amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3144. Mr. FRANKEN submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3145. Mr. MCCONNELL (for himself, Mr. ENSIGN, and Mr. MCCAIN) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3146. Mr. BARRASSO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3147. Mr. BARRASSO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3148. Mr. BARRASSO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3149. Mr. BARRASSO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3150. Mr. BARRASSO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3151. Mr. BARRASSO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3152. Mr. ENSIGN submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3153. Mr. BARRASSO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3154. Mr. BARRASSO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3155. Mr. BARRASSO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3156. Mr. LAUTENBERG (for himself, Mr. CARPER, and Mr. MENENDEZ) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3157. Mrs. SHAHEEN (for herself and Mr. MERKLEY) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3158. Mr. KYL submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3159. Mr. KYL submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3160. Mr. BEGICH submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3161. Mr. THUNE submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3162. Mr. SPECTER (for himself and Mrs. HAGAN) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

SA 3163. Mr. SPECTER submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, supra; which was ordered to lie on the table.

TEXT OF AMENDMENTS

SA 3115. Mr. CASEY submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 1609, after line 23, insert the following:

SEC. 6108. COMMUNITY INTEGRATED NURSING CARE HOMES DEMONSTRATION PROGRAM.

(a) SHORT TITLE.—This section may be cited as the ''Community Integrated Nursing Care Homes Demonstration Program Act'' or the ''CINCH Demonstration Program''.

(b) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary shall establish the CINCH demonstration program to test the viability of multiple small house nursing homes that are embedded within residential neighborhoods and collectively certified to provide services through a single eligible operating entity in order to reduce administrative costs and provide related cost savings to the Medicare and Medicaid programs.

(2) DURATION AND SCOPE.—

(A) DURATION.—The Secretary shall conduct the CINCH demonstration program for a period of 5 years.

(B) SCOPE.—The Secretary shall select not more than 6 sites (as described in paragraph (3)) to participate in the CINCH demonstration program, with each site to be operated by a different eligible operating entity (as described under subsection (c)(2)) and not less than 2 sites to be located in rural areas.

(3) SITES.—

(A) IN GENERAL.—A site shall consist of not less than 2 locations, with each location containing not more than 2 small house nursing homes, that are operated by an eligible operating entity under such entity's nursing home license and provider certification.

(B) LOCATIONS.—

(i) DISTANCES.—Distances between locations within a site may vary based upon market demand and availability, with maximum distances between locations to be established by the eligible operating entity based upon the ability of such entity to—

(I) deliver required services and supervision in a timely and appropriate manner; and

(II) subject to paragraph (5), meet all applicable statutory and regulatory requirements for operation of a nursing home.

(ii) ADJOINING PARCELS.—A location shall—

(I) consist of a single parcel of land or multiple adjoining parcels of land; and

(II) be separate from any other location and operate on a non-adjoining parcel of land from such location.

(C) NUMBER OF SMALL HOUSE NURSING HOMES PER SITE.—A site shall contain not less than 4 small house nursing homes and not greater than—

(i) in rural areas (or a site that encompasses a rural area), 12 small house nursing homes; or

(ii) in urban or suburban areas, 24 small house nursing homes.

(4) CONTINUATION OF TREATMENT AS SINGLE PROVIDER.—The Secretary shall develop a process to allow a site, following the 5-year period for the CINCH demonstration program, to continue operation through a single operating entity and receive certification as a single provider for purposes of Medicare and Medicaid, including provisions to permit such continuation following a change in ownership of a participating small house nursing home.

(5) WAIVER AUTHORITY.—The Secretary may waive such requirements of titles XI, XVIII, and XIX of the Social Security Act as may be necessary to carry out the CINCH demonstration program and shall develop a process that permits sites to be certified and reimbursed under Medicare and Medicaid.

(c) SELECTION.—

(1) TECHNICAL ASSISTANCE PROVIDER.—

(A) IN GENERAL.—Not later than 90 days after the date of enactment of this Act, the Secretary, through a request for proposal process, shall select a technical assistance provider that shall be responsible for assisting and monitoring eligible operating entities (as described under paragraph (2)).

(B) MINIMUM REQUIREMENTS.—In selecting the technical assistance provider, the Secretary shall ensure that such organization—

(i) is a national not-for-profit organization that is in good standing;

(ii) has a consistent, clearly articulated, and research-based model for operation of small house nursing homes;

(iii) has not less than 10 years of experience in providing development, operation, regulatory, policy, and financial consulting services to clients or partners seeking to innovate the provision of long-term care;

(iv) has demonstrated a successful process and record (for not less than 4 years) for selection and assistance of multiple organizations in implementation of a small house nursing home model, including development, operations, and staff training;

(v) has established curricula for training of leadership, clinical, and direct care staff;

(vi) has demonstrated capacity, through its own resources and consultants, to—

(I) collect Minimum Data Set (''MDS'') information and financial data from eligible operating entities; and

(II) benchmark and analyze such financial data on not less than a quarterly basis;

(vii) has the ability to administer the CINCH demonstration program without additional funding from Federal, State, or local governmental sources;

(viii) agrees to provide technical assistance services to eligible operating entities for a fee that is not greater than its usual and customary fee for such services; and

(ix) agrees to maintain a provider network for small house nursing homes participating in the CINCH demonstration program for a fee that is not greater than its usual and customary fee for such services.

(C) PREFERENCES.—In selecting the technical assistance provider, the Secretary shall give preference to an organization that has demonstrated experience in related business activities, including community-based care models, health care financing, and demonstration programs.

(2) ELIGIBLE OPERATING ENTITY.—

(A) IN GENERAL.—Selection of eligible operating entities shall be determined by the technical assistance provider through a request for proposal process on a continual basis.

(B) MINIMUM REQUIREMENTS.—An eligible operating entity seeking to participate in the CINCH demonstration program shall be required to—

(i) commit to maintaining the small house nursing home requirements described under subsection (d) and permit the technical assistance provider to conduct periodic evaluations to ensure adherence to such requirements;

(ii) maintain membership in a small house nursing home provider network that is maintained by the technical assistance provider; and

(iii) ensure that, for each site, at least 30 percent of the total capacity developed under the CINCH demonstration program is provided to residents that are receiving nursing home benefits under Medicaid.

(d) SMALL HOUSE NURSING HOME REQUIREMENTS.—To be eligible to participate in the CINCH demonstration program, a small house nursing home shall—

(1) subject to subsection (b)(5), have been certified by a State or local entity (in accordance with applicable State and local law) to operate a nursing home;

(2) operate in compliance with any direct care and certified nurse assistant staffing requirements under Federal and State law;

(3) provide nursing home services, as required under State law and applicable licensing standards, that shall not be less comprehensive or high-acuity than services provided by the eligible operating entity within the immediate surrounding community;

(4) provide for meals cooked in the small house nursing home and not prepared in a central kitchen and transported to the nursing home;

(5) provide for a universal worker approach to resident care (such as a certified nursing assistant who provides personal care, socialization services, meal preparation services, and laundry and housekeeping services);

(6) provide for direct care staffing at a rate of not less than 4 hours per resident per day, with direct care staff (including certified nurse assistants) to be onsite, awake, and available within each nursing home at all times;

(7) provide for direct nursing care at a rate of not less than 1 hour per resident per day, with a nurse to be awake and available at each location at all times (with nurses to be shared between not more than 2 nursing homes on each site) as part of a nursing staff that meets or exceeds applicable Federal and State requirements for qualifications, services, and availability;

(8) provide for any other clinical, operational, management, or facility staff and services as required under applicable Federal and State requirements, with such staff to be available from centralized or distributed locations;

(9) provide for consistent staff assignments and self-directed work teams of direct care staff;

(10) provide training for all staff involved in the operations of the nursing home (for not less than 120 hours for each universal worker and not less than 60 hours for each leadership and clinical team member, to be completed for the majority of the staff before they start to work in a small house nursing home) concerning the philosophy, operations, and skills required to implement and maintain self-directed care, self-managed work teams, a noninstitutional approach to life and care in long-term care, appropriate safety and emergency skills, cooking from scratch by the direct care staff and food handling and safety, and other elements required for successful operation of the nursing home;

(11) ensure that the percentage of residents in each nursing home who are short-stay rehabilitation residents does not exceed 20 percent at any time (unless the small house nursing home is entirely devoted to providing rehabilitation services), except that a long-term resident transferring back to a nursing home after an acute episode and who is receiving rehabilitation services for which payment is made under the Medicare program shall not be counted toward such limitation;

(12) provide the technical assistance provider with MDS information and financial data in a timely manner on a monthly basis; and

(13) consist of a physical environment designed to look and feel like a home, rather than an institution, and that shall—

(A) be designed to serve as a fully independent and disabled accessible house or apartment, with not more than 10 residents within such house or apartment, and that shall only be connected to or share areas that would be generally shared between private homes (such as a driveway) or apartments (such as a lobby or laundry room);

(B) contain residential-style design elements and materials throughout the home that are similar to those in the immediate surrounding community and that do not use commercial and institutional elements and products (such as a nurses' station, medication carts, hospital or office-type florescent lighting, acoustical tile ceilings, institutional-style railings and corner guards, and room numbering and labeling) unless mandated by authorities with appropriate jurisdiction over the nursing home;

(C) provide private, single occupancy bedrooms that are shared only at the request of a resident to accommodate a spouse, partner, family member, or friend, and that contains a full private bathroom that includes, at a minimum, a toilet, sink, and accessible shower;

(D) contain a living area where residents and staff may socialize, dine, and prepare food together that provides, at a minimum, a living room seating area, a dining area large enough for a single table serving all residents and not less than 2 staff members, and an open full kitchen;

(E) contain ample natural light in each habitable space that is provided through exterior windows and other means, with window areas, exclusive of skylights and clerestories, being a minimum of 10 percent of the area of the room;

(F) have a life-safety rating that is sufficient to meet State and local standards for nursing facilities and appropriately accommodate individuals who cannot evacuate the nursing home without assistance; and

(G) contain built-in safety features to allow all areas of the nursing home to be accessible to residents during the majority of the day and night.

(e) NO ADDITIONAL PAYMENT.—The technical assistance provider, as well as any eligible operating entities and participating small house nursing homes, shall not receive any additional payment or reimbursement under the Medicare or Medicaid programs based upon their participation in the CINCH demonstration program.

(f) EVALUATION AND REPORT.—

(1) IN GENERAL.—Not later than 4 years after the date of enactment of this Act, the technical assistance provider shall evaluate the performance of each of the sites participating under the CINCH demonstration program and shall submit to Congress and the Secretary a report containing the results of such evaluation.

(2) EVALUATION REQUIREMENTS.—The evaluation shall include an analysis of—

(A) not less than 12 months of MDS information and financial data from at least 10 small house nursing homes; and

(B) results from focus groups or surveys regarding health outcomes for residents and program costs.

(g) DEFINITIONS.—In this section:

(1) CINCH DEMONSTRATION PROGRAM.—The term ''CINCH demonstration program'' means the demonstration program conducted under this section.

(2) MEDICAID.—The term ''Medicaid'' means the program for medical assistance established under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.).

(3) MEDICARE.—The term ''Medicare'' means the program for medical assistance established under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

(4) NURSING HOME.—The term ''nursing home'' means—

(A) a skilled nursing facility (as defined in section 1819(a) of the Social Security Act (42 U.S.C. 1395i-3(a))); or

(B) a nursing facility (as defined in section 1919(a) of the Social Security Act (42 U.S.C. 1396r(a))).

(5) RESEARCH-BASED.—The term ''research-based'' means research that—

(A) has been conducted by an objective researcher or research team that has—

(i) no financial or affiliated organizational interest in the success of the model; and

(ii) expertise in long-term care, with not less than 3 research articles relating to long-term care that have been published in leading peer-reviewed journals;

(B) has been conducted according to generally accepted research practices;

(C) has been published in a leading peer-reviewed journal on aging or long-term care; and

(D) indicates a measurable improvement in multiple aspects of quality of life and care.

(6) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(7) RURAL AREA.—The term ''rural area'' means any area other than an urban or suburban area.

(8) SUBURBAN AREA.—The term ''suburban area'' means any urbanized area that is contiguous and adjacent to an urban area.

(9) URBAN AREA.—The term ''urban area'' means a city or town that has a population of greater than 50,000 inhabitants.

SA 3116. Mr. WYDEN (for himself, Ms. COLLINS, and Mr. BAYH) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr.

DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 2028, strike lines 9 and 10 and insert the following:

(3) EFFICIENCY ADJUSTMENT BASED ON PREMIUM INCREASES.—

(A) IN GENERAL.—The portion of the fee determined under paragraph (1) with respect to a covered entity for a calendar year which is attributable to net premiums written shall be multiplied by an amount equal to the sum of—

(i) 50 percent, plus

(ii) the applicable percentage.

(B) APPLICABLE PERCENTAGE.—The applicable percentage is a percentage determined by the Secretary in the following manner:

(i) The applicable percentage for the covered entity with the lowest per-capita premium change shall be 0 percent.

(ii) The applicable percentage for the covered entity with the highest per-capita premium change shall be 100 percent.

(iii) The applicable percentage for each other cover entity shall be based on the degree to which the per-capita premium change for such covered entity is greater than the covered entity with the lowest per-capita premium change, except that in determining such amount the Secretary shall ensure that the aggregate fees for all covered entities under this section for the calendar year (after application of this subsection) is equal to $6,700,000,000.

(iv) Notwithstanding clause (iii), the Secretary may reduce the applicable percentage for a covered entity (but not below zero) with respect to any calendar year if the Secretary determines that the amount of the per-capita premium increase for such entity was primarily due to government restrictions on rates, but only to the extent that the amount of the per-capita premium increase was due to such government restrictions, as determined by the Secretary. In the case of any reduction under the preceding sentence, proper adjustment shall be made to the applicable percentages for other covered entities described in clause (iii) such that the aggregate fees for all covered entities under this section for the calendar year (after application of this subsection) is equal to $6,700,000,000. In no case shall any adjustment cause the applicable percentage for any covered entity to exceed 100 percent.

(C) PER-CAPITA PREMIUM CHANGE.—For purposes of this paragraph—

(i) IN GENERAL.—The term ''per-capita premium change'' means, with respect to any calendar year, the excess of—

(I) the per-capita premium amount for the such calendar year, over

(II) the per capita premium amount for the preceding calendar year.

(ii) PER-CAPITA PREMIUM AMOUNT.—The term ''per-capita premium amount'' means, with respect to any calendar year, the total amount of net premiums written with respect to health insurance for any United States health risk for such calendar year divided by the number of United States health risks which are covered under such net written premiums.

(iii) REPORTING.—

(I) IN GENERAL.—Each covered entity shall include in the report required under subsection (g) the number of United States health risks which are covered under net written premiums with respect to health insurance.

(II) PENALTY.—The rules of subsection (g)(2) shall apply to the information required to be reported under subclause (I).

(4) SECRETARIAL DETERMINATION.—The Secretary shall calculate the amount of each covered entity's fee for any calendar year under this subsection.

SA 3117. Mr. WYDEN (for himself, Ms. COLLINS, and Mr. BAYH) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 164, between lines 2 and 3, insert the following:

SEC. 13___. OPTIONAL FREE CHOICE VOUCHERS.

(a) IN GENERAL.—Any employer may provide a free choice voucher to any employee of such employer, but only if such employer offers free choice vouchers to—

(1) in the case of an offering employer, all employees of such employer who are eligible to participate in an employer-sponsored plan described in subsection (c)(1), and

(2) in the case of any other employer, all employees of the employer.

(b) FREE CHOICE VOUCHER.—

(1) AMOUNT.—

(A) OFFERING EMPLOYERS.—

(i) IN GENERAL.—In the case of an offering employer, the amount of the free choice voucher provided under subsection (a) shall be equal to the monthly portion of the cost of the eligible employer-sponsored plan which would have been paid by the employer if the employee were covered under the plan with respect to which the employer pays the largest portion of the employee's premium. Such amount shall be equal to the amount the employer would pay for an employee with self-only coverage unless such employee elects family coverage (in which case such amount shall be the amount the employer would pay for family coverage).

(ii) DETERMINATION OF COST.—The cost of any health plan shall be determined under the rules similar to the rules of section 2204 of the Public Health Service Act, except that such amount may be adjusted for age and category of coverage in accordance with regulations established by the Secretary.

(B) OTHER EMPLOYERS.—In the case of any other employer, the amount of the voucher provided under subsection (a) shall be not greater than the amount equal to the lowest cost bronze plan of the individual market in the rating area in which the employee resides which—

(i) is offered through an Exchange, and

(ii) provides—

(I) in the case of an employee electing self-only coverage, self-only coverage, and

(II) in any other case, family coverage.

(2) USE OF VOUCHERS.—An Exchange shall credit the amount of any free choice voucher provided under subsection (a) to the monthly premium of any qualified health plan in the Exchange in which the qualified employee is enrolled and the offering employer shall pay any amounts so credited to the Exchange.

(3) PAYMENT OF EXCESS AMOUNTS.—If the amount of the free choice voucher exceeds the amount of the premium of the qualified health plan in which the qualified employee is enrolled for such month, such excess shall be paid to the employee. Any amount paid to the employee under the preceding sentence shall not be taken into account in determining the rate of pay of the employee under the Fair Labor Standards Act of 1938.

(c) OFFERING EMPLOYER.—For purposes of this section, the term ''offering employer'' means any employer who—

(1) offers minimum essential coverage to its employees consisting of coverage through an eligible employer-sponsored plan; and

(2) pays any portion of the costs of such plan.

(d) OTHER DEFINITIONS.—Any term used in this section which is also used in section 5000A of the Internal Revenue Code of 1986 shall have the meaning given such term under such section 5000A.

(e) ACCELERATED ACCESS TO EXCHANGES.—Notwithstanding section 1312(f)(2)(B)—

(1) beginning in 2015, each State may allow issuers of health insurance coverage in the large group market in the State to offer qualified health plans in such market through an Exchange, but only in connection with employers who provide free choice vouchers under subsection (a); and

(2) if a State under paragraph (1) allows issuers to offer qualified plans in the large group market though an Exchange, the term ''qualified employer'' (as defined in section 1312(f)(2)) shall include a large employer that—

(A) provides free choice vouchers to its employees under subsection (a); and

(B) elects to make all full-time employees eligible for 1 or more qualified health plans offered in the large group market through the Exchange.

(f) EXCLUSION FROM INCOME FOR EMPLOYEE.—

(1) IN GENERAL.—Part III of subchapter B of chapter 1 of the Internal Revenue Code of 1986 is amended by inserting after section 139C the following new section:

''SEC. 139D. FREE CHOICE VOUCHERS.

''Gross income shall not include the amount of any free choice voucher provided by an employer under part I of subtitle D of title I of the Patient Protection and Affordable Care Act to the extent that the amount of such voucher does not exceed the amount paid for a qualified health plan (as defined in section 1301 of such Act) by the taxpayer.''.

(2) CLERICAL AMENDMENT.—The table of sections for part III of subchapter B of chapter 1 of such Code is amended by inserting after the item relating to section 139C the following new item:

''Sec. 139D. Free choice vouchers.''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to vouchers provided after December 31, 2013.

(g) DEDUCTION ALLOWED TO EMPLOYER.—

(1) IN GENERAL.—Section 162(a) of the Internal Revenue Code of 1986 is amended by adding at the end the following new sentence: ''For purposes of paragraph (1), the amount of a free choice voucher provided under part I of subtitle D of title I of the Patient Protection and Affordable Care Act shall be treated as an amount for compensation for personal services actually rendered.''.

(2) EFFECTIVE DATE.—The amendments made by this subsection shall apply to vouchers provided after December 31, 2013.

(h) VOUCHER TAKEN INTO ACCOUNT IN DETERMINING PREMIUM CREDIT.—

(1) IN GENERAL.—Subsection (b)(2) of section 36B of the Internal Revenue Code of 1986, as added by section 1401, is amended by adding at the end the following new flush sentence:

''The amount of any monthly premium under subsection subparagraph (A) and the amount of the adjusted monthly premium for the second lowest cost silver plan under subparagraph (B) shall be reduced by the amount of any free choice voucher provided to the taxpayer under section _____ of the Patient Protection and Affordable Care Act.''.

(2) EFFECTIVE DATE.—The amendment made by this subsection shall apply to taxable years beginning after December 31, 2013.

(i) COORDINATION WITH EMPLOYER RESPONSIBILITIES.—

(1) SHARED RESPONSIBILITY PENALTY.—

(A) IN GENERAL.—Subsection (c) of section 4980H of the Internal Revenue Code of 1986, as added by section 1513, is amended by adding at the end the following new paragraph:

''(3) SPECIAL RULES FOR EMPLOYERS PROVIDING FREE CHOICE VOUCHERS.—The assessable payment imposed under paragraph (1) shall be reduced (but not below zero) by the amount of any free choice voucher provided to a full-time employee under section ___ of the Patient Protection and Affordable Care Act for any month during which such employee is enrolled in a qualified health plan with respect to which an applicable premium credit or cost-sharing subsidy is allowed or paid with respect to such employee.''.

(B) EFFECTIVE DATE.—The amendment made by this paragraph shall apply to months beginning after December 31, 2013.

(2) NOTIFICATION REQUIREMENT.—Section 18B(a)(3) of the Fair Labor Standards Act of 1938, as added by section 1512, is amended—

(A) by inserting ''and the employer does not offer a free choice voucher'' after ''Exchange''; and

(B) by striking ''will lose'' and inserting ''may lose''.

SA 3118. Ms. COLLINS (for herself, Mr. WYDEN, and Mr. BAYH) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 116, between lines 2 and 3, insert the following:

(3) SPECIAL RULE FOR INDIVIDUALS AGE 30 AND OVER NOT ELIGIBLE FOR EXCHANGE CREDITS AND REDUCTIONS.—

(A) IN GENERAL.—Subject to subparagraph (B), an individual who has attained at least the age of 30 before the beginning of a plan year shall be treated as an individual described in paragraph (2) if the individual is not eligible for the plan year for the premium tax credit under section 36B of the Internal Revenue Code of 1986 or the cost-sharing reductions under section 1402 with respect to enrollment in a qualified health plan offered through an Exchange. The preceding sentence shall not apply to an individual if the individual is not eligible for such credit or reductions because the individual is eligible to enroll in minimum essential coverage consisting of coverage under a government sponsored program described in section 5000A(f)(1)(A).

(B) REQUIREMENTS.—Subparagraph (A) shall only apply to an individual if the individual elects the application of this paragraph and such election provides that—

(i) the individual acknowledges that coverage under the catastrophic plan is the lowest coverage available, that the plan provides no benefits for any plan year until the individual has incurred cost-sharing expenses in an amount equal to the annual limitation in effect under subsection (c)(1) for the plan year (except as provided for in section 2713), and that these cost-sharing expenses could involve significant financial risk for the individual; and

(ii) the individual agrees that—

(I) the individual will not change such coverage until the next applicable annual or special enrollment period under section 1311(c)(5); and

(II) if the individual elects to change such coverage at the time of such enrollment period, the individual may only enroll in the bronze level of coverage.

(4) STATE AUTHORITY.—In accordance with section 1321(d), a State may impose additional requirements or conditions for catastrophic plans described in this subsection to the extent such requirements or conditions are not inconsistent with the requirements under this subsection.

SA 3119. Mr. WARNER (for himself, Mr. UDALL of Colorado, Mr. UDALL of New Mexico, Mrs. SHAHEEN, Mrs. HAGAN, Mr. MERKLEY, Mr. BEGICH, Mr. BURRIS, Mr. KAUFMAN, Mr. BENNET, Mrs. GILLIBRAND, Mr. FRANKEN, Mr. KIRK, Ms. COLLINS, Ms. KLOBUCHAR, and Mr. WHITEHOUSE) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 1134, strike line 3 and insert the following:

title).

Subtitle G—Modernizing America's Health Care System

PART I—IMPROVING QUALITY AND VALUE THROUGH DELIVERY SYSTEM REFORM

SEC. 3601. QUALITY REPORTING FOR PSYCHIATRIC HOSPITALS.

(a) IN GENERAL.—Section 1886(s) of the Social Security Act, as added by section 3401(f), is amended by adding at the end the following new paragraph:

''(4) QUALITY REPORTING.—

''(A) REDUCTION IN UPDATE FOR FAILURE TO REPORT.—

''(i) IN GENERAL.—Under the system described in paragraph (1), for rate year 2014 and each subsequent rate year, in the case of a psychiatric hospital or psychiatric unit that does not submit data to the Secretary in accordance with subparagraph (C) with respect to such a rate year, any annual update to a standard Federal rate for discharges for the hospital during the rate year, and after application of paragraph (2), shall be reduced by 2 percentage points.

''(ii) SPECIAL RULE.—The application of this subparagraph may result in such annual update being less than 0.0 for a rate year, and may result in payment rates under the system described in paragraph (1) for a rate year being less than such payment rates for the preceding rate year.

''(B) NONCUMULATIVE APPLICATION.—Any reduction under subparagraph (A) shall apply only with respect to the rate year involved and the Secretary shall not take into account such reduction in computing the payment amount under the system described in paragraph (1) for a subsequent rate year.

''(C) SUBMISSION OF QUALITY DATA.—For rate year 2014 and each subsequent rate year, each psychiatric hospital and psychiatric unit shall submit to the Secretary data on quality measures specified under subparagraph (D). Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

''(D) QUALITY MEASURES.—

''(i) IN GENERAL.—Subject to clause (ii), any measure specified by the Secretary under this subparagraph must have been endorsed by the entity with a contract under section 1890(a).

''(ii) EXCEPTION.—In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

''(iii) TIME FRAME.—Not later than October 1, 2012, the Secretary shall publish the measures selected under this subparagraph that will be applicable with respect to rate year 2014.

''(E) PUBLIC AVAILABILITY OF DATA SUBMITTED.—The Secretary shall establish procedures for making data submitted under subparagraph (C) available to the public. Such procedures shall ensure that a psychiatric hospital and a psychiatric unit has the opportunity to review the data that is to be made public with respect to the hospital or unit prior to such data being made public. The Secretary shall report quality measures that relate to services furnished in inpatient settings in psychiatric hospitals and psychiatric units on the Internet website of the Centers for Medicare & Medicaid Services.''.

(b) CONFORMING AMENDMENT.—Section 1890(b)(7)(B)(i)(I) of the Social Security Act, as added by section 3014, is amended by inserting ''1886(s)(4)(D),'' after ''1886(o)(2),''.

SEC. 3602. PILOT TESTING PAY-FOR-PERFORMANCE PROGRAMS FOR CERTAIN MEDICARE PROVIDERS.

(a) IN GENERAL.—Not later than January 1, 2016, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall, for each provider described in subsection (b), conduct a separate pilot program under title XVIII of the Social Security Act to test the implementation of a value-based purchasing program for payments under such title for the provider.

(b) PROVIDERS DESCRIBED.—The providers described in this paragraph are the following:

(1) Psychiatric hospitals (as described in clause (i) of section 1886(d)(1)(B) of such Act (42 U.S.C. 1395ww(d)(1)(B))) and psychiatric units (as described in the matter following clause (v) of such section).

(2) Long-term care hospitals (as described in clause (iv) of such section).

(3) Rehabilitation hospitals (as described in clause (ii) of such section).

(4) PPS-exempt cancer hospitals (as described in clause (v) of such section).

(5) Hospice programs (as defined in section 1861(dd)(2) of such Act (42 U.S.C. 1395x(dd)(2))).

(c) WAIVER AUTHORITY.—The Secretary may waive such requirements of titles XI and XVIII of the Social Security Act as may be necessary solely for purposes of carrying out the pilot programs under this section.

(d) NO ADDITIONAL PROGRAM EXPENDITURES.—Payments under this section under the separate pilot program for value based purchasing (as described in subsection (a)) for each provider type described in paragraphs (1) through (5) of subsection (b) for applicable items and services under title XVIII of the Social Security Act for a year shall be established in a manner that does not result in spending more under each such value based purchasing program for such year than would otherwise be expended for such provider type for such year if the pilot program were not implemented, as estimated by the Secretary.

(e) EXPANSION OF PILOT PROGRAM.—The Secretary may, at any point after January 1, 2018, expand the duration and scope of a pilot program conducted under this subsection, to the extent determined appropriate by the Secretary, if—

(1) the Secretary determines that such expansion is expected to—

(A) reduce spending under title XVIII of the Social Security Act without reducing the quality of care; or

(B) improve the quality of care and reduce spending;

(2) the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce program spending under such title XVIII; and

(3) the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under such title XIII for Medicare beneficiaries.

SEC. 3603. PLANS FOR A VALUE-BASED PURCHASING PROGRAM FOR AMBULATORY SURGICAL CENTERS.

Section 3006 of this Act is amended by adding at the end the following new subsection:

''(f) AMBULATORY SURGICAL CENTERS.—

''(1) IN GENERAL.—The Secretary shall develop a plan to implement a value-based purchasing program for payments under the Medicare program under title XVIII of the Social Security Act for ambulatory surgical centers (as described in section 1833(i) of the Social Security Act (42 U.S.C. 13951(i))).

''(2) DETAILS.—In developing the plan under paragraph (1), the Secretary shall consider the following issues:

''(A) The ongoing development, selection, and modification process for measures (including under section 1890 of the Social Security Act (42 U.S.C. 1395aaa) and section 1890A of such Act, as added by section 3014), to the extent feasible and practicable, of all dimensions of quality and efficiency in ambulatory surgical centers.

''(B) The reporting, collection, and validation of quality data.

''(C) The structure of value-based payment adjustments, including the determination of thresholds or improvements in quality that would substantiate a payment adjustment, the size of such payments, and the sources of funding for the value-based bonus payments.

''(D) Methods for the public disclosure of information on the performance of ambulatory surgical centers.

''(E) Any other issues determined appropriate by the Secretary.

''(3) CONSULTATION.—In developing the plan under paragraph (1), the Secretary shall—

''(A) consult with relevant affected parties; and

''(B) consider experience with such demonstrations that the Secretary determines are relevant to the value-based purchasing program described in paragraph (1).

''(4) REPORT TO CONGRESS.—Not later than January 1, 2011, the Secretary shall submit to Congress a report containing the plan developed under paragraph (1).''.

SEC. 3604. REVISIONS TO NATIONAL PILOT PROGRAM ON PAYMENT BUNDLING.

Section 1866D of the Social Security Act, as added by section 3023, is amended—

(1) in paragraph (a)(2)(B), in the matter preceding clause (i), by striking ''8 conditions'' and inserting ''10 conditions'';

(2) by striking subsection (c)(1)(B) and inserting the following:

''(B) EXPANSION.—The Secretary may, at any point after January 1, 2016, expand the duration and scope of the pilot program, to the extent determined appropriate by the Secretary, if—

''(i) the Secretary determines that such expansion is expected to—

''(I) reduce spending under title XVIII of the Social Security Act without reducing the quality of care; or

''(II) improve the quality of care and reduce spending;

''(ii) the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce program spending under such title XVIII; and

''(iii) the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under this title for individuals.''; and

(3) by striking subsection (g).

SEC. 3605. IMPROVEMENTS TO THE MEDICARE SHARED SAVINGS PROGRAM.

Section 1899 of the Social Security Act, as added by section 3022, is amended by adding at the end the following new subsections:

''(i) OPTION TO USE OTHER PAYMENT MODELS.—

''(1) IN GENERAL.—If the Secretary determines appropriate, the Secretary may use any of the payment models described in paragraph (2) or (3) for making payments under the program rather than the payment model described in subsection (d).

''(2) PARTIAL CAPITATION MODEL.—

''(A) IN GENERAL.—Subject to subparagraph (B), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model to ACOs that are highly integrated systems of care and to ACOs capable of bearing risk, as determined to be appropriate by the Secretary.

''(B) NO ADDITIONAL PROGRAM EXPENDITURES.—Payments to an ACO for items and services under this title for beneficiaries for a year under the partial capitation model shall be established in a manner that does not result in spending more for such ACO for such beneficiaries than would otherwise be expended for such ACO for such beneficiaries for such year if the model were not implemented, as estimated by the Secretary.

''(3) OTHER PAYMENT MODELS.—

''(A) IN GENERAL.—Subject to subparagraph (B), a model described in this paragraph is any payment model that the Secretary determines will improve the quality and efficiency of items and services furnished under this title.

''(B) NO ADDITIONAL PROGRAM EXPENDITURES.—Subparagraph (B) of paragraph (2) shall apply to a payment model under subparagraph (A) in a similar manner as such subparagraph (B) applies to the payment model under paragraph (2).

''(j) INVOLVEMENT IN PRIVATE PAYER AND OTHER THIRD PARTY ARRANGEMENTS.—The Secretary may give preference to ACOs who are participating in similar arrangements with other payers.

''(k) TREATMENT OF PHYSICIAN GROUP PRACTICE DEMONSTRATION.—During the period beginning on the date of the enactment of this section and ending on the date the program is established, the Secretary may enter into an agreement with an ACO under the demonstration under section 1866A, subject to rebasing and other modifications deemed appropriate by the Secretary.''.

SEC. 3606. INCENTIVES TO IMPLEMENT ACTIVITIES TO REDUCE DISPARITIES.

Section 1311(g)(1) of this Act is amended—

(1) in subparagraph (C), by striking ''; and'' and inserting a semicolon;

(2) in subparagraph (D), by striking the period and inserting ''; and''; and

(3) by adding at the end the following:

''(E) the implementation of activities to reduce health and health care disparities, including through the use of language services, community outreach, and cultural competency trainings.''.

SEC. 3607. NATIONAL DIABETES PREVENTION PROGRAM.

Part P of title III of the Public Health Service Act 42 U.S.C. 280g et seq.), as amended by section 5405, is amended by adding at the end the following:

''SEC. 399V-2. NATIONAL DIABETES PREVENTION PROGRAM.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a national diabetes prevention program (referred to in this section as the 'program') targeted at adults at high risk for diabetes in order to eliminate the preventable burden of diabetes.

''(b) PROGRAM ACTIVITIES.—The program described in subsection (a) shall include—

''(1) a grant program for community-based diabetes prevention program model sites;

''(2) a program within the Centers for Disease Control and Prevention to determine eligibility of entities to deliver community-based diabetes prevention services;

''(3) a training and outreach program for lifestyle intervention instructors; and

''(4) evaluation, monitoring and technical assistance, and applied research carried out by the Centers for Disease Control and Prevention.

''(c) ELIGIBLE ENTITIES.—To be eligible for a grant under subsection (b)(1), an entity shall be a State or local health department, a tribal organization, a national network of community-based non-profits focused on health and wellbeing, an academic institution, or other entity, as the Secretary determines.

''(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2010 through 2014.''.

SEC. 3608. SELECTION OF EFFICIENCY MEASURES.

Sections 1890(b)(7) and 1890A of the Social Security Act, as added by section 3014, are amended by striking ''quality'' each place it appears and inserting ''quality and efficiency''.

SEC. 3609. REGIONAL TESTING OF PAYMENT AND SERVICE DELIVERY MODELS UNDER THE CENTER FOR MEDICARE AND MEDICAID INNOVATION.

Section 1115A(a) of the Social Security Act, as added by section 3021, is amended by inserting at the end the following new paragraph:

''(5) TESTING WITHIN CERTAIN GEOGRAPHIC AREAS.—For purposes of testing payment and service delivery models under this section, the Secretary may elect to limit testing of a model to certain geographic areas.''.

SEC. 3610. ADDITIONAL IMPROVEMENTS UNDER THE CENTER FOR MEDICARE AND MEDICAID INNOVATION.

Section 1115A(a) of the Social Security Act, as added by section 3021, is amended—

(1) in subsection (b)(2)—

(A) in subparagraph (A)—

(i) in the second sentence, by striking ''the preceding sentence may include'' and inserting ''this subparagraph may include, but are not limited to,''; and

(ii) by inserting after the first sentence the following new sentence: ''The Secretary shall focus on models expected to reduce program costs under the applicable title while preserving or enhancing the quality of care received by individuals receiving benefits under such title.''; and

(B) in subparagraph (C), by adding at the end the following new clause:

''(viii) Whether the model demonstrates effective linkage with other public sector or private sector payers.'';

(2) in subsection (b)(4), by adding at the end the following new subparagraph:

''(C) MEASURE SELECTION.—To the extent feasible, the Secretary shall select measures under this paragraph that reflect national priorities for quality improvement and patient-centered care consistent with the measures described in 1890(b)(7)(B).''; and

(3) in subsection (c)—

(A) in paragraph (1)(B), by striking ''care and reduce spending; and'' and inserting ''patient care without increasing spending;'';

(B) in paragraph (2), by striking ''reduce program spending under applicable titles.'' and inserting ''reduce (or would not result in any increase in) net program spending under applicable titles; and''; and

(C) by adding at the end the following:

''(3) the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals.

In determining which models or demonstration projects to expand under the preceding sentence, the Secretary shall focus on models and demonstration projects that improve the quality of patient care and reduce spending.''.

SEC. 3611. IMPROVEMENTS TO THE PHYSICIAN QUALITY REPORTING SYSTEM.

(a) IN GENERAL.—Section 1848(m) of the Social Security Act (42 U.S.C. 1395w–4(m)) is amended by adding at the end the following new paragraph:

''(7) ADDITIONAL INCENTIVE PAYMENT.—

''(A) IN GENERAL.—For 2011 through 2014, if an eligible professional meets the requirements described in subparagraph (B), the applicable quality percent for such year, as described in clauses (iii) and (iv) of paragraph (1)(B), shall be increased by 0.5 percentage points.

''(B) REQUIREMENTS DESCRIBED.—In order to qualify for the additional incentive payment described in subparagraph (A), an eligible professional shall meet the following requirements:

''(i) The eligible professional shall—

''(I) satisfactorily submit data on quality measures for purposes of paragraph (1) for a year; and

''(II) have such data submitted on their behalf through a Maintenance of Certification Program (as defined in subparagraph (C)(i)) that meets—

''(aa) the criteria for a registry (as described in subsection (k)(4)); or

''(bb) an alternative form and manner determined appropriate by the Secretary.

''(ii) The eligible professional, more frequently than is required to qualify for or maintain board certification status—

''(I) participates in such a Maintenance of Certification program for a year; and

''(II) successfully completes a qualified Maintenance of Certification Program practice assessment (as defined in subparagraph (C)(ii)) for such year.

''(iii) A Maintenance of Certification program submits to the Secretary, on behalf of the eligible professional, information—

''(I) in a form and manner specified by the Secretary, that the eligible professional has successfully met the requirements of clause (ii) (which may be in the form of a structural measure);

''(II) if requested by the Secretary, on the survey of patient experience with care (as described in subparagraph (C)(ii)(II)); and

''(III) as the Secretary may require, on the methods, measures, and data used under the Maintenance of Certification Program and the qualified Maintenance of Certification Program practice assessment.

''(C) DEFINITIONS.—For purposes of this paragraph:

''(i) The term 'Maintenance of Certification Program' means a continuous assessment program, such as qualified American Board of Medical Specialties Maintenance of Certification program or an equivalent program (as determined by the Secretary), that advances quality and the lifelong learning and self-assessment of board certified specialty physicians by focusing on the competencies of patient care, medical knowledge, practice-based learning, interpersonal and communication skills and professionalism. Such a program shall include the following:

''(I) The program requires the physician to maintain a valid, unrestricted medical license in the United States.

''(II) The program requires a physician to participate in educational and self-assessment programs that require an assessment of what was learned.

''(III) The program requires a physician to demonstrate, through a formalized, secure examination, that the physician has the fundamental diagnostic skills, medical knowledge, and clinical judgment to provide quality care in their respective specialty.

''(IV) The program requires successful completion of a qualified Maintenance of Certification Program practice assessment as described in clause (ii).

''(ii) The term 'qualified Maintenance of Certification Program practice assessment' means an assessment of a physician's practice that—

''(I) includes an initial assessment of an eligible professional's practice that is designed to demonstrate the physician's use of evidence-based medicine;

''(II) includes a survey of patient experience with care; and

''(III) requires a physician to implement a quality improvement intervention to address a practice weakness identified in the initial assessment under subclause (I) and then to remeasure to assess performance improvement after such intervention.''.

(b) AUTHORITY.—Section 3002(c) of this Act is amended by adding at the end the following new paragraph:

''(3) AUTHORITY.—For years after 2014, if the Secretary of Health and Human Services determines it to be appropriate, the Secretary may incorporate participation in a Maintenance of Certification Program and successful completion of a qualified Maintenance of Certification Program practice assessment into the composite of measures of quality of care furnished pursuant to the physician fee schedule payment modifier, as described in section 1848(p)(2) of the Social Security Act (42 U.S.C. 1395w–4(p)(2)).''.

(c) ELIMINATION OF MA REGIONAL PLAN STABILIZATION FUND.—

(1) IN GENERAL.—Section 1858 of the Social Security Act (42 U.S.C. 1395w–27a) is amended by striking subsection (e).

(2) TRANSITION.—Any amount contained in the MA Regional Plan Stabilization Fund as of the date of the enactment of this Act shall be transferred to the Federal Supplementary Medical Insurance Trust Fund.

SEC. 3612. IMPROVEMENT IN PART D MEDICATION THERAPY MANAGEMENT (MTM) PROGRAMS.

(a) IN GENERAL.—Section 1860D–4(c)(2) of the Social Security Act (42 U.S.C. 1395w–104(c)(2)) is amended—

(1) by redesignating subparagraphs (C), (D), and (E) as subparagraphs (E), (F), and (G), respectively; and

(2) by inserting after subparagraph (B) the following new subparagraphs:

''(C) REQUIRED INTERVENTIONS.—For plan years beginning on or after the date that is 2 years after the date of the enactment of the Patient Protection and Affordable Care Act, prescription drug plan sponsors shall offer medication therapy management services to targeted beneficiaries described in subparagraph (A)(ii) that include, at a minimum, the following to increase adherence to prescription medications or other goals deemed necessary by the Secretary:

''(i) An annual comprehensive medication review furnished person-to-person or using telehealth technologies (as defined by the Secretary) by a licensed pharmacist or other qualified provider. The comprehensive medication review—

''(I) shall include a review of the individual's medications and may result in the creation of a recommended medication action plan or other actions in consultation with the individual and with input from the prescriber to the extent necessary and practicable; and

''(II) shall include providing the individual with a written or printed summary of the results of the review.

The Secretary, in consultation with relevant stakeholders, shall develop a standardized format for the action plan under subclause (I) and the summary under subclause (II).

''(ii) Follow-up interventions as warranted based on the findings of the annual medication review or the targeted medication enrollment and which may be provided person-to-person or using telehealth technologies (as defined by the Secretary).

''(D) ASSESSMENT.—The prescription drug plan sponsor shall have in place a process to assess, at least on a quarterly basis, the medication use of individuals who are at risk but not enrolled in the medication therapy management program, including individuals who have experienced a transition in care, if the prescription drug plan sponsor has access to that information.

''(E) AUTOMATIC ENROLLMENT WITH ABILITY TO OPT-OUT.—The prescription drug plan sponsor shall have in place a process to—

''(i) subject to clause (ii), automatically enroll targeted beneficiaries described in subparagraph (A)(ii), including beneficiaries identified under subparagraph (D), in the medication therapy management program required under this subsection; and

''(ii) permit such beneficiaries to opt-out of enrollment in such program.''.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall limit the authority of the Secretary of Health and Human Services to modify or broaden requirements for a medication therapy management program under part D of title XVIII of the Social Security Act or to study new models for medication therapy management through the Center for Medicare and Medicaid Innovation under section 1115A of such Act, as added by section 3021.

SEC. 3613. EVALUATION OF TELEHEALTH UNDER THE CENTER FOR MEDICARE AND MEDICAID INNOVATION.

Section 1115A(b)(2)(B) of the Social Security Act, as added by section 3021, is amended by adding at the end the following new clause:

''(xix) Utilizing, in particular in entities located in medically underserved areas and facilities of the Indian Health Service (whether operated by such Service or by an Indian tribe or tribal organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act)), telehealth services—

''(I) in treating behavioral health issues (such as post-traumatic stress disorder) and stroke; and

''(II) to improve the capacity of non-medical providers and non-specialized medical providers to provide health services for patients with chronic complex conditions.''.

SEC. 3614. REVISIONS TO THE EXTENSION FOR THE RURAL COMMUNITY HOSPITAL DEMONSTRATION PROGRAM.

(a) IN GENERAL.—Subsection (g) of section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2272), as added by section 3123(a) of this Act, is amended to read as follows:

''(g) FIVE-YEAR EXTENSION OF DEMONSTRATION PROGRAM.—

''(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, the Secretary shall conduct the demonstration program under this section for an additional 5-year period (in this section referred to as the '5-year extension period') that begins on the date immediately following the last day of the initial 5-year period under subsection (a)(5).

''(2) EXPANSION OF DEMONSTRATION STATES.—Notwithstanding subsection (a)(2), during the 5-year extension period, the Secretary shall expand the number of States with low population densities determined by the Secretary under such subsection to 20. In determining which States to include in such expansion, the Secretary shall use the same criteria and data that the Secretary used to determine the States under such subsection for purposes of the initial 5-year period.

''(3) INCREASE IN MAXIMUM NUMBER OF HOSPITALS PARTICIPATING IN THE DEMONSTRATION PROGRAM.—Notwithstanding subsection (a)(4), during the 5-year extension period, not more than 30 rural community hospitals may participate in the demonstration program under this section.

''(4) HOSPITALS IN DEMONSTRATION PROGRAM ON DATE OF ENACTMENT.—In the case of a rural community hospital that is participating in the demonstration program under this section as of the last day of the initial 5-year period, the Secretary—

''(A) shall provide for the continued participation of such rural community hospital in the demonstration program during the 5-year extension period unless the rural community hospital makes an election, in such form and manner as the Secretary may specify, to discontinue such participation; and

''(B) in calculating the amount of payment under subsection (b) to the rural community hospital for covered inpatient hospital services furnished by the hospital during such 5-year extension period, shall substitute, under paragraph (1)(A) of such subsection—

''(i) the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the first day of the 5-year extension period, for

''(ii) the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the implementation of the demonstration program.''.

(b) CONFORMING AMENDMENTS.—Subsection (a)(5) of section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2272), as amended by section 3123(b) of this Act, is amended by striking ''1-year extension'' and inserting ''5-year extension''.

PART II—PROMOTING TRANSPARENCY AND COMPETITION

SEC. 3621. DEVELOPING METHODOLOGY TO ASSESS HEALTH PLAN VALUE.

(a) DEVELOPMENT.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), in consultation with relevant stakeholders including health insurance issuers, health care consumers, employers, health care providers, and other entities determined appropriate by the Secretary, shall develop a methodology to measure health plan value. Such methodology shall take into consideration, where applicable—

(1) the overall cost to enrollees under the plan;

(2) the quality of the care provided for under the plan;

(3) the efficiency of the plan in providing care;

(4) the relative risk of the plan's enrollees as compared to other plans;

(5) the actuarial value or other comparative measure of the benefits covered under the plan; and

(6) other factors determined relevant by the Secretary.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary shall submit to Congress a report concerning the methodology developed under subsection (a).

SEC. 3622. DATA COLLECTION; PUBLIC REPORTING.

Section 399II(a) of the Public Health Service Act, as added by section 3015, is amended to read as follows:

''(a) IN GENERAL.—

''(1) ESTABLISHMENT OF STRATEGIC FRAMEWORK.—The Secretary shall establish and implement an overall strategic framework to carry out the public reporting of performance information, as described in section 399JJ. Such strategic framework may include methods and related timelines for implementing nationally consistent data collection, data aggregation, and analysis methods.

''(2) COLLECTION AND AGGREGATION OF DATA.—The Secretary shall collect and aggregate consistent data on quality and resource use measures from information systems used to support health care delivery, and may award grants or contracts for this purpose. The Secretary shall align such collection and aggregation efforts with the requirements and assistance regarding the expansion of health information technology systems, the interoperability of such technology systems, and related standards that are in effect on the date of enactment of the Patient Protection and Affordable Care Act.

''(3) SCOPE.—The Secretary shall ensure that the data collection, data aggregation, and analysis systems described in paragraph (1) involve an increasingly broad range of patient populations, providers, and geographic areas over time.''.

SEC. 3623. MODERNIZING COMPUTER AND DATA SYSTEMS OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES TO SUPPORT IMPROVEMENTS IN CARE DELIVERY.

(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall develop a plan (and detailed budget for the resources needed to implement such plan) to modernize the computer and data systems of the Centers for Medicare & Medicaid Services (in this section referred to as ''CMS'').

(b) CONSIDERATIONS.—In developing the plan, the Secretary shall consider how such modernized computer system could—

(1) in accordance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, make available data in a reliable and timely manner to providers of services and suppliers to support their efforts to better manage and coordinate care furnished to beneficiaries of CMS programs; and

(2) support consistent evaluations of payment and delivery system reforms under CMS programs.

(c) POSTING OF PLAN.—By not later than 9 months after the date of the enactment of this Act, the Secretary shall post on the website of the Centers for Medicare & Medicaid Services the plan described in subsection (a).

