair market values (determined without regard to section 7701(g)) of all assets subject to such liability.

(c) APPLICATION TO PROVISIONS OTHER THAN SUBCHAPTER C.—

(1) SECTION 584.—Section 584(h)(3) of the Internal Revenue Code of 1986 is amended—

(A) by striking '', and the fact that any property transferred by the common trust fund is subject to a liability,'' in subparagraph (A),

(B) by striking clause (ii) of subparagraph (B) and inserting:

''(ii) ASSUMED LIABILITIES.—For purposes of clause (i), the term 'assumed liabilities' means any liability of the common trust fund assumed by any regulated investment company in connection with the transfer referred to in paragraph (1)(A).

''(C) ASSUMPTION.—For purposes of this paragraph, in determining the amount of any liability assumed, the rules of section 357(c)(4) shall apply.''

(2) SECTION 1031.—The last sentence of section 1031(d) of such Code is amended—

(A) by striking ''assumed a liability of the taxpayer or acquired from the taxpayer property subject to a liability'' and inserting ''assumed (as determined under section 357(c)(4)) a liability of the taxpayer'', and

(B) by striking ''or acquisition (in the amount of the liability)''.

(d) CONFORMING AMENDMENTS.—

(1) Section 351(h)(1) of the Internal Revenue Code of 1986 is amended by striking '', or acquires property subject to a liability,''.

(2) Section 357 of such Code is amended by striking ''or acquisition'' each place it appears in subsection (a) or (b).

(3) Section 357(b)(1) of such Code Is amended by striking ''or acquired''.

(4) Section 357(c)(1) of such Code is amended by striking '', plus the amount of the liabilities to which the property is subject,''.

(5) Section 357(c)(3) of such Code is amended by striking ''or to which the property transferred is subject''.

(6) Section 358(d)(1) of such Code is amended by striking ''or acquisition (in the amount of the liability)''.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to transfers after the date of the enactment of this Act.

SEC. ___604. EXCISE TAX ON PURCHASE OF STRUCTURED SETTLEMENT AGREEMENTS.

(a) IN GENERAL.—Subtitle D of the Internal Revenue Code of 1986 (relating to miscellaneous excise taxes) is amended by adding at the end the following:

''CHAPTER 48—STRUCTURED SETTLEMENT AGREEMENTS

''Sec. 5000A. Tax on purchases of structured settlement agreements.

''SEC. 5000A. TAX ON PURCHASES OF STRUCTURED SETTLEMENT AGREEMENTS.

''(a) IMPOSITION OF TAX.—There is hereby imposed on any person who purchases the right to receive payments under a structured settlement agreement a tax equal to 10 percent of the amount of the purchase price.

''(b) EXCEPTION FOR COURT-ORDERED PURCHASES.—Subsection (a) shall not apply to any purchase which is pursuant to a court order which finds that such purchase is necessary because of the extraordinary and unanticipated needs of the individual with the personal injuries or sickness giving rise to the structured settlement agreement.

''(c) STRUCTURED SETTLEMENT AGREEMENT.—For purposes of this section, the term 'structured settlement agreement' means—

''(1) any right to receive (whether by suit or agreement) periodic payments as damages on account of personal injuries or sickness, or

''(2) any right to receive periodic payments as compensation for personal injuries or sickness under any workmen's compensation act.

''(d) PURCHASE.—For purposes of this section, the term 'purchase' has the meaning given such term by section 179(d)(2).''

(b) CONFORMING AMENDMENT.—The table of chapters for subtitle D of the Internal Revenue Code of 1986 is amended by adding at the end the following:

''CHAPTER 48. Structured settlement agreements.''

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to purchases after the date of enactment of this Act.

SEC. ___605. CLARIFICATION AND EXPANSION OF MATHEMATICAL ERROR ASSESSMENT PROCEDURES.

(a) TIN DEEMED INCORRECT IF INFORMATION ON RETURN DIFFERS WITH AGENCY RECORDS.—Section 6213(g)(2) of the Internal Revenue Code of 1986 (defining mathematical or clerical error) is amended by adding at the end the following flush sentence:

''A taxpayer shall be treated as having omitted a correct TIN for purposes of the preceding sentence if information provided by the taxpayer on the return with respect to the individual whose TIN was provided differs from the information the Secretary obtains from the person issuing the TIN.''

(b) EXPANSION OF MATHEMATICAL ERROR PROCEDURES TO CASES WHERE TIN ESTABLISHES INDIVIDUAL NOT ELIGIBLE FOR TAX

CREDIT.—Section 6213(g)(2) of the Internal Revenue Code of 1986 is amended by striking ''and'' at the end of subparagraph (I), by striking the period at the end of the first subparagraph (J) (relating to higher education credit) and inserting a comma, by redesignating the second subparagraph (J) (relating to earned income credit) as subparagraph (K) and by striking the period at the end and inserting '', and'', and by adding at the end the following new subparagraph:

''(L) the inclusion of a TIN on a return with respect to an individual for whom a credit is claimed under section 21, 24, or 32 if, on the basis of data obtained by the Secretary from the person issuing the TIN, it is established that the individual does not meet any applicable age requirements for such credit.''

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years ending after the date of the enactment of this Act.

SEC. ___606. MODIFICATION TO FOREIGN TAX CREDIT CARRYBACK AND CARRYOVER PERIODS.

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

(1) by striking ''in the second preceding taxable year,'', and

(2) by striking ''or fifth'' and inserting ''fifth, sixth, or seventh''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to credits arising in taxable years beginning after December 31, 2001.

SEC. ___607. DEPOSIT REQUIREMENTS FOR FUTA TAXES.

(a) IN GENERAL.—Section 6157 of the Internal Revenue Code of 1986 (relating to payment of Federal unemployment tax on quarterly or other time period basis) is amended by adding at the end the following new subsection:

''(d) DEPOSITS OF FUTA TAXES.—

''(1) GENERAL RULE.—Except as otherwise provided in this subsection or in regulations prescribed by the Secretary, the taxes imposed by section 3301 which are attributable to wages paid during any calendar quarter shall be deposited on or before the last day of the first month following the close of such calendar quarter.

''(2) MONTHLY DEPOSIT RULE.—

''(A) IN GENERAL.—In the case of a monthly depositor for any calendar year, the taxes imposed by section 3301 which are attributable to wages paid during any month in such calendar year shall be deposited on or before the last day of the following month.

''(B) MONTHLY DEPOSITOR.—For purposes of subparagraph (A), an employer is a monthly depositor for any calendar year if the employer's liability for taxes imposed by section 3301 for the preceding calendar year was equal to or greater than $1,100. All persons treated as one employer under subsection (a) or (b) shall be treated as one employer for purposes of this subparagraph.

''(C) SAFE HARBOR FOR MONTHLY DEPOSITORS.—No penalties shall be imposed under this title with respect to—

''(i) deposits required under this paragraph for the first month of a calendar quarter if the amount deposited by the last day of the second month of such quarter is at least equal to the lesser of—

''(I) 30 percent of the taxes imposed by section 3301 which are attributable to wages paid during such quarter, or

''(II) 90 percent of the taxes imposed by section 3301 which are attributable to wages paid during the first month of such quarter, and

''(ii) deposits required under this paragraph for the second month of a calendar quarter if the amount deposited by the last day of the third month of such quarter is at least equal to the lesser of—

''(I) 60 percent of the taxes imposed by section 3301 which are attributable to wages paid during such quarter, or

''(II) 90 percent of the taxes imposed by section 3301 which are attributable to wages paid during the first 2 months of such quarter.

''(3) DEPOSIT REQUIRED ONLY ON BANKING DAYS.—If taxes are required to be deposited under this subsection on any day which is not a banking day, such taxes shall be treated as timely deposited if deposited on the first banking day thereafter.

''(4) WAGES.—For purposes of this subsection, the term 'wages' has the meaning given to such term by section 3306(b).''

(b) APPLICATION TO DEPOSITS REQUIRED BY STATE GOVERNMENTS.—

(1) IN GENERAL.—Section 303 of the Social Security Act (42 U.S.C. 503) is amended by adding at the end the following new subsection:

''(k)(1) The State agency charged with the administration of the State law shall provide that any deposit required under the State law to the unemployment fund of the State with respect to wages paid for any month during a calendar year by an employer is required to be made by the last day of the following month if such employer is treated as a monthly depositor for such calendar year for purposes of section 6157(d) of the Internal Revenue Code of 1986 (or if the State so elects, at such other time as is not later than the time provided under subparagraph (C) of section 6157(d)(2) of such Code).

''(2) Whenever the Secretary of Labor, after reasonable notice and opportunity for hearing to the State agency charged with the administration of State law, finds that there is a failure to comply substantially with the requirements of paragraph (1), the Secretary of Labor shall notify such State agency that further payments will not be made to the State until the Secretary is satisfied that there is no longer any such failure. Until the Secretary of Labor is so satisfied, he shall make no further certification to the Secretary of the Treasury with respect to such State.''

(2) CONFORMING AMENDMENT.—Section 304(a)(2) of the Social Security Act (42 U.S.C. 504(a)(2)) is amended by striking ''or (j)'' and inserting ''(j), or (k)''.

(c) CONFORMING AMENDMENTS.—

(1) The last sentence of section 6157(a) of the Internal Revenue Code of 1986 is amended by striking ''and such time''.

(2) Section 6157(b) of such Code is amended by striking ''referred to in paragraph (1) or (2) of subsection (a)''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to months beginning after December 31, 2003.

SEC. ___608. INFORMATION REQUIREMENTS.

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

''(7) INFORMATION FROM GROUP HEALTH PLANS.—

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

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

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

''(i) ELEMENTS CONCERNING THE INDIVIDUAL.—

''(I) The individual's name.

''(II) The individual's date of birth.

''(III) The individual's sex.

''(IV) The individual's social security insurance number.

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

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

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

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

''(II) That person's social security insurance number.

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

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

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

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

''(iii) PLAN ELEMENTS.—

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

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

''(iv) ELEMENTS CONCERNING THE EMPLOYER.—

''(I) The employer's name.

''(II) The employer's address.

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

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

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

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect 180 days after the date of enactment of this Act.

PRODUCT LIABILITY REFORM ACT OF 1998

LOTT AMENDMENT NO. 3064

Mr. LOTT proposed an amendment to the bill, S. 648, supra; as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Product Liability Reform Act of 1998''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

SEC. 2. FINDINGS; PURPOSES.

(a) FINDINGS.—Congress finds that—

(1) although damage awards in product liability actions can encourage the production of safer products, they also can have a direct effect on interstate commerce and our Nation's consumers by, among other things, increasing the cost and decreasing the availability of products;

(2) some of the rules of law governing product liability actions are inconsistent within and among the States, resulting in differences in State laws that can be inequitable to both plaintiffs and defendants and can impose burdens on interstate commerce;

(3) product liability awards can jeopardize the financial well-being of individuals and industries, particularly the Nation's small businesses;

(4) because the product liability laws of one State can have adverse effects on consumers and businesses in many other States, it is appropriate for the Federal Government to enact national, uniform product liability laws that preempt State laws; and

(5) it is the constitutional role of the Federal Government to remove barriers to interstate commerce.

(b) PURPOSES.—Based on the powers under clause 3 of section 8 of article I of the United States Constitution, the purposes of this Act are to promote the free flow of goods and services and to lessen burdens on interstate commerce by—

(1) establishing certain uniform legal principles of product liability that provide a fair balance among the interests of product users, manufacturers, and product sellers;

(2) providing for reasonable standards concerning, and limits on, punitive damages over and above the actual damages suffered by a claimant;

(3) ensuring the fair allocation of liability in product liability actions;

(4) reducing the unacceptable costs and delays in product liability actions caused by excessive litigation that harm both plaintiffs and defendants;

(5) establishing greater fairness, rationality, and predictability in product liability actions; and

(6) providing fair and expeditious judicial procedures that are necessary to complement and effectuate the legal principles established by this Act.

TITLE I—PRODUCT LIABILITY REFORM

SEC. 101. DEFINITIONS.

In this title:

(1) ALCOHOLIC PRODUCT.—The term ''alcoholic product'' includes any product that contains not less than ½ of 1 percent of alcohol by volume and is intended for human consumption.

(2) CLAIMANT.—The term ''claimant'' means any person who brings an action covered by this title and any person on whose behalf such an action is brought. If such an action is brought through or on behalf of an estate, the term includes the claimant's decedent. If such an action is brought through or on behalf of a minor or incompetent, the term includes the claimant's legal guardian.

(3) CLAIMANT'S BENEFITS.—The term ''claimant's benefits'' means the amount paid to an employee as workers' compensation benefits.

(4) CLEAR AND CONVINCING EVIDENCE.—The term ''clear and convincing evidence'' is that measure or degree of proof that will produce in the mind of the trier of fact a firm belief or conviction as to the truth of the allegations sought to be established. The level of proof required to satisfy that standard is more than that required under a preponderance of the evidence, but less than that required for proof beyond a reasonable doubt.

(5) COMMERCIAL LOSS.—The term ''commercial loss'' means—

(A) any loss or damage solely to a product itself;

(B) loss relating to a dispute over the value of a product; or

(C) consequential economic loss.

(6) COMPENSATORY DAMAGES.—The term ''compensatory damages'' means damages awarded for economic and noneconomic loss.

(7) DRAM-SHOP.—The term ''dram-shop'' means a drinking establishment where alcoholic products are sold to be consumed on the premises.

(8) DURABLE GOOD.—The term ''durable good'' means any product, or any component of any such product, which—

(A)(i) has a normal life expectancy of 3 or more years; or

(ii) is of a character subject to allowance for depreciation under the Internal Revenue Code of 1986; and

(B) is—

(i) used in a trade or business;

(ii) held for the production of income; or

(iii) sold or donated to a governmental or private entity for the production of goods, training, demonstration, or any other similar purpose.

(9) ECONOMIC LOSS.—The term ''economic loss'' means any pecuniary loss resulting from harm (including the loss of earnings or other benefits related to employment, medical expense loss, replacement services loss, loss due to death, burial costs, and loss of business or employment opportunities) to the extent recovery for that loss is allowed under applicable State law.

(10) HARM.—The term ''harm''—

(A) means any physical injury, illness, disease, or death, or damage to property caused by a product; and

(B) does not include commercial loss.

(11) INSURER.—The term ''insurer'' means the employer of a claimant if the employer is self-insured or if the employer is not self-insured, the workers' compensation insurer of the employer.

(12) MANUFACTURER.—The term ''manufacturer'' means—

(A) any person who is engaged in a business to produce, create, make, or construct any product (or component part of a product) and who—

(i) designs or formulates the product (or component part of the product); or

(ii) has engaged another person to design or formulate the product (or component part of the product);

(B) a product seller, but only with respect to those aspects of a product (or component part of a product) which are created or affected when, before placing the product in the stream of commerce, the product seller—

(i) produces, creates, makes, constructs and designs, or formulates an aspect of the product (or component part of the product) made by another person; or

(ii) has engaged another person to design or formulate an aspect of the product (or component part of the product) made by another person; or

(C) any product seller not described in subparagraph (B) which holds itself out as a manufacturer to the user of the product.

(13) NONECONOMIC LOSS.—The term ''noneconomic loss'' means subjective, nonmonetary loss resulting from harm, including pain, suffering, inconvenience, mental suffering, emotional distress, loss of society and companionship, loss of consortium, injury to reputation, and humiliation.

(14) PERSON.—The term ''person'' means any individual, corporation, company, association, firm, partnership, society, joint stock company, or any other entity (including any governmental entity).

(15) PRODUCT.—

(A) IN GENERAL.—The term ''product'' means any object, substance, mixture, or raw material in a gaseous, liquid, or solid state that—

(i) is capable of delivery itself or as an assembled whole, in a mixed or combined state, or as a component part or ingredient;

(ii) is produced for introduction into trade or commerce;

(iii) has intrinsic economic value; and

(iv) is intended for sale or lease to persons for commercial or personal use.

(B) EXCLUSION.—The term ''product'' does not include—

(i) tissue, organs, blood, and blood products used for therapeutic or medical purposes, except to the extent that such tissue, organs, blood, and blood products (or the provision thereof) are subject, under applicable State law, to a standard of liability other than negligence; or

(ii) electricity, water delivered by a utility, natural gas, or steam.