SEC. 3624. EXPANSION OF THE SCOPE OF THE INDEPENDENT MEDICARE ADVISORY BOARD.

(a) ANNUAL PUBLIC REPORT.—

(1) REPORT.—Section 1899A of the Social Security Act, as added by section 3403, is amended by adding at the end the following new subsection:

''(n) ANNUAL PUBLIC REPORT.—

''(1) IN GENERAL.—Not later than July 1, 2014, and annually thereafter, the Board shall produce a public report containing standardized information on system-wide health care costs, patient access to care, utilization, and quality-of-care that allows for comparison by region, types of services, types of providers, and both private payers and the program under this title.

''(2) REQUIREMENTS.—Each report produced pursuant to paragraph (1) shall include information with respect to the following areas:

''(A) The quality and costs of care for the population at the most local level determined practical by the Board (with quality and costs compared to national benchmarks and reflecting rates of change, taking into account quality measures described in section 1890(b)(7)(B)).

''(B) Beneficiary and consumer access to care, patient and caregiver experience of care, and the cost-sharing or out-of-pocket burden on patients.

''(C) Epidemiological shifts and demographic changes.

''(D) The proliferation, effectiveness, and utilization of health care technologies, including variation in provider practice patterns and costs.

''(E) Any other areas that the Board determines affect overall spending and quality of care in the private sector.''.

(2) ALIGNMENT WITH MEDICARE PROPOSALS.—Section 1899A(c)(2)(B) of the Social Security Act, as added by section 3403, is amended—

(A) in clause (v), by striking ''and'' at the end;

(B) in clause (vi), by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following new clause:

''(vii) take into account the data and findings contained in the annual reports under subsection (n) in order to develop proposals that can most effectively promote the delivery of efficient, high quality care to Medicare beneficiaries.''.

(b) ADVISORY RECOMMENDATIONS FOR NON-FEDERAL HEALTH CARE PROGRAMS.—Section 1899A of the Social Security Act, as added by section 3403 and as amended by subsection (a)(1), is amended by adding at the end the following new subsection:

''(o) ADVISORY RECOMMENDATIONS FOR NON-FEDERAL HEALTH CARE PROGRAMS.—

''(1) IN GENERAL.—Not later than January 15, 2015, and at least once every two years thereafter, the Board shall submit to Congress and the President recommendations to slow the growth in national health expenditures (excluding expenditures under this title and in other Federal health care programs) while preserving or enhancing quality of care, such as recommendations—

''(A) that the Secretary or other Federal agencies can implement administratively;

''(B) that may require legislation to be enacted by Congress in order to be implemented;

''(C) that may require legislation to be enacted by State or local governments in order to be implemented;

''(D) that private sector entities can voluntarily implement; and

''(E) with respect to other areas determined appropriate by the Board.

''(2) COORDINATION.—In making recommendations under paragraph (1), the Board shall coordinate such recommendations with recommendations contained in proposals and advisory reports produced by the Board under subsection (c).

''(3) AVAILABLE TO PUBLIC.—The Board shall make recommendations submitted to Congress and the President under this subsection available to the public.''.

(c) RULE OF CONSTRUCTION.—Nothing in the amendments made by this section shall preclude the Independent Medicare Advisory Board, as established under section 1899A of the Social Security Act (as added by section 3403), from solely using data from public or private sources to carry out the amendments made by subsections (a)(1) and (b).

SEC. 3625. ADDITIONAL PRIORITY FOR THE NATIONAL HEALTH CARE WORKFORCE COMMISSION.

Section 5101(d)(4)(A) of this Act is amended by adding at the end the following new clause:

''(v) An analysis of, and recommendations for, eliminating the barriers to entering and staying in primary care, including provider compensation.''.

PART III—PROMOTING ACCOUNTABILITY AND RESPONSIBILITY

SEC. 3631. HEALTH CARE FRAUD ENFORCEMENT.

(a) FRAUD SENTENCING GUIDELINES.—

(1) DEFINITION.—In this subsection, the term ''Federal health care offense'' has the meaning given that term in section 24 of title 18, United States Code, as amended by this Act.

(2) REVIEW AND AMENDMENTS.—Pursuant to the authority under section 994 of title 28, United States Code, and in accordance with this subsection, the United States Sentencing Commission shall—

(A) review the Federal Sentencing Guidelines and policy statements applicable to persons convicted of Federal health care offenses;

(B) amend the Federal Sentencing Guidelines and policy statements applicable to persons convicted of Federal health care offenses involving Government health care programs to provide that the aggregate dollar amount of fraudulent bills submitted to the Government health care program shall constitute prima facie evidence of the amount of the intended loss by the defendant; and

(C) amend the Federal Sentencing Guidelines to provide—

(i) a 2-level increase in the offense level for any defendant convicted of a Federal health care offense relating to a Government health care program which involves a loss of not less than $1,000,000 and less than $7,000,000;

(ii) a 3-level increase in the offense level for any defendant convicted of a Federal health care offense relating to a Government health care program which involves a loss of not less than $7,000,000 and less than $20,000,000;

(iii) a 4-level increase in the offense level for any defendant convicted of a Federal health care offense relating to a Government health care program which involves a loss of not less than $20,000,000; and

(iv) if appropriate, otherwise amend the Federal Sentencing Guidelines and policy statements applicable to persons convicted of Federal health care offenses involving Government health care programs.

(3) REQUIREMENTS.—In carrying this subsection, the United States Sentencing Commission shall—

(A) ensure that the Federal Sentencing Guidelines and policy statements—

(i) reflect the serious harms associated with health care fraud and the need for aggressive and appropriate law enforcement action to prevent such fraud; and

(ii) provide increased penalties for persons convicted of health care fraud offenses in appropriate circumstances;

(B) consult with individuals or groups representing health care fraud victims, law enforcement officials, the health care industry, and the Federal judiciary as part of the review described in paragraph (2);

(C) ensure reasonable consistency with other relevant directives and with other guidelines under the Federal Sentencing Guidelines;

(D) account for any aggravating or mitigating circumstances that might justify exceptions, including circumstances for which the Federal Sentencing Guidelines, as in effect on the date of enactment of this Act, provide sentencing enhancements;

(E) make any necessary conforming changes to the Federal Sentencing Guidelines; and

(F) ensure that the Federal Sentencing Guidelines adequately meet the purposes of sentencing.

(b) INTENT REQUIREMENT FOR HEALTH CARE FRAUD.—Section 1347 of title 18, United States Code, is amended—

(1) by inserting ''(a)'' before ''Whoever knowingly''; and

(2) by adding at the end the following:

''(b) With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.''.

(c) HEALTH CARE FRAUD OFFENSE.—Section 24(a) of title 18, United States Code, is amended—

(1) in paragraph (1), by striking the semicolon and inserting ''or section 1128B of the Social Security Act (42 U.S.C. 1320a–7b); or''; and

(2) in paragraph (2)—

(A) by inserting ''1349,'' after ''1343,''; and

(B) by inserting ''section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), or section 501 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1131),'' after ''title,''.

(d) SUBPOENA AUTHORITY RELATING TO HEALTH CARE.—

(1) SUBPOENAS UNDER THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996.—Section 1510(b) of title 18, United States Code, is amended—

(A) in paragraph (1), by striking ''to the grand jury''; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking ''grand jury subpoena'' and inserting ''subpoena for records''; and

(ii) in the matter following subparagraph (B), by striking ''to the grand jury''.

(2) SUBPOENAS UNDER THE CIVIL RIGHTS OF INSTITUTIONALIZED PERSONS ACT.—The Civil Rights of Institutionalized Persons Act (42 U.S.C. 1997 et seq.) is amended by inserting after section 3 the following:

''SEC. 3A. SUBPOENA AUTHORITY.

''(a) AUTHORITY.—The Attorney General, or at the direction of the Attorney General, any officer or employee of the Department of Justice may require by subpoena access to any institution that is the subject of an investigation under this Act and to any document, record, material, file, report, memorandum, policy, procedure, investigation, video or audio recording, or quality assurance report relating to any institution that is the subject of an investigation under this Act to determine whether there are conditions which deprive persons residing in or confined to the institution of any rights, privileges, or immunities secured or protected by the Constitution or laws of the United States.

''(b) ISSUANCE AND ENFORCEMENT OF SUBPOENAS.—

''(1) ISSUANCE.—Subpoenas issued under this section—

''(A) shall bear the signature of the Attorney General or any officer or employee of the Department of Justice as designated by the Attorney General; and

''(B) shall be served by any person or class of persons designated by the Attorney General or a designated officer or employee for that purpose.

''(2) ENFORCEMENT.—In the case of contumacy or failure to obey a subpoena issued under this section, the United States district court for the judicial district in which the institution is located may issue an order requiring compliance. Any failure to obey the order of the court may be punished by the court as a contempt that court.

''(c) PROTECTION OF SUBPOENAED RECORDS AND INFORMATION.—Any document, record, material, file, report, memorandum, policy, procedure, investigation, video or audio recording, or quality assurance report or other information obtained under a subpoena issued under this section—

''(1) may not be used for any purpose other than to protect the rights, privileges, or immunities secured or protected by the Constitution or laws of the United States of persons who reside, have resided, or will reside in an institution;

''(2) may not be transmitted by or within the Department of Justice for any purpose other than to protect the rights, privileges, or immunities secured or protected by the Constitution or laws of the United States of persons who reside, have resided, or will reside in an institution; and

''(3) shall be redacted, obscured, or otherwise altered if used in any publicly available manner so as to prevent the disclosure of any personally identifiable information.''.

SEC. 3632. DEVELOPMENT OF STANDARDS FOR FINANCIAL AND ADMINISTRATIVE TRANSACTIONS.

(a) ADDITIONAL TRANSACTION STANDARDS AND OPERATING RULES.—

(1) DEVELOPMENT OF ADDITIONAL TRANSACTION STANDARDS AND OPERATING RULES.—Section 1173(a) of the Social Security Act (42 U.S.C. 1320d–2(a)), as amended by section 1104(b)(2), is amended—

(A) in paragraph (1)(B), by inserting before the period the following: '', and subject to the requirements under paragraph (5)''; and

(B) by adding at the end the following new paragraph:

''(5) CONSIDERATION OF STANDARDIZATION OF ACTIVITIES AND ITEMS.—

''(A) IN GENERAL.—For purposes of carrying out paragraph (1)(B), the Secretary shall solicit, not later than January 1, 2012, and not less than every 3 years thereafter, input from entities described in subparagraph (B) on—

''(i) whether there could be greater uniformity in financial and administrative activities and items, as determined appropriate by the Secretary; and

''(ii) whether such activities should be considered financial and administrative transactions (as described in paragraph (1)(B)) for which the adoption of standards and operating rules would improve the operation of the health care system and reduce administrative costs.

''(B) SOLICITATION OF INPUT.—For purposes of subparagraph (A), the Secretary shall seek input from—

''(i) the National Committee on Vital and Health Statistics, the Health Information Technology Policy Committee, and the Health Information Technology Standards Committee; and

''(ii) standard setting organizations and stakeholders, as determined appropriate by the Secretary.''.

(b) ACTIVITIES AND ITEMS FOR INITIAL CONSIDERATION.—For purposes of section 1173(a)(5) of the Social Security Act, as added by subsection (a), the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall, not later than January 1, 2012, seek input on activities and items relating to the following areas:

(1) Whether the application process, including the use of a uniform application form, for enrollment of health care providers by health plans could be made electronic and standardized.

(2) Whether standards and operating rules described in section 1173 of the Social Security Act should apply to the health care transactions of automobile insurance, worker's compensation, and other programs or persons not described in section 1172(a) of such Act (42 U.S.C. 1320d–1(a)).

(3) Whether standardized forms could apply to financial audits required by health plans, Federal and State agencies (including State auditors, the Office of the Inspector General of the Department of Health and Human Services, and the Centers for Medicare & Medicaid Services), and other relevant entities as determined appropriate by the Secretary.

(4) Whether there could be greater transparency and consistency of methodologies and processes used to establish claim edits used by health plans (as described in section 1171(5) of the Social Security Act (42 U.S.C. 1320d(5))).

(5) Whether health plans should be required to publish their timeliness of payment rules.

(c) ICD CODING CROSSWALKS.—

(1) ICD-9 TO ICD-10 CROSSWALK.—The Secretary shall task the ICD-9-CM Coordination and Maintenance Committee to convene a meeting, not later than January 1, 2011, to receive input from appropriate stakeholders (including health plans, health care providers, and clinicians) regarding the crosswalk between the Ninth and Tenth Revisions of the International Classification of Diseases (ICD-9 and ICD-10, respectively) that is posted on the website of the Centers for Medicare & Medicaid Services, and make recommendations about appropriate revisions to such crosswalk.

(2) REVISION OF CROSSWALK.—For purposes of the crosswalk described in paragraph (1), the Secretary shall make appropriate revisions and post any such revised crosswalk on the website of the Centers for Medicare & Medicaid Services.

(3) USE OF REVISED CROSSWALK.—For purposes of paragraph (2), any revised crosswalk shall be treated as a code set for which a standard has been adopted by the Secretary for purposes of section 1173(c)(1)(B) of the Social Security Act (42 U.S.C. 1320d–2(c)(1)(B)).

(4) SUBSEQUENT CROSSWALKS.—For subsequent revisions of the International Classification of Diseases that are adopted by the Secretary as a standard code set under section 1173(c) of the Social Security Act (42 U.S.C. 1320d–2(c)), the Secretary shall, after consultation with the appropriate stakeholders, post on the website of the Centers for Medicare & Medicaid Services a crosswalk between the previous and subsequent version of the International Classification of Diseases not later than the date of implementation of such subsequent revision.

SA 3120. Mr. CRAPO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

Beginning on page 1997, strike line 1 and all that follows through page 1998, line 12.

SA 3121. Mr. CRAPO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

Beginning on page 2045, strike line 1 and all that follows through page 2046, line 24.

SA 3122. Mr. CRAPO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 1998, strike lines 13 through 24.

SA 3123. Mr. CRAPO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

Beginning on page 2034, strike line 16 and all that follows through page 2035, line 15.

SA 3124. Mr. CRAPO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

Beginning on page 2040, strike line 18 and all that follows through page 2044, line 7.

SA 3125. Mr. CRAPO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 1999, strike lines 1 through 20.

SA 3126. Mr. CRAPO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 2074, after line 25, insert the following:

SEC. 9024. EXEMPTION FROM TAXES, FEES, AND PENALTIES.

(a) IN GENERAL.—No tax, fee, or penalty imposed by this Act shall apply to any taxpayer for any taxable year if, as determined by the Secretary of the Treasury, such tax, fee, or penalty would increase the rate of tax imposed on such taxpayer under any provision of the Internal Revenue Code of 1986 or any other applicable Federal law in effect on the day before the date of the enactment of this Act, as compared to the rate of tax imposed on such taxpayer under such provision of law on December 31, 1999.

(b) NEW TAXPAYERS.—In the case of a taxpayer that was not in existence on December 31, 1999, or that had no Federal tax liability on such date, subsection (a) shall be applied by substituting ''December 31 of the first calendar year after 1999 in which such taxpayer had Federal tax liability greater than zero'' for ''December 31, 1999''.

SA 3127. Mr. MERKLEY (for himself and Mrs. MURRAY) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 1382, between lines 10 and 11, insert the following:

(c) ADVANCED TECHNOLOGY EDUCATION PROGRAM FOR NURSING.—Title VIII of the Public Health Service Act is amended by inserting after section 831A (42 U.S.C. 296b), as added by subsection (b), the following:

''SEC. 831B. ADVANCED TECHNOLOGY EDUCATION PROGRAM FOR NURSING.

''(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall establish a grant program to assist consortia in advancing nursing education and the career ladder.

''(b) PROGRAM DESIGN.—The grant program established under subsection (a) shall—

''(1) be designed to strengthen and expand the nursing career ladder, particularly with regard to innovative programs that encourage registered nurses to pursue advanced degrees in nursing, with an emphasis on integrating innovative technology into nursing education programs; and

''(2) place emphasis on the needs of nontraditional students and underserved groups.

''(c) APPLICATIONS.—An application for a grant under subsection (a) shall be submitted—

''(1) by a two-year educational institution on behalf of the consortia seeking the grant; and

''(2) at such time, in such manner, and containing such information as the Secretary may require.

''(d) ADVANCED TECHNOLOGY EDUCATION PROJECTS IN NURSING.—Funds made available

through a grant under subsection (a) shall be used to support nursing education projects, to enhance nursing education programs, and to assist students in transferring academic credit from a two-year educational institution to an advanced degree program in nursing through activities such as—

''(1) alignment and enhancement of curriculum to ensure that academic credit earned at a two-year educational institutions can be transferred to baccalaureate or graduate degree programs in nursing;

''(2) establishment of innovative partnerships and articulation agreements to facilitate the transfer by students of academic credit from a two-year educational institution to an advanced degree program in nursing;

''(3) the purchase or lease of state-of-the-art technologies essential in developing innovative nursing education programs and in preparing nursing students to use current and future health technologies, such as simulation and visualization tools and telehealth;

''(4) the acquisition of technical support necessary for developing innovative nursing curriculum and advanced technology training capabilities among nursing faculty;

''(5) professional development and training of nursing faculty, both full- and part-time, in the nursing profession;

''(6) development and dissemination of exemplary curricula and instructional materials in nursing;

''(7) development and implementation of innovative workshops, mentoring activities, and professional development activities for nursing students, registered nurses, and nursing faculty to encourage education advancement and retention in a nursing career; and

''(8) development and implementing internship programs for nurses or nursing students to encourage mentoring.

''(e) DEFINITION.—In this section—

''(1) the term 'consortia' means a collaboration that—

''(A) shall include a two-year educational institution in partnership with a four-year college or university; and

''(B) may include one or more of the following: another two-year or four-year college or university, a school of nursing, the private sector, a State or local government, a State workforce investment board, a local workforce investment board, a community-based allied health program, a health professions school, a teaching hospital, a graduate medical education program, an academic health center, and any other appropriate public or private non-profit entity;

in order to inform and improve nursing education programs;

''(2) the term 'four-year educational institution' means a department, division, or other administrative unit in a college or university which provides primarily or exclusively an accredited program in professional nursing and related subjects leading to the degree of bachelor of arts, bachelor of science, bachelor of nursing, or to an equivalent degree, or to a graduate degree in nursing, or to an equivalent degree, and including advanced training related to such program of education provided by such school;

''(3) the term 'local workforce investment board' refers to a local workforce investment board established under section 117 of the Workforce Investment Act of 1998 (29 U.S.C. 2832);

''(4) the term 'State workforce investment board' refers to a State workforce investment board established under section 111 of the Workforce Investment Act of 1998 (29 U.S.C. 2821); and

''(5) the term 'two-year educational institution' means a department, division, or other administrative unit in a junior or community college which provides primarily or exclusively a two-year accredited nursing program leading to an associate degree in nursing or an equivalent degree, but only if such program, or such unit or college, is accredited.

''(f) FUNDING.—There are authorized to be appropriated to award grants under this section, $12,000,000 for fiscal year 2010 and such sums as may be necessary for each of fiscal years 2011 through 2015.''.

SA 3128. Mr. KOHL submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 921, between lines 20 and 21, insert the following:

SEC. 3210. EXPANSION OF 340B PROGRAM COVERED ENTITIES AND RECEIPT BY CERTAIN PACE PROGRAMS AND SNPS OF PERCENTAGE OF SAVINGS FROM PARTICIPATION IN 340B PROGRAM.

(a) EXPANSION OF 340B PROGRAM COVERED ENTITIES.—Section 340B(a)(4) of the Public Health Service Act (42 U.S.C. 256b(a)(4)), as amended by section 7101, is further amended by adding at the end the following:

''(P) An entity that is—

''(i) a PACE program under section 1894 of the Social Security Act; or

''(ii) a specialized MA plan for special needs individuals described in section 1859(b)(6)(B)(ii) of such Act, all or nearly all of whom are nursing home certifiable, that is fully integrated with capitated contracts with States for Medicaid benefits.''.

(b) RECEIPT BY CERTAIN PACE PROGRAMS AND SNPS OF PERCENTAGE OF SAVINGS FROM PARTICIPATION IN 340B PROGRAM.—

(1) PACE PROGRAMS.—Section 1894 of the Social Security Act (42 U.S.C. 1395eee), as amended by section 3201(i), is further amended—

(A) by redesignating subsections (i) and (j) as subsections (j) and (k), respectively; and

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

''(i) RECEIPT BY CERTAIN PACE PROGRAMS OF PERCENTAGE OF SAVINGS FROM PARTICIPATION IN 340B PROGRAM.—

''(1) IN GENERAL.—An applicable PACE program is eligible to receive from the Secretary an amount equal to 10 percent of the estimated savings to the program under this title as a result of participation in the program under section 340B of the Public Health Service Act (as determined by the Secretary).

''(2) APPLICABLE PACE PROGRAM DEFINED.—For purposes of paragraph (1), the term 'applicable PACE program' means a PACE program that—

''(A) is participating in the program under section 340B of the Public Health Service Act;

''(B) submits to the Secretary an application in such form and manner, and containing such information, as the Secretary may specify; and

''(C) has in effect a plan approved by the Secretary for the use of any amounts received by the program or plan under paragraph (1) to provide enhanced formulary coverage, medication management, or disease management to enrollees.''.

(2) SNPS.—Section 1859 of the Social Security Act (42 U.S.C. 1395w–28), as amended by section 3208, is further amended by adding at the end the following new subsection:

''(h) RECEIPT BY CERTAIN SNPS OF PERCENTAGE OF SAVINGS FROM PARTICIPATION IN 340B PROGRAM.—

''(1) IN GENERAL.—An applicable specialized MA plan for specialized needs individuals is eligible to receive from the Secretary an amount equal to 10 percent of the estimated savings to the program under this title as a result of participation in the program under section 340B of the Public Health Service Act (as determined by the Secretary).

''(2) APPLICABLE SPECIALIZED MA PLAN FOR SPECIAL NEEDS INDIVIDUALS DEFINED.—For purposes of paragraph (1), the term 'applicable specialized MA plan for special needs individuals' means a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii), all or nearly all of whom are nursing home certifiable, that is fully integrated with capitated contracts with States for Medicaid benefits that—

''(A) is participating in the program under section 340B of the Public Health Service Act;

''(B) submits to the Secretary an application in such form and manner, and containing such information, as the Secretary may specify; and

''(C) has in effect a plan approved by the Secretary for the use of any amounts received by the program or plan under paragraph (1) to provide enhanced formulary coverage, medication management, or disease management to enrollees.''.

(c) DEVELOPMENT OF NEW PROGRAM.—The Secretary of Health and Human Services may develop and implement a program whereby such Secretary enters into an agreement with manufacturers that participate in the program under section 340B of the Public Health Service Act (42 U.S.C. 256b) under which enrollees in PACE programs under section 1894 of the Social Security Act (42 U.S.C. 1395eee) and specialized MA plans for special needs individuals described in section 1859(b)(6)(B)(ii) of such Act (42 U.S.C. 1395w–28) may receive covered drugs (as defined under such section 340B) from pharmacies selected by the PACE program or specialized MA plan, including local pharmacies.

SA 3129. Mrs. MURRAY submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 1411, between lines 5 and 6, insert the following:

SEC. 5316. SECONDARY SCHOOL HEALTH SCIENCES TRAINING PROGRAM.

(a) PROGRAM AUTHORIZED.—

(1) IN GENERAL.—The Secretary is authorized to establish a health sciences training program consisting of awarding grants, on a competitive basis, to eligible recipients to enable the eligible recipients to prepare secondary school students for careers in health professions.

(2) CONSULTATION AND COLLABORATION.—The Secretary of Education shall—

(A) consult with the Secretary of Health and Human Services and the Secretary of Labor prior to the issuance of a solicitation for grant applications under this section; and

(B) specifically collaborate with the Secretary of Health and Human Services to coordinate the program under this section with any programs administered by the Health Resources and Services Administration that create a pipeline of professionals for the health care workforce.

(b) DEVELOPMENT AND IMPLEMENTATION OF HEALTH SCIENCES PROGRAMS OF STUDY.—An eligible recipient receiving a grant under this section shall use grant funds—

(1) to implement a secondary school health sciences program of study that—

(A) meets the requirements for a career and technical program of study under section 122(c)(1)(A) of the Carl D. Perkins Career and Technical Education Act of 2006 (20 U.S.C. 2342(c)(1)(A));

(B) is aligned with—

(i) the career and technical programs of study supported by the State in which the eligible recipient is located, in accordance with the State's plan under section 122(c) of such Act (20 U.S.C. 2342(c)); and

(ii) any technical standards required for State licensure in a health profession; and

(C) prepares students for—

(i) a postsecondary certificate, credential, or accredited associate's or baccalaureate degree program in the health profession; or

(ii) an accredited baccalaureate degree program in an academic major related to the health profession; and

(2) to increase the interest of secondary school students in applying to, and enrolling in, programs described in clause (i) or (ii) of paragraph (1)(C), including through—

(A) work-study programs;

(B) pre-apprenticeship programs;

(C) programs to increase awareness of careers in health professions; or

(D) other activities to increase such interest.

(c) ELIGIBILITY.—To be eligible for a grant under this section, an eligible recipient shall—

(1) provide assurances that activities under the grant will be carried out in partnership with—

(A) an accredited health professions school or program at the postsecondary level; and

(B) a public or private nonprofit hospital or public or private nonprofit entity with a focus on health sciences or health professions; and

(2) provide an explanation of how activities under the grant are consistent with the State plan and local plan being implemented under sections 122 and 134, respectively, of the Carl D. Perkins Career and Technical Education Act of 2006 (20 U.S.C. 2342, 2354), for the area to be served by the grant.

(d) PREFERENCE.—In awarding grants under this section, the Secretary shall give preference to an eligible recipient that has a demonstrated record of not less than one of the following:

(1) Graduating, or collaborating with an eligible recipient that graduates, a high or significantly improved percentage of students who have exhibited mastery in secondary school State science standards.

(2) Graduating students from disadvantaged backgrounds, including racial and ethnic minorities who are underrepresented in—

(A) the programs described in clause (i) or (ii) of subsection (b)(1)(C); or

(B) the health professions.

(e) REPORT.—The Secretary shall submit to Congress an annual report on the program carried out under this section.

(f) DEFINITIONS.—In this section:

(1) ELIGIBLE RECIPIENT.—The term ''eligible recipient'' means an eligible recipient described in section 3(14)(A) of the Carl D. Perkins Career and Technical Education Act of 2006 (20 U.S.C. 2302(14)(A)).

(2) HEALTH CARE WORKFORCE.—The term ''health care workforce'' has the meaning given the term in section 5101(i).

(3) HEALTH PROFESSION.—The term ''health profession'' means the profession of a member of the health care workforce.

(4) LOCAL EDUCATIONAL AGENCY.—The term ''local educational agency'' has the meaning given the term in section 9101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(5) SECONDARY SCHOOL.—The term ''secondary school''—

(A) means a secondary school, as defined in section 9101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801); and

(B) includes a middle school.

(6) SECRETARY.—The term ''Secretary'' means the Secretary of Education, except as otherwise specified.

(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2011 through 2015.

SA 3130. Mr. JOHANNS submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 245, between lines 14 and 15, and insert the following:

(B) SPECIAL RULE FOR LOW-INCOME ADULTS NOT ELIGIBLE FOR MEDICAID.—If a taxpayer is an individual who, but for the application of section 1902(k)(2) of the Social Security Act, a State would be required under subclause (VIII) of subsection (a)(10)(A)(i) to provide medical assistance to under the State Medicaid plan, the taxpayer shall—

(i) for purposes of the credit under this section, be treated as an applicable taxpayer and the applicable percentage with respect to such taxpayer shall be 2.0 percent; and

(ii) for purposes of reduced cost-sharing under section 1402 of the Patient Protection and Affordable Care Act, shall be treated as having household income of more than 100 percent but less than 150 percent of the poverty line (as so defined) applicable to a family of the size involved.

On page 398, between lines 9 and 10, insert the following:

(B) SPECIAL RULES FOR STATES WITH A BUDGET DEFICIT OR AT RISK OF HAVING TO RAISE TAXES OR BEING UNABLE TO DELIVER ESSENTIAL STATE FUNCTIONS.—Section 1902(k) of such Act (42 U.S.C. 1396a(k)), as added by subparagraph (A), is amended by adding at the end the following:

''(2) If a State submits a certification to the Secretary in 2013 that in 2014, complying with the requirement under subclause (VIII) of subsection (a)(10)(A)(i) to provide medical assistance to individuals described in that subclause would cause the State to have a budget deficit, or require the State to raise taxes, or reduce or eliminate spending for education, transportation, law enforcement or other essential State functions, then, in the case of individuals described in the subclause who have attained 19 years of age, the State only shall be required to provide medical assistance under that subclause to those individuals with income (as determined under subsection (e)(14)) that does not exceed 75 percent of the poverty line (as defined in section 2110(c)(5)) applicable to a family of the size involved.''.

SA 3131. Mr. KOHL (for himself and Mr. DURBIN) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

TITLE ____—PROHIBITION ON DATA MINING

SEC. __01. PURPOSE.

(a) IN GENERAL.—It is the purpose of this title to—

(1) safeguard the confidentiality of prescribing information;

(2) protect the integrity of the doctor-patient relationship;

(3) maintain the integrity and public trust in the medical profession;

(4) combat vexatious and harassing sales practices;

(5) restrain undue influence exerted by pharmaceutical industry marketing representatives over prescribing decisions; and

(6) improve the quality and lower the cost of health care.

(b) RULE OF CONSTRUCTION.—Nothing in this title shall be construed to regulate the monitoring of prescribing practices for uses other than marketing (such as quality control, research unrelated to marketing, or use by governments or other entities not in the business of selling health care products).

SEC. __02. DEFINITIONS.

In this title:

(1) BONA FIDE CLINICAL TRIAL.—The term ''bona fide clinical trial'' means any research project that—

(A) prospectively assigns human subjects to intervention and comparison groups to study the cause and effect relationship between a medical intervention and a health outcome;

(B) has received approval from an appropriate Institutional Review Board; and

(C) has been registered at ClinicalTrials.Gov prior to commencement.

(2) COMPANY MAKING OR SELLING PRESCRIBED PRODUCTS.—The term ''company making or selling prescribed products'' means a pharmacy, a pharmacy benefit manager, a pharmaceutical manufacturer, pharmaceutical wholesaler, or any other entity whose primary purpose is the marketing of pharmaceutical product for financial gain. Such term does not include health plans, health care providers, or State or Federal public health programs and research organizations.

(3) INDIVIDUAL IDENTIFYING INFORMATION.—The term ''individual identifying information'' means information that directly or indirectly identifies a prescriber or a patient, where the information is derived from or relates to a prescription for any prescribed product.

(4) HEALTH CARE PROVIDER.—The term ''health care provider'' means a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

(5) HEALTH PLAN.—

(A) IN GENERAL.—The term ''health plan'' means an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the Public Health Service Act (42 U.S.C. 300gg–91(a)(2))). Such term includes the following (singly or in combination):

(i) A group health plan, as defined in section 2791 of the Public Health Service Act (42 U.S.C. 300gg-91).

(ii) A health insurance issuer, as defined in section 2791 of the Public Health Service Act (42 U.S.C. 300gg-91).

(iii) A health maintenance organization, as defined in section 2791 of the Public Health Service Act (42 U.S.C. 300gg-91).

(iv) Part A or part B of the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

(v) The Medicaid program under title XIX of the Act, 42 U.S.C. 1396, et seq.

(vi) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1))).

(vii) An issuer of a long-term care policy, excluding a nursing home fixed-indemnity policy.

(viii) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

(ix) The health care program for active military personnel under title 10, United States Code.

(x) The veterans health care program under chapter 17 of title 38, United States Code.

(xi) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) (as defined in section 1072(4) of title 10, United States Code).

(xii) The Indian Health Service program under the Indian Health Care Improvement Act (25 U.S.C. 1601, et seq).

(xiii) The Federal Employees Health Benefits Program under chapter 89 of title 5, United States Code.

(xiv) An approved State child health plan under title XXI of the Social Security Act, providing benefits for child health assistance that meet the requirements of section 2103 of such Act (42 U.S.C. 1397, et seq).

(xv) The Medicare+Choice program under Part C of title XVIII of the Social Security Act (42 U.S.C. 1395w–21 et seq.).

(xvi) A high risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals.

(xvii) Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the Public Health Service Act (42 U.S.C. 300gg–91(a)(2))).

(B) LIMITATION.—Such terms shall not include the following:

(i) Any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 2791(c)(1) of the Public Health Service Act (42 U.S.C. 300gg–91(c)(1)).

(ii) A government-funded program (other than a program listed in clauses (i) through (xvi) of subparagraph (A)—

(I) whose principal purpose is other than providing, or paying the cost of, health care; or

(II) whose principal activity is—

(aa) the direct provision of health care to persons; or

(bb) the making of grants to fund the direct provision of health care to persons.

(6) MARKETING.—The term ''marketing'' means any activity advertising, promoting, or selling a prescribed product for commercial gain, including—

(A) identifying individuals to receive a message promoting use of a particular product;

(B) identifying individuals to receive any form of gift, product sample, consultancy, or any other item, service, compensation or employment of value;

(C) planning the substance of a sales representative visit or communication or the substance of an advertisement or other promotional message or document; or

(D) evaluating or compensating sales representatives.

(7) PERSON.—The term ''person'' means a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

(8) PHARMACY.—The term ''pharmacy'' means any person licensed under State or Federal law to dispense prescribed products.

(9) PRESCRIBED PRODUCT.—The term ''prescribed product'' includes a biological product as defined in section 351 of the Public Health Service Act (42 U.S.C. 262) and a device or a drug as defined in section 201 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321).

(10) REGULATED RECORD.—The term ''regulated record'' means information or documentation from a prescription.

SEC. __03. PRIVACY PROTECTIONS.

(a) PROHIBITION.—No company or person in possession of regulated records, or their agents, or those acting on their behalf shall knowingly disclose, sell, or use regulated records containing individual identifying information for marketing a prescribed product.

(b) PERMITTED TRANSFERS.—A regulated record containing individual identifying information may be transferred to another entity, including to another branch or subsidiary of the same entity, only if the transfer provides satisfactory assurance that the recipient will safeguard the records from being disclosed or used for a marketing purpose prohibited under this section.

(c) PERMITTED USES.—

(1) IN GENERAL.—Regulated records containing individual identifying information may be disclosed, sold, transferred, exchanged, or used for any purpose other than marketing a prescribed product, including—

(A) to fill a valid prescription, including communication by a pharmacist about patient safety or generic substitution, or in response to patient or physician questions about a medication, as well as any transfer necessary for billing or pharmacy reimbursement;

(B) to conduct of a bona fide clinical trial;

(C) to disseminate safety warnings, labeling changes, risk evaluation and mitigation strategies (REMS) compliance communications, or to facilitate adverse event reporting, or to otherwise implement a REMS;

(D) for the purposes of academic detailing or public health communications;

(E) for the administration of a patient's health insurance or benefits plan, including determining compliance with the terms of coverage or medical necessity; or

(F) to comply with existing State or Federal law.

(2) RULES OF CONSTRUCTION.—This section shall not be construed to—

(A) prohibit any communication between a health care provider and patients under his or her care, or any communication between health care providers for the purpose of patient care;

(B) prohibit the use of data by a health plan or a pharmacy benefit manager where such plan or manager is acting in the fiduciary interest of such organizations, for purposes of planning, conducting, or evaluating formulary compliance or quality assurance program based on evidence based prescribing or cost-containment goals;

(C) prohibit conduct that involves the collection, use, transfer, or sale of regulated records for marketing purposes if—

(i) the data involved does not contain individually identifying information; and

(ii) there is no reasonable basis to believe that the data can be used to obtain individually identifying information; and

(D) prevent any person from disclosing regulated records to the identified individual as long as the information does not include protected information pertaining to any other person.

(d) REGULATIONS.—The Attorney General may promulgate regulations as necessary to implement this title.

(e) ENFORCEMENT.—Any person who knowingly fails to comply with the requirements of this title, or regulations promulgated pursuant to this title, by using or disclosing regulated records in a manner not authorized by this title, or regulations, shall be subject to an civil penalty of at least $10,000, and not more than $50,000, per violation, as assessed by the Attorney General. Each disclosure of a regulated record shall constitute a violation of this title. The Attorney General shall take necessary action to enforce the payment of penalties assessed under this section.

SEC. __04. SEVERABILITY.

If any provision of this title, or its application to any person or circumstance, is held invalid, the remainder of this title, or the application of the provision, to other persons or circumstances shall not be affected.

SEC. __05. NO EFFECT ON TRUTHFUL SPEECH TO DOCTORS OR PATIENTS.

Nothing in this title shall be construed to regulate the content, time, place, or manner of any discussion between a prescriber and their patient, or a prescriber and any person representing a prescription drug manufacturer.

SA 3132. Mrs. MCCASKILL submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 40, between lines 21 and 22, insert the following:

SEC. 1003A. STUDY TO PROVIDE HEALTH CARE INFLATION TRANSPARENCY AND ACCOUNTABILITY.

(a) FINDINGS.—Congress finds the following:

(1) Manufacturers of drugs have increased wholesale prices of brand-name drugs by approximately 9 percent in the period from 2008 to 2009, while all other sectors of the economy experienced a 1.3 percent decline in such period.

(2) Insurance brokers and benefits consultants predict that the small business clients of such brokers and consultants will experience an increase in premiums by an average of approximately 15 percent for 2010, which is double the rate of such increase that occurred for 2009.

(b) DEFINITIONS.—In this section:

(1) HEALTH CARE SECTOR.—The term ''health care sector'' includes manufacturers of drugs, manufacturers of devices, hospitals, insurance companies, laboratories, and health care providers that are affected by this Act (and the amendments made by this Act).

(2) HEALTH INSURANCE ISSUER.—The term ''health insurance issuer'' means those health insurance issuers subject to section 2794(a) of the Public Health Service Act (as added by section 1003)

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

(c) ANNUAL STUDY.—

(1) IN GENERAL.—The Secretary, in coordination with the Attorney General and the Chairman of the Federal Trade Commission, shall, on an annual basis, collect and study data on pricing in the health care sector. Such data shall include the information provided to the Secretary under section 2794(b)(1)(A) of the Public Health Service Act (as added by section 1003).

(2) INITIAL STUDY.—The initial such study shall be for the 1-year period beginning on July 1, 2009, and ending on the date of the first report under subsection (e).

(3) SUBSEQUENT STUDIES.—Each subsequent study shall be for the 1-year period following the date of the preceding report under subsection (e).

(d) COLLECTION OF DATA.—Health insurance issuers and entities operating within the health care sector shall provide to the Secretary information on price, demographics, and any other variable or factor the Secretary may deem necessary to determine if premiums, retail or wholesale prices, or other costs are being increased unreasonably, including information about the actuarial value of the plans of the issuer and the medical loss ratio of such plans.

(e) REPORTS.—

(1) IN GENERAL.—Based on the annual study conducted under subsection (c), the Secretary, in coordination with the Attorney General and the Chairman of the Federal Trade Commission, shall publish an annual report on the excess price inflation in the health care sector that occurred during the period described in such subsection.

(2) EXCESS PRICE INFLATION.—For purposes of the report, the term ''excess price inflation'' shall be defined by the Secretary, in consultation with the Attorney General, the Director of the Congressional Budget Office, and other Government experts and economists as the Secretary determines appropriate.

(f) EFFECT OF STUDY AND REPORTS.—

(1) REIMBURSEMENT RATES.—The results of the study and report under this section shall be taken into account—

(A) when reimbursement rates for Federal health programs are established for the years following such report; and

(B) by States, when making recommendations under section 2974(b)(1)(B) of the Public Health Service Act (as added by section 1003).

(2) REBATES.—

(A) HEALTH INSURANCE ISSUERS.—Based on a study conducted under subsection (c), if insurance premiums of a health insurance issuer are determined by the Secretary, in coordination with the Attorney General and the Chairman of the Federal Trade Commission, to meet the definition of excess price inflation, such issuer shall provide to each enrollee of such issuer a rebate. The amount of the rebate shall be calculated using the formula described under section 2718(b) of the Public Health Service Act (as added by section 1001), except for the amount of the excess price inflation shall be substituted for the amount of the premium revenues.

(B) HEALTH CARE SECTOR ENTITIES.—Based on a study conducted under subsection (c), if the Secretary determines, in coordination with the Attorney General and the Chairman of the Federal Trade Commission, that an entity within the health care sector has increased price of goods or services related to such entity's participation in the health care sector, such as drugs or devices, sufficient to meet the definition of excess price inflation, then such entity shall pay to the Treasury the amount of the excess price inflation for the purpose of deficit reduction.

(3) APPEAL OF DETERMINATION.—The Secretary shall establish an effective appeals process under which a health insurance issuer or health care entity within the health care sector may appeal the determination of excess price inflation described in paragraph (2). In making an appeals determination, the Secretary may consult with the Attorney General, the Chairman of the Federal Trade Commission, the Director of the Congressional Budget Office, and other Government experts and economists as the Secretary determines appropriate.

(g) PUBLIC AVAILABILITY.—The Secretary shall make each report under subsection (e), and the supporting data describing excess price inflation in the health care sector, available to the public.

SA 3133. Mr. WICKER submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 2074, after line 25, add the following:

TITLE X—ADDITIONAL PROVISIONS

Subtitle A—Physician Payment Update Commission

SEC. 10001. SHORT TITLE.

This subtitle may be cited as the ''Physician Payment Update Commission Act''.

SEC. 10002. ESTABLISHMENT OF PHYSICIAN PAYMENT UPDATE COMMISSION.

(a) MEDICARE PHYSICIAN FEE SCHEDULE UPDATE AND SUNSET OF MEDICARE SUSTAINABLE GROWTH RATE FORMULA.—

(1) UPDATE FOR 2010 AND 2011.—Section 1848(d)(10) of the Social Security Act (42 U.S.C. 1395w–4(d)(10)), as added by section 3101, is amended to read as follows:

''(10) UPDATE FOR 2010 AND 2011.—

''(A) IN GENERAL.—The update to the single conversion factor established in paragraph (1)(C) for 2010 and 2011 shall be 0 percent.

''(B) NO EFFECT ON COMPUTATION OF CONVERSION FACTOR FOR 2012 AND SUBSEQUENT YEARS.—The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2012 and subsequent years as if subparagraph (A) had never applied.''.

(2) SUNSET OF MEDICARE SUSTAINABLE GROWTH RATE FORMULA.—Effective January 1, 2012, subsection (f) of section 1848 of the Social Security Act (42 U.S.C. 1395w–4) is repealed.

(b) ESTABLISHMENT OF PHYSICIAN PAYMENT UPDATE COMMISSION.—

(1) IN GENERAL.—There is established a commission to be known as the ''Physician Payment Update Commission'' (referred to in this section as the ''Commission'').

(2) MEMBERSHIP.—

(A) COMPOSITION.—The Commission shall be composed of 17 members appointed by the Comptroller General of the United States, upon the recommendation of the majority and minority leaders of the Senate and the Speaker and minority leader of the House of Representatives.

(B) DATE OF APPOINTMENTS.—Members of the Commission shall be appointed not later than 2 months after the date of enactment of this Act.

(3) QUALIFICATIONS.—

(A) IN GENERAL.—The membership of the Commission shall include individuals with national recognition for their expertise in health finance and economics, actuarial science, integrated delivery systems, allopathic and osteopathic medicine and other areas of health services, and other related fields, who provide a mix of different professionals, broad geographic representation, and a balance between urban and rural representatives.

(B) INCLUSION.—The members of the Commission shall include (but not be limited to) physicians and other health professionals, employers, third-party payers, individuals skilled in the conduct and interpretation of biomedical, health services, and health economics research and technology assessment. Such membership shall also include representatives of consumers and the elderly.

(C) MAJORITY PHYSICIANS AND OTHER HEALTH PROFESSIONALS.—Individuals who are physicians or other health professionals shall constitute a majority of the membership of the Commission.

(4) TERM; VACANCIES.—

(A) TERM.—A member shall be appointed for the life of the Commission.

(B) VACANCIES.—A vacancy on the Commission—

(i) shall not affect the powers of the Commission; and

(ii) shall be filled in the same manner as the original appointment was made.

(5) MEETINGS.—The Commission shall meet at the call of the Chairperson.

(6) QUORUM.—A majority of the members of the Commission shall constitute a quorum, but a lesser number of members may hold hearings.

(7) CHAIRPERSON.—The Comptroller General shall designate a member of the Commission, at the time of the appointment of the member, as Chairperson.

(c) DUTIES.—

(1) STUDY.—The Commission shall conduct a study of all matters relating to payment rates under the Medicare physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4).

(2) RECOMMENDATIONS.—The Commission shall develop recommendations on the establishment of a new physician payment system under the Medicare program that would appropriately reimburse physicians by keeping pace with increases in medical practice costs and providing stable, positive Medicare updates.

(3) REPORT.—Not later than December 1, 2010, the Commission shall submit to the appropriate Committees of Congress and the Medicare Payment Advisory Commission—

(A) a detailed statement of the findings and conclusions of the Commission;

(B) the recommendations of the Commission for such legislation and administrative actions as the Commission considers appropriate (including proposed legislative language to carry out such recommendations); and

(C) a long-term CBO cost estimate regarding such recommendations (as described under subsection (i)).

(d) POWERS.—

(1) HEARINGS.—The Commission may hold such hearings, meet and act at such times and places, take such testimony, and receive such evidence as the Commission considers advisable to carry out this section.

(2) INFORMATION FROM FEDERAL AGENCIES.—

(A) IN GENERAL.—The Commission may secure directly from a Federal agency such information as the Commission considers necessary to carry out this section.

(B) PROVISION OF INFORMATION.—On request of the Chairperson of the Commission, the head of the agency shall provide the information to the Commission.

(3) POSTAL SERVICES.—The Commission may use the United States mails in the same manner and under the same conditions as other agencies of the Federal Government.

(e) COMMISSION PERSONNEL MATTERS.—

(1) COMPENSATION OF MEMBERS.—

(A) IN GENERAL.—Members of the Commission shall serve without compensation in addition to the compensation received for the services of the member as an officer or employee of the Federal Government.

(B) TRAVEL EXPENSES.—A member of the Commission shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for an employee of an agency under subchapter I of chapter 57 of title 5, United States Code, while away from the home or regular place of business of the member in the performance of the duties of the Commission.

(2) STAFF AND SUPPORT SERVICES.—

(A) EXECUTIVE DIRECTOR.—The Chairperson shall appoint an executive director of the Commission.

(B) STAFF.—With the approval of the Commission, the executive director may appoint such personnel as the executive director considers appropriate.

(C) APPLICABILITY OF CIVIL SERVICE LAWS.—The staff of the Commission shall be appointed without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title (relating to classification and General Schedule pay rates).

(D) EXPERTS AND CONSULTANTS.—With the approval of the Commission, the executive director may procure temporary and intermittent services under section 3109(b) of title 5, United States Code.

(f) TERMINATION OF COMMISSION.—The Commission shall terminate 30 days after the date on which the Commission submits its report under subsection (c)(3).

(g) REVIEW AND RESPONSE TO RECOMMENDATIONS BY THE MEDICARE PAYMENT ADVISORY COMMISSION.—

(1) IN GENERAL.—Not later than February 1, 2011, the Medicare Payment Advisory Commission shall—

(A) review the recommendations included in the report submitted under subsection (c)(3);

(B) examine the budget consequences of such recommendations, directly or through consultation with appropriate expert entities; and

(C) submit to the appropriate Committees of Congress a report on such review.

(2) CONTENTS OF REPORT ON REVIEW OF COMMISSION RECOMMENDATIONS.—The report submitted under paragraph (1)(C) shall include—

(A) if the Medicare Payment Advisory Commission supports the recommendations of the Commission, the reasons for such support; or

(B) if the Medicare Payment Advisory Commission does not support such recommendations, the recommendations of the Medicare Payment Advisory Commission, together with an explanation as to why the Medicare Payment Advisory Commission does not support the recommendations of the Commission.

(h) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for the Commission to carry out this section. Such appropriation shall be payable from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t).

(i) LONG-TERM CBO COST ESTIMATE.—

(1) PREPARATION AND SUBMISSION.—When the Commission submits a written request to the Director of the Congressional Budget Office for a long-term CBO cost estimate of recommended legislation or administrative actions (as described under subsection (c)(3)), the Director shall prepare the estimate and have it published in the Congressional Record as expeditiously as possible.

(2) CONTENT.—A long-term CBO cost estimate shall include—

(A) an estimate of the cost of each provision (if practicable) or group of provisions of the recommended legislation or administrative actions for first fiscal year it would take effect and for each of the 49 fiscal years thereafter; and

(B) a statement of any estimated future costs not reflected by the estimate described in subparagraph (A).

(3) FORM.—To the extent that a long-term CBO cost estimate presented in dollars is impracticable, the Director of the Congressional Budget Office may instead present the estimate in terms of percentages of gross domestic product, with rounding to the nearest 1/10 of 1 percent of gross domestic product.

(4) LIMITATIONS ON DISCRETIONARY SPENDING.—A long-term CBO cost estimate shall only consider the effects of provisions affecting revenues and direct spending (as defined by the Balanced Budget and Emergency Deficit Control Act of 1985), and shall not assume that any changes in outlays will result from limitations on, or reductions in, annual appropriations.

(j) EXPEDITED CONSIDERATION OF COMMISSION RECOMMENDATIONS.—

(1) INTRODUCTION.—

(A) IN GENERAL.—The proposed legislative language contained in the report submitted pursuant to subsection (c)(3) (referred to in this subsection as the ''Commission bill'') shall be introduced within the first 10 calendar days of the 112th Congress (or on the first session day thereafter) in the House of Representatives and in the Senate by the majority leader of each House of Congress, for himself, the minority leader of each House of Congress, for himself, or any member of the House designated by the majority leader or minority leader. If the Commission bill is not introduced in accordance with the preceding sentence in either House of Congress, then any Member of that House may introduce the Commission bill on any day thereafter. Upon introduction, the Commission bill shall be referred to the appropriate committees under subparagraph (B).

(B) COMMITTEE CONSIDERATION.—A Commission bill introduced in either House of Congress shall be jointly referred to the committee or committees of jurisdiction, which shall report the bill without any revision and with a favorable recommendation, an unfavorable recommendation, or without recommendation, not later than 10 calendar days after the date of introduction of the bill in that House. If any committee fails to report the bill within that period, that committee shall be automatically discharged from consideration of the bill, and the bill shall be placed on the appropriate calendar.

(2) EXPEDITED PROCEDURE.—

(A) IN THE HOUSE OF REPRESENTATIVES.—

(i) IN GENERAL.—Not later than 5 days of session after the date on which a Commission bill is reported or discharged from all committees to which it was referred, the majority leader of the House of Representatives or the majority leader's designee shall move to proceed to the consideration of the Commission bill. It shall also be in order for any Member of the House of Representatives to move to proceed to the consideration of the Commission bill at any time after the conclusion of such 5-day period.

(ii) MOTION TO PROCEED.—A motion to proceed to the consideration of the Commission bill is highly privileged in the House of Representatives and is not debatable. The motion is not subject to amendment or to a motion to postpone consideration of the Commission bill. A motion to proceed to the consideration of other business shall not be in order. A motion to reconsider the vote by which the motion to proceed is agreed to or not agreed to shall not be in order. If the motion to proceed is agreed to, the House of Representatives shall immediately proceed to consideration of the Commission bill without intervening motion, order, or other business, and the Commission bill shall remain the unfinished business of the House of Representatives until disposed of.

(iii) LIMITS ON DEBATE.—Debate in the House of Representatives on a Commission bill under this paragraph shall not exceed a total of 100 hours, which shall be divided equally between those favoring and those opposing the bill. A motion further to limit debate is in order and shall not be debatable. It shall not be in order to move to recommit a Commission bill under this paragraph or to move to reconsider the vote by which the bill is agreed to or disagreed to.

(iv) APPEALS.—Appeals from decisions of the chair relating to the application of the Rules of the House of Representatives to the procedure relating to a Commission bill shall be decided without debate.

(v) APPLICATION OF HOUSE RULES.—Except to the extent specifically provided in this paragraph, consideration of a Commission bill shall be governed by the Rules of the House of Representatives. It shall not be in order in the House of Representatives to consider any Commission bill introduced pursuant to the provisions of this subsection under a suspension of the rules or under a special rule.

(vi) NO AMENDMENTS.—No amendment to the Commission bill shall be in order in the House of Representatives.

(vii) VOTE ON FINAL PASSAGE.—In the House of Representatives, immediately following the conclusion of consideration of the Commission bill, the vote on final passage of the Commission bill shall occur without any intervening action or motion, requiring an affirmative vote of 3/5 of the Members, duly chosen and sworn. If the Commission bill is passed, the Clerk of the House of Representatives shall cause the bill to be transmitted to the Senate before the close of the next day of session of the House.

(B) IN THE SENATE.—

(i) IN GENERAL.—Not later than 5 days of session after the date on which a Commission bill is reported or discharged from all committees to which it was referred, the majority leader of the Senate or the majority leader's designee shall move to proceed to the consideration of the Commission bill. It shall also be in order for any Member of the Senate to move to proceed to the consideration of the Commission bill at any time after the conclusion of such 5-day period.

(ii) MOTION TO PROCEED.—A motion to proceed to the consideration of the Commission bill is privileged in the Senate and is not debatable. The motion is not subject to amendment or to a motion to postpone consideration of the Commission bill. A motion to proceed to consideration of the Commission bill may be made even though a previous motion to the same effect has been disagreed to. A motion to proceed to the consideration of other business shall not be in order. A motion to reconsider the vote by which the motion to proceed is agreed to or not agreed to shall not be in order. If the motion to proceed is agreed to, the Senate shall immediately proceed to consideration of the Commission bill without intervening motion,

order, or other business, and the Commission bill shall remain the unfinished business of the Senate until disposed of.

(iii) LIMITS ON DEBATE.—In the Senate, consideration of the Commission bill and on all debatable motions and appeals in connection therewith shall not exceed a total of 100 hours, which shall be divided equally between those favoring and those opposing the Commission bill. A motion further to limit debate on the Commission bill is in order and is not debatable. Any debatable motion or appeal is debatable for not to exceed 1 hour, to be divided equally between those favoring and those opposing the motion or appeal. All time used for consideration of the Commission bill, including time used for quorum calls and voting, shall be counted against the total 100 hours of consideration.

(iv) NO AMENDMENTS.—No amendment to the Commission bill shall be in order in the Senate.

(v) MOTION TO RECOMMIT.—A motion to recommit a Commission bill shall not be in order under this paragraph.

(vi) VOTE ON FINAL PASSAGE.—In the Senate, immediately following the conclusion of consideration of the Commission bill and a request to establish the presence of a quorum, the vote on final passage of the Commission bill shall occur and shall require an affirmative vote of ⅗ of the Members, duly chosen and sworn.

(vii) OTHER MOTIONS NOT IN ORDER.—A motion to postpone or a motion to proceed to the consideration of other business is not in order in the Senate. A motion to reconsider the vote by which the Commission bill is agreed to or not agreed to is not in order in the Senate.

(viii) CONSIDERATION OF THE HOUSE BILL.—

(I) IN GENERAL.—If the Senate has received the House companion bill to the Commission bill introduced in the Senate prior to the vote required under clause (vi) and the House companion bill is identical to the Commission bill introduced in the Senate, then the Senate shall consider, and the vote under clause (vi) shall occur on, the House companion bill.

(II) PROCEDURE AFTER VOTE ON SENATE BILL.—If the Senate votes, pursuant to clause (vi), on the bill introduced in the Senate, the Senate bill shall be held pending receipt of the House message on the bill. Upon receipt of the House companion bill, if the House bill is identical to the Senate bill, the House bill shall be deemed to be considered, read for the third time, and the vote on passage of the Senate bill shall be considered to be the vote on the bill received from the House.

(C) NO SUSPENSION.—No motion to suspend the application of this paragraph shall be in order in the Senate or in the House of Representatives.

Subtitle B—Medical Care Access Protection

SEC. 10101. SHORT TITLE.

This subtitle may be cited as the ''Medical Care Access Protection Act of 2009'' or the ''MCAP Act''.

SEC. 10102. FINDINGS AND PURPOSE.

(a) FINDINGS.—

(1) EFFECT ON HEALTH CARE ACCESS AND COSTS.—Congress finds that our current civil justice system is adversely affecting patient access to health care services, better patient care, and cost-efficient health care, in that the health care liability system is a costly and ineffective mechanism for resolving claims of health care liability and compensating injured patients, and is a deterrent to the sharing of information among health care professionals which impedes efforts to improve patient safety and quality of care.

(2) EFFECT ON INTERSTATE COMMERCE.—Congress finds that the health care and insurance industries are industries affecting interstate commerce and the health care liability litigation systems existing throughout the United States are activities that affect interstate commerce by contributing to the high costs of health care and premiums for health care liability insurance purchased by health care system providers.

(3) EFFECT ON FEDERAL SPENDING.—Congress finds that the health care liability litigation systems existing throughout the United States have a significant effect on the amount, distribution, and use of Federal funds because of—

(A) the large number of individuals who receive health care benefits under programs operated or financed by the Federal Government;

(B) the large number of individuals who benefit because of the exclusion from Federal taxes of the amounts spent to provide them with health insurance benefits; and

(C) the large number of health care providers who provide items or services for which the Federal Government makes payments.

(b) PURPOSE.—It is the purpose of this subtitle to implement reasonable, comprehensive, and effective health care liability reforms designed to—

(1) improve the availability of health care services in cases in which health care liability actions have been shown to be a factor in the decreased availability of services;

(2) reduce the incidence of ''defensive medicine'' and lower the cost of health care liability insurance, all of which contribute to the escalation of health care costs;

(3) ensure that persons with meritorious health care injury claims receive fair and adequate compensation, including reasonable noneconomic damages;

(4) improve the fairness and cost-effectiveness of our current health care liability system to resolve disputes over, and provide compensation for, health care liability by reducing uncertainty in the amount of compensation provided to injured individuals; and

(5) provide an increased sharing of information in the health care system which will reduce unintended injury and improve patient care.

SEC. 10103. DEFINITIONS.

In this subtitle:

(1) ALTERNATIVE DISPUTE RESOLUTION SYSTEM; ADR.—The term ''alternative dispute resolution system'' or ''ADR'' means a system that provides for the resolution of health care lawsuits in a manner other than through a civil action brought in a State or Federal court.

(2) CLAIMANT.—The term ''claimant'' means any person who brings a health care lawsuit, including a person who asserts or claims a right to legal or equitable contribution, indemnity or subrogation, arising out of a health care liability claim or action, and any person on whose behalf such a claim is asserted or such an action is brought, whether deceased, incompetent, or a minor.

(3) COLLATERAL SOURCE BENEFITS.—The term ''collateral source benefits'' means any amount paid or reasonably likely to be paid in the future to or on behalf of the claimant, or any service, product or other benefit provided or reasonably likely to be provided in the future to or on behalf of the claimant, as a result of the injury or wrongful death, pursuant to—

(A) any State or Federal health, sickness, income-disability, accident, or workers' compensation law;

(B) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(C) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; and

(D) any other publicly or privately funded program.

(4) COMPENSATORY DAMAGES.—The term ''compensatory damages'' means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities, damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature. Such term includes economic damages and noneconomic damages, as such terms are defined in this section.

(5) CONTINGENT FEE.—The term ''contingent fee'' includes all compensation to any person or persons which is payable only if a recovery is effected on behalf of one or more claimants.

(6) ECONOMIC DAMAGES.—The term ''economic damages'' means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities.

(7) HEALTH CARE GOODS OR SERVICES.—The term ''health care goods or services'' means any goods or services provided by a health care institution, provider, or by any individual working under the supervision of a health care provider, that relates to the diagnosis, prevention, care, or treatment of any human disease or impairment, or the assessment of the health of human beings.

(8) HEALTH CARE INSTITUTION.—The term ''health care institution'' means any entity licensed under Federal or State law to provide health care services (including but not limited to ambulatory surgical centers, assisted living facilities, emergency medical services providers, hospices, hospitals and hospital systems, nursing homes, or other entities licensed to provide such services).

(9) HEALTH CARE LAWSUIT.—The term ''health care lawsuit'' means any health care liability claim concerning the provision of health care goods or services affecting interstate commerce, or any health care liability action concerning the provision of (or the failure to provide) health care goods or services affecting interstate commerce, brought in a State or Federal court or pursuant to an alternative dispute resolution system, against a health care provider or a health care institution regardless of the theory of liability on which the claim is based, or the number of claimants, plaintiffs, defendants, or other parties, or the number of claims or causes of action, in which the claimant alleges a health care liability claim.

(10) HEALTH CARE LIABILITY ACTION.—The term ''health care liability action'' means a civil action brought in a State or Federal Court or pursuant to an alternative dispute resolution system, against a health care provider or a health care institution regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action, in which the claimant alleges a health care liability claim.

(11) HEALTH CARE LIABILITY CLAIM.—The term ''health care liability claim'' means a demand by any person, whether or not pursuant to ADR, against a health care provider or health care institution, including third-party claims, cross-claims, counter-claims, or contribution claims, which are based upon the provision of, use of, or payment for (or the failure to provide, use, or pay for) health care services, regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action.

(12) HEALTH CARE PROVIDER.—

(A) IN GENERAL.—The term ''health care provider'' means any person (including but not limited to a physician (as defined by section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r)), registered nurse, dentist, podiatrist, pharmacist, chiropractor, or optometrist) required by State or Federal law to be licensed, registered, or certified to provide health care services, and being either so licensed, registered, or certified, or exempted from such requirement by other statute or regulation.

(B) TREATMENT OF CERTAIN PROFESSIONAL ASSOCIATIONS.—For purposes of this subtitle, a professional association that is organized under State law by an individual physician or group of physicians, a partnership or limited liability partnership formed by a group of physicians, a nonprofit health corporation certified under State law, or a company formed by a group of physicians under State law shall be treated as a health care provider under subparagraph (A).

(13) MALICIOUS INTENT TO INJURE.—The term ''malicious intent to injure'' means intentionally causing or attempting to cause physical injury other than providing health care goods or services.

(14) NONECONOMIC DAMAGES.—The term ''noneconomic damages'' means damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature.

(15) PUNITIVE DAMAGES.—The term ''punitive damages'' means damages awarded, for the purpose of punishment or deterrence, and not solely for compensatory purposes, against a health care provider or health care institution. Punitive damages are neither economic nor noneconomic damages.

(16) RECOVERY.—The term ''recovery'' means the net sum recovered after deducting any disbursements or costs incurred in connection with prosecution or settlement of the claim, including all costs paid or advanced by any person. Costs of health care incurred by the plaintiff and the attorneys' office overhead costs or charges for legal services are not deductible disbursements or costs for such purpose.

(17) STATE.—The term ''State'' means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, the Trust Territory of the Pacific Islands, and any other territory or possession of the United States, or any political subdivision thereof.

SEC. 10104. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.

(a) IN GENERAL.—Except as otherwise provided for in this section, the time for the commencement of a health care lawsuit shall be 3 years after the date of manifestation of injury or 1 year after the claimant discovers, or through the use of reasonable diligence should have discovered, the injury, whichever occurs first.

(b) GENERAL EXCEPTION.—The time for the commencement of a health care lawsuit shall not exceed 3 years after the date of manifestation of injury unless the tolling of time was delayed as a result of—

(1) fraud;

(2) intentional concealment; or

(3) the presence of a foreign body, which has no therapeutic or diagnostic purpose or effect, in the person of the injured person.

(c) MINORS.—An action by a minor shall be commenced within 3 years from the date of the alleged manifestation of injury except that if such minor is under the full age of 6 years, such action shall be commenced within 3 years of the manifestation of injury, or prior to the eighth birthday of the minor, whichever provides a longer period. Such time limitation shall be tolled for minors for any period during which a parent or guardian and a health care provider or health care institution have committed fraud or collusion in the failure to bring an action on behalf of the injured minor.

(d) RULE 11 SANCTIONS.—Whenever a Federal or State court determines (whether by motion of the parties or whether on the motion of the court) that there has been a violation of Rule 11 of the Federal Rules of Civil Procedure (or a similar violation of applicable State court rules) in a health care liability action to which this subtitle applies, the court shall impose upon the attorneys, law firms, or pro se litigants that have violated Rule 11 or are responsible for the violation, an appropriate sanction, which shall include an order to pay the other party or parties for the reasonable expenses incurred as a direct result of the filing of the pleading, motion, or other paper that is the subject of the violation, including a reasonable attorneys' fee. Such sanction shall be sufficient to deter repetition of such conduct or comparable conduct by others similarly situated, and to compensate the party or parties injured by such conduct.

SEC. 10105. COMPENSATING PATIENT INJURY.

(a) UNLIMITED AMOUNT OF DAMAGES FOR ACTUAL ECONOMIC LOSSES IN HEALTH CARE LAWSUITS.—In any health care lawsuit, nothing in this subtitle shall limit the recovery by a claimant of the full amount of the available economic damages, notwithstanding the limitation contained in subsection (b).

(b) ADDITIONAL NONECONOMIC DAMAGES.—

(1) HEALTH CARE PROVIDERS.—In any health care lawsuit where final judgment is rendered against a health care provider, the amount of noneconomic damages recovered from the provider, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties other than a health care institution against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence.

(2) HEALTH CARE INSTITUTIONS.—

(A) SINGLE INSTITUTION.—In any health care lawsuit where final judgment is rendered against a single health care institution, the amount of noneconomic damages recovered from the institution, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence.

(B) MULTIPLE INSTITUTIONS.—In any health care lawsuit where final judgment is rendered against more than one health care institution, the amount of noneconomic damages recovered from each institution, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence, except that the total amount recovered from all such institutions in such lawsuit shall not exceed $500,000.

(c) NO DISCOUNT OF AWARD FOR NONECONOMIC DAMAGES.—In any health care lawsuit—

(1) an award for future noneconomic damages shall not be discounted to present value;

(2) the jury shall not be informed about the maximum award for noneconomic damages under subsection (b);

(3) an award for noneconomic damages in excess of the limitations provided for in subsection (b) shall be reduced either before the entry of judgment, or by amendment of the judgment after entry of judgment, and such reduction shall be made before accounting for any other reduction in damages required by law; and

(4) if separate awards are rendered for past and future noneconomic damages and the combined awards exceed the limitations described in subsection (b), the future noneconomic damages shall be reduced first.

(d) FAIR SHARE RULE.—In any health care lawsuit, each party shall be liable for that party's several share of any damages only and not for the share of any other person. Each party shall be liable only for the amount of damages allocated to such party in direct proportion to such party's percentage of responsibility. A separate judgment shall be rendered against each such party for the amount allocated to such party. For purposes of this section, the trier of fact shall determine the proportion of responsibility of each party for the claimant's harm.

SEC. 10106. MAXIMIZING PATIENT RECOVERY.

(a) COURT SUPERVISION OF SHARE OF DAMAGES ACTUALLY PAID TO CLAIMANTS.—

(1) IN GENERAL.—In any health care lawsuit, the court shall supervise the arrangements for payment of damages to protect against conflicts of interest that may have the effect of reducing the amount of damages awarded that are actually paid to claimants.

(2) CONTINGENCY FEES.—

(A) IN GENERAL.—In any health care lawsuit in which the attorney for a party claims a financial stake in the outcome by virtue of a contingent fee, the court shall have the power to restrict the payment of a claimant's damage recovery to such attorney, and to redirect such damages to the claimant based upon the interests of justice and principles of equity.

(B) LIMITATION.—The total of all contingent fees for representing all claimants in a health care lawsuit shall not exceed the following limits:

(i) 40 percent of the first $50,000 recovered by the claimant(s).

(ii) 33⅓ percent of the next $50,000 recovered by the claimant(s).

(iii) 25 percent of the next $500,000 recovered by the claimant(s).

(iv) 15 percent of any amount by which the recovery by the claimant(s) is in excess of $600,000.

(b) APPLICABILITY.—

(1) IN GENERAL.—The limitations in subsection (a) shall apply whether the recovery is by judgment, settlement, mediation, arbitration, or any other form of alternative dispute resolution.

(2) MINORS.—In a health care lawsuit involving a minor or incompetent person, a court retains the authority to authorize or approve a fee that is less than the maximum permitted under this section.

(c) EXPERT WITNESSES.—

(1) REQUIREMENT.—No individual shall be qualified to testify as an expert witness concerning issues of negligence in any health

care lawsuit against a defendant unless such individual—

(A) except as required under paragraph (2), is a health care professional who—

(i) is appropriately credentialed or licensed in 1 or more States to deliver health care services; and

(ii) typically treats the diagnosis or condition or provides the type of treatment under review; and

(B) can demonstrate by competent evidence that, as a result of training, education, knowledge, and experience in the evaluation, diagnosis, and treatment of the disease or injury which is the subject matter of the lawsuit against the defendant, the individual was substantially familiar with applicable standards of care and practice as they relate to the act or omission which is the subject of the lawsuit on the date of the incident.

(2) PHYSICIAN REVIEW.—In a health care lawsuit, if the claim of the plaintiff involved treatment that is recommended or provided by a physician (allopathic or osteopathic), an individual shall not be qualified to be an expert witness under this subsection with respect to issues of negligence concerning such treatment unless such individual is a physician.

(3) SPECIALTIES AND SUBSPECIALTIES.—With respect to a lawsuit described in paragraph (1), a court shall not permit an expert in one medical specialty or subspecialty to testify against a defendant in another medical specialty or subspecialty unless, in addition to a showing of substantial familiarity in accordance with paragraph (1)(B), there is a showing that the standards of care and practice in the two specialty or subspecialty fields are similar.

(4) LIMITATION.—The limitations in this subsection shall not apply to expert witnesses testifying as to the degree or permanency of medical or physical impairment.

SEC. 10107. ADDITIONAL HEALTH BENEFITS.

(a) IN GENERAL.—The amount of any damages received by a claimant in any health care lawsuit shall be reduced by the court by the amount of any collateral source benefits to which the claimant is entitled, less any insurance premiums or other payments made by the claimant (or by the spouse, parent, child, or legal guardian of the claimant) to obtain or secure such benefits.

(b) PRESERVATION OF CURRENT LAW.—Where a payor of collateral source benefits has a right of recovery by reimbursement or subrogation and such right is permitted under Federal or State law, subsection (a) shall not apply.

(c) APPLICATION OF PROVISION.—This section shall apply to any health care lawsuit that is settled or resolved by a fact finder.

SEC. 10108. PUNITIVE DAMAGES.

(a) PUNITIVE DAMAGES PERMITTED.—

(1) IN GENERAL.—Punitive damages may, if otherwise available under applicable State or Federal law, be awarded against any person in a health care lawsuit only if it is proven by clear and convincing evidence that such person acted with malicious intent to injure the claimant, or that such person deliberately failed to avoid unnecessary injury that such person knew the claimant was substantially certain to suffer.

(2) FILING OF LAWSUIT.—No demand for punitive damages shall be included in a health care lawsuit as initially filed. A court may allow a claimant to file an amended pleading for punitive damages only upon a motion by the claimant and after a finding by the court, upon review of supporting and opposing affidavits or after a hearing, after weighing the evidence, that the claimant has established by a substantial probability that the claimant will prevail on the claim for punitive damages.

(3) SEPARATE PROCEEDING.—At the request of any party in a health care lawsuit, the trier of fact shall consider in a separate proceeding—

(A) whether punitive damages are to be awarded and the amount of such award; and

(B) the amount of punitive damages following a determination of punitive liability. If a separate proceeding is requested, evidence relevant only to the claim for punitive damages, as determined by applicable State law, shall be inadmissible in any proceeding to determine whether compensatory damages are to be awarded.

(4) LIMITATION WHERE NO COMPENSATORY DAMAGES ARE AWARDED.—In any health care lawsuit where no judgment for compensatory damages is rendered against a person, no punitive damages may be awarded with respect to the claim in such lawsuit against such person.

(b) DETERMINING AMOUNT OF PUNITIVE DAMAGES.—

(1) FACTORS CONSIDERED.—In determining the amount of punitive damages under this section, the trier of fact shall consider only the following:

(A) the severity of the harm caused by the conduct of such party;

(B) the duration of the conduct or any concealment of it by such party;

(C) the profitability of the conduct to such party;

(D) the number of products sold or medical procedures rendered for compensation, as the case may be, by such party, of the kind causing the harm complained of by the claimant;

(E) any criminal penalties imposed on such party, as a result of the conduct complained of by the claimant; and

(F) the amount of any civil fines assessed against such party as a result of the conduct complained of by the claimant.

(2) MAXIMUM AWARD.—The amount of punitive damages awarded in a health care lawsuit may not exceed an amount equal to two times the amount of economic damages awarded in the lawsuit or $250,000, whichever is greater. The jury shall not be informed of the limitation under the preceding sentence.

(c) LIABILITY OF HEALTH CARE PROVIDERS.—

(1) IN GENERAL.—A health care provider who prescribes, or who dispenses pursuant to a prescription, a drug, biological product, or medical device approved by the Food and Drug Administration, for an approved indication of the drug, biological product, or medical device, shall not be named as a party to a product liability lawsuit invoking such drug, biological product, or medical device and shall not be liable to a claimant in a class action lawsuit against the manufacturer, distributor, or product seller of such drug, biological product, or medical device.

(2) MEDICAL PRODUCT.—The term ''medical product'' means a drug or device intended for humans. The terms ''drug'' and ''device'' have the meanings given such terms in sections 201(g)(1) and 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321), respectively, including any component or raw material used therein, but excluding health care services.

SEC. 10109. AUTHORIZATION OF PAYMENT OF FUTURE DAMAGES TO CLAIMANTS IN HEALTH CARE LAWSUITS.

(a) IN GENERAL.—In any health care lawsuit, if an award of future damages, without reduction to present value, equaling or exceeding $50,000 is made against a party with sufficient insurance or other assets to fund a periodic payment of such a judgment, the court shall, at the request of any party, enter a judgment ordering that the future damages be paid by periodic payments in accordance with the Uniform Periodic Payment of Judgments Act promulgated by the National Conference of Commissioners on Uniform State Laws.

(b) APPLICABILITY.—This section applies to all actions which have not been first set for trial or retrial before the effective date of this subtitle.

SEC. 10110. EFFECT ON OTHER LAWS.

(a) GENERAL VACCINE INJURY.—

(1) IN GENERAL.—To the extent that title XXI of the Public Health Service Act establishes a Federal rule of law applicable to a civil action brought for a vaccine-related injury or death—

(A) this subtitle shall not affect the application of the rule of law to such an action; and

(B) any rule of law prescribed by this subtitle in conflict with a rule of law of such title XXI shall not apply to such action.

(2) EXCEPTION.—If there is an aspect of a civil action brought for a vaccine-related injury or death to which a Federal rule of law under title XXI of the Public Health Service Act does not apply, then this subtitle or otherwise applicable law (as determined under this subtitle) will apply to such aspect of such action.

(b) SMALLPOX VACCINE INJURY.—

(1) IN GENERAL.—To the extent that part C of title II of the Public Health Service Act establishes a Federal rule of law applicable to a civil action brought for a smallpox vaccine-related injury or death—

(A) this subtitle shall not affect the application of the rule of law to such an action; and

(B) any rule of law prescribed by this subtitle in conflict with a rule of law of such part C shall not apply to such action.

(2) EXCEPTION.—If there is an aspect of a civil action brought for a smallpox vaccine-related injury or death to which a Federal rule of law under part C of title II of the Public Health Service Act does not apply, then this subtitle or otherwise applicable law (as determined under this subtitle) will apply to such aspect of such action.

(c) OTHER FEDERAL LAW.—Except as provided in this section, nothing in this subtitle shall be deemed to affect any defense available, or any limitation on liability that applies to, a defendant in a health care lawsuit or action under any other provision of Federal law.

SEC. 10111. STATE FLEXIBILITY AND PROTECTION OF STATES' RIGHTS.

(a) HEALTH CARE LAWSUITS.—The provisions governing health care lawsuits set forth in this subtitle shall preempt, subject to subsections (b) and (c), State law to the extent that State law prevents the application of any provisions of law established by or under this subtitle. The provisions governing health care lawsuits set forth in this subtitle supersede chapter 171 of title 28, United States Code, to the extent that such chapter—

(1) provides for a greater amount of damages or contingent fees, a longer period in which a health care lawsuit may be commenced, or a reduced applicability or scope of periodic payment of future damages, than provided in this subtitle; or

(2) prohibits the introduction of evidence regarding collateral source benefits.

(b) PREEMPTION OF CERTAIN STATE LAWS.—No provision of this subtitle shall be construed to preempt any State law (whether effective before, on, or after the date of the enactment of this Act) that specifies a particular monetary amount of compensatory or punitive damages (or the total amount of damages) that may be awarded in a health care lawsuit, regardless of whether such monetary amount is greater or lesser than is provided for under this subtitle, notwithstanding section 10105(a).

(c) PROTECTION OF STATE'S RIGHTS AND OTHER LAWS.—

(1) IN GENERAL.—Any issue that is not governed by a provision of law established by or under this subtitle (including the State standards of negligence) shall be governed by otherwise applicable Federal or State law.

(2) RULE OF CONSTRUCTION.—Nothing in this subtitle shall be construed to—

(A) preempt or supersede any Federal or State law that imposes greater procedural or substantive protections (such as a shorter statute of limitations) for a health care provider or health care institution from liability, loss, or damages than those provided by this subtitle;

(B) preempt or supercede any State law that permits and provides for the enforcement of any arbitration agreement related to a health care liability claim whether enacted prior to or after the date of enactment of this Act;

(C) create a cause of action that is not otherwise available under Federal or State law; or

(D) affect the scope of preemption of any other Federal law.

SEC. 10112. APPLICABILITY; EFFECTIVE DATE.

This subtitle shall apply to any health care lawsuit brought in a Federal or State court, or subject to an alternative dispute resolution system, that is initiated on or after the date of the enactment of this Act, except that any health care lawsuit arising from an injury occurring prior to the date of enactment of this Act shall be governed by the applicable statute of limitations provisions in effect at the time the injury occurred.

Subtitle C—Rescission of Unused Stimulus Funds

SEC. 10201. RESCISSION IN ARRA.

Effective as of October 1, 2010, any unobligated balances available on such date of funds made available by division A of the American Recovery and Reinvestment Act of 2009 (Public Law 111–5) are rescinded.

SA 3134. Mr. BURR (for himself, Mrs. HUTCHISON, and Mr. WICKER) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 2074, after line 25 insert the following:

TITLE X—ADDITIONAL PROVISIONS

Subtitle A—Medicare Physician Fee Schedule Update for 2010, 2011, and 2012

SEC. 10001. MEDICARE PHYSICIAN FEE SCHEDULE UPDATE FOR 2010, 2011, AND 2012.

Section 1848(d)(10) of the Social Security Act (42 U.S.C. 1395w–4(d)), as added by section 3101, is amended to read as follows:

''(10) UPDATE FOR 2010, 2011, AND 2012.—

''(A) IN GENERAL.—Subject to paragraphs (7)(B), (8)(B), and (9)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for each of 2010, 2011, and 2012, the update to the single conversion factor shall be 0.5 percent.

''(B) NO EFFECT ON COMPUTATION OF CONVERSION FACTOR FOR 2013 AND SUBSEQUENT YEARS.—The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2013 and subsequent years as if subparagraph (A) had never applied.''.

Subtitle B—Medical Care Access Protection

SEC. 10101. FINDINGS AND PURPOSE.

(a) FINDINGS.—

(1) EFFECT ON HEALTH CARE ACCESS AND COSTS.—Congress finds that our current civil justice system is adversely affecting patient access to health care services, better patient care, and cost-efficient health care, in that the health care liability system is a costly and ineffective mechanism for resolving claims of health care liability and compensating injured patients, and is a deterrent to the sharing of information among health care professionals which impedes efforts to improve patient safety and quality of care.

(2) EFFECT ON INTERSTATE COMMERCE.—Congress finds that the health care and insurance industries are industries affecting interstate commerce and the health care liability litigation systems existing throughout the United States are activities that affect interstate commerce by contributing to the high costs of health care and premiums for health care liability insurance purchased by health care system providers.

(3) EFFECT ON FEDERAL SPENDING.—Congress finds that the health care liability litigation systems existing throughout the United States have a significant effect on the amount, distribution, and use of Federal funds because of—

(A) the large number of individuals who receive health care benefits under programs operated or financed by the Federal Government;

(B) the large number of individuals who benefit because of the exclusion from Federal taxes of the amounts spent to provide them with health insurance benefits; and

(C) the large number of health care providers who provide items or services for which the Federal Government makes payments.

(b) PURPOSE.—It is the purpose of this subtitle to implement reasonable, comprehensive, and effective health care liability reforms designed to—

(1) improve the availability of health care services in cases in which health care liability actions have been shown to be a factor in the decreased availability of services;

(2) reduce the incidence of ''defensive medicine'' and lower the cost of health care liability insurance, all of which contribute to the escalation of health care costs;

(3) ensure that persons with meritorious health care injury claims receive fair and adequate compensation, including reasonable noneconomic damages;

(4) improve the fairness and cost-effectiveness of our current health care liability system to resolve disputes over, and provide compensation for, health care liability by reducing uncertainty in the amount of compensation provided to injured individuals; and

(5) provide an increased sharing of information in the health care system which will reduce unintended injury and improve patient care.

SEC. 10102. DEFINITIONS.

In this subtitle:

(1) ALTERNATIVE DISPUTE RESOLUTION SYSTEM; ADR.—The term ''alternative dispute resolution system'' or ''ADR'' means a system that provides for the resolution of health care lawsuits in a manner other than through a civil action brought in a State or Federal court.

(2) CLAIMANT.—The term ''claimant'' means any person who brings a health care lawsuit, including a person who asserts or claims a right to legal or equitable contribution, indemnity or subrogation, arising out of a health care liability claim or action, and any person on whose behalf such a claim is asserted or such an action is brought, whether deceased, incompetent, or a minor.

(3) COLLATERAL SOURCE BENEFITS.—The term ''collateral source benefits'' means any amount paid or reasonably likely to be paid in the future to or on behalf of the claimant, or any service, product or other benefit provided or reasonably likely to be provided in the future to or on behalf of the claimant, as a result of the injury or wrongful death, pursuant to—

(A) any State or Federal health, sickness, income-disability, accident, or workers' compensation law;

(B) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(C) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; and

(D) any other publicly or privately funded program.

(4) COMPENSATORY DAMAGES.—The term ''compensatory damages'' means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities, damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature. Such term includes economic damages and noneconomic damages, as such terms are defined in this section.

(5) CONTINGENT FEE.—The term ''contingent fee'' includes all compensation to any person or persons which is payable only if a recovery is effected on behalf of one or more claimants.

(6) ECONOMIC DAMAGES.—The term ''economic damages'' means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities.

(7) HEALTH CARE GOODS OR SERVICES.—The term ''health care goods or services'' means any goods or services provided by a health care institution, provider, or by any individual working under the supervision of a health care provider, that relates to the diagnosis, prevention, care, or treatment of any human disease or impairment, or the assessment of the health of human beings.

(8) HEALTH CARE INSTITUTION.—The term ''health care institution'' means any entity licensed under Federal or State law to provide health care services (including but not limited to ambulatory surgical centers, assisted living facilities, emergency medical services providers, hospices, hospitals and hospital systems, nursing homes, or other entities licensed to provide such services).

(9) HEALTH CARE LAWSUIT.—The term ''health care lawsuit'' means any health care liability claim concerning the provision of health care goods or services affecting interstate commerce, or any health care liability action concerning the provision of (or the failure to provide) health care goods or services affecting interstate commerce, brought in a State or Federal court or pursuant to an alternative dispute resolution system, against a health care provider or a health

care institution regardless of the theory of liability on which the claim is based, or the number of claimants, plaintiffs, defendants, or other parties, or the number of claims or causes of action, in which the claimant alleges a health care liability claim.

(10) HEALTH CARE LIABILITY ACTION.—The term ''health care liability action'' means a civil action brought in a State or Federal Court or pursuant to an alternative dispute resolution system, against a health care provider or a health care institution regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action, in which the claimant alleges a health care liability claim.

(11) HEALTH CARE LIABILITY CLAIM.—The term ''health care liability claim'' means a demand by any person, whether or not pursuant to ADR, against a health care provider or health care institution, including third-party claims, cross-claims, counter-claims, or contribution claims, which are based upon the provision of, use of, or payment for (or the failure to provide, use, or pay for) health care services, regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action.

(12) HEALTH CARE PROVIDER.—

(A) IN GENERAL.—The term ''health care provider'' means any person (including but not limited to a physician (as defined by section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r)), registered nurse, dentist, podiatrist, pharmacist, chiropractor, or optometrist) required by State or Federal law to be licensed, registered, or certified to provide health care services, and being either so licensed, registered, or certified, or exempted from such requirement by other statute or regulation.

(B) TREATMENT OF CERTAIN PROFESSIONAL ASSOCIATIONS.—For purposes of this subtitle, a professional association that is organized under State law by an individual physician or group of physicians, a partnership or limited liability partnership formed by a group of physicians, a nonprofit health corporation certified under State law, or a company formed by a group of physicians under State law shall be treated as a health care provider under subparagraph (A).

(13) MALICIOUS INTENT TO INJURE.—The term ''malicious intent to injure'' means intentionally causing or attempting to cause physical injury other than providing health care goods or services.

(14) NONECONOMIC DAMAGES.—The term ''noneconomic damages'' means damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature.

(15) PUNITIVE DAMAGES.—The term ''punitive damages'' means damages awarded, for the purpose of punishment or deterrence, and not solely for compensatory purposes, against a health care provider or health care institution. Punitive damages are neither economic nor noneconomic damages.

(16) RECOVERY.—The term ''recovery'' means the net sum recovered after deducting any disbursements or costs incurred in connection with prosecution or settlement of the claim, including all costs paid or advanced by any person. Costs of health care incurred by the plaintiff and the attorneys' office overhead costs or charges for legal services are not deductible disbursements or costs for such purpose.

(17) STATE.—The term ''State'' means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, the Trust Territory of the Pacific Islands, and any other territory or possession of the United States, or any political subdivision thereof.

SEC. 10103. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.

(a) IN GENERAL.—Except as otherwise provided for in this section, the time for the commencement of a health care lawsuit shall be 3 years after the date of manifestation of injury or 1 year after the claimant discovers, or through the use of reasonable diligence should have discovered, the injury, whichever occurs first.

(b) GENERAL EXCEPTION.—The time for the commencement of a health care lawsuit shall not exceed 3 years after the date of manifestation of injury unless the tolling of time was delayed as a result of—

(1) fraud;

(2) intentional concealment; or

(3) the presence of a foreign body, which has no therapeutic or diagnostic purpose or effect, in the person of the injured person.

(c) MINORS.—An action by a minor shall be commenced within 3 years from the date of the alleged manifestation of injury except that if such minor is under the full age of 6 years, such action shall be commenced within 3 years of the manifestation of injury, or prior to the eighth birthday of the minor, whichever provides a longer period. Such time limitation shall be tolled for minors for any period during which a parent or guardian and a health care provider or health care institution have committed fraud or collusion in the failure to bring an action on behalf of the injured minor.

(d) RULE 11 SANCTIONS.—Whenever a Federal or State court determines (whether by motion of the parties or whether on the motion of the court) that there has been a violation of Rule 11 of the Federal Rules of Civil Procedure (or a similar violation of applicable State court rules) in a health care liability action to which this subtitle applies, the court shall impose upon the attorneys, law firms, or pro se litigants that have violated Rule 11 or are responsible for the violation, an appropriate sanction, which shall include an order to pay the other party or parties for the reasonable expenses incurred as a direct result of the filing of the pleading, motion, or other paper that is the subject of the violation, including a reasonable attorneys' fee. Such sanction shall be sufficient to deter repetition of such conduct or comparable conduct by others similarly situated, and to compensate the party or parties injured by such conduct.

SEC. 10104. COMPENSATING PATIENT INJURY.

(a) UNLIMITED AMOUNT OF DAMAGES FOR ACTUAL ECONOMIC LOSSES IN HEALTH CARE LAWSUITS.—In any health care lawsuit, nothing in this subtitle shall limit the recovery by a claimant of the full amount of the available economic damages, notwithstanding the limitation contained in subsection (b).

(b) ADDITIONAL NONECONOMIC DAMAGES.—

(1) HEALTH CARE PROVIDERS.—In any health care lawsuit where final judgment is rendered against a health care provider, the amount of noneconomic damages recovered from the provider, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties other than a health care institution against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence.

(2) HEALTH CARE INSTITUTIONS.—

(A) SINGLE INSTITUTION.—In any health care lawsuit where final judgment is rendered against a single health care institution, the amount of noneconomic damages recovered from the institution, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence.

(B) MULTIPLE INSTITUTIONS.—In any health care lawsuit where final judgment is rendered against more than one health care institution, the amount of noneconomic damages recovered from each institution, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence, except that the total amount recovered from all such institutions in such lawsuit shall not exceed $500,000.

(c) NO DISCOUNT OF AWARD FOR NONECONOMIC DAMAGES.—In any health care lawsuit—

(1) an award for future noneconomic damages shall not be discounted to present value;

(2) the jury shall not be informed about the maximum award for noneconomic damages under subsection (b);

(3) an award for noneconomic damages in excess of the limitations provided for in subsection (b) shall be reduced either before the entry of judgment, or by amendment of the judgment after entry of judgment, and such reduction shall be made before accounting for any other reduction in damages required by law; and

(4) if separate awards are rendered for past and future noneconomic damages and the combined awards exceed the limitations described in subsection (b), the future noneconomic damages shall be reduced first.

(d) FAIR SHARE RULE.—In any health care lawsuit, each party shall be liable for that party's several share of any damages only and not for the share of any other person. Each party shall be liable only for the amount of damages allocated to such party in direct proportion to such party's percentage of responsibility. A separate judgment shall be rendered against each such party for the amount allocated to such party. For purposes of this section, the trier of fact shall determine the proportion of responsibility of each party for the claimant's harm.

SEC. 10105. MAXIMIZING PATIENT RECOVERY.

(a) COURT SUPERVISION OF SHARE OF DAMAGES ACTUALLY PAID TO CLAIMANTS.—

(1) IN GENERAL.—In any health care lawsuit, the court shall supervise the arrangements for payment of damages to protect against conflicts of interest that may have the effect of reducing the amount of damages awarded that are actually paid to claimants.

(2) CONTINGENCY FEES.—

(A) IN GENERAL.—In any health care lawsuit in which the attorney for a party claims a financial stake in the outcome by virtue of a contingent fee, the court shall have the power to restrict the payment of a claimant's damage recovery to such attorney, and to redirect such damages to the claimant based upon the interests of justice and principles of equity.

(B) LIMITATION.—The total of all contingent fees for representing all claimants in a health care lawsuit shall not exceed the following limits:

(i) 40 percent of the first $50,000 recovered by the claimant(s).

(ii) 33⅓ percent of the next $50,000 recovered by the claimant(s).

(iii) 25 percent of the next $500,000 recovered by the claimant(s).

(iv) 15 percent of any amount by which the recovery by the claimant(s) is in excess of $600,000.

(b) APPLICABILITY.—

(1) IN GENERAL.—The limitations in subsection (a) shall apply whether the recovery is by judgment, settlement, mediation, arbitration, or any other form of alternative dispute resolution.

(2) MINORS.—In a health care lawsuit involving a minor or incompetent person, a court retains the authority to authorize or approve a fee that is less than the maximum permitted under this section.

(c) EXPERT WITNESSES.—

(1) REQUIREMENT.—No individual shall be qualified to testify as an expert witness concerning issues of negligence in any health care lawsuit against a defendant unless such individual—

(A) except as required under paragraph (2), is a health care professional who—

(i) is appropriately credentialed or licensed in 1 or more States to deliver health care services; and

(ii) typically treats the diagnosis or condition or provides the type of treatment under review; and

(B) can demonstrate by competent evidence that, as a result of training, education, knowledge, and experience in the evaluation, diagnosis, and treatment of the disease or injury which is the subject matter of the lawsuit against the defendant, the individual was substantially familiar with applicable standards of care and practice as they relate to the act or omission which is the subject of the lawsuit on the date of the incident.

(2) PHYSICIAN REVIEW.—In a health care lawsuit, if the claim of the plaintiff involved treatment that is recommended or provided by a physician (allopathic or osteopathic), an individual shall not be qualified to be an expert witness under this subsection with respect to issues of negligence concerning such treatment unless such individual is a physician.

(3) SPECIALTIES AND SUBSPECIALTIES.—With respect to a lawsuit described in paragraph (1), a court shall not permit an expert in one medical specialty or subspecialty to testify against a defendant in another medical specialty or subspecialty unless, in addition to a showing of substantial familiarity in accordance with paragraph (1)(B), there is a showing that the standards of care and practice in the two specialty or subspecialty fields are similar.

(4) LIMITATION.—The limitations in this subsection shall not apply to expert witnesses testifying as to the degree or permanency of medical or physical impairment.

SEC. 10106. ADDITIONAL HEALTH BENEFITS.

(a) IN GENERAL.—The amount of any damages received by a claimant in any health care lawsuit shall be reduced by the court by the amount of any collateral source benefits to which the claimant is entitled, less any insurance premiums or other payments made by the claimant (or by the spouse, parent, child, or legal guardian of the claimant) to obtain or secure such benefits.

(b) PRESERVATION OF CURRENT LAW.—Where a payor of collateral source benefits has a right of recovery by reimbursement or subrogation and such right is permitted under Federal or State law, subsection (a) shall not apply.

(c) APPLICATION OF PROVISION.—This section shall apply to any health care lawsuit that is settled or resolved by a fact finder.

SEC. 10107. PUNITIVE DAMAGES.

(a) PUNITIVE DAMAGES PERMITTED.—

(1) IN GENERAL.—Punitive damages may, if otherwise available under applicable State or Federal law, be awarded against any person in a health care lawsuit only if it is proven by clear and convincing evidence that such person acted with malicious intent to injure the claimant, or that such person deliberately failed to avoid unnecessary injury that such person knew the claimant was substantially certain to suffer.

(2) FILING OF LAWSUIT.—No demand for punitive damages shall be included in a health care lawsuit as initially filed. A court may allow a claimant to file an amended pleading for punitive damages only upon a motion by the claimant and after a finding by the court, upon review of supporting and opposing affidavits or after a hearing, after weighing the evidence, that the claimant has established by a substantial probability that the claimant will prevail on the claim for punitive damages.

(3) SEPARATE PROCEEDING.—At the request of any party in a health care lawsuit, the trier of fact shall consider in a separate proceeding—

(A) whether punitive damages are to be awarded and the amount of such award; and

(B) the amount of punitive damages following a determination of punitive liability. If a separate proceeding is requested, evidence relevant only to the claim for punitive damages, as determined by applicable State law, shall be inadmissible in any proceeding to determine whether compensatory damages are to be awarded.

(4) LIMITATION WHERE NO COMPENSATORY DAMAGES ARE AWARDED.—In any health care lawsuit where no judgment for compensatory damages is rendered against a person, no punitive damages may be awarded with respect to the claim in such lawsuit against such person.

(b) DETERMINING AMOUNT OF PUNITIVE DAMAGES.—

(1) FACTORS CONSIDERED.—In determining the amount of punitive damages under this section, the trier of fact shall consider only the following:

(A) the severity of the harm caused by the conduct of such party;

(B) the duration of the conduct or any concealment of it by such party;

(C) the profitability of the conduct to such party;

(D) the number of products sold or medical procedures rendered for compensation, as the case may be, by such party, of the kind causing the harm complained of by the claimant;

(E) any criminal penalties imposed on such party, as a result of the conduct complained of by the claimant; and

(F) the amount of any civil fines assessed against such party as a result of the conduct complained of by the claimant.

(2) MAXIMUM AWARD.—The amount of punitive damages awarded in a health care lawsuit may not exceed an amount equal to two times the amount of economic damages awarded in the lawsuit or $250,000, whichever is greater. The jury shall not be informed of the limitation under the preceding sentence.

(c) LIABILITY OF HEALTH CARE PROVIDERS.—

(1) IN GENERAL.—A health care provider who prescribes, or who dispenses pursuant to a prescription, a drug, biological product, or medical device approved by the Food and Drug Administration, for an approved indication of the drug, biological product, or medical device, shall not be named as a party to a product liability lawsuit invoking such drug, biological product, or medical device and shall not be liable to a claimant in a class action lawsuit against the manufacturer, distributor, or product seller of such drug, biological product, or medical device.

(2) MEDICAL PRODUCT.—The term ''medical product'' means a drug or device intended for humans. The terms ''drug'' and ''device'' have the meanings given such terms in sections 201(g)(1) and 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321), respectively, including any component or raw material used therein, but excluding health care services.

SEC. 10108. AUTHORIZATION OF PAYMENT OF FUTURE DAMAGES TO CLAIMANTS IN HEALTH CARE LAWSUITS.

(a) IN GENERAL.—In any health care lawsuit, if an award of future damages, without reduction to present value, equaling or exceeding $50,000 is made against a party with sufficient insurance or other assets to fund a periodic payment of such a judgment, the court shall, at the request of any party, enter a judgment ordering that the future damages be paid by periodic payments in accordance with the Uniform Periodic Payment of Judgments Act promulgated by the National Conference of Commissioners on Uniform State Laws.

(b) APPLICABILITY.—This section applies to all actions which have not been first set for trial or retrial before the effective date of this subtitle.

SEC. 10109. EFFECT ON OTHER LAWS.