(16) PRODUCT LIABILITY ACTION.—The term ''product liability action'' means a civil action brought on any theory for harm caused by a product.

(17) PRODUCT SELLER.—

(A) IN GENERAL.—The term ''product seller'' means a person who in the course of a business conducted for that purpose—

(i) sells, distributes, rents, leases, prepares, blends, packages, labels, or otherwise is involved in placing a product in the stream of commerce; or

(ii) installs, repairs, refurbishes, reconditions, or maintains the harm-causing aspect of the product.

(B) EXCLUSION.—The term ''product seller'' does not include—

(i) a seller or lessor of real property;

(ii) a provider of professional services in any case in which the sale or use of a product is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services; or

(iii) any person who—

(I) acts in only a financial capacity with respect to the sale of a product; or

(II) leases a product under a lease arrangement in which the lessor does not initially select the leased product and does not during the lease term ordinarily control the daily operations and maintenance of the product.

(18) PUNITIVE DAMAGES.—The term ''punitive damages'' means damages awarded against any person or entity to punish or deter that person or entity, or others, from engaging in similar behavior in the future.

(19) STATE.—The term ''State'' means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and any other territory or possession of the United States or any political subdivision of any of the foregoing.

(20) TOBACCO PRODUCT.—The term ''tobacco product'' means—

(A) a cigarette, as defined in section 3 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332);

(B) a little cigar, as defined in section 3 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332);

(C) a cigar, as defined in section 5702(a) of the Internal Revenue Code of 1986;

(D) pipe tobacco;

(E) loose rolling tobacco and papers used to contain that tobacco;

(F) a product referred to as smokeless tobacco, as defined in section 9 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4408); and

(G) any other form of tobacco intended for human consumption.

SEC. 102. APPLICABILITY; PREEMPTION.

(a) PREEMPTION.—

(1) IN GENERAL.—Except as provided in paragraph (2) and title II, this title governs any product liability action brought in any Federal or State court on any theory for harm caused by a product.

(2) ACTIONS EXCLUDED.—

(A) ACTIONS FOR COMMERCIAL LOSS.—A civil action brought for commercial loss shall be governed only by applicable commercial law, including applicable State law based on the Uniform Commercial Code.

(B) ACTIONS FOR NEGLIGENT ENTRUSTMENT; NEGLIGENCE PER SE CONCERNING FIREARMS AND AMMUNITION; DRAM-SHOP.—

(i) NEGLIGENT ENTRUSTMENT.—A civil action for negligent entrustment shall not be subject to the provisions of this title governing product liability actions, but shall be subject to any applicable Federal or State law.

(ii) NEGLIGENCE PER SE CONCERNING FIREARMS AND AMMUNITION.—A civil action brought under a theory of negligence per se concerning the use of a firearm or ammunition shall not be subject to the provisions of this title governing product liability actions, but shall be subject to any applicable Federal or State law.

(iii) DRAM-SHOP.—A civil action brought under a theory of dram-shop or third-party liability arising out of the sale or providing of an alcoholic product to an intoxicated person or minor shall not be subject to the provisions of this title, but shall be subject to any applicable Federal or State law.

(C) ACTIONS INVOLVING HARM CAUSED BY A TOBACCO PRODUCT.—A civil action brought for harm caused by a tobacco product shall not be subject to the provisions of this title governing product liability actions, but shall be subject to any applicable Federal or State law.

(D) ACTIONS INVOLVING HARM CAUSED BY A BREAST IMPLANT.—A civil action brought for harm caused by either the silicone gel or the silicone envelope utilized in a breast implant containing silicone gel shall not be subject to the provisions of this title governing product liability actions, but shall be subject to any applicable Federal or State law.

(b) RELATIONSHIP TO STATE LAW.—This title supersedes a State law only to the extent that the State law applies to a matter covered by this title. Any matter that is not governed by this title, including any standard of liability applicable to a manufacturer, shall be governed by any applicable Federal or State law.

(c) EFFECT ON OTHER LAW.—Nothing in this title shall be construed to—

(1) waive or affect any defense of sovereign immunity asserted by any State under any law;

(2) supersede or alter any Federal law;

(3) waive or affect any defense of sovereign immunity asserted by the United States;

(4) affect the applicability of any provision of chapter 97 of title 28, United States Code;

(5) preempt State choice-of-law rules with respect to claims brought by a foreign nation or a citizen of a foreign nation;

(6) affect the right of any court to transfer venue or to apply the law of a foreign nation or to dismiss a claim of a foreign nation or of a citizen of a foreign nation on the ground of inconvenient forum; or

(7) supersede or modify any statutory or common law, including any law providing for an action to abate a nuisance, that authorizes a person to institute an action for civil damages or civil penalties, cleanup costs, injunctions, restitution, cost recovery, punitive damages, or any other form of relief, for remediation of the environment (as defined in section 101(8) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9601(8)).

SEC. 103. LIABILITY RULES APPLICABLE TO PRODUCT SELLERS, RENTERS, AND LESSORS.

(a) GENERAL RULE.—

(1) IN GENERAL.—In any product liability action that is subject to this title, a product seller other than a manufacturer shall be liable to a claimant only if the claimant establishes that—

(A)(i) the product that allegedly caused the harm that is the subject of the complaint was sold, rented, or leased by the product seller;

(ii) the product seller failed to exercise reasonable care with respect to the product; and

(iii) the failure to exercise reasonable care was a proximate cause of the harm to the claimant;

(B)(i) the product seller made an express warranty applicable to the product that allegedly caused the harm that is the subject of the complaint, independent of any express warranty made by a manufacturer as to the same product;

(ii) the product failed to conform to the warranty; and

(iii) the failure of the product to conform to the warranty caused the harm to the claimant; or

(C)(i) the product seller engaged in intentional wrongdoing, as determined under applicable State law; and

(ii) the intentional wrongdoing caused the harm that is the subject of the complaint.

(2) REASONABLE OPPORTUNITY FOR INSPECTION.—For purposes of paragraph (1)(A)(ii), a product seller shall not be considered to have failed to exercise reasonable care with respect to a product based upon an alleged failure to inspect the product, if—

(A) the failure occurred because there was no reasonable opportunity to inspect the product; or

(B) the inspection, in the exercise of reasonable care, would not have revealed the aspect of the product that allegedly caused the claimant's harm.

(b) SPECIAL RULE.—

(1) IN GENERAL.—A product seller shall be deemed to be liable as a manufacturer of a product for harm caused by the product, if—

(A) the manufacturer is not subject to service of process under the laws of any State in which the action may be brought; or

(B) the court determines that the claimant is or would be unable to enforce a judgment against the manufacturer.

(2) STATUTE OF LIMITATIONS.—For purposes of this subsection only, the statute of limitations applicable to claims asserting liability of a product seller as a manufacturer shall be tolled from the date of the filing of a complaint against the manufacturer to the date that judgment is entered against the manufacturer.

(c) RENTED OR LEASED PRODUCTS.—

(1) DEFINITION.—For purposes of paragraph (2), and for determining the applicability of this title to any person subject to that paragraph, the term ''product liability action'' means a civil action brought on any theory for harm caused by a product or product use.

(2) LIABILITY.—Notwithstanding any other provision of law, any person engaged in the business of renting or leasing a product (other than a person excluded from the definition of product seller under section 101(17)(B)) shall be subject to liability in a product liability action under subsection (a), but any person engaged in the business of renting or leasing a product shall not be liable to a claimant for the tortious act of another solely by reason of ownership of that product.

SEC. 104. DEFENSE BASED ON CLAIMANT'S USE OF ALCOHOL OR DRUGS.

(a) GENERAL RULE.—In any product liability action that is subject to this title, it shall be a complete defense to a claim made by a claimant, if the defendant proves that the claimant—

(1) was intoxicated or was under the influence of alcohol or any drug when the accident or other event which resulted in that claimant's harm occurred; and

(2) as a result of the influence of the alcohol or drug, was more than 50 percent responsible for that harm.

(b) CONSTRUCTION.—For purposes of subsection (a)—

(1) the determination of whether a person was intoxicated or was under the influence of alcohol or any drug shall be made pursuant to applicable State law; and

(2) the term ''drug'' means any controlled substance as defined in the Controlled Substances Act (21 U.S.C. 802(6)) that was not legally prescribed for use by the claimant or that was taken by the claimant other than in accordance with the terms of a lawfully issued prescription.