(a) GENERAL VACCINE INJURY.—

(1) IN GENERAL.—To the extent that title XXI of the Public Health Service Act establishes a Federal rule of law applicable to a civil action brought for a vaccine-related injury or death—

(A) this subtitle shall not affect the application of the rule of law to such an action; and

(B) any rule of law prescribed by this subtitle in conflict with a rule of law of such title XXI shall not apply to such action.

(2) EXCEPTION.—If there is an aspect of a civil action brought for a vaccine-related injury or death to which a Federal rule of law under title XXI of the Public Health Service Act does not apply, then this subtitle or otherwise applicable law (as determined under this subtitle) will apply to such aspect of such action.

(b) SMALLPOX VACCINE INJURY.—

(1) IN GENERAL.—To the extent that part C of title II of the Public Health Service Act establishes a Federal rule of law applicable to a civil action brought for a smallpox vaccine-related injury or death—

(A) this subtitle shall not affect the application of the rule of law to such an action; and

(B) any rule of law prescribed by this subtitle in conflict with a rule of law of such part C shall not apply to such action.

(2) EXCEPTION.—If there is an aspect of a civil action brought for a smallpox vaccine-related injury or death to which a Federal rule of law under part C of title II of the Public Health Service Act does not apply, then this subtitle or otherwise applicable law (as determined under this subtitle) will apply to such aspect of such action.

(c) OTHER FEDERAL LAW.—Except as provided in this section, nothing in this subtitle shall be deemed to affect any defense available, or any limitation on liability that applies to, a defendant in a health care lawsuit or action under any other provision of Federal law.

SEC. 10110. STATE FLEXIBILITY AND PROTECTION OF STATES' RIGHTS.

(a) HEALTH CARE LAWSUITS.—The provisions governing health care lawsuits set forth in this subtitle shall preempt, subject to subsections (b) and (c), State law to the extent that State law prevents the application of any provisions of law established by or under this subtitle. The provisions governing health care lawsuits set forth in this subtitle supersede chapter 171 of title 28, United States Code, to the extent that such chapter—

(1) provides for a greater amount of damages or contingent fees, a longer period in which a health care lawsuit may be commenced, or a reduced applicability or scope of periodic payment of future damages, than provided in this subtitle; or

(2) prohibits the introduction of evidence regarding collateral source benefits.

(b) PREEMPTION OF CERTAIN STATE LAWS.—No provision of this subtitle shall be construed to preempt any State law (whether effective before, on, or after the date of the enactment of this Act) that specifies a particular monetary amount of compensatory or punitive damages (or the total amount of damages) that may be awarded in a health care lawsuit, regardless of whether such monetary amount is greater or lesser than is provided for under this subtitle, notwithstanding section 10104(a).

(c) PROTECTION OF STATE'S RIGHTS AND OTHER LAWS.—

(1) IN GENERAL.—Any issue that is not governed by a provision of law established by or under this subtitle (including the State standards of negligence) shall be governed by otherwise applicable Federal or State law.

(2) RULE OF CONSTRUCTION.—Nothing in this subtitle shall be construed to—

(A) preempt or supersede any Federal or State law that imposes greater procedural or substantive protections (such as a shorter statute of limitations) for a health care provider or health care institution from liability, loss, or damages than those provided by this subtitle;

(B) preempt or supercede any State law that permits and provides for the enforcement of any arbitration agreement related to a health care liability claim whether enacted prior to or after the date of enactment of this Act;

(C) create a cause of action that is not otherwise available under Federal or State law; or

(D) affect the scope of preemption of any other Federal law.

SEC. 10111. APPLICABILITY; EFFECTIVE DATE.

This subtitle shall apply to any health care lawsuit brought in a Federal or State court, or subject to an alternative dispute resolution system, that is initiated on or after the date of the enactment of this Act, except that any health care lawsuit arising from an injury occurring prior to the date of enactment of this Act shall be governed by the applicable statute of limitations provisions in effect at the time the injury occurred.

Subtitle C—Rescission of Discretionary Amounts Appropriated by the American Recovery and Reinvestment Act of 2009

SEC. 10201. RESCISSION OF DISCRETIONARY AMOUNTS APPROPRIATED BY THE AMERICAN RECOVERY AND REINVESTMENT ACT OF 2009.

(a) IN GENERAL.—All discretionary amounts made available by the American Recovery and Reinvestment Act of 2009 (123 Stat. 115; Public Law No: 111-5) that are unobligated on the date of the enactment of this Act are hereby rescinded.

(b) ADMINISTRATION.—Not later than 30 days after the date of the enactment of this Act, the Director of the Office of Management and Budget shall—

(1) administer the reduction specified in subsection (a); and

(2) submit to the Committee on Appropriations of the Senate and the Committee on Appropriations of the House of Representatives a report specifying the account and the amount of each reduction made pursuant to subsection (a).

SA 3135. Mr. SANDERS (for himself, Mr. BROWN, Mr. FRANKEN, and Mr. BURRIS) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

Beginning on page 1979, line 20, strike all through page 1996, line 3, and insert the following:

SEC. 9001. SURCHARGE ON HIGH INCOME INDIVIDUALS.

(a) IN GENERAL.—Subchapter A of chapter 1 of the Internal Revenue Code of 1986 is amended by adding at the end the following new part:

"PART VIII—SURCHARGE ON HIGH INCOME INDIVIDUALS

"Sec. 59B. Surcharge on high income individuals.

"SEC. 59B. SURCHARGE ON HIGH INCOME INDIVIDUALS.

"(a) GENERAL RULE.—In the case of a taxpayer other than a corporation, there is hereby imposed (in addition to any other tax imposed by this subtitle) a tax equal to 5.4 percent of so much of the modified adjusted gross income of the taxpayer as exceeds $4,800,000.

"(b) TAXPAYERS NOT MAKING A JOINT RETURN.—In the case of any taxpayer other than a taxpayer making a joint return under section 6013 or a surviving spouse (as defined in section 2(a)), subsection (a) shall be applied by substituting '$2,400,000' for '$4,800,000'.

"(c) MODIFIED ADJUSTED GROSS INCOME.—For purposes of this section, the term 'modified adjusted gross income' means adjusted gross income reduced by any deduction (not taken into account in determining adjusted gross income) allowed for investment interest (as defined in section 163(d)). In the case of an estate or trust, adjusted gross income shall be determined as provided in section 67(e).

"(d) SPECIAL RULES.—

"(1) NONRESIDENT ALIEN.—In the case of a nonresident alien individual, only amounts taken into account in connection with the tax imposed under section 871(b) shall be taken into account under this section.

"(2) CITIZENS AND RESIDENTS LIVING ABROAD.—The dollar amount in effect under subsection (a) (after the application of subsection (b)) shall be decreased by the excess of—

"(A) the amounts excluded from the taxpayer's gross income under section 911, over

"(B) the amounts of any deductions or exclusions disallowed under section 911(d)(6) with respect to the amounts described in subparagraph (A).

"(3) CHARITABLE TRUSTS.—Subsection (a) shall not apply to a trust all the unexpired interests in which are devoted to one or more of the purposes described in section 170(c)(2)(B).

"(4) NOT TREATED AS TAX IMPOSED BY THIS CHAPTER FOR CERTAIN PURPOSES.—The tax imposed under this section shall not be treated as tax imposed by this chapter for purposes of determining the amount of any credit under this chapter or for purposes of section 55.".

(b) CLERICAL AMENDMENT.—The table of parts for subchapter A of chapter 1 of the Internal Revenue Code of 1986 is amended by adding at the end the following new item:

"PART VIII. SURCHARGE ON HIGH INCOME INDIVIDUALS.".

(c) SECTION 15 NOT TO APPLY.—The amendment made by subsection (a) shall not be treated as a change in a rate of tax for purposes of section 15 of the Internal Revenue Code of 1986.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2010.

SA 3136. Mr. UDALL of New Mexico submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, AND MR. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 796, between lines 5 and 6, insert the following:

PART IV—TELEHEALTH AND REMOTE PATIENT MONITORING

SEC. 3031. TELEHEALTH AND REMOTE PATIENT MONITORING.

(a) IMPROVING CREDENTIALING AND PRIVILEGING STANDARDS FOR TELEHEALTH SERVICES.—Section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)) is amended by adding at the end the following new paragraph:

"(5) ESTABLISHMENT OF REMOTE CREDENTIALING AND PRIVILEGING STANDARDS.—

"(A) IN GENERAL.—Not later than 2 years after the date of the enactment of this paragraph, the Secretary shall establish regulations for considering the remote credentialing and privileging standards applicable to telehealth services, including interpretative services, for originating sites under this subsection. Such regulations shall allow an originating site to accept, and not duplicate, the credentialing and privileging processes and decisions made by another site.

"(B) CLARIFICATION REGARDING ACCEPTANCE OF PROCESSES AND DECISIONS PRIOR TO ENACTMENT OF REGULATIONS.—During the period beginning on such date of enactment and ending on the effective date of the regulations under subparagraph (A), the Secretary shall not take any punitive action under any rule or regulation against an originating site on the basis of that site's acceptance, for purposes of receiving telehealth services (including interpretive services), the credentialing and privileging processes and decisions made by another site that is certified by a national body recognized by the Secretary if the site accepting such credentialing and privileging processes is also so certified and complies with the applicable requirements for such acceptance.".

(b) EXPANDING ACCESS TO STROKE TELEHEALTH EVALUATION.—

(1) IN GENERAL.—Section 1834(m)(4) of the Social Security Act (42 U.S.C. 1395m(m)(4)) is amended by adding at the end the following new subparagraph:

"(G) STROKE TELEHEALTH SERVICES.—The term 'stroke telehealth services' means a telehealth service used for the evaluation of individuals with acute stroke.".

(2) EFFECTIVE DATE.—The amendment made by this subsection shall apply to telehealth services furnished on or after the date that is 6 months after the date of enactment of this Act.

(c) IMPROVING ACCESS TO TELEHEALTH SERVICES AT IHS FACILITIES.—

(1) COVERAGE OF METROPOLITAN SITES.—Section 1834(m)(4)(C)(i) of such Act (42 U.S.C. 1395m(m)(4)(C)(i)) is amended—

(A) in subclause (II), by deleting "or" at the end;

(B) in subclause (III), by deleting the period at the end and inserting "; or"; and

(C) by adding at the end the following subclause:

"(IV) from a facility of the Indian Health Service (whether operated by such Service or by an Indian tribe or tribal organization (as

those terms are defined in section 4 of the Indian Health Care Improvement Act)).''.

(2) INCLUSION OF IHS FACILITIES AS ORIGINATING SITES.—Section 1834(m)(4)(C)(ii) of the Social Security Act (42 U.S.C. 1395m(m)(4)(C)(ii)) is amended by adding at the end the following new subclause:

''(IX) A facility of the Indian Health Service, whether operated by such Service or by an Indian tribe or tribal organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act).''.

(3) EFFECTIVE DATE.—The amendments made by this subsection apply to telehealth services furnished on or after the date that is 6 months after the date of enactment of this Act.

(d) COMMUNITY-BASED PATIENT MONITORING.—Section 3026(B) of this Act is amended by adding at the end the following new clause:

''(vi) Utilizing telehealth, remote patient monitoring, and other technology when medically appropriate to enhance care transition services provided across the continuum of care.''.

(e) TELEHEALTH ADVISORY COMMITTEE.—

(1) ESTABLISHMENT.—Section 1868 of the Social Security Act (42 U.S.C. 1395ee) is amended—

(A) in the heading, by adding at the end the following: ''TELEHEALTH ADVISORY COMMITTEE''; and

(B) by adding at the end the following new subsection:

''(c) TELEHEALTH ADVISORY COMMITTEE.—

''(1) IN GENERAL.—A Telehealth Advisory Committee (in this subsection referred to as the 'Advisory Committee') shall be appointed by the Secretary to make annual recommendations to the Secretary on policies of the Centers for Medicare & Medicaid Services regarding telehealth services as established under section 1834(m), including the appropriate addition or deletion of services (and HCPCS codes) to those specified in paragraphs (4)(F)(i) and (4)(F)(ii) of such section and for authorized payment under paragraph (1) of such section, and to Congress on areas in which originating sites are located (as specified in paragraph (4)(C)(i) of such section) and eligible telehealth sites (as described in paragraph (4)(C)(ii) of such section).

''(2) MEMBERSHIP; TERMS.—

''(A) MEMBERSHIP.—

''(i) IN GENERAL.—The Advisory Committee shall be composed of 10 members, to be appointed by the Secretary, of whom—

''(I) 5 shall be practicing physicians;

''(II) 2 shall be practicing nonphysician health care practitioners;

''(III) 2 shall be administrators of telehealth programs; and

''(IV) 1 shall be an informatics or technology expert.

''(ii) REQUIREMENTS FOR APPOINTING MEMBERS.—In appointing members of the Advisory Committee, the Secretary shall—

''(I) ensure that each member has prior experience with the practice of telemedicine or telehealth;

''(II) give preference to individuals who are currently providing telemedicine or telehealth services or who are involved in telemedicine or telehealth programs;

''(III) ensure that the membership of the Advisory Committee represents a balance of specialties and geographic regions; and

''(IV) take into account the recommendations of stakeholders.

''(B) TERMS.—The members of the Advisory Committee shall serve for a 3-year term.

''(C) CONFLICTS OF INTEREST.—A member of the Advisory Committee may not participate with respect to a particular matter considered in a meeting of the Advisory Committee if such member (or an immediate family member of such member) has a financial interest that could be affected by the advice given to the Secretary with respect to such matter.

''(D) PRIORITY AREAS FOR CONSIDERATION.—In making recommendations under paragraph (1), the committee shall consider recommendations to Congress on the following:

''(i) Increasing coverage of telehealth services to all geographic areas of the United States. Such consideration shall take into account the costs to the Federal Government of such increased coverage and the total offsetting savings accrued to the Federal Government as a result of investments in telehealth.

''(ii) Including providing payments under section 1834(m) for store and forward services for all eligible areas. Such consideration should take into account the experience in Alaska and Hawaii in providing such services under this title, including the impact on costs, the effect on the quality and availability of health services, and ways in which the Federal Government can minimize the risk of fraud and abuse for such services.

''(iii) Expanding coverage under this title of remote monitoring services for—

''(I) individuals with chronic diseases;

''(II) individuals recently discharged from a facility that is an originating site under such section; and

''(III) individuals assigned to an accountable care organization under section 1899, individuals discharged from a hospital that receives disproportionate share payments under section 1886(d)(5)(F) who are in need of transitional care, and individuals who are furnished services under the national pilot program on payment bundling under section 1866D.

Each recommendation made under paragraph (1) shall take into consideration the costs to the Federal Government and the total offsetting savings accrued to the Federal Government as a result of investments in telehealth and ways in which the Federal Government can minimize the risk of fraud and abuse for telehealth services.

''(3) REQUIREMENT TO REVIEW AND PROVIDE RECOMMENDATIONS.—The Advisory Committee shall review and provide recommendations to the Secretary on legislation that would allow other providers of services and suppliers to provide telehealth services to Medicare beneficiaries.

''(4) DEADLINE.—Not later than December 31, 2010, the Advisory Committee shall submit to Congress any recommendations to Congress under paragraph (1), including the recommendations considered under paragraph (2)(D).''.

(2) FOLLOWING RECOMMENDATIONS.—Section 1834(m)(4)(F) of such Act (42 U.S.C. 1395m(m)(4)(F)) is amended by adding at the end the following new clause:

''(iii) RECOMMENDATIONS OF THE TELEHEALTH ADVISORY COMMITTEE.—In making determinations under clauses (i) and (ii), the Secretary shall take into account the recommendations of the Telehealth Advisory Committee (established under section 1868(c)) when adding or deleting services (and HCPCS codes) and in establishing policies of the Centers for Medicare & Medicaid Services regarding the delivery of telehealth services. If the Secretary does not implement such a recommendation, the Secretary shall publish in the Federal Register a statement regarding the reason such recommendation was not implemented.''.

(3) WAIVER OF ADMINISTRATIVE LIMITATION.—The Secretary of Health and Human Services shall establish the Telehealth Advisory Committee under the amendment made by paragraph (1) notwithstanding any limitation that may apply to the number of advisory committees that may be established (within the Department of Health and Human Services or otherwise).

(f) LIST OF COVERED TELEHEALTH SERVICES.—Section 1834(m)(4)(F) of such Act (42 U.S.C. 1395m(m)(4)(F)), as amended by subsection (e), is further amended—

(1) by redesignating clauses (ii) and (iii) as clauses (iii) and (iv);

(2) by inserting after clause (i) the following new clause:

''(ii) ORIGINATING SITE SERVICES.—

''(I) IN GENERAL.—Subject to subclause (II), the Secretary may make payments under this subsection to an originating site described in subparagraph (C)(ii) for services originating at the site.

''(II) LIMITATION.—The Secretary may not make such payments with respect to a service described in subclause (I) if the Secretary finds, upon review of the available evidence, that a service is not safe, effective, or medically beneficial when performed as a telehealth service.''; and

(3) by striking clause (iii), as redesignated under paragraph (1), and inserting the following new clause:

''(iii) YEARLY UPDATE.—The Secretary shall establish a process that provides, on an annual basis—

''(I) for the addition of telehealth services (and HCPCS codes), to those specified in clauses (i) and (ii) for authorized payment under this subsection, unless the Secretary finds, upon review of the available evidence, that a service is not safe, effective, or medically beneficial when performed as a telehealth service; and

''(II) for the deletion of such services (and HCPCS codes), from those specified in clauses (i) and (ii) for authorized payment under this subsection, that the Secretary finds, upon review of additional evidence, are not safe, effective, or medically beneficial when performed as a telehealth service.''.

(g) TELEHEALTH ACCESS TO SMALL POPULATION METROPOLITAN COUNTIES.—Section 1834(m)(4)(C)(i)(II) of such Act (42 U.S.C. 1395m(4)(C)(i)(II)) is amended to read as follows:

''(II) in a county with a population of less than 35,000, according to the most recent decennial census, or that is not included in a Metropolitan Statistical Area; or''.

(h) TELEHEALTH ACCESS FOR ''STORE AND FORWARD'' DIAGNOSTIC CONSULTATIONS.—Section 1834(m)(1) of such Act (42 U.S.C. 1395(m)(1)) is amended by adding at the end the following sentence: ''For purposes of the first sentence, in the case of telehealth services that are furnished by a facility of the Indian Health Service, a rural health clinic, a Federally qualified health center, or a critical access hospital (as described in paragraph (4)(C)(ii)) , or a sole community hospital (as defined in section 1886(d)(5)(D)(iii)), the term 'telecommunications system' includes store-and-forward technologies described in the preceding sentence.''.

SA 3137. Mr. BEGICH submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 1339, between lines 18 and 19, insert the following:

SEC. 5211. INCREASING ACCESS TO PRIMARY CARE SERVICES.

(a) STATE GRANTS TO HEALTH CARE PROVIDERS WHO PROVIDE SERVICES TO A HIGH PERCENTAGE OF MEDICALLY UNDERSERVED POPULATIONS OR OTHER SPECIAL POPULATIONS.—

(1) IN GENERAL.—A State may award grants to health care providers who treat a high percentage, as determined by such State, of medically underserved populations or other special populations in such State.

(2) SOURCE OF FUNDS.—A grant program established by a State under paragraph (1) may not be established within a department, agency, or other entity of such State that administers the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), and no Federal or State funds allocated to such Medicaid program, the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), or the TRICARE program under chapter 55 of title 10, United States Code, may be used to award grants or to pay administrative costs associated with a grant program established under paragraph (1).

(b) PROVIDING FOR UNDERSERVED MEDICARE POPULATIONS DEMONSTRATION PROJECT.—Subpart III of part D of title III of the Public Health Service Act (42 U.S.C. 254l et seq.) is amended by adding at the end the following:

''SEC. 338N. PROVIDING FOR UNDERSERVED MEDICARE POPULATIONS DEMONSTRATION PROJECT.

''(a) IN GENERAL.—The Secretary shall establish, in not more than 5 States, a demonstration project, to be known as the Providing for Underserved Medicare Populations Demonstration Project, for the purpose of encouraging health care providers who are recent graduates of a health care program to enter into primary care practice, by providing incentive payments to eligible primary health services providers.

''(b) DEMONSTRATION PROJECT.—

''(1) IN GENERAL.—The Secretary shall grant awards, on a competitive basis, to eligible primary health services providers, as described in paragraph (2). Each recipient of such an award shall receive such award for a period of 3 years, provided such recipient continues to meet the eligibility criteria described in subsection (c).

''(2) AWARD AMOUNTS.—Each award described in paragraph (1) shall be in an amount not to exceed—

''(A) $50,000 per year for the repayment of student loans associated with the health care educational expenses of such recipient; or

''(B) $37,500 per year in cash incentive payments.

''(c) ELIGIBLE PRIMARY HEALTH SERVICES PROVIDERS.—The Secretary shall establish criteria for individuals to be eligible to receive an award under this section, which shall include requirements that such individual—

''(1) be actively employed as a primary health services provider, or have arrangements to commence active employment as a primary health services provider, in one of the 5 States that the Secretary has selected for participation in this demonstration project and in a community with a population of not less than 35,000 and not more than 350,000 and not designated as a health professional shortage area;

''(2) have graduated, not more than 2 years after the date on which such individual would begin receiving incentive payments under this project, from an accredited program that qualifies such individual to maintain employment as a primary health services provider;

''(3) agree that, of the patients receiving care from such primary health services provider in the period during which such individual participates in the project, not less than 60 percent of such patients shall be enrolled in the Medicare program under title XVIII of the Social Security Act;

''(4) be employed, as described in paragraph (1), in a State in which the 65-and-over population is expected to grow at least 50 percent between 2010 and 2020, according to United States Census Bureau projections; and

''(5) meet such other eligibility criteria established by the Secretary.

''(d) DURATION OF PROGRAM.—The Secretary shall make initial awards to individuals under this section for each of fiscal years 2011 through 2013.

''(e) REPORT.—Not later than December 31, 2015, the Secretary shall submit to Congress a report concerning the results of the demonstration project.

''(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $25,000,000 for fiscal years 2011 through 2015.''.

(c) FACULTY LOAN REPAYMENT FOR PHYSICIAN ASSISTANTS.—Section 738(a)(3) of the Public Health Service Act (42 U.S.C.293b(a)(3)) is amended by inserting ''schools offering physician assistant education programs,'' after ''public health,''.

(d) NATIONAL HEALTH SERVICE CORPS.—

(1) FULFILLMENT OF OBLIGATED SERVICE REQUIREMENT THROUGH HALF-TIME SERVICE.—

(A) WAIVERS.—Subsection (i) of section 331 (42 U.S.C. 254d) is amended—

(i) in paragraph (1), by striking ''In carrying out subpart III'' and all that follows through the period and inserting ''In carrying out subpart III, the Secretary may, in accordance with this subsection, issue waivers to individuals who have entered into a contract for obligated service under the Scholarship Program or the Loan Repayment Program under which the individuals are authorized to satisfy the requirement of obligated service through providing clinical practice that is half time.'';

(ii) in paragraph (2)—

(I) in subparagraphs (A)(ii) and (B), by striking ''less than full time'' each place it appears and inserting ''half time'';

(II) in subparagraphs (C) and (F), by striking ''less than full-time service'' each place it appears and inserting ''half-time service''; and

(III) by amending subparagraphs (D) and (E) to read as follows:

''(D) the entity and the Corps member agree in writing that the Corps member will perform half-time clinical practice;

''(E) the Corps member agrees in writing to fulfill all of the service obligations under section 338C through half-time clinical practice and either—

''(i) double the period of obligated service that would otherwise be required; or

''(ii) in the case of contracts entered into under section 338B, accept a minimum service obligation of 2 years with an award amount equal to 50 percent of the amount that would otherwise be payable for full-time service; and''; and

(iii) in paragraph (3), by striking ''In evaluating a demonstration project described in paragraph (1)'' and inserting ''In evaluating waivers issued under paragraph (1)''.

(B) DEFINITIONS.—Subsection (j) of section 331 (42 U.S.C. 254d) is amended by adding at the end the following:

''(5) The terms 'full time' and 'full-time' mean a minimum of 40 hours per week in a clinical practice, for a minimum of 45 weeks per year.

''(6) The terms 'half time' and 'half-time' mean a minimum of 20 hours per week (not to exceed 39 hours per week) in a clinical practice, for a minimum of 45 weeks per year.''.

(2) REAPPOINTMENT TO NATIONAL ADVISORY COUNCIL.—Section 337(b)(1) (42 U.S.C. 254j(b)(1)) is amended by striking ''Members may not be reappointed to the Council.''.

(3) LOAN REPAYMENT AMOUNT.—Section 338B(g)(2)(A) (42 U.S.C. 254l–1(g)(2)(A)) is amended by striking ''$35,000'' and inserting ''$50,000, plus, beginning with fiscal year 2012, an amount determined by the Secretary on an annual basis to reflect inflation,''.

(4) TREATMENT OF TEACHING AS OBLIGATED SERVICE.—Subsection (a) of section 338C (42 U.S.C. 254m) is amended by adding at the end the following: ''The Secretary may treat teaching as clinical practice for up to 20 percent of such period of obligated service.''.

SA 3138. Mrs. HUTCHISON (for herself and Mr. HATCH) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

Strike sections 2551 and 3133.

SA 3139. Mrs. HUTCHISON submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 354, between lines 2 and 3, insert the following:

(D) EXEMPTION FOR EMPLOYERS IN STATES WITH HIGH PREMIUM INCREASES.—

(i) IN GENERAL.—If a State is described in clause (ii), then, on and after the certification date, no employer in such State shall be treated as an applicable large employer for purposes of this section.

(ii) STATE DESCRIBED.—For purposes of this subparagraph—

(I) IN GENERAL.—A State is described in this clause if the applicable State authority determines for any calendar year after 2013 that the percentage increase in average annual premiums for health insurance coverage in such State for the calendar year over the preceding calendar year exceeds the percentage increase for such period in the Consumer Price Index for all urban consumers published by the Department of Labor.

(II) CERTIFICATION DATE.—The term ''certification date'' means the first date on which the applicable State authority certifies a determination described in subclause (I).

(III) APPLICABLE STATE AUTHORITY.—The term ''applicable State authority'' has the meaning given such term by section 2791(d)(1) of the Public Health Service Act.

SA 3140. Mrs. HUTCHISON submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain

other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 339, between lines 16 and 17, insert the following:

''(g) LIMITATION.—

''(1) IN GENERAL.—This section shall not apply to any individual residing in a State where the Secretary makes the determination described in paragraph (2) for a taxable year.

''(2) DETERMINATION.—A determination described in this paragraph is a determination that the average cost of premiums for health insurance coverage within the State for the year involved has increase by a percentage that is greater than the percentage increase in the Consumer Price Index for the year.''.

SA 3141. Mrs. HUTCHISON submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

TITLE__MEDICAL CARE ACCESS PROTECTION

SEC. __1. SHORT TITLE.

This title may be cited as the ''Medical Care Access Protection Act of 2009'' or the ''MCAP Act''.

SEC. __2. DEFINITIONS.

In this title:

(1) ALTERNATIVE DISPUTE RESOLUTION SYSTEM; ADR.—The term ''alternative dispute resolution system'' or ''ADR'' means a system that provides for the resolution of health care lawsuits in a manner other than through a civil action brought in a State or Federal court.

(2) CLAIMANT.—The term ''claimant'' means any person who brings a health care lawsuit, including a person who asserts or claims a right to legal or equitable contribution, indemnity or subrogation, arising out of a health care liability claim or action, and any person on whose behalf such a claim is asserted or such an action is brought, whether deceased, incompetent, or a minor.

(3) COLLATERAL SOURCE BENEFITS.—The term ''collateral source benefits'' means any amount paid or reasonably likely to be paid in the future to or on behalf of the claimant, or any service, product or other benefit provided or reasonably likely to be provided in the future to or on behalf of the claimant, as a result of the injury or wrongful death, pursuant to—

(A) any State or Federal health, sickness, income-disability, accident, or workers' compensation law;

(B) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(C) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; and

(D) any other publicly or privately funded program.

(4) COMPENSATORY DAMAGES.—The term ''compensatory damages'' means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities, damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature. Such term includes economic damages and noneconomic damages, as such terms are defined in this section.

(5) CONTINGENT FEE.—The term ''contingent fee'' includes all compensation to any person or persons which is payable only if a recovery is effected on behalf of one or more claimants.

(6) ECONOMIC DAMAGES.—The term ''economic damages'' means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities.

(7) HEALTH CARE GOODS OR SERVICES.—The term ''health care goods or services'' means any goods or services provided by a health care institution, provider, or by any individual working under the supervision of a health care provider in a medically underserved community, that relates to the diagnosis, prevention, care, or treatment of any human disease or impairment, or the assessment of the health of human beings.

(8) HEALTH CARE INSTITUTION.—The term ''health care institution'' means any entity licensed under Federal or State law to provide health care services (including but not limited to ambulatory surgical centers, assisted living facilities, emergency medical services providers, hospices, hospitals and hospital systems, nursing homes, or other entities licensed to provide such services) in a medically underserved community.

(9) HEALTH CARE LAWSUIT.—The term ''health care lawsuit'' means any health care liability claim concerning the provision of health care goods or services in a medically underserved community, affecting interstate commerce, or any health care liability action concerning the provision of (or the failure to provide) health care goods or services affecting interstate commerce, brought in a State or Federal court or pursuant to an alternative dispute resolution system, against a health care provider who delivers services in a medically underserved community or a health care institution located in a medically underserved community regardless of the theory of liability on which the claim is based, or the number of claimants, plaintiffs, defendants, or other parties, or the number of claims or causes of action, in which the claimant alleges a health care liability claim.

(10) HEALTH CARE LIABILITY ACTION.—The term ''health care liability action'' means a civil action brought in a State or Federal Court or pursuant to an alternative dispute resolution system, against a health care provider who delivers services in a medically underserved community or a health care institution located in a medically underserved community regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action, in which the claimant alleges a health care liability claim.

(11) HEALTH CARE LIABILITY CLAIM.—The term ''health care liability claim'' means a demand by any person, whether or not pursuant to ADR, against a health care provider who delivers services in a medically underserved community or a health care institution located in a medically underserved community, including third-party claims, cross-claims, counter-claims, or contribution claims, which are based upon the provision of, use of, or payment for (or the failure to provide, use, or pay for) health care services, regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action.

(12) HEALTH CARE PROVIDER.—

(A) IN GENERAL.—The term ''health care provider'' means any person (including but not limited to a physician (as defined by section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r)), registered nurse, dentist, podiatrist, pharmacist, chiropractor, or optometrist) required by State or Federal law to be licensed, registered, or certified to provide health care services, and being either so licensed, registered, or certified, or exempted from such requirement by other statute or regulation.

(B) TREATMENT OF CERTAIN PROFESSIONAL ASSOCIATIONS.—For purposes of this title, a professional association that is organized under State law by an individual physician or group of physicians, a partnership or limited liability partnership formed by a group of physicians, a nonprofit health corporation certified under State law, or a company formed by a group of physicians under State law shall be treated as a health care provider under subparagraph (A).

(13) MALICIOUS INTENT TO INJURE.—The term ''malicious intent to injure'' means intentionally causing or attempting to cause physical injury other than providing health care goods or services.

(14) MEDICALLY UNDERSERVED COMMUNITY.—The term ''medically underserved community'' means a health manpower shortage area as designated under section 332 of the Public Health Service Act.

(15) NONECONOMIC DAMAGES.—The term ''noneconomic damages'' means damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature.

(16) PUNITIVE DAMAGES.—The term ''punitive damages'' means damages awarded, for the purpose of punishment or deterrence, and not solely for compensatory purposes, against a health care provider who delivers services in a medically underserved community or a health care institution located in a medically underserved community. Punitive damages are neither economic nor noneconomic damages.

(17) RECOVERY.—The term ''recovery'' means the net sum recovered after deducting any disbursements or costs incurred in connection with prosecution or settlement of the claim, including all costs paid or advanced by any person. Costs of health care incurred by the plaintiff and the attorneys' office overhead costs or charges for legal services are not deductible disbursements or costs for such purpose.

(18) STATE.—The term ''State'' means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, the Trust Territory of the Pacific Islands, and any other territory or possession of the United States, or any political subdivision thereof.

SEC. _3. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.

(a) IN GENERAL.—Except as otherwise provided for in this section, the time for the commencement of a health care lawsuit shall be 3 years after the date of manifestation of injury or 1 year after the claimant discovers, or through the use of reasonable diligence should have discovered, the injury, whichever occurs first.

(b) GENERAL EXCEPTION.—The time for the commencement of a health care lawsuit shall not exceed 3 years after the date of manifestation of injury unless the tolling of time was delayed as a result of—

(1) fraud;

(2) intentional concealment; or

(3) the presence of a foreign body, which has no therapeutic or diagnostic purpose or effect, in the person of the injured person.

(c) MINORS.—An action by a minor shall be commenced within 3 years from the date of the alleged manifestation of injury except that if such minor is under the full age of 6 years, such action shall be commenced within 3 years of the manifestation of injury, or prior to the eighth birthday of the minor, whichever provides a longer period. Such time limitation shall be tolled for minors for any period during which a parent or guardian and a health care provider or health care institution have committed fraud or collusion in the failure to bring an action on behalf of the injured minor.

(d) RULE 11 SANCTIONS.—Whenever a Federal or State court determines (whether by motion of the parties or whether on the motion of the court) that there has been a violation of Rule 11 of the Federal Rules of Civil Procedure (or a similar violation of applicable State court rules) in a health care liability action to which this title applies, the court shall impose upon the attorneys, law firms, or pro se litigants that have violated Rule 11 or are responsible for the violation, an appropriate sanction, which shall include an order to pay the other party or parties for the reasonable expenses incurred as a direct result of the filing of the pleading, motion, or other paper that is the subject of the violation, including a reasonable attorneys' fee. Such sanction shall be sufficient to deter repetition of such conduct or comparable conduct by others similarly situated, and to compensate the party or parties injured by such conduct.

SEC. _4. COMPENSATING PATIENT INJURY.

(a) UNLIMITED AMOUNT OF DAMAGES FOR ACTUAL ECONOMIC LOSSES IN HEALTH CARE LAWSUITS.—In any health care lawsuit, nothing in this title shall limit the recovery by a claimant of the full amount of the available economic damages, notwithstanding the limitation contained in subsection (b).

(b) ADDITIONAL NONECONOMIC DAMAGES.—

(1) HEALTH CARE PROVIDERS.—In any health care lawsuit where final judgment is rendered against a health care provider, the amount of noneconomic damages recovered from the provider, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties other than a health care institution against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence.

(2) HEALTH CARE INSTITUTIONS.—

(A) SINGLE INSTITUTION.—In any health care lawsuit where final judgment is rendered against a single health care institution, the amount of noneconomic damages recovered from the institution, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence.

(B) MULTIPLE INSTITUTIONS.—In any health care lawsuit where final judgment is rendered against more than one health care institution, the amount of noneconomic damages recovered from each institution, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence, except that the total amount recovered from all such institutions in such lawsuit shall not exceed $500,000.

(c) NO DISCOUNT OF AWARD FOR NONECONOMIC DAMAGES.—In any health care lawsuit—

(1) an award for future noneconomic damages shall not be discounted to present value;

(2) the jury shall not be informed about the maximum award for noneconomic damages under subsection (b);

(3) an award for noneconomic damages in excess of the limitations provided for in subsection (b) shall be reduced either before the entry of judgment, or by amendment of the judgment after entry of judgment, and such reduction shall be made before accounting for any other reduction in damages required by law; and

(4) if separate awards are rendered for past and future noneconomic damages and the combined awards exceed the limitations described in subsection (b), the future noneconomic damages shall be reduced first.

(d) FAIR SHARE RULE.—In any health care lawsuit, each party shall be liable for that party's several share of any damages only and not for the share of any other person. Each party shall be liable only for the amount of damages allocated to such party in direct proportion to such party's percentage of responsibility. A separate judgment shall be rendered against each such party for the amount allocated to such party. For purposes of this section, the trier of fact shall determine the proportion of responsibility of each party for the claimant's harm.

SEC. _5. MAXIMIZING PATIENT RECOVERY.

(a) COURT SUPERVISION OF SHARE OF DAMAGES ACTUALLY PAID TO CLAIMANTS.—

(1) IN GENERAL.—In any health care lawsuit, the court shall supervise the arrangements for payment of damages to protect against conflicts of interest that may have the effect of reducing the amount of damages awarded that are actually paid to claimants.

(2) CONTINGENCY FEES.—

(A) IN GENERAL.—In any health care lawsuit in which the attorney for a party claims a financial stake in the outcome by virtue of a contingent fee, the court shall have the power to restrict the payment of a claimant's damage recovery to such attorney, and to redirect such damages to the claimant based upon the interests of justice and principles of equity.

(B) LIMITATION.—The total of all contingent fees for representing all claimants in a health care lawsuit shall not exceed the following limits:

(i) 40 percent of the first $50,000 recovered by the claimant(s).

(ii) 33⅓ percent of the next $50,000 recovered by the claimant(s).

(iii) 25 percent of the next $500,000 recovered by the claimant(s).

(iv) 15 percent of any amount by which the recovery by the claimant(s) is in excess of $600,000.

(b) APPLICABILITY.—

(1) IN GENERAL.—The limitations in subsection (a) shall apply whether the recovery is by judgment, settlement, mediation, arbitration, or any other form of alternative dispute resolution.

(2) MINORS.—In a health care lawsuit involving a minor or incompetent person, a court retains the authority to authorize or approve a fee that is less than the maximum permitted under this section.

(c) EXPERT WITNESSES.—

(1) REQUIREMENT.—No individual shall be qualified to testify as an expert witness concerning issues of negligence in any health care lawsuit against a defendant unless such individual—

(A) except as required under paragraph (2), is a health care professional who—

(i) is appropriately credentialed or licensed in 1 or more States to deliver health care services; and

(ii) typically treats the diagnosis or condition or provides the type of treatment under review; and

(B) can demonstrate by competent evidence that, as a result of training, education, knowledge, and experience in the evaluation, diagnosis, and treatment of the disease or injury which is the subject matter of the lawsuit against the defendant, the individual was substantially familiar with applicable standards of care and practice as they relate to the act or omission which is the subject of the lawsuit on the date of the incident.

(2) PHYSICIAN REVIEW.—In a health care lawsuit, if the claim of the plaintiff involved treatment that is recommended or provided by a physician (allopathic or osteopathic), an individual shall not be qualified to be an expert witness under this subsection with respect to issues of negligence concerning such treatment unless such individual is a physician.

(3) SPECIALTIES AND SUBSPECIALTIES.—With respect to a lawsuit described in paragraph (1), a court shall not permit an expert in one medical specialty or subspecialty to testify against a defendant in another medical specialty or subspecialty unless, in addition to a showing of substantial familiarity in accordance with paragraph (1)(B), there is a showing that the standards of care and practice in the two specialty or subspecialty fields are similar.

(4) LIMITATION.—The limitations in this subsection shall not apply to expert witnesses testifying as to the degree or permanency of medical or physical impairment.

SEC. _6. ADDITIONAL HEALTH BENEFITS.

(a) IN GENERAL.—The amount of any damages received by a claimant in any health care lawsuit shall be reduced by the court by the amount of any collateral source benefits to which the claimant is entitled, less any insurance premiums or other payments made by the claimant (or by the spouse, parent, child, or legal guardian of the claimant) to obtain or secure such benefits.

(b) PRESERVATION OF CURRENT LAW.—Where a payor of collateral source benefits has a right of recovery by reimbursement or subrogation and such right is permitted under Federal or State law, subsection (a) shall not apply.

(c) APPLICATION OF PROVISION.—This section shall apply to any health care lawsuit that is settled or resolved by a fact finder.

SEC. _7. PUNITIVE DAMAGES.

(a) PUNITIVE DAMAGES PERMITTED.—

(1) IN GENERAL.—Punitive damages may, if otherwise available under applicable State or Federal law, be awarded against any person in a health care lawsuit only if it is proven by clear and convincing evidence that such person acted with malicious intent to injure the claimant, or that such person deliberately failed to avoid unnecessary injury that such person knew the claimant was substantially certain to suffer.

(2) FILING OF LAWSUIT.—No demand for punitive damages shall be included in a health care lawsuit as initially filed. A court may

allow a claimant to file an amended pleading for punitive damages only upon a motion by the claimant and after a finding by the court, upon review of supporting and opposing affidavits or after a hearing, after weighing the evidence, that the claimant has established by a substantial probability that the claimant will prevail on the claim for punitive damages.

(3) SEPARATE PROCEEDING.—At the request of any party in a health care lawsuit, the trier of fact shall consider in a separate proceeding—

(A) whether punitive damages are to be awarded and the amount of such award; and

(B) the amount of punitive damages following a determination of punitive liability. If a separate proceeding is requested, evidence relevant only to the claim for punitive damages, as determined by applicable State law, shall be inadmissible in any proceeding to determine whether compensatory damages are to be awarded.

(4) LIMITATION WHERE NO COMPENSATORY DAMAGES ARE AWARDED.—In any health care lawsuit where no judgment for compensatory damages is rendered against a person, no punitive damages may be awarded with respect to the claim in such lawsuit against such person.

(b) DETERMINING AMOUNT OF PUNITIVE DAMAGES.—

(1) FACTORS CONSIDERED.—In determining the amount of punitive damages under this section, the trier of fact shall consider only the following:

(A) the severity of the harm caused by the conduct of such party;

(B) the duration of the conduct or any concealment of it by such party;

(C) the profitability of the conduct to such party;

(D) the number of products sold or medical procedures rendered for compensation, as the case may be, by such party, of the kind causing the harm complained of by the claimant;

(E) any criminal penalties imposed on such party, as a result of the conduct complained of by the claimant; and

(F) the amount of any civil fines assessed against such party as a result of the conduct complained of by the claimant.

(2) MAXIMUM AWARD.—The amount of punitive damages awarded in a health care lawsuit may not exceed an amount equal to two times the amount of economic damages awarded in the lawsuit or $250,000, whichever is greater. The jury shall not be informed of the limitation under the preceding sentence.

(c) LIABILITY OF HEALTH CARE PROVIDERS.—

(1) IN GENERAL.—A health care provider who prescribes, or who dispenses pursuant to a prescription, a drug, biological product, or medical device approved by the Food and Drug Administration, for an approved indication of the drug, biological product, or medical device, shall not be named as a party to a product liability lawsuit invoking such drug, biological product, or medical device and shall not be liable to a claimant in a class action lawsuit against the manufacturer, distributor, or product seller of such drug, biological product, or medical device.

(2) MEDICAL PRODUCT.—The term ''medical product'' means a drug or device intended for humans. The terms ''drug'' and ''device'' have the meanings given such terms in sections 201(g)(1) and 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321), respectively, including any component or raw material used therein, but excluding health care services.

SEC. __8. AUTHORIZATION OF PAYMENT OF FUTURE DAMAGES TO CLAIMANTS IN HEALTH CARE LAWSUITS.

(a) IN GENERAL.—In any health care lawsuit, if an award of future damages, without reduction to present value, equaling or exceeding $50,000 is made against a party with sufficient insurance or other assets to fund a periodic payment of such a judgment, the court shall, at the request of any party, enter a judgment ordering that the future damages be paid by periodic payments in accordance with the Uniform Periodic Payment of Judgments Act promulgated by the National Conference of Commissioners on Uniform State Laws.

(b) APPLICABILITY.—This section applies to all actions which have not been first set for trial or retrial before the effective date of this title.

SEC. __9. EFFECT ON OTHER LAWS.

(a) GENERAL VACCINE INJURY.—

(1) IN GENERAL.—To the extent that title XXI of the Public Health Service Act establishes a Federal rule of law applicable to a civil action brought for a vaccine-related injury or death—

(A) this title shall not affect the application of the rule of law to such an action; and

(B) any rule of law prescribed by this title in conflict with a rule of law of such title XXI shall not apply to such action.

(2) EXCEPTION.—If there is an aspect of a civil action brought for a vaccine-related injury or death to which a Federal rule of law under title XXI of the Public Health Service Act does not apply, then this title or otherwise applicable law (as determined under this title) will apply to such aspect of such action.

(b) SMALLPOX VACCINE INJURY.—

(1) IN GENERAL.—To the extent that part C of title II of the Public Health Service Act establishes a Federal rule of law applicable to a civil action brought for a smallpox vaccine-related injury or death—

(A) this title shall not affect the application of the rule of law to such an action; and

(B) any rule of law prescribed by this title in conflict with a rule of law of such part C shall not apply to such action.

(2) EXCEPTION.—If there is an aspect of a civil action brought for a smallpox vaccine-related injury or death to which a Federal rule of law under part C of title II of the Public Health Service Act does not apply, then this title or otherwise applicable law (as determined under this title) will apply to such aspect of such action.

(c) OTHER FEDERAL LAW.—Except as provided in this section, nothing in this title shall be deemed to affect any defense available, or any limitation on liability that applies to, a defendant in a health care lawsuit or action under any other provision of Federal law.

SEC. __10. STATE FLEXIBILITY AND PROTECTION OF STATES' RIGHTS.

(a) HEALTH CARE LAWSUITS.—The provisions governing health care lawsuits set forth in this title shall preempt, subject to subsections (b) and (c), State law to the extent that State law prevents the application of any provisions of law established by or under this title. The provisions governing health care lawsuits set forth in this title supersede chapter 171 of title 28, United States Code, to the extent that such chapter—

(1) provides for a greater amount of damages or contingent fees, a longer period in which a health care lawsuit may be commenced, or a reduced applicability or scope of periodic payment of future damages, than provided in this title; or

(2) prohibits the introduction of evidence regarding collateral source benefits.

(b) PREEMPTION OF CERTAIN STATE LAWS.—No provision of this title shall be construed to preempt any State law (whether effective before, on, or after the date of the enactment of this title) that specifies a particular monetary amount of compensatory or punitive damages (or the total amount of damages) that may be awarded in a health care lawsuit, regardless of whether such monetary amount is greater or lesser than is provided for under this title, notwithstanding section ___4(a).

(c) PROTECTION OF STATE'S RIGHTS AND OTHER LAWS.—

(1) IN GENERAL.—Any issue that is not governed by a provision of law established by or under this title (including the State standards of negligence) shall be governed by otherwise applicable Federal or State law.

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

(A) preempt or supersede any Federal or State law that imposes greater procedural or substantive protections (such as a shorter statute of limitations) for a health care provider or health care institution from liability, loss, or damages than those provided by this title;

(B) preempt or supercede any State law that permits and provides for the enforcement of any arbitration agreement related to a health care liability claim whether enacted prior to or after the date of enactment of this title;

(C) create a cause of action that is not otherwise available under Federal or State law; or

(D) affect the scope of preemption of any other Federal law.

SEC. __11. APPLICABILITY; EFFECTIVE DATE.

This title shall apply to any health care lawsuit brought in a Federal or State court, or subject to an alternative dispute resolution system, that is initiated on or after the date of the enactment of this title, except that any health care lawsuit arising from an injury occurring prior to the date of enactment of this title shall be governed by the applicable statute of limitations provisions in effect at the time the injury occurred.

SA 3142. Mrs. HUTCHISON submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 2026, strike line 3 and insert the following:

(i) EXCLUSION OF DEVICES FOR CANCER DIAGNOSIS AND TREATMENT.—

(1) IN GENERAL.—The term ''medical device sales'' shall not include sales of any device which is primarily designed to diagnose or treat any form of cancer.

(2) REDUCTION OF AGGREGATE FEE AMOUNT.—The $2,000,000,000 amount in subsection (b)(1) shall be reduced by the amount which bears the same ratio to such $2,000,000,000 amount as the amount of the sales of devices described in paragraph (1) for calendar year 2010 bears to the amount of total medical device sales (without regard to this subsection) for such calendar year, as determined by the Secretary.

(j) APPLICATION OF SECTION.—This section shall

SA 3143. Mrs. HUTCHISON submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain

other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place in title I, insert the following:

SEC. ___. STATE OPT OUT.

(a) IN GENERAL.—The provisions described in subsection (b) shall not apply to

(1) individuals residing within a State;

(2) employers located within a State; and

(3) health coverage offered within a State; if the State enacts a law rejecting such provisions as described in subsection (b) and attests to the Secretary that the State will implement reforms appropriate for application within the State to reduce the uninsured population of the State and increase access to affordable health insurance options.

(b) EFFECT OF STATE LAW.—The provisions described in this subsection are the following:

(1) The insurance market reform provisions of title I (and the amendments made by such title), except for section 2704 of the Public Health Service Act (as added by section 1201 (relating to preexisting condition exclusions).

(2) The requirements relating to obtaining or providing individual and employer health insurance coverage under title I (and the amendments made by such title).

(3) The provisions relating to Medicaid expansion under the amendments made by title I.

(4) The provisions relating to the Medicare program (and the amendments to such program) under title III and (IV).

(5) The provisions relating to the imposition of, or increases in, fees paid by insurance issuers and drug and medical device manufacturers under the amendments made by this Act.

(6) Any other provision of this Act (or an amendment made by this Act), except for this section.