SEC. 105. REDUCTION IN DAMAGES FOR MISUSE OR ALTERATION.

(a) GENERAL RULE.—

(1) IN GENERAL.—In any product liability action that is subject to this title, the damages for which a defendant is otherwise liable under Federal or State law shall be reduced by the percentage of responsibility for the claimant's harm attributable to misuse or alteration of a product by any person if the defendant establishes that such percentage of the claimant's harm was proximately caused by a use or alteration of a product—

(A) in violation of, or contrary to, a defendant's express warnings or instructions if the warnings or instructions are adequate as determined pursuant to applicable Federal or State law; or

(B) involving a risk of harm which was known or should have been known by the ordinary person who uses or consumes the product with the knowledge common to the class of persons who used or would be reasonably anticipated to use the product.

(2) USE INTENDED BY A MANUFACTURER IS NOT MISUSE OR ALTERATION.—For purposes of this title, a use of a product that is intended by the manufacturer of the product does not constitute a misuse or alteration of the product.

(b) WORKPLACE INJURY.—Notwithstanding subsection (a), and except as otherwise provided in section 112, the damages for which a defendant is otherwise liable under State law shall not be reduced by the percentage of responsibility for the claimant's harm attributable to misuse or alteration of the product by the claimant's employer who is immune from suit by the claimant pursuant to the State law applicable to workplace injuries.

SEC. 106. STATUTE OF LIMITATIONS.

(a) IN GENERAL.—Except as provided in subsection (b) and subject to section 107, a product liability action that is subject to this title may be filed not later than 2 years after the date on which the claimant discovered or, in the exercise of reasonable care, should have discovered, the harm that is the subject of the action and the cause of the harm.

(b) EXCEPTIONS.—

(1) PERSON WITH A LEGAL DISABILITY.—A person with a legal disability (as determined under applicable law) may file a product liability action that is subject to this title not later than 2 years after the date on which the person ceases to have the legal disability.

(2) EFFECT OF STAY OR INJUNCTION.—If the commencement of a civil action that is subject to this title is stayed or enjoined, the running of the statute of limitations under this section shall be suspended until the end of the period that the stay or injunction is in effect.

SEC. 107. STATUTE OF REPOSE FOR DURABLE GOODS USED IN A TRADE OR BUSINESS.

(a) IN GENERAL.—Except as provided in subsections (b) and (c), no product liability action that is subject to this title concerning a durable good alleged to have caused harm (other than toxic harm) for which the claimant has received or is eligible to receive workers' compensation may be filed after the 18-year period beginning at the time of delivery of the durable good to its first purchaser or lessee.

(b) EXTENSION OF STATUTE OF REPOSE.—Notwithstanding any other provision of this section and except as provided in section 106(b), a product liability action may be commenced within 2 years after the date of discovery or date on which discovery should have occurred, if the harm, and the cause of the harm, leading to a product liability action described in subsection (a) are discovered or, in the exercise of reasonable care, should have been discovered, before the expiration of the 18-year period under this section.

(c) EXCEPTIONS.—

(1) IN GENERAL.—A motor vehicle, vessel, aircraft, or train, that is used primarily to transport passengers for hire, shall not be subject to this section.

(2) CERTAIN EXPRESS WARRANTIES.—Subsection (a) does not bar a product liability action against a defendant who made an express warranty in writing as to the safety or life expectancy of the specific product involved which was longer than 18 years, except that such subsection shall apply at the expiration of that warranty.

(3) AVIATION LIMITATIONS PERIOD.—Subsection (a) does not affect the limitations period established by the General Aviation Revitalization Act of 1994 (49 U.S.C. 40101 note).

SEC. 108. TRANSITIONAL PROVISION RELATING TO EXTENSION OF PERIOD FOR BRINGING CERTAIN ACTIONS.

If any provision of section 106 or 107 shortens the period during which a product liability action could be otherwise brought pursuant to another provision of law, the claimant may, notwithstanding sections 106 and 107, bring the product liability action not later than 1 year after the date of enactment of this Act.

SEC. 109. ALTERNATIVE DISPUTE RESOLUTION PROCEDURES.

(a) SERVICE OF OFFER.—A claimant or a defendant in a product liability action that is subject to this title may serve upon an adverse party an offer to proceed pursuant to any voluntary, nonbinding alternative dispute resolution procedure established or recognized under the law of the State in which the product liability action is brought or under the rules of the court in which that action is maintained, not later than 60 days after the later of—

(1) service of the initial complaint; or

(2) the expiration of the applicable period for a responsive pleading.

(b) WRITTEN NOTICE OF ACCEPTANCE OR REJECTION.—

(1) IN GENERAL.—Except as provided in subsection (c), not later than 20 days after the service of an offer to proceed under subsection (a), an offeree shall file a written notice of acceptance or rejection of the offer.

(2) EFFECT OF NOTICE.—The filing of a written notice under paragraph (1) shall not constitute a waiver of any objection or defense in the action, including any objection on the grounds of jurisdiction.

(c) EXTENSION.—

(1) IN GENERAL.—The court may, upon motion by an offeree made before the expiration of the 20-day period specified in subsection (b), extend the period for filing a written notice under such subsection for a period of not more than 60 days after the date of expiration of the period specified in subsection (b).

(2) PERMITTED DISCOVERY.—Discovery may be permitted during the period described in paragraph (1).

SEC. 110. PUNITIVE DAMAGES REFORMS.

(a) GENERAL RULE.—

(1) UNIFORM STANDARD FOR AWARD OF PUNITIVE DAMAGES.—To the extent punitive damages are permitted by applicable State law, punitive damages may be awarded against a defendant in any product liability action that is subject to this title if the claimant establishes by clear and convincing evidence that the harm that is the subject of the action was the result of conduct carried out by the defendant with a conscious, flagrant indifference to the rights or safety of others.

(2) BIFURCATION AT REQUEST OF ANY PARTY.—

(A) IN GENERAL.—At the request of any party, the trier of fact in any action that is subject to this section shall consider in a separate proceeding, held subsequent to the determination of the amount of compensatory damages, whether punitive damages are to be awarded for the harm that is the subject of the action and the amount of the award.

(B) INADMISSIBILITY OF EVIDENCE RELATIVE ONLY TO A CLAIM OF PUNITIVE DAMAGES IN A PROCEEDING CONCERNING COMPENSATORY DAMAGES.—If any party requests a separate proceeding under paragraph (1), in a proceeding to determine whether the claimant may be awarded compensatory damages, any evidence, argument, or contention that is relevant only to the claim of punitive damages, as determined by applicable State law, shall be inadmissible.

(b) SPECIAL RULE FOR CERTAIN PERSONS AND ENTITIES.—

(1) IN GENERAL.—In any action described in subsection (a) against a person or entity described in paragraph (2), an award of punitive damages shall not exceed the lesser of—

(A) 2 times the amount of compensatory damages awarded; or

(B) $250,000.

(2) PERSONS AND ENTITIES DESCRIBED.—

(A) IN GENERAL.—A person or entity described in this paragraph is—

(i) an individual whose net worth does not exceed $500,000; or

(ii) an owner of an unincorporated business, or any partnership, corporation, association, unit of local government, or organization that has—

(I) annual revenues of less than or equal to $5,000,000; and

(II) fewer than 25 full-time employees.

(B) ANNUAL REVENUES AND EMPLOYEES.—For the purpose of determining the applicability of this subsection to a corporation, the calculation of—

(i) the annual revenues of that corporation shall include the annual revenues of any parent corporation (or other subsidiary of the parent corporation), subsidiary, branch, division, department, or unit of that corporation; and

(ii) the number of employees of that corporation shall include the number of employees of any parent corporation (or other subsidiary of the parent corporation), subsidiary, branch, division, department, or unit of that corporation.

(C) REFERENCE POINT FOR DETERMINING APPLICABILITY.—In determining the applicability of this subsection, the standards in subparagraphs (A) and (B) shall be applied as of the date of commencement of any action that is subject to this title. The defendant shall have the burden of proving the applicability of this subsection.

SEC. 111. LIABILITY FOR CERTAIN CLAIMS RELATING TO DEATH.