(c) ABOVE-THE-LINE DEDUCTION FOR HEALTH INSURANCE PREMIUMS.—

(1) IN GENERAL.—Section 62(a) of the Internal Revenue Code of 1986 (defining adjusted gross income) is amended by inserting after paragraph (21) the following new paragraph:

''(22) HEALTH INSURANCE PAYMENTS.—

''(A) IN GENERAL.—Any amount allowable as a deduction under section 213 (determined without regard to any income limitation under subsection (a) thereof) by reason of subsection (d)(1)(D) thereof for qualified health insurance.

''(B) QUALIFIED HEALTH INSURANCE.—For purposes of this paragraph—

''(i) IN GENERAL.—The term 'qualified health insurance' means insurance offered to individuals located in a State that enacts a law described in section ___(a) of the Patient Protection and Affordable Care Act which constitutes medical care as defined in section 213(d) without regard to—

''(I) paragraph (1)(C) thereof, and

''(II) so much of paragraph (1)(D) thereof as relates to qualified long-term care insurance contracts.

''(ii) EXCLUSION OF CERTAIN OTHER CONTRACTS.—Such term shall not include insurance if a substantial portion of its benefits are excepted benefits (as defined in section 9832(c)).''.

(2) EFFECTIVE DATE.—The amendment made by this subsection shall apply to taxable years beginning after December 31, 2009.

SA 3144. Mr. FRANKEN submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place in title VI, insert the following:

SEC. ___. ANTI-FRAUD CONSULTATION GROUP.

(a) ESTABLISHMENT.—The Secretary of Health and Human Services jointly with the Attorney General shall establish an anti-fraud consultation group for the purpose of coordinating expertise and best practices relating to the analysis, detection, and prevention of fraud, waste, and abuse arising from, or related to, health care.

(b) COMPOSITION.—The anti-fraud consultation group under subsection (a) shall be composed of individuals, to be appointed jointly by the Secretary of Health and Human Services and the Attorney General, with expertise from both the public and private sectors in fraud arising from, or related to, health care, including law enforcement personnel, health insurance issuers, physicians and other health care providers, insurance anti-fraud organizations, academic experts, consumer groups, and insurance regulators.

(c) DUTIES.—At the request of the Secretary of Health and Human Services and the Attorney General, the anti-fraud consultation group under subsection (a) shall provide advice concerning—

(1) methods of preventing fraud against Federal and State health care programs, consumers, providers, employers, and health insurance issuers;

(2) the evaluation of information and data to improve the ability to detect and prevent fraud;

(3) the enhancement of anti-fraud information data systems, consistent with the protection of personal privacy; and

(4) the coordination of public and private resources in the analysis, detection, and prevention of fraud arising from, or related to, health care.

(d) ANNUAL REPORT.—The anti-fraud consultation group under subsection (a) shall, not later than 1 year after the date of enactment of this Act, and annually thereafter, submit to the Secretary of Health and Human Services and the Attorney General a report concerning the group's—

(1) accomplishments to improve the coordination of public and private health care anti-fraud actions;

(2) development of enhanced techniques for the analysis, detection, and prevention of fraud; and

(3) recommendations for the improvement of anti-fraud programs.

(e) FUNDING.—The Secretary and the Attorney General shall use funds appropriated to the Secretary or Attorney General prior to the date of enactment of this Act, and otherwise available, to carry out this section.

SA 3145. Mr. MCCONNELL (for himself, Mr. ENSIGN, and Mr. MCCAIN) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

In lieu of the matter proposed to be inserted, insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medical Care Access Protection Act of 2009'' or the ''MCAP Act''.

SEC. 2. FINDINGS AND PURPOSE.

(a) FINDINGS.—

(1) EFFECT ON HEALTH CARE ACCESS AND COSTS.—Congress finds that our current civil justice system is adversely affecting patient access to health care services, better patient care, and cost-efficient health care, in that the health care liability system is a costly and ineffective mechanism for resolving claims of health care liability and compensating injured patients, and is a deterrent to the sharing of information among health care professionals which impedes efforts to improve patient safety and quality of care.

(2) EFFECT ON INTERSTATE COMMERCE.—Congress finds that the health care and insurance industries are industries affecting interstate commerce and the health care liability litigation systems existing throughout the United States are activities that affect interstate commerce by contributing to the high costs of health care and premiums for health care liability insurance purchased by health care system providers.

(3) EFFECT ON FEDERAL SPENDING.—Congress finds that the health care liability litigation systems existing throughout the United States have a significant effect on the amount, distribution, and use of Federal funds because of—

(A) the large number of individuals who receive health care benefits under programs operated or financed by the Federal Government;

(B) the large number of individuals who benefit because of the exclusion from Federal taxes of the amounts spent to provide them with health insurance benefits; and

(C) the large number of health care providers who provide items or services for which the Federal Government makes payments.

(b) PURPOSE.—It is the purpose of this Act to implement reasonable, comprehensive, and effective health care liability reforms designed to—

(1) improve the availability of health care services in cases in which health care liability actions have been shown to be a factor in the decreased availability of services;

(2) reduce the incidence of ''defensive medicine'' and lower the cost of health care liability insurance, all of which contribute to the escalation of health care costs;

(3) ensure that persons with meritorious health care injury claims receive fair and adequate compensation, including reasonable noneconomic damages;

(4) improve the fairness and cost-effectiveness of our current health care liability system to resolve disputes over, and provide compensation for, health care liability by reducing uncertainty in the amount of compensation provided to injured individuals; and

(5) provide an increased sharing of information in the health care system which will reduce unintended injury and improve patient care.

SEC. 3. DEFINITIONS.

In this Act:

(1) ALTERNATIVE DISPUTE RESOLUTION SYSTEM; ADR.—The term ''alternative dispute resolution system'' or ''ADR'' means a system that provides for the resolution of health care lawsuits in a manner other than through a civil action brought in a State or Federal court.

(2) CLAIMANT.—The term ''claimant'' means any person who brings a health care lawsuit, including a person who asserts or claims a right to legal or equitable contribution, indemnity or subrogation, arising out

of a health care liability claim or action, and any person on whose behalf such a claim is asserted or such an action is brought, whether deceased, incompetent, or a minor.

(3) COLLATERAL SOURCE BENEFITS.—The term ''collateral source benefits'' means any amount paid or reasonably likely to be paid in the future to or on behalf of the claimant, or any service, product or other benefit provided or reasonably likely to be provided in the future to or on behalf of the claimant, as a result of the injury or wrongful death, pursuant to—

(A) any State or Federal health, sickness, income-disability, accident, or workers' compensation law;

(B) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(C) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; and

(D) any other publicly or privately funded program.

(4) COMPENSATORY DAMAGES.—The term ''compensatory damages'' means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities, damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature. Such term includes economic damages and noneconomic damages, as such terms are defined in this section.

(5) CONTINGENT FEE.—The term ''contingent fee'' includes all compensation to any person or persons which is payable only if a recovery is effected on behalf of one or more claimants.

(6) ECONOMIC DAMAGES.—The term ''economic damages'' means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities.

(7) HEALTH CARE GOODS OR SERVICES.—The term ''health care goods or services'' means any goods or services provided by a health care institution, provider, or by any individual working under the supervision of a health care provider, that relates to the diagnosis, prevention, care, or treatment of any human disease or impairment, or the assessment of the health of human beings.

(8) HEALTH CARE INSTITUTION.—The term ''health care institution'' means any entity licensed under Federal or State law to provide health care services (including but not limited to ambulatory surgical centers, assisted living facilities, emergency medical services providers, hospices, hospitals and hospital systems, nursing homes, or other entities licensed to provide such services).

(9) HEALTH CARE LAWSUIT.—The term ''health care lawsuit'' means any health care liability claim concerning the provision of health care goods or services affecting interstate commerce, or any health care liability action concerning the provision of (or the failure to provide) health care goods or services affecting interstate commerce, brought in a State or Federal court or pursuant to an alternative dispute resolution system, against a health care provider or a health care institution regardless of the theory of liability on which the claim is based, or the number of claimants, plaintiffs, defendants, or other parties, or the number of claims or causes of action, in which the claimant alleges a health care liability claim.

(10) HEALTH CARE LIABILITY ACTION.—The term ''health care liability action'' means a civil action brought in a State or Federal Court or pursuant to an alternative dispute resolution system, against a health care provider or a health care institution regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action, in which the claimant alleges a health care liability claim.

(11) HEALTH CARE LIABILITY CLAIM.—The term ''health care liability claim'' means a demand by any person, whether or not pursuant to ADR, against a health care provider or health care institution, including third-party claims, cross-claims, counter-claims, or contribution claims, which are based upon the provision of, use of, or payment for (or the failure to provide, use, or pay for) health care services, regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action.

(12) HEALTH CARE PROVIDER.—

(A) IN GENERAL.—The term ''health care provider'' means any person (including but not limited to a physician (as defined by section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r)), registered nurse, dentist, podiatrist, pharmacist, chiropractor, or optometrist) required by State or Federal law to be licensed, registered, or certified to provide health care services, and being either so licensed, registered, or certified, or exempted from such requirement by other statute or regulation.

(B) TREATMENT OF CERTAIN PROFESSIONAL ASSOCIATIONS.—For purposes of this Act, a professional association that is organized under State law by an individual physician or group of physicians, a partnership or limited liability partnership formed by a group of physicians, a nonprofit health corporation certified under State law, or a company formed by a group of physicians under State law shall be treated as a health care provider under subparagraph (A).

(13) MALICIOUS INTENT TO INJURE.—The term ''malicious intent to injure'' means intentionally causing or attempting to cause physical injury other than providing health care goods or services.

(14) NONECONOMIC DAMAGES.—The term ''noneconomic damages'' means damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature.

(15) PUNITIVE DAMAGES.—The term ''punitive damages'' means damages awarded, for the purpose of punishment or deterrence, and not solely for compensatory purposes, against a health care provider or health care institution. Punitive damages are neither economic nor noneconomic damages.

(16) RECOVERY.—The term ''recovery'' means the net sum recovered after deducting any disbursements or costs incurred in connection with prosecution or settlement of the claim, including all costs paid or advanced by any person. Costs of health care incurred by the plaintiff and the attorneys' office overhead costs or charges for legal services are not deductible disbursements or costs for such purpose.

(17) STATE.—The term ''State'' means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, the Trust Territory of the Pacific Islands, and any other territory or possession of the United States, or any political subdivision thereof.

SEC. 4. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.

(a) IN GENERAL.—Except as otherwise provided for in this section, the time for the commencement of a health care lawsuit shall be 3 years after the date of manifestation of injury or 1 year after the claimant discovers, or through the use of reasonable diligence should have discovered, the injury, whichever occurs first.

(b) GENERAL EXCEPTION.—The time for the commencement of a health care lawsuit shall not exceed 3 years after the date of manifestation of injury unless the tolling of time was delayed as a result of—

(1) fraud;

(2) intentional concealment; or

(3) the presence of a foreign body, which has no therapeutic or diagnostic purpose or effect, in the person of the injured person.

(c) MINORS.—An action by a minor shall be commenced within 3 years from the date of the alleged manifestation of injury except that if such minor is under the full age of 6 years, such action shall be commenced within 3 years of the manifestation of injury, or prior to the eighth birthday of the minor, whichever provides a longer period. Such time limitation shall be tolled for minors for any period during which a parent or guardian and a health care provider or health care institution have committed fraud or collusion in the failure to bring an action on behalf of the injured minor.

(d) RULE 11 SANCTIONS.—Whenever a Federal or State court determines (whether by motion of the parties or whether on the motion of the court) that there has been a violation of Rule 11 of the Federal Rules of Civil Procedure (or a similar violation of applicable State court rules) in a health care liability action to which this Act applies, the court shall impose upon the attorneys, law firms, or pro se litigants that have violated Rule 11 or are responsible for the violation, an appropriate sanction, which shall include an order to pay the other party or parties for the reasonable expenses incurred as a direct result of the filing of the pleading, motion, or other paper that is the subject of the violation, including a reasonable attorneys' fee. Such sanction shall be sufficient to deter repetition of such conduct or comparable conduct by others similarly situated, and to compensate the party or parties injured by such conduct.

SEC. 5. COMPENSATING PATIENT INJURY.

(a) UNLIMITED AMOUNT OF DAMAGES FOR ACTUAL ECONOMIC LOSSES IN HEALTH CARE LAWSUITS.—In any health care lawsuit, nothing in this Act shall limit the recovery by a claimant of the full amount of the available economic damages, notwithstanding the limitation contained in subsection (b).

(b) ADDITIONAL NONECONOMIC DAMAGES.—

(1) HEALTH CARE PROVIDERS.—In any health care lawsuit where final judgment is rendered against a health care provider, the amount of noneconomic damages recovered from the provider, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties other than a health care institution against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence.

(2) HEALTH CARE INSTITUTIONS.—

(A) SINGLE INSTITUTION.—In any health care lawsuit where final judgment is rendered against a single health care institution, the amount of noneconomic damages recovered from the institution, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence.

(B) MULTIPLE INSTITUTIONS.—In any health care lawsuit where final judgment is rendered against more than one health care institution, the amount of noneconomic damages recovered from each institution, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence, except that the total amount recovered from all such institutions in such lawsuit shall not exceed $500,000.

(c) NO DISCOUNT OF AWARD FOR NONECONOMIC DAMAGES.—In any health care lawsuit—

(1) an award for future noneconomic damages shall not be discounted to present value;

(2) the jury shall not be informed about the maximum award for noneconomic damages under subsection (b);

(3) an award for noneconomic damages in excess of the limitations provided for in subsection (b) shall be reduced either before the entry of judgment, or by amendment of the judgment after entry of judgment, and such reduction shall be made before accounting for any other reduction in damages required by law; and

(4) if separate awards are rendered for past and future noneconomic damages and the combined awards exceed the limitations described in subsection (b), the future noneconomic damages shall be reduced first.

(d) FAIR SHARE RULE.—In any health care lawsuit, each party shall be liable for that party's several share of any damages only and not for the share of any other person. Each party shall be liable only for the amount of damages allocated to such party in direct proportion to such party's percentage of responsibility. A separate judgment shall be rendered against each such party for the amount allocated to such party. For purposes of this section, the trier of fact shall determine the proportion of responsibility of each party for the claimant's harm.

SEC. 6. MAXIMIZING PATIENT RECOVERY.

(a) COURT SUPERVISION OF SHARE OF DAMAGES ACTUALLY PAID TO CLAIMANTS.—

(1) IN GENERAL.—In any health care lawsuit, the court shall supervise the arrangements for payment of damages to protect against conflicts of interest that may have the effect of reducing the amount of damages awarded that are actually paid to claimants.

(2) CONTINGENCY FEES.—

(A) IN GENERAL.—In any health care lawsuit in which the attorney for a party claims a financial stake in the outcome by virtue of a contingent fee, the court shall have the power to restrict the payment of a claimant's damage recovery to such attorney, and to redirect such damages to the claimant based upon the interests of justice and principles of equity.

(B) LIMITATION.—The total of all contingent fees for representing all claimants in a health care lawsuit shall not exceed the following limits:

(i) 40 percent of the first $50,000 recovered by the claimant(s).

(ii) 33⅓ percent of the next $50,000 recovered by the claimant(s).

(iii) 25 percent of the next $500,000 recovered by the claimant(s).

(iv) 15 percent of any amount by which the recovery by the claimant(s) is in excess of $600,000.

(b) APPLICABILITY.—

(1) IN GENERAL.—The limitations in subsection (a) shall apply whether the recovery is by judgment, settlement, mediation, arbitration, or any other form of alternative dispute resolution.

(2) MINORS.—In a health care lawsuit involving a minor or incompetent person, a court retains the authority to authorize or approve a fee that is less than the maximum permitted under this section.

(c) EXPERT WITNESSES.—

(1) REQUIREMENT.—No individual shall be qualified to testify as an expert witness concerning issues of negligence in any health care lawsuit against a defendant unless such individual—

(A) except as required under paragraph (2), is a health care professional who—

(i) is appropriately credentialed or licensed in 1 or more States to deliver health care services; and

(ii) typically treats the diagnosis or condition or provides the type of treatment under review; and

(B) can demonstrate by competent evidence that, as a result of training, education, knowledge, and experience in the evaluation, diagnosis, and treatment of the disease or injury which is the subject matter of the lawsuit against the defendant, the individual was substantially familiar with applicable standards of care and practice as they relate to the act or omission which is the subject of the lawsuit on the date of the incident.

(2) PHYSICIAN REVIEW.—In a health care lawsuit, if the claim of the plaintiff involved treatment that is recommended or provided by a physician (allopathic or osteopathic), an individual shall not be qualified to be an expert witness under this subsection with respect to issues of negligence concerning such treatment unless such individual is a physician.

(3) SPECIALTIES AND SUBSPECIALTIES.—With respect to a lawsuit described in paragraph (1), a court shall not permit an expert in one medical specialty or subspecialty to testify against a defendant in another medical specialty or subspecialty unless, in addition to a showing of substantial familiarity in accordance with paragraph (1)(B), there is a showing that the standards of care and practice in the two specialty or subspecialty fields are similar.

(4) LIMITATION.—The limitations in this subsection shall not apply to expert witnesses testifying as to the degree or permanency of medical or physical impairment.

SEC. 7. ADDITIONAL HEALTH BENEFITS.

(a) IN GENERAL.—The amount of any damages received by a claimant in any health care lawsuit shall be reduced by the court by the amount of any collateral source benefits to which the claimant is entitled, less any insurance premiums or other payments made by the claimant (or by the spouse, parent, child, or legal guardian of the claimant) to obtain or secure such benefits.

(b) PRESERVATION OF CURRENT LAW.—Where a payor of collateral source benefits has a right of recovery by reimbursement or subrogation and such right is permitted under Federal or State law, subsection (a) shall not apply.

(c) APPLICATION OF PROVISION.—This section shall apply to any health care lawsuit that is settled or resolved by a fact finder.

SEC. 8. PUNITIVE DAMAGES.

(a) PUNITIVE DAMAGES PERMITTED.—

(1) IN GENERAL.—Punitive damages may, if otherwise available under applicable State or Federal law, be awarded against any person in a health care lawsuit only if it is proven by clear and convincing evidence that such person acted with malicious intent to injure the claimant, or that such person deliberately failed to avoid unnecessary injury that such person knew the claimant was substantially certain to suffer.

(2) FILING OF LAWSUIT.—No demand for punitive damages shall be included in a health care lawsuit as initially filed. A court may allow a claimant to file an amended pleading for punitive damages only upon a motion by the claimant and after a finding by the court, upon review of supporting and opposing affidavits or after a hearing, after weighing the evidence, that the claimant has established by a substantial probability that the claimant will prevail on the claim for punitive damages.

(3) SEPARATE PROCEEDING.—At the request of any party in a health care lawsuit, the trier of fact shall consider in a separate proceeding—

(A) whether punitive damages are to be awarded and the amount of such award; and

(B) the amount of punitive damages following a determination of punitive liability. If a separate proceeding is requested, evidence relevant only to the claim for punitive damages, as determined by applicable State law, shall be inadmissible in any proceeding to determine whether compensatory damages are to be awarded.

(4) LIMITATION WHERE NO COMPENSATORY DAMAGES ARE AWARDED.—In any health care lawsuit where no judgment for compensatory damages is rendered against a person, no punitive damages may be awarded with respect to the claim in such lawsuit against such person.

(b) DETERMINING AMOUNT OF PUNITIVE DAMAGES.—

(1) FACTORS CONSIDERED.—In determining the amount of punitive damages under this section, the trier of fact shall consider only the following:

(A) the severity of the harm caused by the conduct of such party;

(B) the duration of the conduct or any concealment of it by such party;

(C) the profitability of the conduct to such party;

(D) the number of products sold or medical procedures rendered for compensation, as the case may be, by such party, of the kind causing the harm complained of by the claimant;

(E) any criminal penalties imposed on such party, as a result of the conduct complained of by the claimant; and

(F) the amount of any civil fines assessed against such party as a result of the conduct complained of by the claimant.

(2) MAXIMUM AWARD.—The amount of punitive damages awarded in a health care lawsuit may not exceed an amount equal to two times the amount of economic damages awarded in the lawsuit or $250,000, whichever is greater. The jury shall not be informed of the limitation under the preceding sentence.

(c) LIABILITY OF HEALTH CARE PROVIDERS.—

(1) IN GENERAL.—A health care provider who prescribes, or who dispenses pursuant to a prescription, a drug, biological product, or medical device approved by the Food and Drug Administration, for an approved indication of the drug, biological product, or medical device, shall not be named as a party to a product liability lawsuit invoking such drug, biological product, or medical device and shall not be liable to a claimant in a class action lawsuit against the manufacturer, distributor, or product seller of such drug, biological product, or medical device.

(2) MEDICAL PRODUCT.—The term ''medical product'' means a drug or device intended for humans. The terms ''drug'' and ''device''

have the meanings given such terms in sections 201(g)(1) and 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321), respectively, including any component or raw material used therein, but excluding health care services.

SEC. 9. AUTHORIZATION OF PAYMENT OF FUTURE DAMAGES TO CLAIMANTS IN HEALTH CARE LAWSUITS.

(a) IN GENERAL.—In any health care lawsuit, if an award of future damages, without reduction to present value, equaling or exceeding $50,000 is made against a party with sufficient insurance or other assets to fund a periodic payment of such a judgment, the court shall, at the request of any party, enter a judgment ordering that the future damages be paid by periodic payments in accordance with the Uniform Periodic Payment of Judgments Act promulgated by the National Conference of Commissioners on Uniform State Laws.

(b) APPLICABILITY.—This section applies to all actions which have not been first set for trial or retrial before the effective date of this Act.

SEC. 10. EFFECT ON OTHER LAWS.

(a) GENERAL VACCINE INJURY.—

(1) IN GENERAL.—To the extent that title XXI of the Public Health Service Act establishes a Federal rule of law applicable to a civil action brought for a vaccine-related injury or death—

(A) this Act shall not affect the application of the rule of law to such an action; and

(B) any rule of law prescribed by this Act in conflict with a rule of law of such title XXI shall not apply to such action.

(2) EXCEPTION.—If there is an aspect of a civil action brought for a vaccine-related injury or death to which a Federal rule of law under title XXI of the Public Health Service Act does not apply, then this Act or otherwise applicable law (as determined under this Act) will apply to such aspect of such action.

(b) SMALLPOX VACCINE INJURY.—

(1) IN GENERAL.—To the extent that part C of title II of the Public Health Service Act establishes a Federal rule of law applicable to a civil action brought for a smallpox vaccine-related injury or death—

(A) this Act shall not affect the application of the rule of law to such an action; and

(B) any rule of law prescribed by this Act in conflict with a rule of law of such part C shall not apply to such action.

(2) EXCEPTION.—If there is an aspect of a civil action brought for a smallpox vaccine-related injury or death to which a Federal rule of law under part C of title II of the Public Health Service Act does not apply, then this Act or otherwise applicable law (as determined under this Act) will apply to such aspect of such action.

(c) OTHER FEDERAL LAW.—Except as provided in this section, nothing in this Act shall be deemed to affect any defense available, or any limitation on liability that applies to, a defendant in a health care lawsuit or action under any other provision of Federal law.

SEC. 11. STATE FLEXIBILITY AND PROTECTION OF STATES' RIGHTS.

(a) HEALTH CARE LAWSUITS.—The provisions governing health care lawsuits set forth in this Act shall preempt, subject to subsections (b) and (c), State law to the extent that State law prevents the application of any provisions of law established by or under this Act. The provisions governing health care lawsuits set forth in this Act supersede chapter 171 of title 28, United States Code, to the extent that such chapter—

(1) provides for a greater amount of damages or contingent fees, a longer period in which a health care lawsuit may be commenced, or a reduced applicability or scope of periodic payment of future damages, than provided in this Act; or

(2) prohibits the introduction of evidence regarding collateral source benefits.

(b) PREEMPTION OF CERTAIN STATE LAWS.—No provision of this Act shall be construed to preempt any State law (whether effective before, on, or after the date of the enactment of this Act) that specifies a particular monetary amount of compensatory or punitive damages (or the total amount of damages) that may be awarded in a health care lawsuit, regardless of whether such monetary amount is greater or lesser than is provided for under this Act, notwithstanding section 5(a).

(c) PROTECTION OF STATE'S RIGHTS AND OTHER LAWS.—

(1) IN GENERAL.—Any issue that is not governed by a provision of law established by or under this Act (including the State standards of negligence) shall be governed by otherwise applicable Federal or State law.

(2) RULE OF CONSTRUCTION.—Nothing in this Act shall be construed to—

(A) preempt or supersede any Federal or State law that imposes greater procedural or substantive protections (such as a shorter statute of limitations) for a health care provider or health care institution from liability, loss, or damages than those provided by this Act;

(B) preempt or supercede any State law that permits and provides for the enforcement of any arbitration agreement related to a health care liability claim whether enacted prior to or after the date of enactment of this Act;

(C) create a cause of action that is not otherwise available under Federal or State law; or

(D) affect the scope of preemption of any other Federal law.

SEC. 12. APPLICABILITY; EFFECTIVE DATE.

This Act shall apply to any health care lawsuit brought in a Federal or State court, or subject to an alternative dispute resolution system, that is initiated on or after the date of the enactment of this Act, except that any health care lawsuit arising from an injury occurring prior to the date of enactment of this Act shall be governed by the applicable statute of limitations provisions in effect at the time the injury occurred.

SA 3146. Mr. BARRASSO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 340, between lines 14 and 15, insert the following:

''(g) PENALTIES CREDITED TO INDIVIDUAL ACCOUNTS AND USED FOR PREMIUMS.—

''(1) IN GENERAL.—The Secretary shall not later than January 1, 2014, establish and implement a program under which—

''(A) if a penalty has been imposed under this section with respect to an applicable individual for months during any calendar year, the Secretary—

''(i) establishes an account on behalf of the applicable individual, and

''(ii) credits such account with an amount equal to the amount of the penalty, and

''(B) if the applicable individual subsequently becomes covered under minimum essential coverage for 1 or more months, the Secretary pays to or on behalf of the applicable individual an amount equal to the premiums paid by the individual for such coverage (or, if lesser, the balance in the account established under subparagraph (A)).

''(2) AMOUNTS AVAILABLE ONLY FOR 3 YEARS.—

''(A) IN GENERAL.—If an account is credited under paragraph (1)(A) with an amount for any calendar year, such amount shall be available for payment under paragraph (1)(B) only for premiums for minimum essential coverage for months occurring during the 3 calendar years immediately following such calendar year.

''(B) SPECIAL RULES.—For purposes of this subsection—

''(i) the Secretary need only establish 1 account for an individual, and

''(ii) amounts shall be treated as paid out of an account on a first-in, first-out basis.''.

SA 3147. Mr. BARRASSO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 339, between lines 12 and 13, insert the following:

''(5) HIGH DEDUCTIBLE HEALTH PLAN.—

''(A) IN GENERAL.—If an applicable individual—

''(i) is an employee of an employer who ceases to offer the employee the opportunity to enroll in an eligible employer-sponsored plan, or

''(ii) ceases employment with an employer and is not otherwise eligible to enroll in an eligible employer-sponsored plan,

the applicable individual may enroll in a high deductible health plan described in subparagraph (C) and such plan shall be treated as minimum essential coverage.

''(B) CONTINUED ENROLLMENT.—If an individual described in subparagraph (A) enrolls in a high deductible health plan described in subparagraph (C), such plan shall continue to be treated as minimum essential coverage with respect to that individual during any continuous period of enrollment even if the individual is otherwise eligible to enroll in an eligible employer-sponsored plan.

''(C) PLAN DESCRIBED.—A health plan is described in this subparagraph if it is a high deductible health plan (as defined in section 223(c)(2)) that meets all requirements under such section to be offered in connection with a health savings account. No requirement imposed by any provision of, or any amendment made by, the Patient Protection and Affordable Care Act shall apply with respect to the plan or issuer thereof.

SA 3148. Mr. BARRASSO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 396, between lines 8 and 9, insert the following:

Subtitle H—Sunset if Premiums Increase Too Rapidly

SEC. 1601. SUNSET.

(a) IN GENERAL.—The following requirements shall not apply to health insurance coverage and group health plans offered in the individual or group market within a State during plan years beginning after the sunset date with respect to that market:

(1) Any requirement under section 1301 of this title, section 2707 of the Public Health Service Act, or any other provision of, or amendment made by, this title that a health plan provide an essential health benefits package described in section 1302(a) of this title, including any requirement that the plan provide—

(A) for essential health benefits described in section 1302(b);

(B) in the case of a plan offered in the group market, an annual limitation on the plan's deductible described in section 1302(c)(2); and

(C) a level of coverage described in section 1302(d).

(2) The requirements of section 2701 of the Public Health Service Act (relating to limits on premiums).

(b) COORDINATION WITH QUALIFIED HEALTH PLANS AND PREMIUM TAX CREDITS AND COST-SHARING REDUCTIONS.—In the case of a State to which subsection (a) applies, the Secretary shall establish procedures for establishing which health plans shall be treated as qualified health plans for purposes of the Exchanges established within such State. Such procedures shall ensure that the aggregate amount of premium tax credits under section 36B of the Internal Revenue Code of 1986 and cost-sharing reductions under section 1402 with respect to qualified health plans in the individual market within such State does not exceed the aggregate amount of such credits and reductions that would have been allowed if subsection (a) did not apply to such State.

(c) SUNSET DATE.—For purposes of this section—

(1) IN GENERAL.—The term ''sunset date'' means, with respect to the individual or group market within a State, the first date on which the applicable State authority determines under paragraph (2) that the percentage increase in average annual premiums within such market for a calendar year over the preceding calendar year exceeds the percentage increase for such period in the Consumer Price Index for all urban consumers published by the Department of Labor.

(2) DETERMINATION.—The applicable State authority shall for each calendar year after 2013 make the determination described in paragraph (1).

(3) APPLICABLE STATE AUTHORITY.—The term ''applicable State authority'' has the meaning given such term by section 2791(d)(1) of the Public Health Service Act.

SA 3149. Mr. BARRASSO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 999, between lines 16 and 17, insert the following:

(q) BUDGET-NEUTRAL EXEMPTION OF CERTAIN PROVIDERS.—Notwithstanding the provisions of, and amendments made by, the preceding subsections of this section—

(1) such provisions and amendments shall not apply to a health care provider that—

(A) is described in section 340B(a)(4) of the Public Health Service Act or 1927(c)(1)(D)(i)(IV) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(D)(i)(IV)); and

(B) is located in an area that is not a metropolitan statistical area (as determined by the Bureau of the Census); and

(2) the Secretary of Health and Human Services shall make appropriate adjustments in the application of such provisions and amendments to ensure that the amount of expenditures under title XVIII of the Social Security Act is equal to the amount of expenditures that would have been made under such title if this subsection had not been enacted, as estimated by the Secretary.

SA 3150. Mr. BARRASSO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 186, strike line 23 and insert the following: ''plan. When establishing geographically adjusted premium rates under the preceding sentence, the Secretary shall not take into account direct graduate medical education payments, Medicare disproportionate share payments, and health information technology funding under the American Recovery and Reinvestment Act of 2009.''.

SA 3151. Mr. BARRASSO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 201, between lines 6 and 7, insert the following:

SEC. 1325. PROHIBITION ON FEDERAL BAILOUT OF A CO-OP PLAN OR A COMMUNITY HEALTH INSURANCE OPTION.

(a) PROHIBITION.—Notwithstanding any provision of (or amendment made by) this Act, no Federal funds shall paid to, or used to support the operation of (including ensuring the solvency of), a qualified health plan offered under the Consumer Operated and Oriented Plan (CO-OP) program under section 1322 or a community health insurance option under section 1323.

(b) EXCEPTIONS.—Subsection (a) shall not apply to—

(1) loans and grants under section 1322(b) or loans or payments under section 1323(c); or

(2) any premium tax credit under section 36B of the Internal Revenue Code of 1986 or any cost-sharing reduction under section 1402, or any advance payment of either, with respect to an individual enrolled in a plan or option described in subsection (a).

SA 3152. Mr. ENSIGN submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

TITLE ____—MEDICAL CARE ACCESS PROTECTION

SEC. _1. SHORT TITLE.

This title may be cited as the ''Medical Care Access Protection Act of 2009'' or the ''MCAP Act''.

SEC. _2. DEFINITIONS.

In this title:

(1) ALTERNATIVE DISPUTE RESOLUTION SYSTEM; ADR.—The term ''alternative dispute resolution system'' or ''ADR'' means a system that provides for the resolution of health care lawsuits in a manner other than through a civil action brought in a State or Federal court.

(2) CLAIMANT.—The term ''claimant'' means any person who brings a health care lawsuit, including a person who asserts or claims a right to legal or equitable contribution, indemnity or subrogation, arising out of a health care liability claim or action, and any person on whose behalf such a claim is asserted or such an action is brought, whether deceased, incompetent, or a minor.

(3) COLLATERAL SOURCE BENEFITS.—The term ''collateral source benefits'' means any amount paid or reasonably likely to be paid in the future to or on behalf of the claimant, or any service, product or other benefit provided or reasonably likely to be provided in the future to or on behalf of the claimant, as a result of the injury or wrongful death, pursuant to—

(A) any State or Federal health, sickness, income-disability, accident, or workers' compensation law;

(B) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(C) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; and

(D) any other publicly or privately funded program.

(4) COMPENSATORY DAMAGES.—The term ''compensatory damages'' means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities, damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature. Such term includes economic damages and noneconomic damages, as such terms are defined in this section.

(5) CONTINGENT FEE.—The term ''contingent fee'' includes all compensation to any person or persons which is payable only if a recovery is effected on behalf of one or more claimants.

(6) ECONOMIC DAMAGES.—The term ''economic damages'' means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment

for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities.

(7) HEALTH CARE GOODS OR SERVICES.—The term ''health care goods or services'' means any goods or services provided by a health care institution, provider, or by any individual working under the supervision of a health care provider, that relates to the diagnosis, prevention, care, or treatment of any human disease or impairment, or the assessment of the health of human beings.

(8) HEALTH CARE INSTITUTION.—The term ''health care institution'' means any entity licensed under Federal or State law to provide health care services (including but not limited to ambulatory surgical centers, assisted living facilities, emergency medical services providers, hospices, hospitals and hospital systems, nursing homes, or other entities licensed to provide such services).

(9) HEALTH CARE LAWSUIT.—The term ''health care lawsuit'' means any health care liability claim concerning the provision of health care goods or services affecting interstate commerce, or any health care liability action concerning the provision of (or the failure to provide) health care goods or services affecting interstate commerce, brought in a State or Federal court or pursuant to an alternative dispute resolution system, against a health care provider or a health care institution regardless of the theory of liability on which the claim is based, or the number of claimants, plaintiffs, defendants, or other parties, or the number of claims or causes of action, in which the claimant alleges a health care liability claim.

(10) HEALTH CARE LIABILITY ACTION.—The term ''health care liability action'' means a civil action brought in a State or Federal Court or pursuant to an alternative dispute resolution system, against a health care provider or a health care institution regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action, in which the claimant alleges a health care liability claim.

(11) HEALTH CARE LIABILITY CLAIM.—The term ''health care liability claim'' means a demand by any person, whether or not pursuant to ADR, against a health care provider or health care institution, including third-party claims, cross-claims, counter-claims, or contribution claims, which are based upon the provision of, use of, or payment for (or the failure to provide, use, or pay for) health care services, regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action.

(12) HEALTH CARE PROVIDER.—

(A) IN GENERAL.—The term ''health care provider'' means any person (including but not limited to a physician (as defined by section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r)), registered nurse, dentist, podiatrist, pharmacist, chiropractor, or optometrist) required by State or Federal law to be licensed, registered, or certified to provide health care services, and being either so licensed, registered, or certified, or exempted from such requirement by other statute or regulation.

(B) TREATMENT OF CERTAIN PROFESSIONAL ASSOCIATIONS.—For purposes of this title, a professional association that is organized under State law by an individual physician or group of physicians, a partnership or limited liability partnership formed by a group of physicians, a nonprofit health corporation certified under State law, or a company formed by a group of physicians under State law shall be treated as a health care provider under subparagraph (A).

(13) MALICIOUS INTENT TO INJURE.—The term ''malicious intent to injure'' means intentionally causing or attempting to cause physical injury other than providing health care goods or services.

(14) NONECONOMIC DAMAGES.—The term ''noneconomic damages'' means damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature.

(15) PUNITIVE DAMAGES.—The term ''punitive damages'' means damages awarded, for the purpose of punishment or deterrence, and not solely for compensatory purposes, against a health care provider or health care institution. Punitive damages are neither economic nor noneconomic damages.

(16) RECOVERY.—The term ''recovery'' means the net sum recovered after deducting any disbursements or costs incurred in connection with prosecution or settlement of the claim, including all costs paid or advanced by any person. Costs of health care incurred by the plaintiff and the attorneys' office overhead costs or charges for legal services are not deductible disbursements or costs for such purpose.

(17) STATE.—The term ''State'' means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, the Trust Territory of the Pacific Islands, and any other territory or possession of the United States, or any political subdivision thereof.

SEC. _3. INCREASED FMAP FOR MEDICAL LIABILITY REFORM.

With respect to fiscal years 2011 and 2012, the Secretary of Health and Human Services shall increase by an amount equal to 2 percent of the total amount of Federal payments estimated to be made to a State under section 1903(a)(1) of the Social Security Act (42 U.S.C. 1396b(a)(1)) for providing medical assistance for children under the State Medicaid program during the fiscal year if the Secretary determines that the State has enacted a law that substantially complies with this title.

SEC. _4. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.

(a) IN GENERAL.—Except as otherwise provided for in this section, the time for the commencement of a health care lawsuit shall be 3 years after the date of manifestation of injury or 1 year after the claimant discovers, or through the use of reasonable diligence should have discovered, the injury, whichever occurs first.

(b) GENERAL EXCEPTION.—The time for the commencement of a health care lawsuit shall not exceed 3 years after the date of manifestation of injury unless the tolling of time was delayed as a result of—

(1) fraud;

(2) intentional concealment; or

(3) the presence of a foreign body, which has no therapeutic or diagnostic purpose or effect, in the person of the injured person.

(c) MINORS.—An action by a minor shall be commenced within 3 years from the date of the alleged manifestation of injury except that if such minor is under the full age of 6 years, such action shall be commenced within 3 years of the manifestation of injury, or prior to the eighth birthday of the minor, whichever provides a longer period. Such time limitation shall be tolled for minors for any period during which a parent or guardian and a health care provider or health care institution have committed fraud or collusion in the failure to bring an action on behalf of the injured minor.

(d) RULE 11 SANCTIONS.—Whenever a Federal or State court determines (whether by motion of the parties or whether on the motion of the court) that there has been a violation of Rule 11 of the Federal Rules of Civil Procedure (or a similar violation of applicable State court rules) in a health care liability action to which this title applies, the court shall impose upon the attorneys, law firms, or pro se litigants that have violated Rule 11 or are responsible for the violation, an appropriate sanction, which shall include an order to pay the other party or parties for the reasonable expenses incurred as a direct result of the filing of the pleading, motion, or other paper that is the subject of the violation, including a reasonable attorneys' fee. Such sanction shall be sufficient to deter repetition of such conduct or comparable conduct by others similarly situated, and to compensate the party or parties injured by such conduct.

SEC. _5. COMPENSATING PATIENT INJURY.

(a) UNLIMITED AMOUNT OF DAMAGES FOR ACTUAL ECONOMIC LOSSES IN HEALTH CARE LAWSUITS.—In any health care lawsuit, nothing in this title shall limit the recovery by a claimant of the full amount of the available economic damages, notwithstanding the limitation contained in subsection (b).

(b) ADDITIONAL NONECONOMIC DAMAGES.—

(1) HEALTH CARE PROVIDERS.—In any health care lawsuit where final judgment is rendered against a health care provider, the amount of noneconomic damages recovered from the provider, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties other than a health care institution against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence.

(2) HEALTH CARE INSTITUTIONS.—

(A) SINGLE INSTITUTION.—In any health care lawsuit where final judgment is rendered against a single health care institution, the amount of noneconomic damages recovered from the institution, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence.

(B) MULTIPLE INSTITUTIONS.—In any health care lawsuit where final judgment is rendered against more than one health care institution, the amount of noneconomic damages recovered from each institution, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence, except that the total amount recovered from all such institutions in such lawsuit shall not exceed $500,000.

(c) NO DISCOUNT OF AWARD FOR NONECONOMIC DAMAGES.—In any health care lawsuit—

(1) an award for future noneconomic damages shall not be discounted to present value;

(2) the jury shall not be informed about the maximum award for noneconomic damages under subsection (b);

(3) an award for noneconomic damages in excess of the limitations provided for in subsection (b) shall be reduced either before the entry of judgment, or by amendment of the judgment after entry of judgment, and such reduction shall be made before accounting for any other reduction in damages required by law; and

(4) if separate awards are rendered for past and future noneconomic damages and the combined awards exceed the limitations described in subsection (b), the future noneconomic damages shall be reduced first.

(d) FAIR SHARE RULE.—In any health care lawsuit, each party shall be liable for that party's several share of any damages only and not for the share of any other person. Each party shall be liable only for the amount of damages allocated to such party in direct proportion to such party's percentage of responsibility. A separate judgment shall be rendered against each such party for the amount allocated to such party. For purposes of this section, the trier of fact shall determine the proportion of responsibility of each party for the claimant's harm.

SEC. __6. MAXIMIZING PATIENT RECOVERY.

(a) COURT SUPERVISION OF SHARE OF DAMAGES ACTUALLY PAID TO CLAIMANTS.—

(1) IN GENERAL.—In any health care lawsuit, the court shall supervise the arrangements for payment of damages to protect against conflicts of interest that may have the effect of reducing the amount of damages awarded that are actually paid to claimants.

(2) CONTINGENCY FEES.—

(A) IN GENERAL.—In any health care lawsuit in which the attorney for a party claims a financial stake in the outcome by virtue of a contingent fee, the court shall have the power to restrict the payment of a claimant's damage recovery to such attorney, and to redirect such damages to the claimant based upon the interests of justice and principles of equity.

(B) LIMITATION.—The total of all contingent fees for representing all claimants in a health care lawsuit shall not exceed the following limits:

(i) 40 percent of the first $50,000 recovered by the claimant(s).

(ii) 33⅓ percent of the next $50,000 recovered by the claimant(s).

(iii) 25 percent of the next $500,000 recovered by the claimant(s).

(iv) 15 percent of any amount by which the recovery by the claimant(s) is in excess of $600,000.

(b) APPLICABILITY.—

(1) IN GENERAL.—The limitations in subsection (a) shall apply whether the recovery is by judgment, settlement, mediation, arbitration, or any other form of alternative dispute resolution.

(2) MINORS.—In a health care lawsuit involving a minor or incompetent person, a court retains the authority to authorize or approve a fee that is less than the maximum permitted under this section.

(c) EXPERT WITNESSES.—

(1) REQUIREMENT.—No individual shall be qualified to testify as an expert witness concerning issues of negligence in any health care lawsuit against a defendant unless such individual—

(A) except as required under paragraph (2), is a health care professional who—

(i) is appropriately credentialed or licensed in 1 or more States to deliver health care services; and

(ii) typically treats the diagnosis or condition or provides the type of treatment under review; and

(B) can demonstrate by competent evidence that, as a result of training, education, knowledge, and experience in the evaluation, diagnosis, and treatment of the disease or injury which is the subject matter of the lawsuit against the defendant, the individual was substantially familiar with applicable standards of care and practice as they relate to the act or omission which is the subject of the lawsuit on the date of the incident.

(2) PHYSICIAN REVIEW.—In a health care lawsuit, if the claim of the plaintiff involved treatment that is recommended or provided by a physician (allopathic or osteopathic), an individual shall not be qualified to be an expert witness under this subsection with respect to issues of negligence concerning such treatment unless such individual is a physician.

(3) SPECIALTIES AND SUBSPECIALTIES.—With respect to a lawsuit described in paragraph (1), a court shall not permit an expert in one medical specialty or subspecialty to testify against a defendant in another medical specialty or subspecialty unless, in addition to a showing of substantial familiarity in accordance with paragraph (1)(B), there is a showing that the standards of care and practice in the two specialty or subspecialty fields are similar.

(4) LIMITATION.—The limitations in this subsection shall not apply to expert witnesses testifying as to the degree or permanency of medical or physical impairment.

SEC. __7. ADDITIONAL HEALTH BENEFITS.

(a) IN GENERAL.—The amount of any damages received by a claimant in any health care lawsuit shall be reduced by the court by the amount of any collateral source benefits to which the claimant is entitled, less any insurance premiums or other payments made by the claimant (or by the spouse, parent, child, or legal guardian of the claimant) to obtain or secure such benefits.

(b) PRESERVATION OF CURRENT LAW.—Where a payor of collateral source benefits has a right of recovery by reimbursement or subrogation and such right is permitted under Federal or State law, subsection (a) shall not apply.

(c) APPLICATION OF PROVISION.—This section shall apply to any health care lawsuit that is settled or resolved by a fact finder.

SEC. __8. PUNITIVE DAMAGES.

(a) PUNITIVE DAMAGES PERMITTED.—

(1) IN GENERAL.—Punitive damages may, if otherwise available under applicable State or Federal law, be awarded against any person in a health care lawsuit only if it is proven by clear and convincing evidence that such person acted with malicious intent to injure the claimant, or that such person deliberately failed to avoid unnecessary injury that such person knew the claimant was substantially certain to suffer.

(2) FILING OF LAWSUIT.—No demand for punitive damages shall be included in a health care lawsuit as initially filed. A court may allow a claimant to file an amended pleading for punitive damages only upon a motion by the claimant and after a finding by the court, upon review of supporting and opposing affidavits or after a hearing, after weighing the evidence, that the claimant has established by a substantial probability that the claimant will prevail on the claim for punitive damages.

(3) SEPARATE PROCEEDING.—At the request of any party in a health care lawsuit, the trier of fact shall consider in a separate proceeding—

(A) whether punitive damages are to be awarded and the amount of such award; and

(B) the amount of punitive damages following a determination of punitive liability.

If a separate proceeding is requested, evidence relevant only to the claim for punitive damages, as determined by applicable State law, shall be inadmissible in any proceeding to determine whether compensatory damages are to be awarded.

(4) LIMITATION WHERE NO COMPENSATORY DAMAGES ARE AWARDED.—In any health care lawsuit where no judgment for compensatory damages is rendered against a person, no punitive damages may be awarded with respect to the claim in such lawsuit against such person.

(b) DETERMINING AMOUNT OF PUNITIVE DAMAGES.—

(1) FACTORS CONSIDERED.—In determining the amount of punitive damages under this section, the trier of fact shall consider only the following:

(A) the severity of the harm caused by the conduct of such party;

(B) the duration of the conduct or any concealment of it by such party;

(C) the profitability of the conduct to such party;

(D) the number of products sold or medical procedures rendered for compensation, as the case may be, by such party, of the kind causing the harm complained of by the claimant;

(E) any criminal penalties imposed on such party, as a result of the conduct complained of by the claimant; and

(F) the amount of any civil fines assessed against such party as a result of the conduct complained of by the claimant.

(2) MAXIMUM AWARD.—The amount of punitive damages awarded in a health care lawsuit may not exceed an amount equal to two times the amount of economic damages awarded in the lawsuit or $250,000, whichever is greater. The jury shall not be informed of the limitation under the preceding sentence.

(c) LIABILITY OF HEALTH CARE PROVIDERS.—

(1) IN GENERAL.—A health care provider who prescribes, or who dispenses pursuant to a prescription, a drug, biological product, or medical device approved by the Food and Drug Administration, for an approved indication of the drug, biological product, or medical device, shall not be named as a party to a product liability lawsuit invoking such drug, biological product, or medical device and shall not be liable to a claimant in a class action lawsuit against the manufacturer, distributor, or product seller of such drug, biological product, or medical device.

(2) MEDICAL PRODUCT.—The term ''medical product'' means a drug or device intended for humans. The terms ''drug'' and ''device'' have the meanings given such terms in sections 201(g)(1) and 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321), respectively, including any component or raw material used therein, but excluding health care services.

SEC. __9. AUTHORIZATION OF PAYMENT OF FUTURE DAMAGES TO CLAIMANTS IN HEALTH CARE LAWSUITS.

(a) IN GENERAL.—In any health care lawsuit, if an award of future damages, without reduction to present value, equaling or exceeding $50,000 is made against a party with sufficient insurance or other assets to fund a periodic payment of such a judgment, the court shall, at the request of any party, enter a judgment ordering that the future damages be paid by periodic payments in accordance with the Uniform Periodic Payment of Judgments Act promulgated by the National Conference of Commissioners on Uniform State Laws.

(b) APPLICABILITY.—This section applies to all actions which have not been first set for trial or retrial before the effective date of this title.

SEC. __10. EFFECT ON OTHER LAWS.

(a) GENERAL VACCINE INJURY.—

(1) IN GENERAL.—To the extent that title XXI of the Public Health Service Act establishes a Federal rule of law applicable to a civil action brought for a vaccine-related injury or death—

(A) this title shall not affect the application of the rule of law to such an action; and

(B) any rule of law prescribed by this title in conflict with a rule of law of such title XXI shall not apply to such action.

(2) EXCEPTION.—If there is an aspect of a civil action brought for a vaccine-related injury or death to which a Federal rule of law under title XXI of the Public Health Service Act does not apply, then this title or otherwise applicable law (as determined under

this title) will apply to such aspect of such action.

(b) SMALLPOX VACCINE INJURY.—

(1) IN GENERAL.—To the extent that part C of title II of the Public Health Service Act establishes a Federal rule of law applicable to a civil action brought for a smallpox vaccine-related injury or death—

(A) this title shall not affect the application of the rule of law to such an action; and

(B) any rule of law prescribed by this title in conflict with a rule of law of such part C shall not apply to such action.

(2) EXCEPTION.—If there is an aspect of a civil action brought for a smallpox vaccine-related injury or death to which a Federal rule of law under part C of title II of the Public Health Service Act does not apply, then this title or otherwise applicable law (as determined under this title) will apply to such aspect of such action.

(c) OTHER FEDERAL LAW.—Except as provided in this section, nothing in this title shall be deemed to affect any defense available, or any limitation on liability that applies to, a defendant in a health care lawsuit or action under any other provision of Federal law.

SEC. _11. STATE FLEXIBILITY AND PROTECTION OF STATES' RIGHTS.

(a) HEALTH CARE LAWSUITS.—The provisions governing health care lawsuits set forth in this title shall preempt, subject to subsections (b) and (c), State law to the extent that State law prevents the application of any provisions of law established by or under this title. The provisions governing health care lawsuits set forth in this title supersede chapter 171 of title 28, United States Code, to the extent that such chapter—

(1) provides for a greater amount of damages or contingent fees, a longer period in which a health care lawsuit may be commenced, or a reduced applicability or scope of periodic payment of future damages, than provided in this title; or

(2) prohibits the introduction of evidence regarding collateral source benefits.

(b) PREEMPTION OF CERTAIN STATE LAWS.—No provision of this title shall be construed to preempt any State law (whether effective before, on, or after the date of the enactment of this title) that specifies a particular monetary amount of compensatory or punitive damages (or the total amount of damages) that may be awarded in a health care lawsuit, regardless of whether such monetary amount is greater or lesser than is provided for under this title, notwithstanding section _5(a).

(c) PROTECTION OF STATE'S RIGHTS AND OTHER LAWS.—

(1) IN GENERAL.—Any issue that is not governed by a provision of law established by or under this title (including the State standards of negligence) shall be governed by otherwise applicable Federal or State law.

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

(A) preempt or supersede any Federal or State law that imposes greater procedural or substantive protections (such as a shorter statute of limitations) for a health care provider or health care institution from liability, loss, or damages than those provided by this title;

(B) preempt or supercede any State law that permits and provides for the enforcement of any arbitration agreement related to a health care liability claim whether enacted prior to or after the date of enactment of this title;

(C) create a cause of action that is not otherwise available under Federal or State law; or

(D) affect the scope of preemption of any other Federal law.

SEC. _12. APPLICABILITY; EFFECTIVE DATE.

This title shall apply to any health care lawsuit brought in a Federal or State court, or subject to an alternative dispute resolution system, that is initiated on or after the date of the enactment of this title, except that any health care lawsuit arising from an injury occurring prior to the date of enactment of this title shall be governed by the applicable statute of limitations provisions in effect at the time the injury occurred.

SA 3153. Mr. BARRASSO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 339, between lines 16 and 17, insert the following:

''(g) LIMITATION.—This section shall not apply to an individual for a taxable year if such individual—

''(1) in under 30 years of age when such year begins; or

''(2) has a modified gross income that does not exceed $30,000 for such year.''.

SA 3154. Mr. BARRASSO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 2034, strike lines 8 through 15.

SA 3155. Mr. BARRASSO submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 201, between lines 6 and 7, insert the following:

SEC. 1325. ANNUAL AUDITS.

(a) IN GENERAL.—The Secretary shall enter into contracts with one or more private accounting firms for the conduct of annual audits of the CO-OP program under section 1322 and the community health insurance option program under section 1323. SUch contracts shall require that such firms submit annual reports to the Secretary concerning the results of such audits.

(b) INCLUSION IN MEDICARE TRUSTEES REPORT.—Sections 1817(b) and 1841(b) of the Social Security Act (42 U.S.C. 1395i(b); 1395t(b)) are each amended by inserting at the end the following new sentence: ''Each report submitted under paragraph (2) (beginning with the report for 2014) shall include a description of the results of the audits conducted under section 1325(a) of the Patient Protection and Affordable Care Act for the year involved.''.

SA 3156. Mr. LAUTENBERG (for himself, Mr. CARPER, and Mr. MENENDEZ) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

At the end, add the following:

TITLE X—IMPORTATION OF PRESCRIPTION DRUGS

SEC. 10001. SHORT TITLE.

This title may be cited as the ''Pharmaceutical Market Access and Drug Safety Act of 2009''.

SEC. 10002. FINDINGS.

Congress finds that—

(1) Americans unjustly pay up to 5 times more to fill their prescriptions than consumers in other countries;

(2) the United States is the largest market for pharmaceuticals in the world, yet American consumers pay the highest prices for brand pharmaceuticals in the world;

(3) a prescription drug is neither safe nor effective to an individual who cannot afford it;

(4) allowing and structuring the importation of prescription drugs to ensure access to safe and affordable drugs approved by the Food and Drug Administration will provide a level of safety to American consumers that they do not currently enjoy;

(5) American spend more than $200,000,000,000 on prescription drugs every year;

(6) the Congressional Budget Office has found that the cost of prescription drugs are between 35 to 55 percent less in other highly-developed countries than in the United States; and

(7) promoting competitive market pricing would both contribute to health care savings and allow greater access to therapy, improving health and saving lives.

SEC. 10003. REPEAL OF CERTAIN SECTION REGARDING IMPORTATION OF PRESCRIPTION DRUGS.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804.

SEC. 10004. IMPORTATION OF PRESCRIPTION DRUGS; WAIVER OF CERTAIN IMPORT RESTRICTIONS.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.), as amended by section 10003, is further amended by inserting after section 803 the following:

''SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF PRESCRIPTION DRUGS.

''(a) IMPORTATION OF PRESCRIPTION DRUGS.—

''(1) IN GENERAL.—In the case of qualifying drugs imported or offered for import into the United States from registered exporters or by registered importers—

''(A) the limitation on importation that is established in section 801(d)(1) is waived; and

''(B) the standards referred to in section 801(a) regarding admission of the drugs are subject to subsection (g) of this section (including with respect to qualifying drugs to which section 801(d)(1) does not apply).

''(2) IMPORTERS.—A qualifying drug may not be imported under paragraph (1) unless—

''(A) the drug is imported by a pharmacy, group of pharmacies, or a wholesaler that is a registered importer; or

''(B) the drug is imported by an individual for personal use or for the use of a family

member of the individual (not for resale) from a registered exporter.

''(3) RULE OF CONSTRUCTION.—This section shall apply only with respect to a drug that is imported or offered for import into the United States—

''(A) by a registered importer; or

''(B) from a registered exporter to an individual.

''(4) DEFINITIONS.—

''(A) REGISTERED EXPORTER; REGISTERED IMPORTER.—For purposes of this section:

''(i) The term 'registered exporter' means an exporter for which a registration under subsection (b) has been approved and is in effect.

''(ii) The term 'registered importer' means a pharmacy, group of pharmacies, or a wholesaler for which a registration under subsection (b) has been approved and is in effect.

''(iii) The term 'registration condition' means a condition that must exist for a registration under subsection (b) to be approved.

''(B) QUALIFYING DRUG.—For purposes of this section, the term 'qualifying drug' means a drug for which there is a corresponding U.S. label drug.

''(C) U.S. LABEL DRUG.—For purposes of this section, the term 'U.S. label drug' means a prescription drug that—

''(i) with respect to a qualifying drug, has the same active ingredient or ingredients, route of administration, dosage form, and strength as the qualifying drug;

''(ii) with respect to the qualifying drug, is manufactured by or for the person that manufactures the qualifying drug;

''(iii) is approved under section 505(c); and

''(iv) is not—

''(I) a controlled substance, as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802);

''(II) a biological product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262), including—

''(aa) a therapeutic DNA plasmid product;

''(bb) a therapeutic synthetic peptide product;

''(cc) a monoclonal antibody product for in vivo use; and

''(dd) a therapeutic recombinant DNA-derived product;

''(III) an infused drug, including a peritoneal dialysis solution;

''(IV) an injected drug;

''(V) a drug that is inhaled during surgery;

''(VI) a drug that is the listed drug referred to in 2 or more abbreviated new drug applications under which the drug is commercially marketed; or

''(VII) a sterile opthlamic drug intended for topical use on or in the eye.

''(D) OTHER DEFINITIONS.—For purposes of this section:

''(i)(I) The term 'exporter' means a person that is in the business of exporting a drug to individuals in the United States from Canada or from a permitted country designated by the Secretary under subclause (II), or that, pursuant to submitting a registration under subsection (b), seeks to be in such business.

''(II) The Secretary shall designate a permitted country under subparagraph (E) (other than Canada) as a country from which an exporter may export a drug to individuals in the United States if the Secretary determines that—

''(aa) the country has statutory or regulatory standards that are equivalent to the standards in the United States and Canada with respect to—

''(AA) the training of pharmacists;

''(BB) the practice of pharmacy; and

''(CC) the protection of the privacy of personal medical information; and

''(bb) the importation of drugs to individuals in the United States from the country will not adversely affect public health.

''(ii) The term 'importer' means a pharmacy, a group of pharmacies, or a wholesaler that is in the business of importing a drug into the United States or that, pursuant to submitting a registration under subsection (b), seeks to be in such business.

''(iii) The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

''(iv) The term 'pharmacy' means a person that—

''(I) is licensed by a State to engage in the business of selling prescription drugs at retail; and

''(II) employs 1 or more pharmacists.

''(v) The term 'prescription drug' means a drug that is described in section 503(b)(1).

''(vi) The term 'wholesaler'—

''(I) means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A); and

''(II) does not include a person authorized to import drugs under section 801(d)(1).

''(E) PERMITTED COUNTRY.—The term 'permitted country' means—

''(i) Australia;

''(ii) Canada;

''(iii) a member country of the European Union, but does not include a member country with respect to which—

''(I) the country's Annex to the Treaty of Accession to the European Union 2003 includes a transitional measure for the regulation of human pharmaceutical products that has not expired; or

''(II) the Secretary determines that the requirements described in subclauses (I) and (II) of clause (vii) will not be met by the date on which such transitional measure for the regulation of human pharmaceutical products expires;

''(iv) Japan;

''(v) New Zealand;

''(vi) Switzerland; and

''(vii) a country in which the Secretary determines the following requirements are met:

''(I) The country has statutory or regulatory requirements—

''(aa) that require the review of drugs for safety and effectiveness by an entity of the government of the country;

''(bb) that authorize the approval of only those drugs that have been determined to be safe and effective by experts employed by or acting on behalf of such entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs on the basis of adequate and well-controlled investigations, including clinical investigations, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs;

''(cc) that require the methods used in, and the facilities and controls used for the manufacture, processing, and packing of drugs in the country to be adequate to preserve their identity, quality, purity, and strength;

''(dd) for the reporting of adverse reactions to drugs and procedures to withdraw approval and remove drugs found not to be safe or effective; and

''(ee) that require the labeling and promotion of drugs to be in accordance with the approval of the drug.

''(II) The valid marketing authorization system in the country is equivalent to the systems in the countries described in clauses (i) through (vi).

''(III) The importation of drugs to the United States from the country will not adversely affect public health.

''(b) REGISTRATION OF IMPORTERS AND EXPORTERS.—

''(1) REGISTRATION OF IMPORTERS AND EXPORTERS.—A registration condition is that the importer or exporter involved (referred to in this subsection as a 'registrant') submits to the Secretary a registration containing the following:

''(A)(i) In the case of an exporter, the name of the exporter and an identification of all places of business of the exporter that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the exporter.

''(ii) In the case of an importer, the name of the importer and an identification of the places of business of the importer at which the importer initially receives a qualifying drug after importation (which shall not exceed 3 places of business except by permission of the Secretary).

''(B) Such information as the Secretary determines to be necessary to demonstrate that the registrant is in compliance with registration conditions under—

''(i) in the case of an importer, subsections (c), (d), (e), (g), and (j) (relating to the sources of imported qualifying drugs; the inspection of facilities of the importer; the payment of fees; compliance with the standards referred to in section 801(a); and maintenance of records and samples); or

''(ii) in the case of an exporter, subsections (c), (d), (f), (g), (h), (i), and (j) (relating to the sources of exported qualifying drugs; the inspection of facilities of the exporter and the marking of compliant shipments; the payment of fees; and compliance with the standards referred to in section 801(a); being licensed as a pharmacist; conditions for individual importation; and maintenance of records and samples).

''(C) An agreement by the registrant that the registrant will not under subsection (a) import or export any drug that is not a qualifying drug.

''(D) An agreement by the registrant to—

''(i) notify the Secretary of a recall or withdrawal of a qualifying drug distributed in a permitted country that the registrant has exported or imported, or intends to export or import, to the United States under subsection (a);

''(ii) provide for the return to the registrant of such drug; and

''(iii) cease, or not begin, the exportation or importation of such drug unless the Secretary has notified the registrant that exportation or importation of such drug may proceed.

''(E) An agreement by the registrant to ensure and monitor compliance with each registration condition, to promptly correct any noncompliance with such a condition, and to promptly report to the Secretary any such noncompliance.

''(F) A plan describing the manner in which the registrant will comply with the agreement under subparagraph (E).

''(G) An agreement by the registrant to enforce a contract under subsection (c)(3)(B) against a party in the chain of custody of a qualifying drug with respect to the authority of the Secretary under clauses (ii) and (iii) of that subsection.

''(H) An agreement by the registrant to notify the Secretary not more than 30 days before the registrant intends to make the change, of—

''(i) any change that the registrant intends to make regarding information provided under subparagraph (A) or (B); and

''(ii) any change that the registrant intends to make in the compliance plan under subparagraph (F).

''(I) In the case of an exporter:

''(i) An agreement by the exporter that a qualifying drug will not under subsection (a)

be exported to any individual not authorized pursuant to subsection (a)(2)(B) to be an importer of such drug.

''(ii) An agreement to post a bond, payable to the Treasury of the United States that is equal in value to the lesser of—

''(I) the value of drugs exported by the exporter to the United States in a typical 4-week period over the course of a year under this section; or

''(II) $1,000,000.

''(iii) An agreement by the exporter to comply with applicable provisions of Canadian law, or the law of the permitted country designated under subsection (a)(4)(D)(i)(II) in which the exporter is located, that protect the privacy of personal information with respect to each individual importing a prescription drug from the exporter under subsection (a)(2)(B).

''(iv) An agreement by the exporter to report to the Secretary—

''(I) not later than August 1 of each fiscal year, the total price and the total volume of drugs exported to the United States by the exporter during the 6-month period from January 1 through June 30 of that year; and

''(II) not later than January 1 of each fiscal year, the total price and the total volume of drugs exported to the United States by the exporter during the previous fiscal year.

''(J) In the case of an importer, an agreement by the importer to report to the Secretary—

''(i) not later than August 1 of each fiscal year, the total price and the total volume of drugs imported to the United States by the importer during the 6-month period from January 1 through June 30 of that fiscal year; and

''(ii) not later than January 1 of each fiscal year, the total price and the total volume of drugs imported to the United States by the importer during the previous fiscal year.

''(K) Such other provisions as the Secretary may require by regulation to protect the public health while permitting—

''(i) the importation by pharmacies, groups of pharmacies, and wholesalers as registered importers of qualifying drugs under subsection (a); and

''(ii) importation by individuals of qualifying drugs under subsection (a).

''(2) APPROVAL OR DISAPPROVAL OF REGISTRATION.—

''(A) IN GENERAL.—Not later than 90 days after the date on which a registrant submits to the Secretary a registration under paragraph (1), the Secretary shall notify the registrant whether the registration is approved or is disapproved. The Secretary shall disapprove a registration if there is reason to believe that the registrant is not in compliance with one or more registration conditions, and shall notify the registrant of such reason. In the case of a disapproved registration, the Secretary shall subsequently notify the registrant that the registration is approved if the Secretary determines that the registrant is in compliance with such conditions.

''(B) CHANGES IN REGISTRATION INFORMATION.—Not later than 30 days after receiving a notice under paragraph (1)(H) from a registrant, the Secretary shall determine whether the change involved affects the approval of the registration of the registrant under paragraph (1), and shall inform the registrant of the determination.

''(3) PUBLICATION OF CONTACT INFORMATION FOR REGISTERED EXPORTERS.—Through the Internet website of the Food and Drug Administration and a toll-free telephone number, the Secretary shall make readily available to the public a list of registered exporters, including contact information for the exporters. Promptly after the approval of a registration submitted under paragraph (1), the Secretary shall update the Internet website and the information provided through the toll-free telephone number accordingly.

''(4) SUSPENSION AND TERMINATION.—

''(A) SUSPENSION.—With respect to the effectiveness of a registration submitted under paragraph (1):

''(i) Subject to clause (ii), the Secretary may suspend the registration if the Secretary determines, after notice and opportunity for a hearing, that the registrant has failed to maintain substantial compliance with a registration condition.

''(ii) If the Secretary determines that, under color of the registration, the exporter has exported a drug or the importer has imported a drug that is not a qualifying drug, or a drug that does not comply with subsection (g)(2)(A) or (g)(4), or has exported a qualifying drug to an individual in violation of subsection (i), the Secretary shall immediately suspend the registration. A suspension under the preceding sentence is not subject to the provision by the Secretary of prior notice, and the Secretary shall provide to the registrant an opportunity for a hearing not later than 10 days after the date on which the registration is suspended.

''(iii) The Secretary may reinstate the registration, whether suspended under clause (i) or (ii), if the Secretary determines that the registrant has demonstrated that further violations of registration conditions will not occur.

''(B) TERMINATION.—The Secretary, after notice and opportunity for a hearing, may terminate the registration under paragraph (1) of a registrant if the Secretary determines that the registrant has engaged in a pattern or practice of violating 1 or more registration conditions, or if on 1 or more occasions the Secretary has under subparagraph (A)(ii) suspended the registration of the registrant. The Secretary may make the termination permanent, or for a fixed period of not less than 1 year. During the period in which the registration is terminated, any registration submitted under paragraph (1) by the registrant, or a person that is a partner in the export or import enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.

''(5) DEFAULT OF BOND.—A bond required to be posted by an exporter under paragraph (1)(I)(ii) shall be defaulted and paid to the Treasury of the United States if, after opportunity for an informal hearing, the Secretary determines that the exporter has—

''(A) exported a drug to the United States that is not a qualifying drug or that is not in compliance with subsection (g)(2)(A), (g)(4), or (i); or

''(B) failed to permit the Secretary to conduct an inspection described under subsection (d).

''(c) SOURCES OF QUALIFYING DRUGS.—A registration condition is that the exporter or importer involved agrees that a qualifying drug will under subsection (a) be exported or imported into the United States only if there is compliance with the following:

''(1) The drug was manufactured in an establishment—

''(A) required to register under subsection (h) or (i) of section 510; and

''(B)(i) inspected by the Secretary; or

''(ii) for which the Secretary has elected to rely on a satisfactory report of a good manufacturing practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent under a mutual recognition agreement, as provided for under section 510(i)(3), section 803, or part 26 of title 21, Code of Federal Regulations (or any corresponding successor rule or regulation).

''(2) The establishment is located in any country, and the establishment manufactured the drug for distribution in the United States or for distribution in 1 or more of the permitted countries (without regard to whether in addition the drug is manufactured for distribution in a foreign country that is not a permitted country).

''(3) The exporter or importer obtained the drug—

''(A) directly from the establishment; or

''(B) directly from an entity that, by contract with the exporter or importer—

''(i) provides to the exporter or importer a statement (in such form and containing such information as the Secretary may require) that, for the chain of custody from the establishment, identifies each prior sale, purchase, or trade of the drug (including the date of the transaction and the names and addresses of all parties to the transaction);

''(ii) agrees to permit the Secretary to inspect such statements and related records to determine their accuracy;

''(iii) agrees, with respect to the qualifying drugs involved, to permit the Secretary to inspect warehouses and other facilities, including records, of the entity for purposes of determining whether the facilities are in compliance with any standards under this Act that are applicable to facilities of that type in the United States; and

''(iv) has ensured, through such contractual relationships as may be necessary, that the Secretary has the same authority regarding other parties in the chain of custody from the establishment that the Secretary has under clauses (ii) and (iii) regarding such entity.

''(4)(A) The foreign country from which the importer will import the drug is a permitted country; or

''(B) The foreign country from which the exporter will export the drug is the permitted country in which the exporter is located.

''(5) During any period in which the drug was not in the control of the manufacturer of the drug, the drug did not enter any country that is not a permitted country.

''(6) The exporter or importer retains a sample of each lot of the drug for testing by the Secretary.

''(d) INSPECTION OF FACILITIES; MARKING OF SHIPMENTS.—

''(1) INSPECTION OF FACILITIES.—A registration condition is that, for the purpose of assisting the Secretary in determining whether the exporter involved is in compliance with all other registration conditions—

''(A) the exporter agrees to permit the Secretary—

''(i) to conduct onsite inspections, including monitoring on a day-to-day basis, of places of business of the exporter that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the exporter;

''(ii) to have access, including on a day-to-day basis, to—

''(I) records of the exporter that relate to the export of such drugs, including financial records; and

''(II) samples of such drugs;

''(iii) to carry out the duties described in paragraph (3); and

''(iv) to carry out any other functions determined by the Secretary to be necessary regarding the compliance of the exporter; and

''(B) the Secretary has assigned 1 or more employees of the Secretary to carry out the functions described in this subsection for the Secretary randomly, but not less than 12 times annually, on the premises of places of businesses referred to in subparagraph (A)(i),

and such an assignment remains in effect on a continuous basis.

''(2) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the exporter involved agrees to affix to each shipping container of qualifying drugs exported under subsection (a) such markings as the Secretary determines to be necessary to identify the shipment as being in compliance with all registration conditions. Markings under the preceding sentence shall—

''(A) be designed to prevent affixation of the markings to any shipping container that is not authorized to bear the markings; and

''(B) include anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies.

''(3) CERTAIN DUTIES RELATING TO EXPORTERS.—Duties of the Secretary with respect to an exporter include the following:

''(A) Inspecting, randomly, but not less than 12 times annually, the places of business of the exporter at which qualifying drugs are stored and from which qualifying drugs are shipped.

''(B) During the inspections under subparagraph (A), verifying the chain of custody of a statistically significant sample of qualifying drugs from the establishment in which the drug was manufactured to the exporter, which shall be accomplished or supplemented by the use of anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies, except that a drug that lacks such technologies from the point of manufacture shall not for that reason be excluded from importation by an exporter.

''(C) Randomly reviewing records of exports to individuals for the purpose of determining whether the drugs are being imported by the individuals in accordance with the conditions under subsection (i). Such reviews shall be conducted in a manner that will result in a statistically significant determination of compliance with all such conditions.

''(D) Monitoring the affixing of markings under paragraph (2).

''(E) Inspecting as the Secretary determines is necessary the warehouses and other facilities, including records, of other parties in the chain of custody of qualifying drugs.

''(F) Determining whether the exporter is in compliance with all other registration conditions.

''(4) PRIOR NOTICE OF SHIPMENTS.—A registration condition is that, not less than 8 hours and not more than 5 days in advance of the time of the importation of a shipment of qualifying drugs, the importer involved agrees to submit to the Secretary a notice with respect to the shipment of drugs to be imported or offered for import into the United States under subsection (a). A notice under the preceding sentence shall include—

''(A) the name and complete contact information of the person submitting the notice;

''(B) the name and complete contact information of the importer involved;

''(C) the identity of the drug, including the established name of the drug, the quantity of the drug, and the lot number assigned by the manufacturer;

''(D) the identity of the manufacturer of the drug, including the identity of the establishment at which the drug was manufactured;

''(E) the country from which the drug is shipped;

''(F) the name and complete contact information for the shipper of the drug;

''(G) anticipated arrival information, including the port of arrival and crossing location within that port, and the date and time;

''(H) a summary of the chain of custody of the drug from the establishment in which the drug was manufactured to the importer;

''(I) a declaration as to whether the Secretary has ordered that importation of the drug from the permitted country cease under subsection (g)(2)(C) or (D); and

''(J) such other information as the Secretary may require by regulation.

''(5) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the importer involved agrees, before wholesale distribution (as defined in section 503(e)) of a qualifying drug that has been imported under subsection (a), to affix to each container of such drug such markings or other technology as the Secretary determines necessary to identify the shipment as being in compliance with all registration conditions, except that the markings or other technology shall not be required on a drug that bears comparable, compatible markings or technology from the manufacturer of the drug. Markings or other technology under the preceding sentence shall—

''(A) be designed to prevent affixation of the markings or other technology to any container that is not authorized to bear the markings; and

''(B) shall include anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of such technologies.

''(6) CERTAIN DUTIES RELATING TO IMPORTERS.—Duties of the Secretary with respect to an importer include the following:

''(A) Inspecting, randomly, but not less than 12 times annually, the places of business of the importer at which a qualifying drug is initially received after importation.

''(B) During the inspections under subparagraph (A), verifying the chain of custody of a statistically significant sample of qualifying drugs from the establishment in which the drug was manufactured to the importer, which shall be accomplished or supplemented by the use of anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies, except that a drug that lacks such technologies from the point of manufacture shall not for that reason be excluded from importation by an importer.

''(C) Reviewing notices under paragraph (4).

''(D) Inspecting as the Secretary determines is necessary the warehouses and other facilities, including records of other parties in the chain of custody of qualifying drugs.

''(E) Determining whether the importer is in compliance with all other registration conditions.

''(e) IMPORTER FEES.—

''(1) REGISTRATION FEE.—A registration condition is that the importer involved pays to the Secretary a fee of $10,000 due on the date on which the importer first submits the registration to the Secretary under subsection (b).

''(2) INSPECTION FEE.—A registration condition is that the importer involved pays a fee to the Secretary in accordance with this subsection. Such fee shall be paid not later than October 1 and April 1 of each fiscal year in the amount provided for under paragraph (3).

''(3) AMOUNT OF INSPECTION FEE.—

''(A) AGGREGATE TOTAL OF FEES.—Not later than 30 days before the start of each fiscal year, the Secretary, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, shall establish an aggregate total of fees to be collected under paragraph (2) for importers for that fiscal year that is sufficient, and not more than necessary, to pay the costs for that fiscal year of administering this section with respect to registered importers, including the costs associated with—

''(i) inspecting the facilities of registered importers, and of other entities in the chain of custody of a qualifying drug as necessary, under subsection (d)(6);

''(ii) developing, implementing, and operating under such subsection an electronic system for submission and review of the notices required under subsection (d)(4) with respect to shipments of qualifying drugs under subsection (a) to assess compliance with all registration conditions when such shipments are offered for import into the United States; and

''(iii) inspecting such shipments as necessary, when offered for import into the United States to determine if such a shipment should be refused admission under subsection (g)(5).

''(B) LIMITATION.—Subject to subparagraph (C), the aggregate total of fees collected under paragraph (2) for a fiscal year shall not exceed 2.5 percent of the total price of qualifying drugs imported during that fiscal year into the United States by registered importers under subsection (a).

''(C) TOTAL PRICE OF DRUGS.—

''(i) ESTIMATE.—For the purposes of complying with the limitation described in subparagraph (B) when establishing under subparagraph (A) the aggregate total of fees to be collected under paragraph (2) for a fiscal year, the Secretary shall estimate the total price of qualifying drugs imported into the United States by registered importers during that fiscal year by adding the total price of qualifying drugs imported by each registered importer during the 6-month period from January 1 through June 30 of the previous fiscal year, as reported to the Secretary by each registered importer under subsection (b)(1)(J).

''(ii) CALCULATION.—Not later than March 1 of the fiscal year that follows the fiscal year for which the estimate under clause (i) is made, the Secretary shall calculate the total price of qualifying drugs imported into the United States by registered importers during that fiscal year by adding the total price of qualifying drugs imported by each registered importer during that fiscal year, as reported to the Secretary by each registered importer under subsection (b)(1)(J).

''(iii) ADJUSTMENT.—If the total price of qualifying drugs imported into the United States by registered importers during a fiscal year as calculated under clause (ii) is less than the aggregate total of fees collected under paragraph (2) for that fiscal year, the Secretary shall provide for a pro-rata reduction in the fee due from each registered importer on April 1 of the subsequent fiscal year so that the limitation described in subparagraph (B) is observed.

''(D) INDIVIDUAL IMPORTER FEE.—Subject to the limitation described in subparagraph (B), the fee under paragraph (2) to be paid on October 1 and April 1 by an importer shall be an amount that is proportional to a reasonable estimate by the Secretary of the semiannual share of the importer of the volume of qualifying drugs imported by importers under subsection (a).

''(4) USE OF FEES.—

''(A) IN GENERAL.—Fees collected by the Secretary under paragraphs (1) and (2) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration until expended (without fiscal year limitation), and the Secretary may, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, transfer some proportion of such fees to the appropriation account for salaries and expenses of the Bureau of Customs and Border Protection until expended (without fiscal year limitation).

''(B) AVAILABILITY.—Fees collected by the Secretary under paragraphs (1) and (2) shall be made available to the Food and Drug Administration.

''(C) SOLE PURPOSE.—Fees collected by the Secretary under paragraphs (1) and (2) are only available to the Secretary and, if transferred, to the Secretary of Homeland Security, and are for the sole purpose of paying the costs referred to in paragraph (3)(A).

''(5) COLLECTION OF FEES.—In any case where the Secretary does not receive payment of a fee assessed under paragraph (1) or (2) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(f) EXPORTER FEES.—

''(1) REGISTRATION FEE.—A registration condition is that the exporter involved pays to the Secretary a fee of $10,000 due on the date on which the exporter first submits that registration to the Secretary under subsection (b).

''(2) INSPECTION FEE.—A registration condition is that the exporter involved pays a fee to the Secretary in accordance with this subsection. Such fee shall be paid not later than October 1 and April 1 of each fiscal year in the amount provided for under paragraph (3).

''(3) AMOUNT OF INSPECTION FEE.—

''(A) AGGREGATE TOTAL OF FEES.—Not later than 30 days before the start of each fiscal year, the Secretary, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, shall establish an aggregate total of fees to be collected under paragraph (2) for exporters for that fiscal year that is sufficient, and not more than necessary, to pay the costs for that fiscal year of administering this section with respect to registered exporters, including the costs associated with—

''(i) inspecting the facilities of registered exporters, and of other entities in the chain of custody of a qualifying drug as necessary, under subsection (d)(3);

''(ii) developing, implementing, and operating under such subsection a system to screen marks on shipments of qualifying drugs under subsection (a) that indicate compliance with all registration conditions, when such shipments are offered for import into the United States; and

''(iii) screening such markings, and inspecting such shipments as necessary, when offered for import into the United States to determine if such a shipment should be refused admission under subsection (g)(5).

''(B) LIMITATION.—Subject to subparagraph (C), the aggregate total of fees collected under paragraph (2) for a fiscal year shall not exceed 2.5 percent of the total price of qualifying drugs imported during that fiscal year into the United States by registered exporters under subsection (a).

''(C) TOTAL PRICE OF DRUGS.—

''(i) ESTIMATE.—For the purposes of complying with the limitation described in subparagraph (B) when establishing under subparagraph (A) the aggregate total of fees to be collected under paragraph (2) for a fiscal year, the Secretary shall estimate the total price of qualifying drugs imported into the United States by registered exporters during that fiscal year by adding the total price of qualifying drugs exported by each registered exporter during the 6-month period from January 1 through June 30 of the previous fiscal year, as reported to the Secretary by each registered exporter under subsection (b)(1)(I)(iv).

''(ii) CALCULATION.—Not later than March 1 of the fiscal year that follows the fiscal year for which the estimate under clause (i) is made, the Secretary shall calculate the total price of qualifying drugs imported into the United States by registered exporters during that fiscal year by adding the total price of qualifying drugs exported by each registered exporter during that fiscal year, as reported to the Secretary by each registered exporter under subsection (b)(1)(I)(iv).

''(iii) ADJUSTMENT.—If the total price of qualifying drugs imported into the United States by registered exporters during a fiscal year as calculated under clause (ii) is less than the aggregate total of fees collected under paragraph (2) for that fiscal year, the Secretary shall provide for a pro-rata reduction in the fee due from each registered exporter on April 1 of the subsequent fiscal year so that the limitation described in subparagraph (B) is observed.

''(D) INDIVIDUAL EXPORTER FEE.—Subject to the limitation described in subparagraph (B), the fee under paragraph (2) to be paid on October 1 and April 1 by an exporter shall be an amount that is proportional to a reasonable estimate by the Secretary of the semiannual share of the exporter of the volume of qualifying drugs exported by exporters under subsection (a).

''(4) USE OF FEES.—

''(A) IN GENERAL.—Fees collected by the Secretary under paragraphs (1) and (2) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration until expended (without fiscal year limitation), and the Secretary may, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, transfer some proportion of such fees to the appropriation account for salaries and expenses of the Bureau of Customs and Border Protection until expended (without fiscal year limitation).

''(B) AVAILABILITY.—Fees collected by the Secretary under paragraphs (1) and (2) shall be made available to the Food and Drug Administration.

''(C) SOLE PURPOSE.—Fees collected by the Secretary under paragraphs (1) and (2) are only available to the Secretary and, if transferred, to the Secretary of Homeland Security, and are for the sole purpose of paying the costs referred to in paragraph (3)(A).

''(5) COLLECTION OF FEES.—In any case where the Secretary does not receive payment of a fee assessed under paragraph (1) or (2) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(g) COMPLIANCE WITH SECTION 801(a).—

''(1) IN GENERAL.—A registration condition is that each qualifying drug exported under subsection (a) by the registered exporter involved or imported under subsection (a) by the registered importer involved is in compliance with the standards referred to in section 801(a) regarding admission of the drug into the United States, subject to paragraphs (2), (3), and (4).

''(2) SECTION 505; APPROVAL STATUS.—

''(A) IN GENERAL.—A qualifying drug that is imported or offered for import under subsection (a) shall comply with the conditions established in the approved application under section 505(b) for the U.S. label drug as described under this subsection.

''(B) NOTICE BY MANUFACTURER; GENERAL PROVISIONS.—

''(i) IN GENERAL.—The person that manufactures a qualifying drug that is, or will be, introduced for commercial distribution in a permitted country shall in accordance with this paragraph submit to the Secretary a notice that—

''(I) includes each difference in the qualifying drug from a condition established in the approved application for the U.S. label drug beyond—

''(aa) the variations provided for in the application; and

''(bb) any difference in labeling (except ingredient labeling); or

''(II) states that there is no difference in the qualifying drug from a condition established in the approved application for the U.S. label drug beyond—

''(aa) the variations provided for in the application; and

''(bb) any difference in labeling (except ingredient labeling).

''(ii) INFORMATION IN NOTICE.—A notice under clause (i)(I) shall include the information that the Secretary may require under section 506A, any additional information the Secretary may require (which may include data on bioequivalence if such data are not required under section 506A), and, with respect to the permitted country that approved the qualifying drug for commercial distribution, or with respect to which such approval is sought, include the following:

''(I) The date on which the qualifying drug with such difference was, or will be, introduced for commercial distribution in the permitted country.

''(II) Information demonstrating that the person submitting the notice has also notified the government of the permitted country in writing that the person is submitting to the Secretary a notice under clause (i)(I), which notice describes the difference in the qualifying drug from a condition established in the approved application for the U.S. label drug.

''(III) The information that the person submitted or will submit to the government of the permitted country for purposes of obtaining approval for commercial distribution of the drug in the country which, if in a language other than English, shall be accompanied by an English translation verified to be complete and accurate, with the name, address, and a brief statement of the qualifications of the person that made the translation.

''(iii) CERTIFICATIONS.—The chief executive officer and the chief medical officer of the manufacturer involved shall each certify in the notice under clause (i) that—

''(I) the information provided in the notice is complete and true; and

''(II) a copy of the notice has been provided to the Federal Trade Commission and to the State attorneys general.

''(iv) FEE.—

''(I) IN GENERAL.—If a notice submitted under clause (i) includes a difference that would, under section 506A, require the submission of a supplemental application if made as a change to the U.S. label drug, the person that submits the notice shall pay to the Secretary a fee in the same amount as would apply if the person were paying a fee pursuant to section 736(a)(1)(A)(ii). Fees collected by the Secretary under the preceding sentence are available only to the Secretary and are for the sole purpose of paying the costs of reviewing notices submitted under clause (i).

''(II) FEE AMOUNT FOR CERTAIN YEARS.—If no fee amount is in effect under section 736(a)(1)(A)(ii) for a fiscal year, then the amount paid by a person under subclause (I) shall—

''(aa) for the first fiscal year in which no fee amount under such section in effect, be equal to the fee amount under section 736(a)(1)(A)(ii) for the most recent fiscal year for which such section was in effect, adjusted in accordance with section 736(c); and

''(bb) for each subsequent fiscal year in which no fee amount under such section is effect, be equal to the applicable fee amount for the previous fiscal year, adjusted in accordance with section 736(c).

''(v) TIMING OF SUBMISSION OF NOTICES.—

''(I) PRIOR APPROVAL NOTICES.—A notice under clause (i) to which subparagraph (C) applies shall be submitted to the Secretary not later than 120 days before the qualifying drug with the difference is introduced for commercial distribution in a permitted

country, unless the country requires that distribution of the qualifying drug with the difference begin less than 120 days after the country requires the difference.

''(II) OTHER APPROVAL NOTICES.—A notice under clause (i) to which subparagraph (D) applies shall be submitted to the Secretary not later than the day on which the qualifying drug with the difference is introduced for commercial distribution in a permitted country.

''(III) OTHER NOTICES.—A notice under clause (i) to which subparagraph (E) applies shall be submitted to the Secretary on the date that the qualifying drug is first introduced for commercial distribution in a permitted country and annually thereafter.

''(vi) REVIEW BY SECRETARY.—

''(I) IN GENERAL.—In this paragraph, the difference in a qualifying drug that is submitted in a notice under clause (i) from the U.S. label drug shall be treated by the Secretary as if it were a manufacturing change to the U.S. label drug under section 506A.

''(II) STANDARD OF REVIEW.—Except as provided in subclause (III), the Secretary shall review and approve or disapprove the difference in a notice submitted under clause (i), if required under section 506A, using the safe and effective standard for approving or disapproving a manufacturing change under section 506A.

''(III) BIOEQUIVALENCE.—If the Secretary would approve the difference in a notice submitted under clause (i) using the safe and effective standard under section 506A and if the Secretary determines that the qualifying drug is not bioequivalent to the U.S. label drug, the Secretary shall—

''(aa) include in the labeling provided under paragraph (3) a prominent advisory that the qualifying drug is safe and effective but is not bioequivalent to the U.S. label drug if the Secretary determines that such an advisory is necessary for health care practitioners and patients to use the qualifying drug safely and effectively; or

''(bb) decline to approve the difference if the Secretary determines that the availability of both the qualifying drug and the U.S. label drug would pose a threat to the public health.

''(IV) REVIEW BY THE SECRETARY.—The Secretary shall review and approve or disapprove the difference in a notice submitted under clause (i), if required under section 506A, not later than 120 days after the date on which the notice is submitted.

''(V) ESTABLISHMENT INSPECTION.—If review of such difference would require an inspection of the establishment in which the qualifying drug is manufactured—

''(aa) such inspection by the Secretary shall be authorized; and

''(bb) the Secretary may rely on a satisfactory report of a good manufacturing practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent under a mutual recognition agreement, as provided under section 510(i)(3), section 803, or part 26 of title 21, Code of Federal Regulations (or any corresponding successor rule or regulation).

''(vii) PUBLICATION OF INFORMATION ON NOTICES.—

''(I) IN GENERAL.—Through the Internet website of the Food and Drug Administration and a toll-free telephone number, the Secretary shall readily make available to the public a list of notices submitted under clause (i).

''(II) CONTENTS.—The list under subclause (I) shall include the date on which a notice is submitted and whether—

''(aa) a notice is under review;

''(bb) the Secretary has ordered that importation of the qualifying drug from a permitted country cease; or

''(cc) the importation of the drug is permitted under subsection (a).

''(III) UPDATE.—The Secretary shall promptly update the Internet website with any changes to the list.

''(C) NOTICE; DRUG DIFFERENCE REQUIRING PRIOR APPROVAL.—In the case of a notice under subparagraph (B)(i) that includes a difference that would, under subsection (c) or (d)(3)(B)(i) of section 506A, require the approval of a supplemental application before the difference could be made to the U.S. label drug the following shall occur:

''(i) Promptly after the notice is submitted, the Secretary shall notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general that the notice has been submitted with respect to the qualifying drug involved.

''(ii) If the Secretary has not made a determination whether such a supplemental application regarding the U.S. label drug would be approved or disapproved by the date on which the qualifying drug involved is to be introduced for commercial distribution in a permitted country, the Secretary shall—

''(I) order that the importation of the qualifying drug involved from the permitted country not begin until the Secretary completes review of the notice; and

''(II) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the order.

''(iii) If the Secretary determines that such a supplemental application regarding the U.S. label drug would not be approved, the Secretary shall—

''(I) order that the importation of the qualifying drug involved from the permitted country cease, or provide that an order under clause (ii), if any, remains in effect;

''(II) notify the permitted country that approved the qualifying drug for commercial distribution of the determination; and

''(III) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the determination.

''(iv) If the Secretary determines that such a supplemental application regarding the U.S. label drug would be approved, the Secretary shall—

''(I) vacate the order under clause (ii), if any;

''(II) consider the difference to be a variation provided for in the approved application for the U.S. label drug;

''(III) permit importation of the qualifying drug under subsection (a); and

''(IV) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the determination.

''(D) NOTICE; DRUG DIFFERENCE NOT REQUIRING PRIOR APPROVAL.—In the case of a notice under subparagraph (B)(i) that includes a difference that would, under section 506A(d)(3)(B)(ii), not require the approval of a supplemental application before the difference could be made to the U.S. label drug the following shall occur:

''(i) During the period in which the notice is being reviewed by the Secretary, the authority under this subsection to import the qualifying drug involved continues in effect.

''(ii) If the Secretary determines that such a supplemental application regarding the U.S. label drug would not be approved, the Secretary shall—

''(I) order that the importation of the qualifying drug involved from the permitted country cease;

''(II) notify the permitted country that approved the qualifying drug for commercial distribution of the determination; and

''(III) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the determination.

''(iii) If the Secretary determines that such a supplemental application regarding the U.S. label drug would be approved, the difference shall be considered to be a variation provided for in the approved application for the U.S. label drug.

''(E) NOTICE; DRUG DIFFERENCE NOT REQUIRING APPROVAL; NO DIFFERENCE.—In the case of a notice under subparagraph (B)(i) that includes a difference for which, under section 506A(d)(1)(A), a supplemental application would not be required for the difference to be made to the U.S. label drug, or that states that there is no difference, the Secretary—

''(i) shall consider such difference to be a variation provided for in the approved application for the U.S. label drug;

''(ii) may not order that the importation of the qualifying drug involved cease; and

''(iii) shall promptly notify registered exporters and registered importers.

''(F) DIFFERENCES IN ACTIVE INGREDIENT, ROUTE OF ADMINISTRATION, DOSAGE FORM, OR STRENGTH.—

''(i) IN GENERAL.—A person who manufactures a drug approved under section 505(b) shall submit an application under section 505(b) for approval of another drug that is manufactured for distribution in a permitted country by or for the person that manufactures the drug approved under section 505(b) if—

''(I) there is no qualifying drug in commercial distribution in permitted countries whose combined population represents at least 50 percent of the total population of all permitted countries with the same active ingredient or ingredients, route of administration, dosage form, and strength as the drug approved under section 505(b); and

''(II) each active ingredient of the other drug is related to an active ingredient of the drug approved under section 505(b), as defined in clause (v).

''(ii) APPLICATION UNDER SECTION 505(b).—The application under section 505(b) required under clause (i) shall—

''(I) request approval of the other drug for the indication or indications for which the drug approved under section 505(b) is labeled;

''(II) include the information that the person submitted to the government of the permitted country for purposes of obtaining approval for commercial distribution of the other drug in that country, which if in a language other than English, shall be accompanied by an English translation verified to be complete and accurate, with the name, address, and a brief statement of the qualifications of the person that made the translation;

''(III) include a right of reference to the application for the drug approved under section 505(b); and

''(IV) include such additional information as the Secretary may require.

''(iii) TIMING OF SUBMISSION OF APPLICATION.—An application under section 505(b) required under clause (i) shall be submitted to the Secretary not later than the day on which the information referred to in clause (ii)(II) is submitted to the government of the permitted country.

''(iv) NOTICE OF DECISION ON APPLICATION.—The Secretary shall promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of a determination to approve or to disapprove an application under section 505(b) required under clause (i).

''(v) RELATED ACTIVE INGREDIENTS.—For purposes of clause (i)(II), 2 active ingredients are related if they are—

''(I) the same; or

''(II) different salts, esters, or complexes of the same moiety.

''(3) SECTION 502; LABELING.—

''(A) IMPORTATION BY REGISTERED IMPORTER.—

''(i) IN GENERAL.—In the case of a qualifying drug that is imported or offered for import by a registered importer, such drug shall be considered to be in compliance with section 502 and the labeling requirements under the approved application for the U.S. label drug if the qualifying drug bears—

''(I) a copy of the labeling approved for the U.S. label drug under section 505, without regard to whether the copy bears any trademark involved;

''(II) the name of the manufacturer and location of the manufacturer;

''(III) the lot number assigned by the manufacturer;

''(IV) the name, location, and registration number of the importer; and

''(V) the National Drug Code number assigned to the qualifying drug by the Secretary.

''(ii) REQUEST FOR COPY OF THE LABELING.—The Secretary shall provide such copy to the registered importer involved, upon request of the importer.

''(iii) REQUESTED LABELING.—The labeling provided by the Secretary under clause (ii) shall—

''(I) include the established name, as defined in section 502(e)(3), for each active ingredient in the qualifying drug;

''(II) not include the proprietary name of the U.S. label drug or any active ingredient thereof;

''(III) if required under paragraph (2)(B)(vi)(III), a prominent advisory that the qualifying drug is safe and effective but not bioequivalent to the U.S. label drug; and

''(IV) if the inactive ingredients of the qualifying drug are different from the inactive ingredients for the U.S. label drug, include—

''(aa) a prominent notice that the ingredients of the qualifying drug differ from the ingredients of the U.S. label drug and that the qualifying drug must be dispensed with an advisory to people with allergies about this difference and a list of ingredients; and

''(bb) a list of the ingredients of the qualifying drug as would be required under section 502(e).

''(B) IMPORTATION BY INDIVIDUAL.—

''(i) IN GENERAL.—In the case of a qualifying drug that is imported or offered for import by a registered exporter to an individual, such drug shall be considered to be in compliance with section 502 and the labeling requirements under the approved application for the U.S. label drug if the packaging and labeling of the qualifying drug complies with all applicable regulations promulgated under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.) and the labeling of the qualifying drug includes—

''(I) directions for use by the consumer;

''(II) the lot number assigned by the manufacturer;

''(III) the name and registration number of the exporter;

''(IV) if required under paragraph (2)(B)(vi)(III), a prominent advisory that the drug is safe and effective but not bioequivalent to the U.S. label drug;

''(V) if the inactive ingredients of the drug are different from the inactive ingredients for the U.S. label drug—

''(aa) a prominent advisory that persons with an allergy should check the ingredient list of the drug because the ingredients of the drug differ from the ingredients of the U.S. label drug; and

''(bb) a list of the ingredients of the drug as would be required under section 502(e); and

''(VI) a copy of any special labeling that would be required by the Secretary had the U.S. label drug been dispensed by a pharmacist in the United States, without regard to whether the special labeling bears any trademark involved.

''(ii) PACKAGING.—A qualifying drug offered for import to an individual by an exporter under this section that is packaged in a unit-of-use container (as those items are defined in the United States Pharmacopeia and National Formulary) shall not be repackaged, provided that—

''(I) the packaging complies with all applicable regulations under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.); or

''(II) the consumer consents to waive the requirements of such Act, after being informed that the packaging does not comply with such Act and that the exporter will provide the drug in packaging that is compliant at no additional cost.

''(iii) REQUEST FOR COPY OF SPECIAL LABELING AND INGREDIENT LIST.—The Secretary shall provide to the registered exporter involved a copy of the special labeling, the advisory, and the ingredient list described under clause (i), upon request of the exporter.