(a) IN GENERAL.—Subject to subsection (b), a defendant may be liable for damages that are only punitive in nature without regard to section 110 in any product liability action that is subject to this title—

(1) in which the alleged harm to the claimant is death; and

(2) that is subject to an applicable State law that, as of the date of enactment of this Act, provides, or is construed to provide, for damages that are only punitive in nature.

(b) LIMITATION.—Subsection (a) shall apply to an action that meets the requirements of paragraphs (1) and (2) of that subsection only during such period as the State law provides, or is construed to provide, for damages that are only punitive in nature.

(c) SUNSET.—This section shall cease to be effective on September 1, 1999.

SEC. 112. WORKERS' COMPENSATION SUBROGATION.

(a) GENERAL RULE.—

(1) RIGHT OF SUBROGATION.—

(A) IN GENERAL.—An insurer shall have a right of subrogation against a manufacturer or product seller to recover any claimant's benefits relating to harm that is the subject of a product liability action that is subject to this title.

(B) WRITTEN NOTIFICATION.—To assert a right of subrogation under subparagraph (A), the insurer shall provide written notice to the court in which the product liability action is brought.

(C) INSURER NOT REQUIRED TO BE A PARTY.—An insurer shall not be required to be a necessary and proper party in a product liability action covered under subparagraph (A).

(2) SETTLEMENTS AND OTHER LEGAL PROCEEDINGS.—

(A) IN GENERAL.—In any proceeding relating to harm or settlement with the manufacturer or product seller by a claimant who files a product liability action that is subject to this title, an insurer may participate to assert a right of subrogation for claimant's benefits with respect to any payment made by the manufacturer or product seller by reason of that harm, without regard to whether the payment is made—

(i) as part of a settlement;

(ii) in satisfaction of judgment;

(iii) as consideration for a covenant not to sue; or

(iv) in another manner.

(B) WRITTEN NOTIFICATION.—Except as provided in subparagraph (C), an employee shall not make any settlement with or accept any payment from the manufacturer or product seller without written notification to the insurer.

(C) EXEMPTION.—Subparagraph (B) shall not apply in any case in which the insurer has been compensated for the full amount of the claimant's benefits.

(3) HARM RESULTING FROM ACTION OF EMPLOYER.—

(A) IN GENERAL.—If, with respect to a product liability action that is subject to this title, the manufacturer or product seller chooses to raise to the trier of fact pursuant to the provisions of this section that the harm to the claimant was caused in whole or in part by the claimant's employer, the issue of employer fault shall be submitted to the trier of fact, but only after the manufacturer or product seller has provided timely written notice to the insurer that it is proceeding pursuant to the provisions of this section.

(B) RIGHTS OF INSURER.—Notwithstanding any other provision of law, with respect to an issue of fault submitted to a trier of fact pursuant to subparagraph (A), an insurer shall, in the same manner as any party in the action (even though the insurer is not a named party in the action), have the right to—

(i) appear;

(ii) be represented;

(iii) introduce evidence;

(iv) cross-examine adverse witnesses; and

(v) present arguments to the trier of fact.

(C) REDUCTION OF DAMAGES.—If the trier of fact finds by clear and convincing evidence that the fault of the employer was a substantial factor in causing the harm to the claimant that is the subject of the product liability action—

(i) the court shall reduce by the amount of the claimant's benefits and amounts for which payment, prior to the date of final judgment in the product liability action, has not yet been made for workers' compensation benefits received prior to such date or is otherwise due pursuant to State workers' compensation law—

(I) the damages awarded against the manufacturer or product seller; and

(II) any corresponding insurer's subrogation lien; and

(ii) the manufacturer or product seller shall have no further right by way of contribution or otherwise against the employer.

(D) CERTAIN RIGHTS NOT AFFECTED.—Notwithstanding a finding by the trier of fact described in subparagraph (C), the insurer shall not lose—

(i) any right of subrogation related to any—

(I) intentional tort committed against the claimant by a coemployee; or

(II) act committed by a coemployee outside the scope of normal work practices; or

(ii) any rights to credits against future liability established pursuant to applicable State workers' compensation law.

(b) ATTORNEY'S FEES.—If, in a product liability action that is subject to this section, the manufacturer or product seller raises the issue of employer fault pursuant to this section and the trier of fact finds that the fault of the employer was not a substantial factor in causing the harm to the claimant, the court shall require the manufacturer or product seller to reimburse the insurer for reasonable attorney's fees and court costs, as determined by the court, incurred by the insurer in litigating the issue of employer fault, unless the court finds that the position of the manufacturer or product seller was substantially justified or that special circumstances make such a reimbursement unjust.

TITLE II—BIOMATERIALS ACCESS ASSURANCE

SEC. 201. SHORT TITLE.

This title may be cited as the ''Biomaterials Access Assurance Act of 1998''.

SEC. 202. FINDINGS.

Congress find that—

(1) each year millions of citizens of the United States depend on the availability of lifesaving or life-enhancing medical devices, many of which are permanently implantable within the human body;

(2) a continued supply of raw materials and component parts is necessary for the invention, development, improvement, and maintenance of the supply of the devices;

(3) most of the medical devices are made with raw materials and component parts that—

(A) move in interstate commerce;

(B) are not designed or manufactured specifically for use in medical devices; and

(C) come in contact with internal human tissue;

(4) the raw materials and component parts also are used in a variety of nonmedical products;

(5) because small quantities of the raw materials and component parts are used for medical devices, sales of raw materials and component parts for medical devices constitute an extremely small portion of the overall market for the raw materials and component parts;

(6) under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), manufacturers of medical devices are required to demonstrate that the medical devices are safe and effective, including demonstrating that the products are properly designed and have adequate warnings or instructions;

(7) notwithstanding the fact that raw materials and component parts suppliers do not design, produce, or test a final medical device, the suppliers have been the subject of actions alleging inadequate—

(A) design and testing of medical devices manufactured with materials or parts supplied by the suppliers; or

(B) warnings related to the use of such medical devices;

(8) even though suppliers of raw materials and component parts have very rarely been held liable in such actions, such suppliers have ceased supplying certain raw materials and component parts for use in medical devices for a number of reasons, including concerns about the costs of such litigation;

(9) unless alternate sources of supply can be found, the unavailability of raw materials and component parts for medical devices will lead to unavailability of lifesaving and life-enhancing medical devices;

(10) because other suppliers of the raw materials and component parts in foreign nations are refusing to sell raw materials or component parts for use in manufacturing certain medical devices in the United States, the prospects for development of new sources of supply for the full range of threatened raw materials and component parts for medical devices are remote;

(11) it is unlikely that the small market for such raw materials and component parts in the United States could support the large investment needed to develop new suppliers of such raw materials and component parts;

(12) attempts to develop such new suppliers would raise the cost of medical devices;

(13) courts that have considered the duties of the suppliers of the raw materials and component parts have generally found that the suppliers do not have a duty—

(A) to evaluate the safety and efficacy of the use of a raw material or component part in a medical device; and

(B) to warn consumers concerning the safety and effectiveness of a medical device;

(14) because medical devices and the raw materials and component parts used in their manufacture move in interstate commerce, a shortage of such raw materials and component parts affects interstate commerce;

(15) in order to safeguard the availability of a wide variety of lifesaving and life-enhancing medical devices, immediate action is needed—

(A) to clarify the permissible bases of liability for suppliers of raw materials and component parts for medical devices; and

(B) to provide expeditious procedures to dispose of unwarranted suits against the suppliers in such manner as to minimize litigation costs;

(16) the several States and their courts are the primary architects and regulators of our tort system; Congress, however, must, in certain circumstances involving the national interest, address tort issues, and a threatened shortage of raw materials and component parts for life-saving medical devices is one such circumstance; and

(17) the protections set forth in this title are needed to assure the continued supply of materials for life-saving medical devices; however, negligent suppliers should not be protected.

SEC. 203. DEFINITIONS.

As used in this title:

(1) BIOMATERIALS SUPPLIER.—

(A) IN GENERAL.—The term ''biomaterials supplier'' means an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant.

(B) PERSONS INCLUDED.—Such term includes any person who—

(i) has submitted master files to the Secretary for purposes of premarket approval of a medical device; or

(ii) licenses a biomaterials supplier to produce component parts or raw materials.