''(iv) REQUESTED LABELING AND INGREDIENT LIST.—The labeling and ingredient list provided by the Secretary under clause (iii) shall—

''(I) include the established name, as defined in section 502(e)(3), for each active ingredient in the drug; and

''(II) not include the proprietary name of the U.S. label drug or any active ingredient thereof.

''(4) SECTION 501; ADULTERATION.—A qualifying drug that is imported or offered for import under subsection (a) shall be considered to be in compliance with section 501 if the drug is in compliance with subsection (c).

''(5) STANDARDS FOR REFUSING ADMISSION.—A drug exported under subsection (a) from a registered exporter or imported by a registered importer may be refused admission into the United States if 1 or more of the following applies:

''(A) The drug is not a qualifying drug.

''(B) A notice for the drug required under paragraph (2)(B) has not been submitted to the Secretary.

''(C) The Secretary has ordered that importation of the drug from the permitted country cease under subparagraph (C) or (D) of paragraph (2).

''(D) The drug does not comply with paragraph (3) or (4).

''(E) The shipping container appears damaged in a way that may affect the strength, quality, or purity of the drug.

''(F) The Secretary becomes aware that—

''(i) the drug may be counterfeit;

''(ii) the drug may have been prepared, packed, or held under insanitary conditions; or

''(iii) the methods used in, or the facilities or controls used for, the manufacturing, processing, packing, or holding of the drug do not conform to good manufacturing practice.

''(G) The Secretary has obtained an injunction under section 302 that prohibits the distribution of the drug in interstate commerce.

''(H) The Secretary has under section 505(e) withdrawn approval of the drug.

''(I) The manufacturer of the drug has instituted a recall of the drug.

''(J) If the drug is imported or offered for import by a registered importer without submission of a notice in accordance with subsection (d)(4).

''(K) If the drug is imported or offered for import from a registered exporter to an individual and 1 or more of the following applies:

''(i) The shipping container for such drug does not bear the markings required under subsection (d)(2).

''(ii) The markings on the shipping container appear to be counterfeit.

''(iii) The shipping container or markings appear to have been tampered with.

''(h) EXPORTER LICENSURE IN PERMITTED COUNTRY.—A registration condition is that the exporter involved agrees that a qualifying drug will be exported to an individual only if the Secretary has verified that—

''(1) the exporter is authorized under the law of the permitted country in which the exporter is located to dispense prescription drugs; and

''(2) the exporter employs persons that are licensed under the law of the permitted country in which the exporter is located to dispense prescription drugs in sufficient number to dispense safely the drugs exported by the exporter to individuals, and the exporter assigns to those persons responsibility for dispensing such drugs to individuals.

''(i) INDIVIDUALS; CONDITIONS FOR IMPORTATION.—

''(1) IN GENERAL.—For purposes of subsection (a)(2)(B), the importation of a qualifying drug by an individual is in accordance with this subsection if the following conditions are met:

''(A) The drug is accompanied by a copy of a prescription for the drug, which prescription—

''(i) is valid under applicable Federal and State laws; and

''(ii) was issued by a practitioner who, under the law of a State of which the individual is a resident, or in which the individual receives care from the practitioner who issues the prescription, is authorized to administer prescription drugs.

''(B) The drug is accompanied by a copy of the documentation that was required under the law or regulations of the permitted country in which the exporter is located, as a condition of dispensing the drug to the individual.

''(C) The copies referred to in subparagraphs (A)(i) and (B) are marked in a manner sufficient—

''(i) to indicate that the prescription, and the equivalent document in the permitted country in which the exporter is located, have been filled; and

''(ii) to prevent a duplicative filling by another pharmacist.

''(D) The individual has provided to the registered exporter a complete list of all drugs used by the individual for review by the individuals who dispense the drug.

''(E) The quantity of the drug does not exceed a 90-day supply.

''(F) The drug is not an ineligible subpart H drug. For purposes of this section, a prescription drug is an 'ineligible subpart H drug' if the drug was approved by the Secretary under subpart H of part 314 of title 21, Code of Federal Regulations (relating to accelerated approval), with restrictions under section 520 of such part to assure safe use, and the Secretary has published in the Federal Register a notice that the Secretary has determined that good cause exists to prohibit the drug from being imported pursuant to this subsection.

''(2) NOTICE REGARDING DRUG REFUSED ADMISSION.—If a registered exporter ships a drug to an individual pursuant to subsection (a)(2)(B) and the drug is refused admission to the United States, a written notice shall be

sent to the individual and to the exporter that informs the individual and the exporter of such refusal and the reason for the refusal.

''(j) MAINTENANCE OF RECORDS AND SAMPLES.—

''(1) IN GENERAL.—A registration condition is that the importer or exporter involved shall—

''(A) maintain records required under this section for not less than 2 years; and

''(B) maintain samples of each lot of a qualifying drug required under this section for not more than 2 years.

''(2) PLACE OF RECORD MAINTENANCE.—The records described under paragraph (1) shall be maintained—

''(A) in the case of an importer, at the place of business of the importer at which the importer initially receives the qualifying drug after importation; or

''(B) in the case of an exporter, at the facility from which the exporter ships the qualifying drug to the United States.

''(k) DRUG RECALLS.—

''(1) MANUFACTURERS.—A person that manufactures a qualifying drug imported from a permitted country under this section shall promptly inform the Secretary—

''(A) if the drug is recalled or withdrawn from the market in a permitted country;

''(B) how the drug may be identified, including lot number; and

''(C) the reason for the recall or withdrawal.

''(2) SECRETARY.—With respect to each permitted country, the Secretary shall—

''(A) enter into an agreement with the government of the country to receive information about recalls and withdrawals of qualifying drugs in the country; or

''(B) monitor recalls and withdrawals of qualifying drugs in the country using any information that is available to the public in any media.

''(3) NOTICE.—The Secretary may notify, as appropriate, registered exporters, registered importers, wholesalers, pharmacies, or the public of a recall or withdrawal of a qualifying drug in a permitted country.

''(l) DRUG LABELING AND PACKAGING.—

''(1) IN GENERAL.—When a qualifying drug that is imported into the United States by an importer under subsection (a) is dispensed by a pharmacist to an individual, the pharmacist shall provide that the packaging and labeling of the drug complies with all applicable regulations promulgated under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.) and shall include with any other labeling provided to the individual the following:

''(A) The lot number assigned by the manufacturer.

''(B) The name and registration number of the importer.

''(C) If required under paragraph (2)(B)(vi)(III) of subsection (g), a prominent advisory that the drug is safe and effective but not bioequivalent to the U.S. label drug.

''(D) If the inactive ingredients of the drug are different from the inactive ingredients for the U.S. label drug—

''(i) a prominent advisory that persons with allergies should check the ingredient list of the drug because the ingredients of the drug differ from the ingredients of the U.S. label drug; and

''(ii) a list of the ingredients of the drug as would be required under section 502(e).

''(2) PACKAGING.—A qualifying drug that is packaged in a unit-of-use container (as those terms are defined in the United States Pharmacopeia and National Formulary) shall not be repackaged, provided that—

''(A) the packaging complies with all applicable regulations under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.); or

''(B) the consumer consents to waive the requirements of such Act, after being informed that the packaging does not comply with such Act and that the pharmacist will provide the drug in packaging that is compliant at no additional cost.

''(m) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, this section does not authorize the importation into the United States of a qualifying drug donated or otherwise supplied for free or at nominal cost by the manufacturer of the drug to a charitable or humanitarian organization, including the United Nations and affiliates, or to a government of a foreign country.

''(n) UNFAIR AND DISCRIMINATORY ACTS AND PRACTICES.—

''(1) IN GENERAL.—It is unlawful for a manufacturer, directly or indirectly (including by being a party to a licensing agreement or other agreement), to—

''(A) discriminate by charging a higher price for a prescription drug sold to a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section than the price that is charged, inclusive of rebates or other incentives to the permitted country or other person, to another person that is in the same country and that does not export a qualifying drug into the United States under this section;

''(B) discriminate by charging a higher price for a prescription drug sold to a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section than the price that is charged to another person in the United States that does not import a qualifying drug under this section, or that does not distribute, sell, or use such a drug;

''(C) discriminate by denying, restricting, or delaying supplies of a prescription drug to a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section or to a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section;

''(D) discriminate by publicly, privately, or otherwise refusing to do business with a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section or with a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section;

''(E) knowingly fail to submit a notice under subsection (g)(2)(B)(i), knowingly fail to submit such a notice on or before the date specified in subsection (g)(2)(B)(v) or as otherwise required under paragraphs (3), (4), and (5) of section 10004(e) of the Pharmaceutical Market Access and Drug Safety Act of 2009, knowingly submit such a notice that makes a materially false, fictitious, or fraudulent statement, or knowingly fail to provide promptly any information requested by the Secretary to review such a notice;

''(F) knowingly fail to submit an application required under subsection (g)(2)(F), knowingly fail to submit such an application on or before the date specified in subsection (g)(2)(F)(iii), knowingly submit such an application that makes a materially false, fictitious, or fraudulent statement, or knowingly fail to provide promptly any information requested by the Secretary to review such an application;

''(G) cause there to be a difference (including a difference in active ingredient, route of administration, dosage form, strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) between a prescription drug for distribution in the United States and the drug for distribution in a permitted country;

''(H) refuse to allow an inspection authorized under this section of an establishment that manufactures a qualifying drug that is, or will be, introduced for commercial distribution in a permitted country;

''(I) fail to conform to the methods used in, or the facilities used for, the manufacturing, processing, packing, or holding of a qualifying drug that is, or will be, introduced for commercial distribution in a permitted country to good manufacturing practice under this Act;

''(J) become a party to a licensing agreement or other agreement related to a qualifying drug that fails to provide for compliance with all requirements of this section with respect to such drug;

''(K) enter into a contract that restricts, prohibits, or delays the importation of a qualifying drug under this section;

''(L) engage in any other action to restrict, prohibit, or delay the importation of a qualifying drug under this section; or

''(M) engage in any other action that the Federal Trade Commission determines to discriminate against a person that engages or attempts to engage in the importation of a qualifying drug under this section.

''(2) REFERRAL OF POTENTIAL VIOLATIONS.—The Secretary shall promptly refer to the Federal Trade Commission each potential violation of subparagraph (E), (F), (G), (H), or (I) of paragraph (1) that becomes known to the Secretary.

''(3) AFFIRMATIVE DEFENSE.—

''(A) DISCRIMINATION.—It shall be an affirmative defense to a charge that a manufacturer has discriminated under subparagraph (A), (B), (C), (D), or (M) of paragraph (1) that the higher price charged for a prescription drug sold to a person, the denial, restriction, or delay of supplies of a prescription drug to a person, the refusal to do business with a person, or other discriminatory activity against a person, is not based, in whole or in part, on—

''(i) the person exporting or importing a qualifying drug into the United States under this section; or

''(ii) the person distributing, selling, or using a qualifying drug imported into the United States under this section.

''(B) DRUG DIFFERENCES.—It shall be an affirmative defense to a charge that a manufacturer has caused there to be a difference described in subparagraph (G) of paragraph (1) that—

''(i) the difference was required by the country in which the drug is distributed;

''(ii) the Secretary has determined that the difference was necessary to improve the safety or effectiveness of the drug;

''(iii) the person manufacturing the drug for distribution in the United States has given notice to the Secretary under subsection (g)(2)(B)(i) that the drug for distribution in the United States is not different from a drug for distribution in permitted countries whose combined population represents at least 50 percent of the total population of all permitted countries; or

''(iv) the difference was not caused, in whole or in part, for the purpose of restricting importation of the drug into the United States under this section.

''(4) EFFECT OF SUBSECTION.—

''(A) SALES IN OTHER COUNTRIES.—This subsection applies only to the sale or distribution of a prescription drug in a country if the manufacturer of the drug chooses to sell or distribute the drug in the country. Nothing in this subsection shall be construed to compel the manufacturer of a drug to distribute or sell the drug in a country.

''(B) DISCOUNTS TO INSURERS, HEALTH PLANS, PHARMACY BENEFIT MANAGERS, AND COVERED ENTITIES.—Nothing in this subsection shall be construed to—

''(i) prevent or restrict a manufacturer of a prescription drug from providing discounts to an insurer, health plan, pharmacy benefit manager in the United States, or covered entity in the drug discount program under section 340B of the Public Health Service Act (42 U.S.C. 256b) in return for inclusion of the drug on a formulary;

''(ii) require that such discounts be made available to other purchasers of the prescription drug; or

''(iii) prevent or restrict any other measures taken by an insurer, health plan, or pharmacy benefit manager to encourage consumption of such prescription drug.

''(C) CHARITABLE CONTRIBUTIONS.—Nothing in this subsection shall be construed to—

''(i) prevent a manufacturer from donating a prescription drug, or supplying a prescription drug at nominal cost, to a charitable or humanitarian organization, including the United Nations and affiliates, or to a government of a foreign country; or

''(ii) apply to such donations or supplying of a prescription drug.

''(5) ENFORCEMENT.—

''(A) UNFAIR OR DECEPTIVE ACT OR PRACTICE.—A violation of this subsection shall be treated as a violation of a rule defining an unfair or deceptive act or practice prescribed under section 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57a(a)(1)(B)).

''(B) ACTIONS BY THE COMMISSION.—The Federal Trade Commission—

''(i) shall enforce this subsection in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this section; and

''(ii) may seek monetary relief threefold the damages sustained, in addition to any other remedy available to the Federal Trade Commission under the Federal Trade Commission Act (15 U.S.C. 41 et seq.).

''(6) ACTIONS BY STATES.—

''(A) IN GENERAL.—

''(i) CIVIL ACTIONS.—In any case in which the attorney general of a State has reason to believe that an interest of the residents of that State have been adversely affected by any manufacturer that violates paragraph (1), the attorney general of a State may bring a civil action on behalf of the residents of the State, and persons doing business in the State, in a district court of the United States of appropriate jurisdiction to—

''(I) enjoin that practice;

''(II) enforce compliance with this subsection;

''(III) obtain damages, restitution, or other compensation on behalf of residents of the State and persons doing business in the State, including threefold the damages; or

''(IV) obtain such other relief as the court may consider to be appropriate.

''(ii) NOTICE.—

''(I) IN GENERAL.—Before filing an action under clause (i), the attorney general of the State involved shall provide to the Federal Trade Commission—

''(aa) written notice of that action; and

''(bb) a copy of the complaint for that action.

''(II) EXEMPTION.—Subclause (I) shall not apply with respect to the filing of an action by an attorney general of a State under this paragraph, if the attorney general determines that it is not feasible to provide the notice described in that subclause before filing of the action. In such case, the attorney general of a State shall provide notice and a copy of the complaint to the Federal Trade Commission at the same time as the attorney general files the action.

''(B) INTERVENTION.—

''(i) IN GENERAL.—On receiving notice under subparagraph (A)(ii), the Federal Trade Commission shall have the right to intervene in the action that is the subject of the notice.

''(ii) EFFECT OF INTERVENTION.—If the Federal Trade Commission intervenes in an action under subparagraph (A), it shall have the right—

''(I) to be heard with respect to any matter that arises in that action; and

''(II) to file a petition for appeal.

''(C) CONSTRUCTION.—For purposes of bringing any civil action under subparagraph (A), nothing in this subsection shall be construed to prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of that State to—

''(i) conduct investigations;

''(ii) administer oaths or affirmations; or

''(iii) compel the attendance of witnesses or the production of documentary and other evidence.

''(D) ACTIONS BY THE COMMISSION.—In any case in which an action is instituted by or on behalf of the Federal Trade Commission for a violation of paragraph (1), a State may not, during the pendency of that action, institute an action under subparagraph (A) for the same violation against any defendant named in the complaint in that action.

''(E) VENUE.—Any action brought under subparagraph (A) may be brought in the district court of the United States that meets applicable requirements relating to venue under section 1391 of title 28, United States Code.

''(F) SERVICE OF PROCESS.—In an action brought under subparagraph (A), process may be served in any district in which the defendant—

''(i) is an inhabitant; or

''(ii) may be found.

''(G) MEASUREMENT OF DAMAGES.—In any action under this paragraph to enforce a cause of action under this subsection in which there has been a determination that a defendant has violated a provision of this subsection, damages may be proved and assessed in the aggregate by statistical or sampling methods, by the computation of illegal overcharges or by such other reasonable system of estimating aggregate damages as the court in its discretion may permit without the necessity of separately proving the individual claim of, or amount of damage to, persons on whose behalf the suit was brought.

''(H) EXCLUSION ON DUPLICATIVE RELIEF.—The district court shall exclude from the amount of monetary relief awarded in an action under this paragraph brought by the attorney general of a State any amount of monetary relief which duplicates amounts which have been awarded for the same injury.

''(7) EFFECT ON ANTITRUST LAWS.—Nothing in this subsection shall be construed to modify, impair, or supersede the operation of the antitrust laws. For the purpose of this subsection, the term 'antitrust laws' has the meaning given it in the first section of the Clayton Act, except that it includes section 5 of the Federal Trade Commission Act to the extent that such section 5 applies to unfair methods of competition.

''(8) MANUFACTURER.—In this subsection, the term 'manufacturer' means any entity, including any affiliate or licensee of that entity, that is engaged in—

''(A) the production, preparation, propagation, compounding, conversion, or processing of a prescription drug, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

''(B) the packaging, repackaging, labeling, relabeling, or distribution of a prescription drug.''.

(b) PROHIBITED ACTS.—The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 301 (21 U.S.C. 331), by striking paragraph (aa) and inserting the following:

''(aa)(1) The sale or trade by a pharmacist, or by a business organization of which the pharmacist is a part, of a qualifying drug that under section 804(a)(2)(A) was imported by the pharmacist, other than—

''(A) a sale at retail made pursuant to dispensing the drug to a customer of the pharmacist or organization; or

''(B) a sale or trade of the drug to a pharmacy or a wholesaler registered to import drugs under section 804.

''(2) The sale or trade by an individual of a qualifying drug that under section 804(a)(2)(B) was imported by the individual.

''(3) The making of a materially false, fictitious, or fraudulent statement or representation, or a material omission, in a notice under clause (i) of section 804(g)(2)(B) or in an application required under section 804(g)(2)(F), or the failure to submit such a notice or application.

''(4) The importation of a drug in violation of a registration condition or other requirement under section 804, the falsification of any record required to be maintained, or provided to the Secretary, under such section, or the violation of any registration condition or other requirement under such section.''; and

(2) in section 303(a) (21 U.S.C. 333(a)), by striking paragraph (6) and inserting the following:

''(6) Notwithstanding subsection (a), any person that knowingly violates section 301(i)(2) or (3) or section 301(aa)(4) shall be imprisoned not more than 10 years, or fined in accordance with title 18, United States Code, or both.''.

(c) AMENDMENT OF CERTAIN PROVISIONS.—

(1) IN GENERAL.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by striking subsection (g) and inserting the following:

''(g) With respect to a prescription drug that is imported or offered for import into the United States by an individual who is not in the business of such importation, that is not shipped by a registered exporter under section 804, and that is refused admission under subsection (a), the Secretary shall notify the individual that—

''(1) the drug has been refused admission because the drug was not a lawful import under section 804;

''(2) the drug is not otherwise subject to a waiver of the requirements of subsection (a);

''(3) the individual may under section 804 lawfully import certain prescription drugs from exporters registered with the Secretary under section 804; and

''(4) the individual can find information about such importation, including a list of registered exporters, on the Internet website of the Food and Drug Administration or through a toll-free telephone number required under section 804.''.

(2) ESTABLISHMENT REGISTRATION.—Section 510(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)) is amended in paragraph (1) by inserting after ''import into the United States'' the following: '', including a drug that is, or may be, imported or offered for import into the United States under section 804,''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date that is 90 days after the date of enactment of this Act.

(d) EXHAUSTION.—

(1) IN GENERAL.—Section 271 of title 35, United States Code, is amended—

(A) by redesignating subsections (h) and (i) as (i) and (j), respectively; and

(B) by inserting after subsection (g) the following:

''(h) It shall not be an act of infringement to use, offer to sell, or sell within the United States or to import into the United States any patented invention under section 804 of the Federal Food, Drug, and Cosmetic Act that was first sold abroad by or under authority of the owner or licensee of such patent.''.

(2) RULE OF CONSTRUCTION.—Nothing in the amendment made by paragraph (1) shall be construed to affect the ability of a patent owner or licensee to enforce their patent, subject to such amendment.

(e) EFFECT OF SECTION 804.—

(1) IN GENERAL.—Section 804 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall permit the importation of qualifying drugs (as defined in such section 804) into the United States without regard to the status of the issuance of implementing regulations—

(A) from exporters registered under such section 804 on the date that is 90 days after the date of enactment of this Act; and

(B) from permitted countries, as defined in such section 804, by importers registered under such section 804 on the date that is 1 year after the date of enactment of this Act.

(2) REVIEW OF REGISTRATION BY CERTAIN EXPORTERS.—

(A) REVIEW PRIORITY.—In the review of registrations submitted under subsection (b) of such section 804, registrations submitted by entities in Canada that are significant exporters of prescription drugs to individuals in the United States as of the date of enactment of this Act will have priority during the 90 day period that begins on such date of enactment.

(B) PERIOD FOR REVIEW.—During such 90-day period, the reference in subsection (b)(2)(A) of such section 804 to 90 days (relating to approval or disapproval of registrations) is, as applied to such entities, deemed to be 30 days.

(C) LIMITATION.—That an exporter in Canada exports, or has exported, prescription drugs to individuals in the United States on or before the date that is 90 days after the date of enactment of this Act shall not serve as a basis, in whole or in part, for disapproving a registration under such section 804 from the exporter.

(D) FIRST YEAR LIMIT ON NUMBER OF EXPORTERS.—During the 1-year period beginning on the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') may limit the number of registered exporters under such section 804 to not less than 50, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(E) SECOND YEAR LIMIT ON NUMBER OF EXPORTERS.—During the 1-year period beginning on the date that is 1 year after the date of enactment of this Act, the Secretary may limit the number of registered exporters under such section 804 to not less than 100, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(F) FURTHER LIMIT ON NUMBER OF EXPORTERS.—During any 1-year period beginning on a date that is 2 or more years after the date of enactment of this Act, the Secretary may limit the number of registered exporters under such section 804 to not less than 25 more than the number of such exporters during the previous 1-year period, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(3) LIMITS ON NUMBER OF IMPORTERS.—

(A) FIRST YEAR LIMIT ON NUMBER OF IMPORTERS.—During the 1-year period beginning on the date that is 1 year after the date of enactment of this Act, the Secretary may limit the number of registered importers under such section 804 to not less than 100 (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups), so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs imported into the United States.

(B) SECOND YEAR LIMIT ON NUMBER OF IMPORTERS.—During the 1-year period beginning on the date that is 2 years after the date of enactment of this Act, the Secretary may limit the number of registered importers under such section 804 to not less than 200 (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups), so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs into the United States.

(C) FURTHER LIMIT ON NUMBER OF IMPORTERS.—During any 1-year period beginning on a date that is 3 or more years after the date of enactment of this Act, the Secretary may limit the number of registered importers under such section 804 to not less than 50 more (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups) than the number of such importers during the previous 1-year period, so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs to the United States.

(4) NOTICES FOR DRUGS FOR IMPORT FROM CANADA.—The notice with respect to a qualifying drug introduced for commercial distribution in Canada as of the date of enactment of this Act that is required under subsection (g)(2)(B)(i) of such section 804 shall be submitted to the Secretary not later than 30 days after the date of enactment of this Act if—

(A) the U.S. label drug (as defined in such section 804) for the qualifying drug is 1 of the 100 prescription drugs with the highest dollar volume of sales in the United States based on the 12 calendar month period most recently completed before the date of enactment of this Act; or

(B) the notice is a notice under subsection (g)(2)(B)(i)(II) of such section 804.

(5) NOTICE FOR DRUGS FOR IMPORT FROM OTHER COUNTRIES.—The notice with respect to a qualifying drug introduced for commercial distribution in a permitted country other than Canada as of the date of enactment of this Act that is required under subsection (g)(2)(B)(i) of such section 804 shall be submitted to the Secretary not later than 180 days after the date of enactment of this Act if—

(A) the U.S. label drug for the qualifying drug is 1 of the 100 prescription drugs with the highest dollar volume of sales in the United States based on the 12 calendar month period that is first completed on the date that is 120 days after the date of enactment of this Act; or

(B) the notice is a notice under subsection (g)(2)(B)(i)(II) of such section 804.

(6) NOTICE FOR OTHER DRUGS FOR IMPORT.—

(A) GUIDANCE ON SUBMISSION DATES.—The Secretary shall by guidance establish a series of submission dates for the notices under subsection (g)(2)(B)(i) of such section 804 with respect to qualifying drugs introduced for commercial distribution as of the date of enactment of this Act and that are not required to be submitted under paragraph (4) or (5).

(B) CONSISTENT AND EFFICIENT USE OF RESOURCES.—The Secretary shall establish the dates described under subparagraph (A) so that such notices described under subparagraph (A) are submitted and reviewed at a rate that allows consistent and efficient use of the resources and staff available to the Secretary for such reviews. The Secretary may condition the requirement to submit such a notice, and the review of such a notice, on the submission by a registered exporter or a registered importer to the Secretary of a notice that such exporter or importer intends to import such qualifying drug to the United States under such section 804.

(C) PRIORITY FOR DRUGS WITH HIGHER SALES.—The Secretary shall establish the dates described under subparagraph (A) so that the Secretary reviews the notices described under such subparagraph with respect to qualifying drugs with higher dollar volume of sales in the United States before the notices with respect to drugs with lower sales in the United States.

(7) NOTICES FOR DRUGS APPROVED AFTER EFFECTIVE DATE.—The notice required under subsection (g)(2)(B)(i) of such section 804 for a qualifying drug first introduced for commercial distribution in a permitted country (as defined in such section 804) after the date of enactment of this Act shall be submitted to and reviewed by the Secretary as provided under subsection (g)(2)(B) of such section 804, without regard to paragraph (4), (5), or (6).

(8) REPORT.—Beginning with the first full fiscal year after the date of enactment of this Act, not later than 90 days after the end of each fiscal year during which the Secretary reviews a notice referred to in paragraph (4), (5), or (6), the Secretary shall submit a report to Congress concerning the progress of the Food and Drug Administration in reviewing the notices referred to in paragraphs (4), (5), and (6).

(9) USER FEES.—

(A) EXPORTERS.—When establishing an aggregate total of fees to be collected from exporters under subsection (f)(2) of such section 804, the Secretary shall, under subsection (f)(3)(C)(i) of such section 804, estimate the total price of drugs imported under subsection (a) of such section 804 into the United States by registered exporters during the first fiscal year in which this title takes effect to be an amount equal to the amount which bears the same ratio to $1,000,000,000 as the number of days in such fiscal year during which this title is effective bears to 365.

(B) IMPORTERS.—When establishing an aggregate total of fees to be collected from importers under subsection (e)(2) of such section 804, the Secretary shall, under subsection (e)(3)(C)(i) of such section 804, estimate the total price of drugs imported under subsection (a) of such section 804 into the United States by registered importers during—

(i) the first fiscal year in which this title takes effect to be an amount equal to the amount which bears the same ratio to $1,000,000,000 as the number of days in such fiscal year during which this title is effective bears to 365; and

(ii) the second fiscal year in which this title is in effect to be $3,000,000,000.

(C) SECOND YEAR ADJUSTMENT.—

(i) REPORTS.—Not later than February 20 of the second fiscal year in which this title is in effect, registered importers shall report to the Secretary the total price and the total

volume of drugs imported to the United States by the importer during the 4-month period from October 1 through January 31 of such fiscal year.

(ii) REESTIMATE.—Notwithstanding subsection (e)(3)(C)(ii) of such section 804 or subparagraph (B), the Secretary shall reestimate the total price of qualifying drugs imported under subsection (a) of such section 804 into the United States by registered importers during the second fiscal year in which this title is in effect. Such reestimate shall be equal to—

(I) the total price of qualifying drugs imported by each importer as reported under clause (i); multiplied by

(II) 3.

(iii) ADJUSTMENT.—The Secretary shall adjust the fee due on April 1 of the second fiscal year in which this title is in effect, from each importer so that the aggregate total of fees collected under subsection (e)(2) for such fiscal year does not exceed the total price of qualifying drugs imported under subsection (a) of such section 804 into the United States by registered importers during such fiscal year as reestimated under clause (ii).

(D) FAILURE TO PAY FEES.—Notwithstanding any other provision of this section, the Secretary may prohibit a registered importer or exporter that is required to pay user fees under subsection (e) or (f) of such section 804 and that fails to pay such fees within 30 days after the date on which it is due, from importing or offering for importation a qualifying drug under such section 804 until such fee is paid.

(E) ANNUAL REPORT.—

(i) FOOD AND DRUG ADMINISTRATION.—Not later than 180 days after the end of each fiscal year during which fees are collected under subsection (e), (f), or (g)(2)(B)(iv) of such section 804, the Secretary shall prepare and submit to the House of Representatives and the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for the fiscal year for which the report is made and credited to the Food and Drug Administration.

(ii) CUSTOMS AND BORDER PROTECTION.—Not later than 180 days after the end of each fiscal year during which fees are collected under subsection (e) or (f) of such section 804, the Secretary of Homeland Security, in consultation with the Secretary of the Treasury, shall prepare and submit to the House of Representatives and the Senate a report on the use, by the Bureau of Customs and Border Protection, of the fees, if any, transferred by the Secretary to the Bureau of Customs and Border Protection for the fiscal year for which the report is made.

(10) SPECIAL RULE REGARDING IMPORTATION BY INDIVIDUALS.—

(A) IN GENERAL.—Notwithstanding any provision of this title (or an amendment made by this title), the Secretary shall expedite the designation of any additional permitted countries from which an individual may import a qualifying drug into the United States under such section 804 if any action implemented by the Government of Canada has the effect of limiting or prohibiting the importation of qualifying drugs into the United States from Canada.

(B) TIMING AND CRITERIA.—The Secretary shall designate such additional permitted countries under subparagraph (A)—

(i) not later than 6 months after the date of the action by the Government of Canada described under such subparagraph; and

(ii) using the criteria described under subsection (a)(4)(D)(i)(II) of such section 804.

(f) IMPLEMENTATION OF SECTION 804.—

(1) INTERIM RULE.—The Secretary may promulgate an interim rule for implementing section 804 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a) of this section.

(2) NO NOTICE OF PROPOSED RULEMAKING.—The interim rule described under paragraph (1) may be developed and promulgated by the Secretary without providing general notice of proposed rulemaking.

(3) FINAL RULE.—Not later than 1 year after the date on which the Secretary promulgates an interim rule under paragraph (1), the Secretary shall, in accordance with procedures under section 553 of title 5, United States Code, promulgate a final rule for implementing such section 804, which may incorporate by reference provisions of the interim rule provided for under paragraph (1), to the extent that such provisions are not modified.

(g) CONSUMER EDUCATION.—The Secretary shall carry out activities that educate consumers—

(1) with regard to the availability of qualifying drugs for import for personal use from an exporter registered with and approved by the Food and Drug Administration under section 804 of the Federal Food, Drug, and Cosmetic Act, as added by this section, including information on how to verify whether an exporter is registered and approved by use of the Internet website of the Food and Drug Administration and the toll-free telephone number required by this title;

(2) that drugs that consumers attempt to import from an exporter that is not registered with and approved by the Food and Drug Administration can be seized by the United States Customs Service and destroyed, and that such drugs may be counterfeit, unapproved, unsafe, or ineffective;

(3) with regard to the suspension and termination of any registration of a registered importer or exporter under such section 804; and

(4) with regard to the availability at domestic retail pharmacies of qualifying drugs imported under such section 804 by domestic wholesalers and pharmacies registered with and approved by the Food and Drug Administration.

(h) EFFECT ON ADMINISTRATION PRACTICES.—Notwithstanding any provision of this title (and the amendments made by this title), the practices and policies of the Food and Drug Administration and Bureau of Customs and Border Protection, in effect on January 1, 2004, with respect to the importation of prescription drugs into the United States by an individual, on the person of such individual, for personal use, shall remain in effect.

(i) REPORT TO CONGRESS.—The Federal Trade Commission shall, on an annual basis, submit to Congress a report that describes any action taken during the period for which the report is being prepared to enforce the provisions of section 804(n) of the Federal Food, Drug, and Cosmetic Act (as added by this title), including any pending investigations or civil actions under such section.

SEC. 10005. DISPOSITION OF CERTAIN DRUGS DENIED ADMISSION INTO UNITED STATES.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.), as amended by section 10004, is further amended by adding at the end the following section:

"SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED ADMISSION.

''(a) IN GENERAL.—The Secretary of Homeland Security shall deliver to the Secretary a shipment of drugs that is imported or offered for import into the United States if—

''(1) the shipment has a declared value of less than $10,000; and

''(2)(A) the shipping container for such drugs does not bear the markings required under section 804(d)(2); or

''(B) the Secretary has requested delivery of such shipment of drugs.

''(b) NO BOND OR EXPORT.—Section 801(b) does not authorize the delivery to the owner or consignee of drugs delivered to the Secretary under subsection (a) pursuant to the execution of a bond, and such drugs may not be exported.

''(c) DESTRUCTION OF VIOLATIVE SHIPMENT.—The Secretary shall destroy a shipment of drugs delivered by the Secretary of Homeland Security to the Secretary under subsection (a) if—

''(1) in the case of drugs that are imported or offered for import from a registered exporter under section 804, the drugs are in violation of any standard described in section 804(g)(5); or

''(2) in the case of drugs that are not imported or offered for import from a registered exporter under section 804, the drugs are in violation of a standard referred to in section 801(a) or 801(d)(1).

''(d) CERTAIN PROCEDURES.—

''(1) IN GENERAL.—The delivery and destruction of drugs under this section may be carried out without notice to the importer, owner, or consignee of the drugs except as required by section 801(g) or section 804(i)(2). The issuance of receipts for the drugs, and recordkeeping activities regarding the drugs, may be carried out on a summary basis.

''(2) OBJECTIVE OF PROCEDURES.—Procedures promulgated under paragraph (1) shall be designed toward the objective of ensuring that, with respect to efficiently utilizing Federal resources available for carrying out this section, a substantial majority of shipments of drugs subject to described in subsection (c) are identified and destroyed.

''(e) EVIDENCE EXCEPTION.—Drugs may not be destroyed under subsection (c) to the extent that the Attorney General of the United States determines that the drugs should be preserved as evidence or potential evidence with respect to an offense against the United States.

''(f) RULE OF CONSTRUCTION.—This section may not be construed as having any legal effect on applicable law with respect to a shipment of drugs that is imported or offered for import into the United States and has a declared value equal to or greater than $10,000.''.

(b) PROCEDURES.—Procedures for carrying out section 805 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall be established not later than 90 days after the date of the enactment of this Act.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date that is 90 days after the date of enactment of this Act.

SEC. 10006. WHOLESALE DISTRIBUTION OF DRUGS; STATEMENTS REGARDING PRIOR SALE, PURCHASE, OR TRADE.

(a) STRIKING OF EXEMPTIONS; APPLICABILITY TO REGISTERED EXPORTERS.—Section 503(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is amended—

(1) in paragraph (1)—

(A) by striking ''and who is not the manufacturer or an authorized distributor of record of such drug'';

(B) by striking ''to an authorized distributor of record or''; and

(C) by striking subparagraph (B) and inserting the following:

''(B) The fact that a drug subject to subsection (b) is exported from the United States does not with respect to such drug exempt any person that is engaged in the business of the wholesale distribution of the drug from providing the statement described in subparagraph (A) to the person that receives the drug pursuant to the export of the drug.

''(C)(i) The Secretary shall by regulation establish requirements that supersede subparagraph (A) (referred to in this subparagraph as 'alternative requirements') to identify the chain of custody of a drug subject to subsection (b) from the manufacturer of the drug throughout the wholesale distribution of the drug to a pharmacist who intends to sell the drug at retail if the Secretary determines that the alternative requirements, which may include standardized anti-counterfeiting or track-and-trace technologies, will identify such chain of custody or the identity of the discrete package of the drug from which the drug is dispensed with equal or greater certainty to the requirements of subparagraph (A), and that the alternative requirements are economically and technically feasible.

''(ii) When the Secretary promulgates a final rule to establish such alternative requirements, the final rule in addition shall, with respect to the registration condition established in clause (i) of section 804(c)(3)(B), establish a condition equivalent to the alternative requirements, and such equivalent condition may be met in lieu of the registration condition established in such clause (i).'';

(2) in paragraph (2)(A), by adding at the end the following: ''The preceding sentence may not be construed as having any applicability with respect to a registered exporter under section 804.''; and

(3) in paragraph (3), by striking ''and subsection (d)—'' in the matter preceding subparagraph (A) and all that follows through ''the term 'wholesale distribution' means'' in subparagraph (B) and inserting the following: ''and subsection (d), the term 'wholesale distribution' means''.

(b) CONFORMING AMENDMENT.—Section 503(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(d)) is amended by adding at the end the following:

''(4) Each manufacturer of a drug subject to subsection (b) shall maintain at its corporate offices a current list of the authorized distributors of record of such drug.

''(5) For purposes of this subsection, the term 'authorized distributors of record' means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.''.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by paragraphs (1) and (3) of subsection (a) and by subsection (b) shall take effect on January 1, 2012.

(2) DRUGS IMPORTED BY REGISTERED IMPORTERS UNDER SECTION 804.—Notwithstanding paragraph (1), the amendments made by paragraphs (1) and (3) of subsection (a) and by subsection (b) shall take effect on the date that is 90 days after the date of enactment of this Act with respect to qualifying drugs imported under section 804 of the Federal Food, Drug, and Cosmetic Act, as added by section 10004.

(3) EFFECT WITH RESPECT TO REGISTERED EXPORTERS.—The amendment made by subsection (a)(2) shall take effect on the date that is 90 days after the date of enactment of this Act.

(4) ALTERNATIVE REQUIREMENTS.—The Secretary shall issue regulations to establish the alternative requirements, referred to in the amendment made by subsection (a)(1), that take effect not later than January 1, 2012.

(5) INTERMEDIATE REQUIREMENTS.—The Secretary shall by regulation require the use of standardized anti-counterfeiting or track-and-trace technologies on prescription drugs at the case and pallet level effective not later than 1 year after the date of enactment of this Act.

(6) ADDITIONAL REQUIREMENTS.—

(A) IN GENERAL.—Notwithstanding any other provision of this section, the Secretary shall, not later than 18 months after the date of enactment of this Act, require that the packaging of any prescription drug incorporates—

(i) a standardized numerical identifier unique to each package of such drug, applied at the point of manufacturing and repackaging (in which case the numerical identifier shall be linked to the numerical identifier applied at the point of manufacturing); and

(ii)(I) overt optically variable counterfeit-resistant technologies that—

(aa) are visible to the naked eye, providing for visual identification of product authenticity without the need for readers, microscopes, lighting devices, or scanners;

(bb) are similar to that used by the Bureau of Engraving and Printing to secure United States currency;

(cc) are manufactured and distributed in a highly secure, tightly controlled environment; and

(dd) incorporate additional layers of nonvisible convert security features up to and including forensic capability, as described in subparagraph (B); or

(II) technologies that have a function of security comparable to that described in subclause (I), as determined by the Secretary.

(B) STANDARDS FOR PACKAGING.—For the purpose of making it more difficult to counterfeit the packaging of drugs subject to this paragraph, the manufacturers of such drugs shall incorporate the technologies described in subparagraph (A) into at least 1 additional element of the physical packaging of the drugs, including blister packs, shrink wrap, package labels, package seals, bottles, and boxes.

SEC. 10007. INTERNET SALES OF PRESCRIPTION DRUGS.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 503B the following:

''SEC. 503C. INTERNET SALES OF PRESCRIPTION DRUGS.

''(a) REQUIREMENTS REGARDING INFORMATION ON INTERNET SITE.—

''(1) IN GENERAL.—A person may not dispense a prescription drug pursuant to a sale of the drug by such person if—

''(A) the purchaser of the drug submitted the purchase order for the drug, or conducted any other part of the sales transaction for the drug, through an Internet site;

''(B) the person dispenses the drug to the purchaser by mailing or shipping the drug to the purchaser; and

''(C) such site, or any other Internet site used by such person for purposes of sales of a prescription drug, fails to meet each of the requirements specified in paragraph (2), other than a site or pages on a site that—

''(i) are not intended to be accessed by purchasers or prospective purchasers; or

''(ii) provide an Internet information location tool within the meaning of section 231(e)(5) of the Communications Act of 1934 (47 U.S.C. 231(e)(5)).

''(2) REQUIREMENTS.—With respect to an Internet site, the requirements referred to in subparagraph (C) of paragraph (1) for a person to whom such paragraph applies are as follows:

''(A) Each page of the site shall include either the following information or a link to a page that provides the following information:

''(i) The name of such person.

''(ii) Each State in which the person is authorized by law to dispense prescription drugs.

''(iii) The address and telephone number of each place of business of the person with respect to sales of prescription drugs through the Internet, other than a place of business that does not mail or ship prescription drugs to purchasers.

''(iv) The name of each individual who serves as a pharmacist for prescription drugs that are mailed or shipped pursuant to the site, and each State in which the individual is authorized by law to dispense prescription drugs.

''(v) If the person provides for medical consultations through the site for purposes of providing prescriptions, the name of each individual who provides such consultations; each State in which the individual is licensed or otherwise authorized by law to provide such consultations or practice medicine; and the type or types of health professions for which the individual holds such licenses or other authorizations.

''(B) A link to which paragraph (1) applies shall be displayed in a clear and prominent place and manner, and shall include in the caption for the link the words 'licensing and contact information'.

''(b) INTERNET SALES WITHOUT APPROPRIATE MEDICAL RELATIONSHIPS.—

''(1) IN GENERAL.—Except as provided in paragraph (2), a person may not dispense a prescription drug, or sell such a drug, if—

''(A) for purposes of such dispensing or sale, the purchaser communicated with the person through the Internet;

''(B) the patient for whom the drug was dispensed or purchased did not, when such communications began, have a prescription for the drug that is valid in the United States;

''(C) pursuant to such communications, the person provided for the involvement of a practitioner, or an individual represented by the person as a practitioner, and the practitioner or such individual issued a prescription for the drug that was purchased;

''(D) the person knew, or had reason to know, that the practitioner or the individual referred to in subparagraph (C) did not, when issuing the prescription, have a qualifying medical relationship with the patient; and

''(E) the person received payment for the dispensing or sale of the drug.

For purposes of subparagraph (E), payment is received if money or other valuable consideration is received.

''(2) EXCEPTIONS.—Paragraph (1) does not apply to—

''(A) the dispensing or selling of a prescription drug pursuant to telemedicine practices sponsored by—

''(i) a hospital that has in effect a provider agreement under title XVIII of the Social Security Act (relating to the Medicare program); or

''(ii) a group practice that has not fewer than 100 physicians who have in effect provider agreements under such title; or

''(B) the dispensing or selling of a prescription drug pursuant to practices that promote the public health, as determined by the Secretary by regulation.

''(3) QUALIFYING MEDICAL RELATIONSHIP.—

''(A) IN GENERAL.—With respect to issuing a prescription for a drug for a patient, a practitioner has a qualifying medical relationship with the patient for purposes of this section if—

''(i) at least one in-person medical evaluation of the patient has been conducted by the practitioner; or

''(ii) the practitioner conducts a medical evaluation of the patient as a covering practitioner.

''(B) IN-PERSON MEDICAL EVALUATION.—A medical evaluation by a practitioner is an in-person medical evaluation for purposes of this section if the practitioner is in the physical presence of the patient as part of conducting the evaluation, without regard to

whether portions of the evaluation are conducted by other health professionals.

''(C) COVERING PRACTITIONER.—With respect to a patient, a practitioner is a covering practitioner for purposes of this section if the practitioner conducts a medical evaluation of the patient at the request of a practitioner who has conducted at least one in-person medical evaluation of the patient and is temporarily unavailable to conduct the evaluation of the patient. A practitioner is a covering practitioner without regard to whether the practitioner has conducted any in-person medical evaluation of the patient involved.

''(4) RULES OF CONSTRUCTION.—

''(A) INDIVIDUALS REPRESENTED AS PRACTITIONERS.—A person who is not a practitioner (as defined in subsection (e)(1)) lacks legal capacity under this section to have a qualifying medical relationship with any patient.

''(B) STANDARD PRACTICE OF PHARMACY.—Paragraph (1) may not be construed as prohibiting any conduct that is a standard practice in the practice of pharmacy.

''(C) APPLICABILITY OF REQUIREMENTS.—Paragraph (3) may not be construed as having any applicability beyond this section, and does not affect any State law, or interpretation of State law, concerning the practice of medicine.

''(c) ACTIONS BY STATES.—

''(1) IN GENERAL.—Whenever an attorney general of any State has reason to believe that the interests of the residents of that State have been or are being threatened or adversely affected because any person has engaged or is engaging in a pattern or practice that violates section 301(l), the State may bring a civil action on behalf of its residents in an appropriate district court of the United States to enjoin such practice, to enforce compliance with such section (including a nationwide injunction), to obtain damages, restitution, or other compensation on behalf of residents of such State, to obtain reasonable attorneys fees and costs if the State prevails in the civil action, or to obtain such further and other relief as the court may deem appropriate.

''(2) NOTICE.—The State shall serve prior written notice of any civil action under paragraph (1) or (5)(B) upon the Secretary and provide the Secretary with a copy of its complaint, except that if it is not feasible for the State to provide such prior notice, the State shall serve such notice immediately upon instituting such action. Upon receiving a notice respecting a civil action, the Secretary shall have the right—

''(A) to intervene in such action;

''(B) upon so intervening, to be heard on all matters arising therein; and

''(C) to file petitions for appeal.

''(3) CONSTRUCTION.—For purposes of bringing any civil action under paragraph (1), nothing in this chapter shall prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of such State to conduct investigations or to administer oaths or affirmations or to compel the attendance of witnesses or the production of documentary and other evidence.

''(4) VENUE; SERVICE OF PROCESS.—Any civil action brought under paragraph (1) in a district court of the United States may be brought in the district in which the defendant is found, is an inhabitant, or transacts business or wherever venue is proper under section 1391 of title 28, United States Code. Process in such an action may be served in any district in which the defendant is an inhabitant or in which the defendant may be found.

''(5) ACTIONS BY OTHER STATE OFFICIALS.—

''(A) Nothing contained in this section shall prohibit an authorized State official from proceeding in State court on the basis of an alleged violation of any civil or criminal statute of such State.

''(B) In addition to actions brought by an attorney general of a State under paragraph (1), such an action may be brought by officers of such State who are authorized by the State to bring actions in such State on behalf of its residents.

''(d) EFFECT OF SECTION.—This section shall not apply to a person that is a registered exporter under section 804.

''(e) GENERAL DEFINITIONS.—For purposes of this section:

''(1) The term 'practitioner' means a practitioner referred to in section 503(b)(1) with respect to issuing a written or oral prescription.

''(2) The term 'prescription drug' means a drug that is described in section 503(b)(1).

''(3) The term 'qualifying medical relationship', with respect to a practitioner and a patient, has the meaning indicated for such term in subsection (b).

''(f) INTERNET-RELATED DEFINITIONS.—

''(1) IN GENERAL.—For purposes of this section:

''(A) The term 'Internet' means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected world-wide network of networks that employ the transmission control protocol/internet protocol, or any predecessor or successor protocols to such protocol, to communicate information of all kinds by wire or radio.

''(B) The term 'link', with respect to the Internet, means one or more letters, words, numbers, symbols, or graphic items that appear on a page of an Internet site for the purpose of serving, when activated, as a method for executing an electronic command—

''(i) to move from viewing one portion of a page on such site to another portion of the page;

''(ii) to move from viewing one page on such site to another page on such site; or

''(iii) to move from viewing a page on one Internet site to a page on another Internet site.

''(C) The term 'page', with respect to the Internet, means a document or other file accessed at an Internet site.

''(D)(i) The terms 'site' and 'address', with respect to the Internet, mean a specific location on the Internet that is determined by Internet Protocol numbers. Such term includes the domain name, if any.

''(ii) The term 'domain name' means a method of representing an Internet address without direct reference to the Internet Protocol numbers for the address, including methods that use designations such as '.com', '.edu', '.gov', '.net', or '.org'.

''(iii) The term 'Internet Protocol numbers' includes any successor protocol for determining a specific location on the Internet.

''(2) AUTHORITY OF SECRETARY.—The Secretary may by regulation modify any definition under paragraph (1) to take into account changes in technology.

''(g) INTERACTIVE COMPUTER SERVICE; ADVERTISING.—No provider of an interactive computer service, as defined in section 230(f)(2) of the Communications Act of 1934 (47 U.S.C. 230(f)(2)), or of advertising services shall be liable under this section for dispensing or selling prescription drugs in violation of this section on account of another person's selling or dispensing such drugs, provided that the provider of the interactive computer service or of advertising services does not own or exercise corporate control over such person.