(2) CLAIMANT.—

(A) IN GENERAL.—The term ''claimant'' means any person who brings a civil action, or on whose behalf a civil action is brought, arising from harm allegedly caused directly or indirectly by an implant, including a person other than the individual into whose body, or in contact with whose blood or tissue, the implant is placed, who claims to have suffered harm as a result of the implant.

(B) ACTION BROUGHT ON BEHALF OF AN ESTATE.—With respect to an action brought on behalf of or through the estate of an individual into whose body, or in contact with whose blood or tissue the implant is placed, such term includes the decedent that is the subject of the action.

(C) ACTION BROUGHT ON BEHALF OF A MINOR OR INCOMPETENT.—With respect to an action

brought on behalf of or through a minor or incompetent, such term includes the parent or guardian of the minor or incompetent.

(D) EXCLUSIONS.—Such term does not include—

(i) a provider of professional health care services, in any case in which—

(I) the sale or use of an implant is incidental to the transaction; and

(II) the essence of the transaction is the furnishing of judgment, skill, or services;

(ii) a person acting in the capacity of a manufacturer, seller, or biomaterials supplier;

(iii) a person alleging harm caused by either the silicone gel or the silicone envelope utilized in a breast implant containing silicone gel, except that—

(I) neither the exclusion provided by this clause nor any other provision of this title may be construed as a finding that silicone gel (or any other form of silicone) may or may not cause harm; and

(II) the existence of the exclusion under this clause may not—

(aa) be disclosed to a jury in any civil action or other proceeding; and

(bb) except as necessary to establish the applicability of this title, otherwise be presented in any civil action or other proceeding.

(3) COMPONENT PART.—

(A) IN GENERAL.—The term ''component part'' means a manufactured piece of an implant.

(B) CERTAIN COMPONENTS.—Such term includes a manufactured piece of an implant that—

(i) has significant nonimplant applications; and

(ii) alone, has no implant value or purpose, but when combined with other component parts and materials, constitutes an implant.

(4) HARM.—

(A) IN GENERAL.—The term ''harm'' means—

(i) any injury to or damage suffered by an individual;

(ii) any illness, disease, or death of that individual resulting from that injury or damage; and

(iii) any loss to that individual or any other individual resulting from that injury or damage.

(B) EXCLUSION.—The term does not include any commercial loss or loss of or damage to an implant.

(5) IMPLANT.—The term ''implant'' means—

(A) a medical device that is intended by the manufacturer of the device—

(i) to be placed into a surgically or naturally formed or existing cavity of the body for a period of at least 30 days; or

(ii) to remain in contact with bodily fluids or internal human tissue through a surgically produced opening for any period of time,

(B) suture materials used in implant procedures; and

(C) containers and their related products to be used to collect fluids or tissue from the body or to infuse or otherwise introduce fluids or tissue into the body, in conjunction with a medical device described in the above subparagraph (A).

(6) MANUFACTURER.—The term ''manufacturer'' means any person who, with respect to an implant—

(A) is engaged in the manufacture, preparation, propagation, compounding, or processing (as defined in section 510(a)(1)) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(a)(1)) of the implant; and

(B) is required—

(i) to register with the Secretary pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) and the regulations issued under such section; and

(ii) to include the implant on a list of devices filed with the Secretary pursuant to section 510(j) of such Act (21 U.S.C. 360(j)) and the regulations issued under such section.

(7) MEDICAL DEVICE.—The term ''medical device'' means a device, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) and includes any device component of any combination product as that term is used in section 503(g) of such Act (21 U.S.C. 353(g)).

(8) RAW MATERIAL.—The term ''raw material'' means a substance or product that—

(A) has a generic use; and

(B) may be used in an application other than an implant.

(9) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(10) SELLER.—

(A) IN GENERAL.—The term ''seller'' means a person who, in the course of a business conducted for that purpose, sells, distributes, leases, packages, labels, or otherwise places an implant in the stream of commerce.

(B) EXCLUSIONS.—The term does not include—

(i) a seller or lessor of real property;

(ii) a provider of professional services, in any case in which the sale or use of an implant is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services; or

(iii) any person who acts in only a financial capacity with respect to the sale of an implant.

SEC. 204. GENERAL REQUIREMENTS; APPLICABILITY; PREEMPTION.

(a) GENERAL REQUIREMENTS.—

(1) IN GENERAL.—In any civil action covered by this title, a biomaterials supplier may raise as a defense the exclusion from liability set forth in section 205(a).

(2) PROCEDURES.—Notwithstanding any other provision of law, the Federal or State court in which a civil action covered by this title is pending shall, in connection with a motion for dismissal or judgment based on a defense described in paragraph (1), use the procedures set forth in section 206.

(b) APPLICABILITY.—

(1) IN GENERAL.—Except as provided in paragraph (2), notwithstanding any other provision of law, this title applies to any civil action brought by a claimant, whether in a Federal or State court, against a manufacturer, seller, or biomaterials supplier, on the basis of any legal theory, for harm allegedly caused by an implant.

(2) EXCLUSION.—A civil action brought by a purchaser of a medical device for use in providing professional services against a manufacturer, seller, or biomaterials supplier for loss or damage to an implant or for commercial loss to the purchaser—

(A) shall not be considered an action that is subject to this title; and

(B) shall be governed by applicable commercial or contract law.

(c) SCOPE OF PREEMPTION.—

(1) IN GENERAL.—This title supersedes any State law regarding recovery for harm caused by an implant and any rule of procedure applicable to a civil action to recover damages for such harm only to the extent that this title establishes a rule of law applicable to the recovery of such damages.

(2) APPLICABILITY OF OTHER LAWS.—Any issue that arises under this title and that is not governed by a rule of law applicable to the recovery of damages described in paragraph (1) shall be governed by applicable Federal or State law.

(d) STATUTORY CONSTRUCTION.—Nothing in this title may be construed—

(1) to affect any defense available to a defendant under any other provisions of Federal or State law in an action alleging harm caused by an implant; or

(2) to create a cause of action or Federal court jurisdiction pursuant to sections 1331 or 1337 of title 28, United States Code, that otherwise would not exist under applicable Federal or State law.

SEC. 205. LIABILITY OF BIOMATERIALS SUPPLIERS.

(a) IN GENERAL.—

(1) EXCLUSION FROM LIABILITY.—Except as provided in paragraph (2) or section 207, a biomaterials supplier shall not be liable for harm to a claimant caused by an implant.

(2) LIABILITY.—A biomaterials supplier that—

(A) is a manufacturer may be liable for harm to a claimant described in subsection (b);

(B) is a seller may be liable for harm to a claimant described in subsection (c); and

(C) furnishes raw materials or component parts that fail to meet applicable contractual requirements or specifications may be liable for harm to a claimant described in subsection (d).

(b) LIABILITY AS MANUFACTURER.—

(1) IN GENERAL.—A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant if the biomaterials supplier is the manufacturer of the implant.

(2) GROUNDS FOR LIABILITY.—The biomaterials supplier may be considered the manufacturer of the implant that allegedly caused harm to a claimant only if the biomaterials supplier—

(A)(i) has or should have registered with the Secretary pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) and the regulations issued under such section; and

(ii) included or should have included the implant on a list of devices filed with the Secretary pursuant to section 510(j) of such Act (21 U.S.C. 360(j)) and the regulations issued under such section;

(B) is the subject of a declaration issued by the Secretary pursuant to paragraph (3) that states that the supplier, with respect to the implant that allegedly caused harm to the claimant, was required to—

(i) register with the Secretary under section 510 of such Act (21 U.S.C. 360), and the regulations issued under such section, but failed to do so; or

(ii) include the implant on a list of devices filed with the Secretary pursuant to section 510(j) of such Act (21 U.S.C. 360(j)) and the regulations issued under such section, but failed to do so; or

(C) is related by common ownership or control to a person meeting all the requirements described in subparagraph (A) or (B), if the court deciding a motion to dismiss in accordance with section 206(c)(3)(B)(i) finds, on the basis of affidavits submitted in accordance with section 206, that it is necessary to impose liability on the biomaterials supplier as a manufacturer because the related manufacturer meeting the requirements of subparagraph (A) or (B) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(3) ADMINISTRATIVE PROCEDURES.—

(A) IN GENERAL.—The Secretary may issue a declaration described in paragraph (2)(B) on the motion of the Secretary or on petition by any person, after providing—

(i) notice to the affected persons; and

(ii) an opportunity for an informal hearing.

(B) DOCKETING AND FINAL DECISION.—Immediately upon receipt of a petition filed pursuant to this paragraph, the Secretary shall docket the petition. Not later than 120 days

after the petition is filed, the Secretary shall issue a final decision on the petition.

(C) APPLICABILITY OF STATUTE OF LIMITATIONS.—Any applicable statute of limitations shall toll during the period during which a claimant has filed a petition with the Secretary under this paragraph.

(c) LIABILITY AS SELLER.—A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable as a seller for harm to a claimant caused by an implant only if—

(1) the biomaterials supplier—

(A) held title to the implant that allegedly caused harm to the claimant as a result of purchasing the implant after—

(i) the manufacture of the implant; and

(ii) the entrance of the implant in the stream of commerce; and

(B) subsequently resold the implant; or

(2) the biomaterials supplier is related by common ownership or control to a person meeting all the requirements described in paragraph (1), if a court deciding a motion to dismiss in accordance with section 206(c)(3)(B)(ii) finds, on the basis of affidavits submitted in accordance with section 206, that it is necessary to impose liability on the biomaterials supplier as a seller because the related seller meeting the requirements of paragraph (1) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(d) LIABILITY FOR VIOLATING CONTRACTUAL REQUIREMENTS OR SPECIFICATIONS.—A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant, if the claimant in an action shows, by a preponderance of the evidence, that—

(1) the raw materials or component parts delivered by the biomaterials supplier either—

(A) did not constitute the product described in the contract between the biomaterials supplier and the person who contracted for delivery of the product; or

(B) failed to meet any specifications that were—

(i) accepted, pursuant to applicable law, by the biomaterials supplier;

(ii)(I) published by the biomaterials supplier;

(II) provided to the manufacturer by the biomaterials supplier; or

(III) contained in a master file that was submitted by the biomaterials supplier to the Secretary and that is currently maintained by the biomaterials supplier for purposes of premarket approval of medical devices; or

(iii) included in the submissions for purposes of premarket approval or review by the Secretary under section 510, 513, 515, or 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360, 360c, 360e, or 360j), and received clearance from the Secretary if such specifications were accepted, pursuant to applicable law, by the biomaterials supplier; and

(2) such conduct was an actual and proximate cause of the harm to the claimant.

SEC. 206. PROCEDURES FOR DISMISSAL OF CIVIL ACTIONS AGAINST BIOMATERIALS SUPPLIERS.

(a) MOTION TO DISMISS.—In any action that is subject to this title, a biomaterials supplier who is a defendant in such action may, at any time during which a motion to dismiss may be filed under an applicable law, move to dismiss the action against it on the grounds that—

(1) the defendant is a biomaterials supplier; and

(2)(A) the defendant should not, for the purposes of—

(i) section 205(b), be considered to be a manufacturer of the implant that is subject to such section; or

(ii) section 205(c), be considered to be a seller of the implant that allegedly caused harm to the claimant; or

(B)(i) the claimant has failed to establish, pursuant to section 205(d), that the supplier furnished raw materials or component parts in violation of contractual requirements or specifications; or

(ii) the claimant has failed to comply with the procedural requirements of subsection (b).

(b) MANUFACTURER OF IMPLANT SHALL BE NAMED A PARTY.—The claimant shall be required to name the manufacturer of the implant as a party to the action, unless—

(1) the manufacturer is subject to service of process solely in a jurisdiction in which the biomaterials supplier is not domiciled or subject to a service of process; or

(2) an action against the manufacturer is barred by applicable law or rule of practice.

(c) PROCEEDING ON MOTION TO DISMISS.—The following rules shall apply to any proceeding on a motion to dismiss filed under this section:

(1) AFFIDAVITS RELATING TO LISTING AND DECLARATIONS.—

(A) IN GENERAL.—The defendant in the action may submit an affidavit demonstrating that the defendant has not included the implant on a list, if any, filed with the Secretary pursuant to section 510(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)).

(B) RESPONSE TO MOTION TO DISMISS.—In response to the motion to dismiss, the claimant may submit an affidavit demonstrating that—

(i) the Secretary has, with respect to the defendant and the implant that allegedly caused harm to the claimant, issued a declaration pursuant to section 205(b)(2)(B); or

(ii) the defendant who filed the motion to dismiss is a seller of the implant who is liable under section 205(c).

(2) EFFECT OF MOTION TO DISMISS ON DISCOVERY.—

(A) IN GENERAL.—If a defendant files a motion to dismiss under paragraph (1) or (2) of subsection (a), no discovery shall be permitted in connection to the action that is the subject of the motion, other than discovery necessary to determine a motion to dismiss for lack of jurisdiction, until such time as the court rules on the motion to dismiss in accordance with the affidavits submitted by the parties in accordance with this section.

(B) DISCOVERY.—If a defendant files a motion to dismiss under subsection (a)(2)(B)(i) on the grounds that the biomaterials supplier did not furnish raw materials or component parts in violation of contractual requirements or specifications, the court may permit discovery, as ordered by the court. The discovery conducted pursuant to this subparagraph shall be limited to issues that are directly relevant to—

(i) the pending motion to dismiss; or

(ii) the jurisdiction of the court.

(3) AFFIDAVITS RELATING STATUS OF DEFENDANT.—

(A) IN GENERAL.—Except as provided in clauses (i) and (ii) of subparagraph (B), the court shall consider a defendant to be a biomaterials supplier who is not subject to an action for harm to a claimant caused by an implant, other than an action relating to liability for a violation of contractual requirements or specifications described in section 205(d).

(B) RESPONSES TO MOTION TO DISMISS.—The court shall grant a motion to dismiss any action that asserts liability of the defendant under subsection (b) or (c) of section 205 on the grounds that the defendant is not a manufacturer subject to such section 205(b) or seller subject to section 205(c), unless the claimant submits a valid affidavit that demonstrates that—

(i) with respect to a motion to dismiss contending the defendant is not a manufacturer, the defendant meets the applicable requirements for liability as a manufacturer under section 205(b); or

(ii) with respect to a motion to dismiss contending that the defendant is not a seller, the defendant meets the applicable requirements for liability as a seller under section 205(c).

(4) BASIS OF RULING ON MOTION TO DISMISS.—

(A) IN GENERAL.—The court shall rule on a motion to dismiss filed under subsection (a) solely on the basis of the pleadings of the parties made pursuant to this section and any affidavits submitted by the parties pursuant to this section.

(B) MOTION FOR SUMMARY JUDGMENT.— Notwithstanding any other provision of law, if the court determines that the pleadings and affidavits made by parties pursuant to this section raise genuine issues concerning material facts with respect to a motion concerning contractual requirements and specifications, the court may deem the motion to dismiss to be a motion for summary judgment made pursuant to subsection (d).

(d) SUMMARY JUDGMENT.—

(1) IN GENERAL.—

(A) BASIS FOR ENTRY OF JUDGMENT.—A biomaterials supplier shall be entitled to entry of judgment without trial if the court finds there is no genuine issue concerning any material fact for each applicable element set forth in paragraphs (1) and (2) of section 205(d).

(B) ISSUES OF MATERIAL FACT.—With respect to a finding made under subparagraph (A), the court shall consider a genuine issue of material fact to exist only if the evidence submitted by claimant would be sufficient to allow a reasonable jury to reach a verdict for the claimant if the jury found the evidence to be credible.

(2) DISCOVERY MADE PRIOR TO A RULING ON A MOTION FOR SUMMARY JUDGMENT.—If, under applicable rules, the court permits discovery prior to a ruling on a motion for summary judgment made pursuant to this subsection, such discovery shall be limited solely to establishing whether a genuine issue of material fact exists as to the applicable elements set forth in paragraphs (1) and (2) of section 205(d).

(3) DISCOVERY WITH RESPECT TO A BIOMATERIALS SUPPLIER.—A biomaterials supplier shall be subject to discovery in connection with a motion seeking dismissal or summary judgment on the basis of the inapplicability of section 205(d) or the failure to establish the applicable elements of section 205(d) solely to the extent permitted by the applicable Federal or State rules for discovery against nonparties.

(e) STAY PENDING PETITION FOR DECLARATION.—If a claimant has filed a petition for a declaration pursuant to section 205(b)(3)(A) with respect to a defendant, and the Secretary has not issued a final decision on the petition, the court shall stay all proceedings with respect to that defendant until such time as the Secretary has issued a final decision on the petition.

(f) DISMISSAL WITH PREJUDICE.—An order granting a motion to dismiss or for summary judgment pursuant to this section shall be entered with prejudice, except insofar as the moving defendant may be rejoined to the action as provided in section 207.

(g) MANUFACTURER CONDUCT OF LITIGATION.—The manufacturer of an implant that is the subject of an action covered under this title shall be permitted to conduct litigation

on any motion for summary judgment or dismissal filed by a biomaterials supplier who is a defendant under this section on behalf of such supplier if the manufacturer and any other defendant in such action enter into a valid and applicable contractual agreement under which the manufacturer agrees to bear the cost of such litigation or to conduct such litigation.

SEC. 207. SUBSEQUENT IMPLEADER OF DISMISSED DEFENDANT.

(a) IMPLEADING OF DISMISSED DEFENDANT.—A court, upon motion by a manufacturer or a claimant within 90 days after entry of a final judgment in an action by the claimant against a manufacturer, and notwithstanding any otherwise applicable statute of limitations, may implead a biomaterials supplier who has been dismissed from the action pursuant to this title if—

(1) the manufacturer has made an assertion, either in a motion or other pleading filed with the court or in an opening or closing statement at trial, or as part of a claim for contribution or indemnification, and the court makes a finding based on the court's independent review of the evidence contained in the record of the action, that under applicable law—

(A) the negligence or intentionally tortious conduct of the dismissed supplier was an actual and proximate cause of the harm to the claimant; and

(B) the manufacturer's liability for damages should be reduced in whole or in part because of such negligence or intentionally tortious conduct; or

(2) the claimant has moved to implead the supplier and the court makes a finding based on the court's independent review of the evidence contained in the record of the action, that under applicable law—

(A) the negligence or intentionally tortious conduct of the dismissed supplier was an actual and proximate cause of the harm to the claimant; and

(B) the claimant is unlikely to be able to recover the full amount of its damages from the remaining defendants.

(b) STANDARD OF LIABILITY.—Notwithstanding any preliminary finding under subsection (a), a biomaterials supplier who has been impleaded into an action subject to this title, as provided for in this section—

(1) may, prior to entry of judgment on the claim against it, supplement the record of the proceeding that was developed prior to the grant of the motion for impleader under subsection (a); and

(2) may be found liable to a manufacturer or a claimant only to the extent required and permitted by any applicable Federal or State law other than this title in an action alleging harm caused by an implant.

(c) DISCOVERY.—Nothing in this section shall give a claimant or any other party the right to obtain discovery from a biomaterials supplier defendant at any time prior to grant of a motion for impleader beyond that allowed under section 206.

TITLE III—LIMITATIONS ON APPLICABILITY; EFFECTIVE DATE

SEC. 301. FEDERAL CAUSE OF ACTION PRECLUDED.

The district courts of the United States shall not have jurisdiction pursuant to this Act based on section 1331 or 1337 of title 28, United States Code.

SEC. 302. EFFECTIVE DATE.

This Act shall apply with respect to any action commenced on or after the date of enactment of this Act without regard to whether the harm that is the subject of the action or the conduct that caused the harm occurred before that date of enactment.

DEPARTMENT OF VETERANS AFFAIRS AND HOUSING AND URBAN DEVELOPMENT, AND INDEPENDENT AGENCIES APPROPRIATIONS ACT, 1999

BROWNBACK AMENDMENT NO. 3065

(Ordered to lie on the table.)

Mr. BROWNBACK submitted an amendment intended to be proposed by him to the bill, S. 2168, supra; as follows:

On page 93, between lines 18 and 19, insert the following:

SEC. 423. USE OF STATE REVOLVING LOAN FUNDS FOR MUNICIPALITIES FOR DEVELOPMENT OF WATER SYSTEMS.

Section 1452(a)(2) of the Safe Drinking Water Act (42 U.S.C. 300j–12(a)(2)) is amended in the first sentence by striking ''community water systems and nonprofit noncommunity water systems'' and inserting ''community water systems, nonprofit noncommunity water systems, and municipalities for the development of such water systems''.

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

Mr. GORTON. Mr. President, I ask unanimous consent that the full Committee on Environment and Public Works be granted permission to conduct a hearing Tuesday, July 7, 9:00 a.m., Hearing Room (SD–406) on the following wildlife legislation: S 2094, Fish and Wildlife Revenue Enhancement Act of 1998; S. 361, Rhino and Tiger Product Labeling Act; H.R. 2807, Rhino and Tiger Product Labeling Act; H.R. 3113, Rhinoceros and Tiger Conservation Reauthorization Act of 1998; S. 263, Bear Protection Act; S. 659, Great Lakes Fish and Wildlife Restoration Act of 1997; S. 2244, National Wildlife Refuge System Volunteer and Partnership Enhancement Act of 1998; and S. 1970, the Neotropical Migratory Bird Conservation Act.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON THE JUDICIARY

Mr. GORTON. Mr. President, I ask unanimous consent that the Committee on the Judiciary, be authorized to hold an executive business meeting during the session of the Senate on Tuesday, July 7, 1998, at 10:30 a.m., in room 226, of the Senate Dirksen Office Building.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON ANTITRUST, BUSINESS RIGHTS, AND COMPETITION

Mr. GORTON. Mr. President, I ask unanimous consent that the Subcommittee on Antitrust, Business Rights, and Competition, of the Senate Judiciary Committee, be authorized to meet during the session of the Senate on Tuesday, July 7, 1998 at 9:00 a.m. to hold a hearing in room 342, Senate Dirksen Building, on: ''Covergence and Consolidation in the Entertainment and Information Industries: What Does the Future Hold?''

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON INTERNATIONAL TRADE

Mr. GORTON. Mr. President, the Finance Committee Subcommittee on International Trade requests unanimous consent to conduct a hearing on Tuesday, July 7, 1998, beginning at 10:00 a.m. in room 215 Dirksen.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON SOCIAL SECURITY AND FAMILY POLICY

Mr. GORTON. Mr. President, the Finance Committee Subcommittee on Social Security and Family Policy requests unanimous consent to conduct a hearing on Tuesday, July 7, 1998, beginning at 2:00 p.m. in room 215 Dirksen.

The PRESIDING OFFICER. Without objection, it is so ordered.

ADDITIONAL STATEMENTS

TRIBUTE TO JENNY CHUASIRIPORN

● Ms. MIKULSKI. Mr. President, I rise today to pay tribute to an outstanding young Maryland woman, Jenny Chuasiriporn. Yesterday, Jenny, a 20-year-old amateur golfer, placed second in the U.S. Women's Open following a ''sudden death'' round with the ultimate winner, Se Ri Pak. Although Jenny did not place first in the U.S. Women's Open, she won a place in my heart and in the hearts of many others.

Jenny Chuasiriporn is a senior at Duke University and is from Timonium, Maryland. Her pursuit of excellence in golf is truly a family affair. Her 21-year-old brother, Joey, was her caddy and coach. Her parents were also at the Blackwolf Run Golf Course in Wisconsin to cheer on their daughter, having closed up their family business, the Bangkok Place restaurant on York Road, to be with her.

Now, I will be the first to admit that I do not share much with Jenny in regard to the quality of my golf game. My golf handicap is pretty close to the height of the Washington Monument! But I do think I'm a pretty good putter. And I know from first hand experience that the game of golf takes an extraordinary amount of concentration and consistency to drive down the fairway, angle that chip shot, and putt slowly and surely. Jenny has that great concentration and consistency. She is and will be a great golfer. I, on the other hand, will stick with the Senate!

Jenny also exhibited strong endurance. On Sunday, she hit a forty foot birdie putt that forced the tournament into a playoff round. After an 18-hole playoff round, the game was still tied between Jenny and Se Ri. Then the tournament went into what they call a ''sudden death'' round. It was the first sudden death round in the U.S. Women's Open 53-year history. Finally, on the second hole of ''sudden death'', Se Ri Pak hit an 18-foot birdie to win the tournament. But Jenny Chuasiriporn, the young Maryland amateur, had held on tight for five long days of golf and can surely call herself a winner.