''(h) NO EFFECT ON OTHER REQUIREMENTS; COORDINATION.—The requirements of this section are in addition to, and do not supersede, any requirements under the Controlled Substances Act or the Controlled Substances Import and Export Act (or any regulation promulgated under either such Act) regarding Internet pharmacies and controlled substances. In promulgating regulations to carry out this section, the Secretary shall coordinate with the Attorney General to ensure that such regulations do not duplicate or conflict with the requirements described in the previous sentence, and that such regulations and requirements coordinate to the extent practicable.''.

(b) INCLUSION AS PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by inserting after paragraph (k) the following:

''(l) The dispensing or selling of a prescription drug in violation of section 503C.''.

(c) INTERNET SALES OF PRESCRIPTION DRUGS; CONSIDERATION BY SECRETARY OF PRACTICES AND PROCEDURES FOR CERTIFICATION OF LEGITIMATE BUSINESSES.—In carrying out section 503C of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of this section), the Secretary of Health and Human Services shall take into consideration the practices and procedures of public or private entities that certify that businesses selling prescription drugs through Internet sites are legitimate businesses, including practices and procedures regarding disclosure formats and verification programs.

(d) REPORTS REGARDING INTERNET-RELATED VIOLATIONS OF FEDERAL AND STATE LAWS ON DISPENSING OF DRUGS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall, pursuant to the submission of an application meeting the criteria of the Secretary, make an award of a grant or contract to the National Clearinghouse on Internet Prescribing (operated by the Federation of State Medical Boards) for the purpose of—

(A) identifying Internet sites that appear to be in violation of Federal or State laws concerning the dispensing of drugs;

(B) reporting such sites to State medical licensing boards and State pharmacy licensing boards, and to the Attorney General and the Secretary, for further investigation; and

(C) submitting, for each fiscal year for which the award under this subsection is made, a report to the Secretary describing investigations undertaken with respect to violations described in subparagraph (A).

(2) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out paragraph (1), there is authorized to be appropriated $100,000 for each of the first 3 fiscal years in which this section is in effect.

(e) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) take effect 90 days after the date of enactment of this Act, without regard to whether a final rule to implement such amendments has been promulgated by the Secretary of Health and Human Services under section 701(a) of the Federal Food, Drug, and Cosmetic Act. The preceding sentence may not be construed as affecting the authority of such Secretary to promulgate such a final rule.

SEC. 10008. PROHIBITING PAYMENTS TO UNREGISTERED FOREIGN PHARMACIES.

(a) IN GENERAL.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

''(h) RESTRICTED TRANSACTIONS.—

''(1) IN GENERAL.—The introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system is prohibited.

''(2) PAYMENT SYSTEM.—

''(A) IN GENERAL.—The term 'payment system' means a system used by a person described in subparagraph (B) to effect a credit

transaction, electronic fund transfer, or money transmitting service that may be used in connection with, or to facilitate, a restricted transaction, and includes—

''(i) a credit card system;

''(ii) an international, national, regional, or local network used to effect a credit transaction, an electronic fund transfer, or a money transmitting service; and

''(iii) any other system that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic fund transfers, or money transmitting services.

''(B) PERSONS DESCRIBED.—A person referred to in subparagraph (A) is—

''(i) a creditor;

''(ii) a credit card issuer;

''(iii) a financial institution;

''(iv) an operator of a terminal at which an electronic fund transfer may be initiated;

''(v) a money transmitting business; or

''(vi) a participant in an international, national, regional, or local network used to effect a credit transaction, electronic fund transfer, or money transmitting service.

''(3) RESTRICTED TRANSACTION.—The term 'restricted transaction' means a transaction or transmittal, on behalf of an individual who places an unlawful drug importation request to any person engaged in the operation of an unregistered foreign pharmacy, of—

''(A) credit, or the proceeds of credit, extended to or on behalf of the individual for the purpose of the unlawful drug importation request (including credit extended through the use of a credit card);

''(B) an electronic fund transfer or funds transmitted by or through a money transmitting business, or the proceeds of an electronic fund transfer or money transmitting service, from or on behalf of the individual for the purpose of the unlawful drug importation request;

''(C) a check, draft, or similar instrument which is drawn by or on behalf of the individual for the purpose of the unlawful drug importation request and is drawn on or payable at or through any financial institution; or

''(D) the proceeds of any other form of financial transaction (identified by the Board by regulation) that involves a financial institution as a payor or financial intermediary on behalf of or for the benefit of the individual for the purpose of the unlawful drug importation request.

''(4) UNLAWFUL DRUG IMPORTATION REQUEST.—The term 'unlawful drug importation request' means the request, or transmittal of a request, made to an unregistered foreign pharmacy for a prescription drug by mail (including a private carrier), facsimile, phone, or electronic mail, or by a means that involves the use, in whole or in part, of the Internet.

''(5) UNREGISTERED FOREIGN PHARMACY.—The term 'unregistered foreign pharmacy' means a person in a country other than the United States that is not a registered exporter under section 804.

''(6) OTHER DEFINITIONS.—

''(A) CREDIT; CREDITOR; CREDIT CARD.—The terms 'credit', 'creditor', and 'credit card' have the meanings given the terms in section 103 of the Truth in Lending Act (15 U.S.C. 1602).

''(B) ACCESS DEVICE; ELECTRONIC FUND TRANSFER.—The terms 'access device' and 'electronic fund transfer'—

''(i) have the meaning given the term in section 903 of the Electronic Fund Transfer Act (15 U.S.C. 1693a); and

''(ii) the term 'electronic fund transfer' also includes any fund transfer covered under Article 4A of the Uniform Commercial Code, as in effect in any State.

''(C) FINANCIAL INSTITUTION.—The term 'financial institution'—

''(i) has the meaning given the term in section 903 of the Electronic Transfer Fund Act (15 U.S.C. 1693a); and

''(ii) includes a financial institution (as defined in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809)).

''(D) MONEY TRANSMITTING BUSINESS; MONEY TRANSMITTING SERVICE.—The terms 'money transmitting business' and 'money transmitting service' have the meaning given the terms in section 5330(d) of title 31, United States Code.

''(E) BOARD.—The term 'Board' means the Board of Governors of the Federal Reserve System.

''(7) POLICIES AND PROCEDURES REQUIRED TO PREVENT RESTRICTED TRANSACTIONS.—

''(A) REGULATIONS.—The Board shall promulgate regulations requiring—

''(i) an operator of a credit card system;

''(ii) an operator of an international, national, regional, or local network used to effect a credit transaction, an electronic fund transfer, or a money transmitting service;

''(iii) an operator of any other payment system that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic transfers or money transmitting services where at least one party to the transaction or transfer is an individual; and

''(iv) any other person described in paragraph (2)(B) and specified by the Board in such regulations,

to establish policies and procedures that are reasonably designed to prevent the introduction of a restricted transaction into a payment system or the completion of a restricted transaction using a payment system

''(B) REQUIREMENTS FOR POLICIES AND PROCEDURES.—In promulgating regulations under subparagraph (A), the Board shall—

''(i) identify types of policies and procedures, including nonexclusive examples, that shall be considered to be reasonably designed to prevent the introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system; and

''(ii) to the extent practicable, permit any payment system, or person described in paragraph (2)(B), as applicable, to choose among alternative means of preventing the introduction or completion of restricted transactions.

''(C) NO LIABILITY FOR BLOCKING OR REFUSING TO HONOR RESTRICTED TRANSACTION.—

''(i) IN GENERAL.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, and any participant in such payment system that prevents or otherwise refuses to honor transactions in an effort to implement the policies and procedures required under this subsection or to otherwise comply with this subsection shall not be liable to any party for such action.

''(ii) COMPLIANCE.—A person described in paragraph (2)(B) meets the requirements of this subsection if the person relies on and complies with the policies and procedures of a payment system of which the person is a member or in which the person is a participant, and such policies and procedures of the payment system comply with the requirements of the regulations promulgated under subparagraph (A).

''(D) ENFORCEMENT.—

''(i) IN GENERAL.—This subsection, and the regulations promulgated under this subsection, shall be enforced exclusively by the Federal functional regulators and the Federal Trade Commission under applicable law in the manner provided in section 505(a) of the Gramm-Leach-Bliley Act (15 U.S.C. 6805(a)).

''(ii) FACTORS TO BE CONSIDERED.—In considering any enforcement action under this subsection against a payment system or person described in paragraph (2)(B), the Federal functional regulators and the Federal Trade Commission shall consider the following factors:

''(I) The extent to which the payment system or person knowingly permits restricted transactions.

''(II) The history of the payment system or person in connection with permitting restricted transactions.

''(III) The extent to which the payment system or person has established and is maintaining policies and procedures in compliance with regulations prescribed under this subsection.

''(8) TRANSACTIONS PERMITTED.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, is authorized to engage in transactions with foreign pharmacies in connection with investigating violations or potential violations of any rule or requirement adopted by the payment system or person in connection with complying with paragraph (7). A payment system, or such a person, and its agents and employees shall not be found to be in violation of, or liable under, any Federal, State or other law by virtue of engaging in any such transaction.

''(9) RELATION TO STATE LAWS.—No requirement, prohibition, or liability may be imposed on a payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, under the laws of any state with respect to any payment transaction by an individual because the payment transaction involves a payment to a foreign pharmacy.

''(10) TIMING OF REQUIREMENTS.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, must adopt policies and procedures reasonably designed to comply with any regulations required under paragraph (7) within 60 days after such regulations are issued in final form.

''(11) COMPLIANCE.—A payment system, and any person described in paragraph (2)(B), shall not be deemed to be in violation of paragraph (1)—

''(A)(i) if an alleged violation of paragraph (1) occurs prior to the mandatory compliance date of the regulations issued under paragraph (7); and

''(ii) such entity has adopted or relied on policies and procedures that are reasonably designed to prevent the introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system; or

''(B)(i) if an alleged violation of paragraph (1) occurs after the mandatory compliance date of such regulations; and

''(ii) such entity is in compliance with such regulations.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall take effect on the day that is 90 days after the date of enactment of this Act.

(c) IMPLEMENTATION.—The Board of Governors of the Federal Reserve System shall promulgate regulations as required by subsection (h)(7) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), as added by subsection (a), not later than 90 days after the date of enactment of this Act.

SEC. 10009. IMPORTATION EXEMPTION UNDER CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT.

Section 1006(a)(2) of the Controlled Substances Import and Export Act (21 U.S.C. 956(a)(2)) is amended by striking ''not import the controlled substance into the United States in an amount that exceeds 50 dosage

units of the controlled substance.'' and inserting ''import into the United States not more than 10 dosage units combined of all such controlled substances.''.

SEC. 10010. SEVERABILITY.

If any provision of this title, an amendment by this title, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this title, the amendments made by this title, and the application of the provisions of such to any person or circumstance shall not affected thereby.

SEC. 10011. CERTIFICATION.

(a) IN GENERAL.—This title (other than this section), and the amendments made by this title, shall become effective only if the Secretary of Health and Human Services certifies to Congress that the implementation of this title, and the amendments made by this title, will—

(1) pose no additional risk to the public's health and safety; and

(2) result in a significant reduction in the cost of covered products to the American consumer.

(b) EFFECTIVE DATE.—Notwithstanding any other provision of this title, or of any amendment made by this title—

(1) any reference in this title, or in such amendments, to the date of enactment of this title shall be deemed to be a reference to the date of the certification under subsection (a); and

(2) each reference to ''January 1, 2012'' in section 10006(c) shall be substituted with ''90 days after the effective date of this title''.

SA 3157. Mrs. SHAHEEN (for herself, and Mr. MERKLEY) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 1703, between lines 4 and 5, insert the following:

SEC. 6303. IMPROVEMENTS TO COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH.

Section 1181 of the Social Security Act (as added by section 6301) is amended—

(1) in subsection (d)(2)(B)—

(A) in clause (ii)(IV)—

(i) by inserting '', as described in subparagraph (A)(ii),'' after ''original research''; and

(ii) by inserting '', as long as the researcher enters into a data use agreement with the Institute for use of the data from the original research, as appropriate'' after ''publication''; and

(B) by amending clause (iv) to read as follows:

''(iv) SUBSEQUENT USE OF THE DATA.—The Institute shall not allow the subsequent use of data from original research in work-for-hire contracts with individuals, entities, or instrumentalities that have a financial interest in the results, unless approved under a data use agreement with the Institute.'';

(2) in subsection (d)(8)(A)(iv), by striking ''not be construed as mandates for'' and inserting ''do not include''; and

(3) in subsection (f)(1)(C), by amending clause (ii) to read as follows:

''(ii) 5 members representing physicians and providers, including 3 members representing physicians (at least 1 of whom is a surgeon), 1 of whom is either a nurse or a State-licensed integrative health care practitioner, and 1 of whom is a representative of a hospital.''.

SA 3158. Mr. KYL submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

At the end, insert the following:

TITLE__—PROVIDING TAX EQUITY

Subtitle A—Use of Health Savings Accounts for Non-Group High Deductible Health Plan Premiums

SEC. __001. USE OF HEALTH SAVINGS ACCOUNTS FOR NON-GROUP HIGH DEDUCTIBLE HEALTH PLAN PREMIUMS.

(a) IN GENERAL.—Section 223(d)(2)(C) of the Internal Revenue Code of 1986 (relating to exceptions) is amended by striking ''or'' at the end of clause (iii), by striking the period at the end of clause (iv) and inserting '', or'', and by adding at the end the following new clause:

''(v) a high deductible health plan, other than a group health plan (as defined in section 5000(b)(1)).''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 2009.

Subtitle B—Medical Care Access Protection

SEC. __101. SHORT TITLE.

This subtitle may be cited as the ''Medical Care Access Protection Act of 2009'' or the ''MCAP Act''.

SEC. __102. FINDINGS AND PURPOSE.

(a) FINDINGS.—

(1) EFFECT ON HEALTH CARE ACCESS AND COSTS.—Congress finds that our current civil justice system is adversely affecting patient access to health care services, better patient care, and cost-efficient health care, in that the health care liability system is a costly and ineffective mechanism for resolving claims of health care liability and compensating injured patients, and is a deterrent to the sharing of information among health care professionals which impedes efforts to improve patient safety and quality of care.

(2) EFFECT ON INTERSTATE COMMERCE.—Congress finds that the health care and insurance industries are industries affecting interstate commerce and the health care liability litigation systems existing throughout the United States are activities that affect interstate commerce by contributing to the high costs of health care and premiums for health care liability insurance purchased by health care system providers.

(3) EFFECT ON FEDERAL SPENDING.—Congress finds that the health care liability litigation systems existing throughout the United States have a significant effect on the amount, distribution, and use of Federal funds because of—

(A) the large number of individuals who receive health care benefits under programs operated or financed by the Federal Government;

(B) the large number of individuals who benefit because of the exclusion from Federal taxes of the amounts spent to provide them with health insurance benefits; and

(C) the large number of health care providers who provide items or services for which the Federal Government makes payments.

(b) PURPOSE.—It is the purpose of this subtitle to implement reasonable, comprehensive, and effective health care liability reforms designed to—

(1) improve the availability of health care services in cases in which health care liability actions have been shown to be a factor in the decreased availability of services;

(2) reduce the incidence of ''defensive medicine'' and lower the cost of health care liability insurance, all of which contribute to the escalation of health care costs;

(3) ensure that persons with meritorious health care injury claims receive fair and adequate compensation, including reasonable noneconomic damages;

(4) improve the fairness and cost-effectiveness of our current health care liability system to resolve disputes over, and provide compensation for, health care liability by reducing uncertainty in the amount of compensation provided to injured individuals; and

(5) provide an increased sharing of information in the health care system which will reduce unintended injury and improve patient care.

SEC. __103. DEFINITIONS.

In this subtitle:

(1) ALTERNATIVE DISPUTE RESOLUTION SYSTEM; ADR.—The term ''alternative dispute resolution system'' or ''ADR'' means a system that provides for the resolution of health care lawsuits in a manner other than through a civil action brought in a State or Federal court.

(2) CLAIMANT.—The term ''claimant'' means any person who brings a health care lawsuit, including a person who asserts or claims a right to legal or equitable contribution, indemnity or subrogation, arising out of a health care liability claim or action, and any person on whose behalf such a claim is asserted or such an action is brought, whether deceased, incompetent, or a minor.

(3) COLLATERAL SOURCE BENEFITS.—The term ''collateral source benefits'' means any amount paid or reasonably likely to be paid in the future to or on behalf of the claimant, or any service, product or other benefit provided or reasonably likely to be provided in the future to or on behalf of the claimant, as a result of the injury or wrongful death, pursuant to—

(A) any State or Federal health, sickness, income-disability, accident, or workers' compensation law;

(B) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(C) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; and

(D) any other publicly or privately funded program.

(4) COMPENSATORY DAMAGES.—The term ''compensatory damages'' means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities, damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature. Such term includes economic damages and noneconomic damages, as such terms are defined in this section.

(5) CONTINGENT FEE.—The term ''contingent fee'' includes all compensation to any

person or persons which is payable only if a recovery is effected on behalf of one or more claimants.

(6) ECONOMIC DAMAGES.—The term ''economic damages'' means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities.

(7) HEALTH CARE GOODS OR SERVICES.—The term ''health care goods or services'' means any goods or services provided by a health care institution, provider, or by any individual working under the supervision of a health care provider, that relates to the diagnosis, prevention, care, or treatment of any human disease or impairment, or the assessment of the health of human beings.

(8) HEALTH CARE INSTITUTION.—The term ''health care institution'' means any entity licensed under Federal or State law to provide health care services (including but not limited to ambulatory surgical centers, assisted living facilities, emergency medical services providers, hospices, hospitals and hospital systems, nursing homes, or other entities licensed to provide such services).

(9) HEALTH CARE LAWSUIT.—The term ''health care lawsuit'' means any health care liability claim concerning the provision of health care goods or services affecting interstate commerce, or any health care liability action concerning the provision of (or the failure to provide) health care goods or services affecting interstate commerce, brought in a State or Federal court or pursuant to an alternative dispute resolution system, against a health care provider or a health care institution regardless of the theory of liability on which the claim is based, or the number of claimants, plaintiffs, defendants, or other parties, or the number of claims or causes of action, in which the claimant alleges a health care liability claim.

(10) HEALTH CARE LIABILITY ACTION.—The term ''health care liability action'' means a civil action brought in a State or Federal Court or pursuant to an alternative dispute resolution system, against a health care provider or a health care institution regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action, in which the claimant alleges a health care liability claim.

(11) HEALTH CARE LIABILITY CLAIM.—The term ''health care liability claim'' means a demand by any person, whether or not pursuant to ADR, against a health care provider or health care institution, including third-party claims, cross-claims, counter-claims, or contribution claims, which are based upon the provision of, use of, or payment for (or the failure to provide, use, or pay for) health care services, regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action.

(12) HEALTH CARE PROVIDER.—

(A) IN GENERAL.—The term ''health care provider'' means any person (including but not limited to a physician (as defined by section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r)), registered nurse, dentist, podiatrist, pharmacist, chiropractor, or optometrist) required by State or Federal law to be licensed, registered, or certified to provide health care services, and being either so licensed, registered, or certified, or exempted from such requirement by other statute or regulation.

(B) TREATMENT OF CERTAIN PROFESSIONAL ASSOCIATIONS.—For purposes of this subtitle, a professional association that is organized under State law by an individual physician or group of physicians, a partnership or limited liability partnership formed by a group of physicians, a nonprofit health corporation certified under State law, or a company formed by a group of physicians under State law shall be treated as a health care provider under subparagraph (A).

(13) MALICIOUS INTENT TO INJURE.—The term ''malicious intent to injure'' means intentionally causing or attempting to cause physical injury other than providing health care goods or services.

(14) NONECONOMIC DAMAGES.—The term ''noneconomic damages'' means damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature.

(15) PUNITIVE DAMAGES.—The term ''punitive damages'' means damages awarded, for the purpose of punishment or deterrence, and not solely for compensatory purposes, against a health care provider or health care institution. Punitive damages are neither economic nor noneconomic damages.

(16) RECOVERY.—The term ''recovery'' means the net sum recovered after deducting any disbursements or costs incurred in connection with prosecution or settlement of the claim, including all costs paid or advanced by any person. Costs of health care incurred by the plaintiff and the attorneys' office overhead costs or charges for legal services are not deductible disbursements or costs for such purpose.

(17) STATE.—The term ''State'' means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, the Trust Territory of the Pacific Islands, and any other territory or possession of the United States, or any political subdivision thereof.

SEC. _104. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.

(a) IN GENERAL.—Except as otherwise provided for in this section, the time for the commencement of a health care lawsuit shall be 3 years after the date of manifestation of injury or 1 year after the claimant discovers, or through the use of reasonable diligence should have discovered, the injury, whichever occurs first.

(b) GENERAL EXCEPTION.—The time for the commencement of a health care lawsuit shall not exceed 3 years after the date of manifestation of injury unless the tolling of time was delayed as a result of—

(1) fraud;

(2) intentional concealment; or

(3) the presence of a foreign body, which has no therapeutic or diagnostic purpose or effect, in the person of the injured person.

(c) MINORS.—An action by a minor shall be commenced within 3 years from the date of the alleged manifestation of injury except that if such minor is under the full age of 6 years, such action shall be commenced within 3 years of the manifestation of injury, or prior to the eighth birthday of the minor, whichever provides a longer period. Such time limitation shall be tolled for minors for any period during which a parent or guardian and a health care provider or health care institution have committed fraud or collusion in the failure to bring an action on behalf of the injured minor.

(d) RULE 11 SANCTIONS.—Whenever a Federal or State court determines (whether by motion of the parties or whether on the motion of the court) that there has been a violation of Rule 11 of the Federal Rules of Civil Procedure (or a similar violation of applicable State court rules) in a health care liability action to which this subtitle applies, the court shall impose upon the attorneys, law firms, or pro se litigants that have violated Rule 11 or are responsible for the violation, an appropriate sanction, which shall include an order to pay the other party or parties for the reasonable expenses incurred as a direct result of the filing of the pleading, motion, or other paper that is the subject of the violation, including a reasonable attorneys' fee. Such sanction shall be sufficient to deter repetition of such conduct or comparable conduct by others similarly situated, and to compensate the party or parties injured by such conduct.

SEC. _105. COMPENSATING PATIENT INJURY.

(a) UNLIMITED AMOUNT OF DAMAGES FOR ACTUAL ECONOMIC LOSSES IN HEALTH CARE LAWSUITS.—In any health care lawsuit, nothing in this subtitle shall limit the recovery by a claimant of the full amount of the available economic damages, notwithstanding the limitation contained in subsection (b).

(b) ADDITIONAL NONECONOMIC DAMAGES.—

(1) HEALTH CARE PROVIDERS.—In any health care lawsuit where final judgment is rendered against a health care provider, the amount of noneconomic damages recovered from the provider, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties other than a health care institution against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence.

(2) HEALTH CARE INSTITUTIONS.—

(A) SINGLE INSTITUTION.—In any health care lawsuit where final judgment is rendered against a single health care institution, the amount of noneconomic damages recovered from the institution, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence.

(B) MULTIPLE INSTITUTIONS.—In any health care lawsuit where final judgment is rendered against more than one health care institution, the amount of noneconomic damages recovered from each institution, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence, except that the total amount recovered from all such institutions in such lawsuit shall not exceed $500,000.

(c) NO DISCOUNT OF AWARD FOR NONECONOMIC DAMAGES.—In any health care lawsuit—

(1) an award for future noneconomic damages shall not be discounted to present value;

(2) the jury shall not be informed about the maximum award for noneconomic damages under subsection (b);

(3) an award for noneconomic damages in excess of the limitations provided for in subsection (b) shall be reduced either before the entry of judgment, or by amendment of the judgment after entry of judgment, and such reduction shall be made before accounting for any other reduction in damages required by law; and

(4) if separate awards are rendered for past and future noneconomic damages and the combined awards exceed the limitations described in subsection (b), the future noneconomic damages shall be reduced first.

(d) FAIR SHARE RULE.—In any health care lawsuit, each party shall be liable for that

party's several share of any damages only and not for the share of any other person. Each party shall be liable only for the amount of damages allocated to such party in direct proportion to such party's percentage of responsibility. A separate judgment shall be rendered against each such party for the amount allocated to such party. For purposes of this section, the trier of fact shall determine the proportion of responsibility of each party for the claimant's harm.

SEC. __106. MAXIMIZING PATIENT RECOVERY.

(a) COURT SUPERVISION OF SHARE OF DAMAGES ACTUALLY PAID TO CLAIMANTS.—

(1) IN GENERAL.—In any health care lawsuit, the court shall supervise the arrangements for payment of damages to protect against conflicts of interest that may have the effect of reducing the amount of damages awarded that are actually paid to claimants.

(2) CONTINGENCY FEES.—

(A) IN GENERAL.—In any health care lawsuit in which the attorney for a party claims a financial stake in the outcome by virtue of a contingent fee, the court shall have the power to restrict the payment of a claimant's damage recovery to such attorney, and to redirect such damages to the claimant based upon the interests of justice and principles of equity.

(B) LIMITATION.—The total of all contingent fees for representing all claimants in a health care lawsuit shall not exceed the following limits:

(i) 40 percent of the first $50,000 recovered by the claimant(s).

(ii) 33⅓ percent of the next $50,000 recovered by the claimant(s).

(iii) 25 percent of the next $500,000 recovered by the claimant(s).

(iv) 15 percent of any amount by which the recovery by the claimant(s) is in excess of $600,000.

(b) APPLICABILITY.—

(1) IN GENERAL.—The limitations in subsection (a) shall apply whether the recovery is by judgment, settlement, mediation, arbitration, or any other form of alternative dispute resolution.

(2) MINORS.—In a health care lawsuit involving a minor or incompetent person, a court retains the authority to authorize or approve a fee that is less than the maximum permitted under this section.

(c) EXPERT WITNESSES.—

(1) REQUIREMENT.—No individual shall be qualified to testify as an expert witness concerning issues of negligence in any health care lawsuit against a defendant unless such individual—

(A) except as required under paragraph (2), is a health care professional who—

(i) is appropriately credentialed or licensed in 1 or more States to deliver health care services; and

(ii) typically treats the diagnosis or condition or provides the type of treatment under review; and

(B) can demonstrate by competent evidence that, as a result of training, education, knowledge, and experience in the evaluation, diagnosis, and treatment of the disease or injury which is the subject matter of the lawsuit against the defendant, the individual was substantially familiar with applicable standards of care and practice as they relate to the act or omission which is the subject of the lawsuit on the date of the incident.

(2) PHYSICIAN REVIEW.—In a health care lawsuit, if the claim of the plaintiff involved treatment that is recommended or provided by a physician (allopathic or osteopathic), an individual shall not be qualified to be an expert witness under this subsection with respect to issues of negligence concerning such treatment unless such individual is a physician.

(3) SPECIALTIES AND SUBSPECIALTIES.—With respect to a lawsuit described in paragraph (1), a court shall not permit an expert in one medical specialty or subspecialty to testify against a defendant in another medical specialty or subspecialty unless, in addition to a showing of substantial familiarity in accordance with paragraph (1)(B), there is a showing that the standards of care and practice in the two specialty or subspecialty fields are similar.

(4) LIMITATION.—The limitations in this subsection shall not apply to expert witnesses testifying as to the degree or permanency of medical or physical impairment.

SEC. __107. ADDITIONAL HEALTH BENEFITS.

(a) IN GENERAL.—The amount of any damages received by a claimant in any health care lawsuit shall be reduced by the court by the amount of any collateral source benefits to which the claimant is entitled, less any insurance premiums or other payments made by the claimant (or by the spouse, parent, child, or legal guardian of the claimant) to obtain or secure such benefits.

(b) PRESERVATION OF CURRENT LAW.—Where a payor of collateral source benefits has a right of recovery by reimbursement or subrogation and such right is permitted under Federal or State law, subsection (a) shall not apply.

(c) APPLICATION OF PROVISION.—This section shall apply to any health care lawsuit that is settled or resolved by a fact finder.

SEC. __108. PUNITIVE DAMAGES.

(a) PUNITIVE DAMAGES PERMITTED.—

(1) IN GENERAL.—Punitive damages may, if otherwise available under applicable State or Federal law, be awarded against any person in a health care lawsuit only if it is proven by clear and convincing evidence that such person acted with malicious intent to injure the claimant, or that such person deliberately failed to avoid unnecessary injury that such person knew the claimant was substantially certain to suffer.

(2) FILING OF LAWSUIT.—No demand for punitive damages shall be included in a health care lawsuit as initially filed. A court may allow a claimant to file an amended pleading for punitive damages only upon a motion by the claimant and after a finding by the court, upon review of supporting and opposing affidavits or after a hearing, after weighing the evidence, that the claimant has established by a substantial probability that the claimant will prevail on the claim for punitive damages.

(3) SEPARATE PROCEEDING.—At the request of any party in a health care lawsuit, the trier of fact shall consider in a separate proceeding—

(A) whether punitive damages are to be awarded and the amount of such award; and

(B) the amount of punitive damages following a determination of punitive liability. If a separate proceeding is requested, evidence relevant only to the claim for punitive damages, as determined by applicable State law, shall be inadmissible in any proceeding to determine whether compensatory damages are to be awarded.

(4) LIMITATION WHERE NO COMPENSATORY DAMAGES ARE AWARDED.—In any health care lawsuit where no judgment for compensatory damages is rendered against a person, no punitive damages may be awarded with respect to the claim in such lawsuit against such person.

(b) DETERMINING AMOUNT OF PUNITIVE DAMAGES.—

(1) FACTORS CONSIDERED.—In determining the amount of punitive damages under this section, the trier of fact shall consider only the following:

(A) the severity of the harm caused by the conduct of such party;

(B) the duration of the conduct or any concealment of it by such party;

(C) the profitability of the conduct to such party;

(D) the number of products sold or medical procedures rendered for compensation, as the case may be, by such party, of the kind causing the harm complained of by the claimant;

(E) any criminal penalties imposed on such party, as a result of the conduct complained of by the claimant; and

(F) the amount of any civil fines assessed against such party as a result of the conduct complained of by the claimant.

(2) MAXIMUM AWARD.—The amount of punitive damages awarded in a health care lawsuit may not exceed an amount equal to two times the amount of economic damages awarded in the lawsuit or $250,000, whichever is greater. The jury shall not be informed of the limitation under the preceding sentence.

(c) LIABILITY OF HEALTH CARE PROVIDERS.—

(1) IN GENERAL.—A health care provider who prescribes, or who dispenses pursuant to a prescription, a drug, biological product, or medical device approved by the Food and Drug Administration, for an approved indication of the drug, biological product, or medical device, shall not be named as a party to a product liability lawsuit invoking such drug, biological product, or medical device and shall not be liable to a claimant in a class action lawsuit against the manufacturer, distributor, or product seller of such drug, biological product, or medical device.

(2) MEDICAL PRODUCT.—The term ''medical product'' means a drug or device intended for humans. The terms ''drug'' and ''device'' have the meanings given such terms in sections 201(g)(1) and 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321), respectively, including any component or raw material used therein, but excluding health care services.

SEC. __109. AUTHORIZATION OF PAYMENT OF FUTURE DAMAGES TO CLAIMANTS IN HEALTH CARE LAWSUITS.

(a) IN GENERAL.—In any health care lawsuit, if an award of future damages, without reduction to present value, equaling or exceeding $50,000 is made against a party with sufficient insurance or other assets to fund a periodic payment of such a judgment, the court shall, at the request of any party, enter a judgment ordering that the future damages be paid by periodic payments in accordance with the Uniform Periodic Payment of Judgments Act promulgated by the National Conference of Commissioners on Uniform State Laws.

(b) APPLICABILITY.—This section applies to all actions which have not been first set for trial or retrial before the effective date of this subtitle.

SEC. __110. EFFECT ON OTHER LAWS.

(a) GENERAL VACCINE INJURY.—

(1) IN GENERAL.—To the extent that title XXI of the Public Health Service Act establishes a Federal rule of law applicable to a civil action brought for a vaccine-related injury or death—

(A) this subtitle shall not affect the application of the rule of law to such an action; and

(B) any rule of law prescribed by this subtitle in conflict with a rule of law of such title XXI shall not apply to such action.

(2) EXCEPTION.—If there is an aspect of a civil action brought for a vaccine-related injury or death to which a Federal rule of law under title XXI of the Public Health Service Act does not apply, then this subtitle or otherwise applicable law (as determined under this subtitle) will apply to such aspect of such action.

(b) SMALLPOX VACCINE INJURY.—

(1) IN GENERAL.—To the extent that part C of title II of the Public Health Service Act

establishes a Federal rule of law applicable to a civil action brought for a smallpox vaccine-related injury or death—

(A) this subtitle shall not affect the application of the rule of law to such an action; and

(B) any rule of law prescribed by this subtitle in conflict with a rule of law of such part C shall not apply to such action.

(2) EXCEPTION.—If there is an aspect of a civil action brought for a smallpox vaccine-related injury or death to which a Federal rule of law under part C of title II of the Public Health Service Act does not apply, then this subtitle or otherwise applicable law (as determined under this subtitle) will apply to such aspect of such action.

(c) OTHER FEDERAL LAW.—Except as provided in this section, nothing in this subtitle shall be deemed to affect any defense available, or any limitation on liability that applies to, a defendant in a health care lawsuit or action under any other provision of Federal law.

SEC. __111. STATE FLEXIBILITY AND PROTECTION OF STATES' RIGHTS.

(a) HEALTH CARE LAWSUITS.—The provisions governing health care lawsuits set forth in this subtitle shall preempt, subject to subsections (b) and (c), State law to the extent that State law prevents the application of any provisions of law established by or under this subtitle. The provisions governing health care lawsuits set forth in this subtitle supersede chapter 171 of title 28, United States Code, to the extent that such chapter—

(1) provides for a greater amount of damages or contingent fees, a longer period in which a health care lawsuit may be commenced, or a reduced applicability or scope of periodic payment of future damages, than provided in this subtitle; or

(2) prohibits the introduction of evidence regarding collateral source benefits.

(b) PREEMPTION OF CERTAIN STATE LAWS.—No provision of this subtitle shall be construed to preempt any State law (whether effective before, on, or after the date of the enactment of this Act) that specifies a particular monetary amount of compensatory or punitive damages (or the total amount of damages) that may be awarded in a health care lawsuit, regardless of whether such monetary amount is greater or lesser than is provided for under this subtitle, notwithstanding section __105(a).

(c) PROTECTION OF STATE'S RIGHTS AND OTHER LAWS.—

(1) IN GENERAL.—Any issue that is not governed by a provision of law established by or under this subtitle (including the State standards of negligence) shall be governed by otherwise applicable Federal or State law.

(2) RULE OF CONSTRUCTION.—Nothing in this subtitle shall be construed to—

(A) preempt or supersede any Federal or State law that imposes greater procedural or substantive protections (such as a shorter statute of limitations) for a health care provider or health care institution from liability, loss, or damages than those provided by this subtitle;

(B) preempt or supercede any State law that permits and provides for the enforcement of any arbitration agreement related to a health care liability claim whether enacted prior to or after the date of enactment of this Act;

(C) create a cause of action that is not otherwise available under Federal or State law; or

(D) affect the scope of preemption of any other Federal law.

SEC. __112. APPLICABILITY; EFFECTIVE DATE.

This subtitle shall apply to any health care lawsuit brought in a Federal or State court, or subject to an alternative dispute resolution system, that is initiated on or after the date of the enactment of this Act, except that any health care lawsuit arising from an injury occurring prior to the date of enactment of this Act shall be governed by the applicable statute of limitations provisions in effect at the time the injury occurred.

SA 3159. Mr. KYL submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

At the end, insert the following:

TITLE K__—HSA CONTRIBUTION LIMIT

Subtitle A—Increase in HSA Contribution Limit

SEC. __001. INCREASE IN LIMIT FOR HSA CONTRIBUTIONS TO EQUAL MAXIMUM HIGH DEDUCTIBLE HEALTH PLAN OUT-OF-POCKET LIMIT.

(a) IN GENERAL.—Section 223(b)(2) of the Internal Revenue Code of 1986 (relating to exceptions) is amended—

(1) by striking ''$2,250'' in subparagraph (A) and inserting ''the dollar amount specified under subsection (c)(2)(A)(ii)(I) for such taxable year'', and

(2) by striking ''$4,500'' in subparagraph (B) and inserting ''the dollar amount specified under subsection (c)(2)(A)(ii)(II) for such taxable year''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to months beginning after the date of the enactment of this Act.

Subtitle B—Medical Care Access Protection

SEC. __101. SHORT TITLE.

This subtitle may be cited as the ''Medical Care Access Protection Act of 2009'' or the ''MCAP Act''.

SEC. __102. FINDINGS AND PURPOSE.

(a) FINDINGS.—

(1) EFFECT ON HEALTH CARE ACCESS AND COSTS.—Congress finds that our current civil justice system is adversely affecting patient access to health care services, better patient care, and cost-efficient health care, in that the health care liability system is a costly and ineffective mechanism for resolving claims of health care liability and compensating injured patients, and is a deterrent to the sharing of information among health care professionals which impedes efforts to improve patient safety and quality of care.

(2) EFFECT ON INTERSTATE COMMERCE.—Congress finds that the health care and insurance industries are industries affecting interstate commerce and the health care liability litigation systems existing throughout the United States are activities that affect interstate commerce by contributing to the high costs of health care and premiums for health care liability insurance purchased by health care system providers.

(3) EFFECT ON FEDERAL SPENDING.—Congress finds that the health care liability litigation systems existing throughout the United States have a significant effect on the amount, distribution, and use of Federal funds because of—

(A) the large number of individuals who receive health care benefits under programs operated or financed by the Federal Government;

(B) the large number of individuals who benefit because of the exclusion from Federal taxes of the amounts spent to provide them with health insurance benefits; and

(C) the large number of health care providers who provide items or services for which the Federal Government makes payments.

(b) PURPOSE.—It is the purpose of this subtitle to implement reasonable, comprehensive, and effective health care liability reforms designed to—

(1) improve the availability of health care services in cases in which health care liability actions have been shown to be a factor in the decreased availability of services;

(2) reduce the incidence of ''defensive medicine'' and lower the cost of health care liability insurance, all of which contribute to the escalation of health care costs;

(3) ensure that persons with meritorious health care injury claims receive fair and adequate compensation, including reasonable noneconomic damages;

(4) improve the fairness and cost-effectiveness of our current health care liability system to resolve disputes over, and provide compensation for, health care liability by reducing uncertainty in the amount of compensation provided to injured individuals; and

(5) provide an increased sharing of information in the health care system which will reduce unintended injury and improve patient care.

SEC. __103. DEFINITIONS.

In this subtitle:

(1) ALTERNATIVE DISPUTE RESOLUTION SYSTEM; ADR.—The term ''alternative dispute resolution system'' or ''ADR'' means a system that provides for the resolution of health care lawsuits in a manner other than through a civil action brought in a State or Federal court.

(2) CLAIMANT.—The term ''claimant'' means any person who brings a health care lawsuit, including a person who asserts or claims a right to legal or equitable contribution, indemnity or subrogation, arising out of a health care liability claim or action, and any person on whose behalf such a claim is asserted or such an action is brought, whether deceased, incompetent, or a minor.

(3) COLLATERAL SOURCE BENEFITS.—The term ''collateral source benefits'' means any amount paid or reasonably likely to be paid in the future to or on behalf of the claimant, or any service, product or other benefit provided or reasonably likely to be provided in the future to or on behalf of the claimant, as a result of the injury or wrongful death, pursuant to—

(A) any State or Federal health, sickness, income-disability, accident, or workers' compensation law;

(B) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(C) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; and

(D) any other publicly or privately funded program.

(4) COMPENSATORY DAMAGES.—The term ''compensatory damages'' means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities, damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of

society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature. Such term includes economic damages and noneconomic damages, as such terms are defined in this section.

(5) CONTINGENT FEE.—The term ''contingent fee'' includes all compensation to any person or persons which is payable only if a recovery is effected on behalf of one or more claimants.

(6) ECONOMIC DAMAGES.—The term ''economic damages'' means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities.

(7) HEALTH CARE GOODS OR SERVICES.—The term ''health care goods or services'' means any goods or services provided by a health care institution, provider, or by any individual working under the supervision of a health care provider, that relates to the diagnosis, prevention, care, or treatment of any human disease or impairment, or the assessment of the health of human beings.

(8) HEALTH CARE INSTITUTION.—The term ''health care institution'' means any entity licensed under Federal or State law to provide health care services (including but not limited to ambulatory surgical centers, assisted living facilities, emergency medical services providers, hospices, hospitals and hospital systems, nursing homes, or other entities licensed to provide such services).

(9) HEALTH CARE LAWSUIT.—The term ''health care lawsuit'' means any health care liability claim concerning the provision of health care goods or services affecting interstate commerce, or any health care liability action concerning the provision of (or the failure to provide) health care goods or services affecting interstate commerce, brought in a State or Federal court or pursuant to an alternative dispute resolution system, against a health care provider or a health care institution regardless of the theory of liability on which the claim is based, or the number of claimants, plaintiffs, defendants, or other parties, or the number of claims or causes of action, in which the claimant alleges a health care liability claim.

(10) HEALTH CARE LIABILITY ACTION.—The term ''health care liability action'' means a civil action brought in a State or Federal Court or pursuant to an alternative dispute resolution system, against a health care provider or a health care institution regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action, in which the claimant alleges a health care liability claim.

(11) HEALTH CARE LIABILITY CLAIM.—The term ''health care liability claim'' means a demand by any person, whether or not pursuant to ADR, against a health care provider or health care institution, including third-party claims, cross-claims, counter-claims, or contribution claims, which are based upon the provision of, use of, or payment for (or the failure to provide, use, or pay for) health care services, regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action.

(12) HEALTH CARE PROVIDER.—

(A) IN GENERAL.—The term ''health care provider'' means any person (including but not limited to a physician (as defined by section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r)), registered nurse, dentist, podiatrist, pharmacist, chiropractor, or optometrist) required by State or Federal law to be licensed, registered, or certified to provide health care services, and being either so licensed, registered, or certified, or exempted from such requirement by other statute or regulation.

(B) TREATMENT OF CERTAIN PROFESSIONAL ASSOCIATIONS.—For purposes of this subtitle, a professional association that is organized under State law by an individual physician or group of physicians, a partnership or limited liability partnership formed by a group of physicians, a nonprofit health corporation certified under State law, or a company formed by a group of physicians under State law shall be treated as a health care provider under subparagraph (A).

(13) MALICIOUS INTENT TO INJURE.—The term ''malicious intent to injure'' means intentionally causing or attempting to cause physical injury other than providing health care goods or services.

(14) NONECONOMIC DAMAGES.—The term ''noneconomic damages'' means damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature.

(15) PUNITIVE DAMAGES.—The term ''punitive damages'' means damages awarded, for the purpose of punishment or deterrence, and not solely for compensatory purposes, against a health care provider or health care institution. Punitive damages are neither economic nor noneconomic damages.

(16) RECOVERY.—The term ''recovery'' means the net sum recovered after deducting any disbursements or costs incurred in connection with prosecution or settlement of the claim, including all costs paid or advanced by any person. Costs of health care incurred by the plaintiff and the attorneys' office overhead costs or charges for legal services are not deductible disbursements or costs for such purpose.

(17) STATE.—The term ''State'' means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, the Trust Territory of the Pacific Islands, and any other territory or possession of the United States, or any political subdivision thereof.

SEC. __104. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.

(a) IN GENERAL.—Except as otherwise provided for in this section, the time for the commencement of a health care lawsuit shall be 3 years after the date of manifestation of injury or 1 year after the claimant discovers, or through the use of reasonable diligence should have discovered, the injury, whichever occurs first.

(b) GENERAL EXCEPTION.—The time for the commencement of a health care lawsuit shall not exceed 3 years after the date of manifestation of injury unless the tolling of time was delayed as a result of—

(1) fraud;

(2) intentional concealment; or

(3) the presence of a foreign body, which has no therapeutic or diagnostic purpose or effect, in the person of the injured person.

(c) MINORS.—An action by a minor shall be commenced within 3 years from the date of the alleged manifestation of injury except that if such minor is under the full age of 6 years, such action shall be commenced within 3 years of the manifestation of injury, or prior to the eighth birthday of the minor, whichever provides a longer period. Such time limitation shall be tolled for minors for any period during which a parent or guardian and a health care provider or health care institution have committed fraud or collusion in the failure to bring an action on behalf of the injured minor.

(d) RULE 11 SANCTIONS.—Whenever a Federal or State court determines (whether by motion of the parties or whether on the motion of the court) that there has been a violation of Rule 11 of the Federal Rules of Civil Procedure (or a similar violation of applicable State court rules) in a health care liability action to which this subtitle applies, the court shall impose upon the attorneys, law firms, or pro se litigants that have violated Rule 11 or are responsible for the violation, an appropriate sanction, which shall include an order to pay the other party or parties for the reasonable expenses incurred as a direct result of the filing of the pleading, motion, or other paper that is the subject of the violation, including a reasonable attorneys' fee. Such sanction shall be sufficient to deter repetition of such conduct or comparable conduct by others similarly situated, and to compensate the party or parties injured by such conduct.

SEC. __105. COMPENSATING PATIENT INJURY.

(a) UNLIMITED AMOUNT OF DAMAGES FOR ACTUAL ECONOMIC LOSSES IN HEALTH CARE LAWSUITS.—In any health care lawsuit, nothing in this subtitle shall limit the recovery by a claimant of the full amount of the available economic damages, notwithstanding the limitation contained in subsection (b).

(b) ADDITIONAL NONECONOMIC DAMAGES.—

(1) HEALTH CARE PROVIDERS.—In any health care lawsuit where final judgment is rendered against a health care provider, the amount of noneconomic damages recovered from the provider, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties other than a health care institution against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence.

(2) HEALTH CARE INSTITUTIONS.—

(A) SINGLE INSTITUTION.—In any health care lawsuit where final judgment is rendered against a single health care institution, the amount of noneconomic damages recovered from the institution, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence.

(B) MULTIPLE INSTITUTIONS.—In any health care lawsuit where final judgment is rendered against more than one health care institution, the amount of noneconomic damages recovered from each institution, if otherwise available under applicable Federal or State law, may be as much as $250,000, regardless of the number of parties against whom the action is brought or the number of separate claims or actions brought with respect to the same occurrence, except that the total amount recovered from all such institutions in such lawsuit shall not exceed $500,000.

(c) NO DISCOUNT OF AWARD FOR NONECONOMIC DAMAGES.—In any health care lawsuit—

(1) an award for future noneconomic damages shall not be discounted to present value;

(2) the jury shall not be informed about the maximum award for noneconomic damages under subsection (b);

(3) an award for noneconomic damages in excess of the limitations provided for in subsection (b) shall be reduced either before the entry of judgment, or by amendment of the judgment after entry of judgment, and such reduction shall be made before accounting

for any other reduction in damages required by law; and

(4) if separate awards are rendered for past and future noneconomic damages and the combined awards exceed the limitations described in subsection (b), the future noneconomic damages shall be reduced first.

(d) FAIR SHARE RULE.—In any health care lawsuit, each party shall be liable for that party's several share of any damages only and not for the share of any other person. Each party shall be liable only for the amount of damages allocated to such party in direct proportion to such party's percentage of responsibility. A separate judgment shall be rendered against each such party for the amount allocated to such party. For purposes of this section, the trier of fact shall determine the proportion of responsibility of each party for the claimant's harm.

SEC. __106. MAXIMIZING PATIENT RECOVERY.

(a) COURT SUPERVISION OF SHARE OF DAMAGES ACTUALLY PAID TO CLAIMANTS.—

(1) IN GENERAL.—In any health care lawsuit, the court shall supervise the arrangements for payment of damages to protect against conflicts of interest that may have the effect of reducing the amount of damages awarded that are actually paid to claimants.

(2) CONTINGENCY FEES.—

(A) IN GENERAL.—In any health care lawsuit in which the attorney for a party claims a financial stake in the outcome by virtue of a contingent fee, the court shall have the power to restrict the payment of a claimant's damage recovery to such attorney, and to redirect such damages to the claimant based upon the interests of justice and principles of equity.

(B) LIMITATION.—The total of all contingent fees for representing all claimants in a health care lawsuit shall not exceed the following limits:

(i) 40 percent of the first $50,000 recovered by the claimant(s).

(ii) 33⅓ percent of the next $50,000 recovered by the claimant(s).

(iii) 25 percent of the next $500,000 recovered by the claimant(s).

(iv) 15 percent of any amount by which the recovery by the claimant(s) is in excess of $600,000.

(b) APPLICABILITY.—

(1) IN GENERAL.—The limitations in subsection (a) shall apply whether the recovery is by judgment, settlement, mediation, arbitration, or any other form of alternative dispute resolution.

(2) MINORS.—In a health care lawsuit involving a minor or incompetent person, a court retains the authority to authorize or approve a fee that is less than the maximum permitted under this section.

(c) EXPERT WITNESSES.—

(1) REQUIREMENT.—No individual shall be qualified to testify as an expert witness concerning issues of negligence in any health care lawsuit against a defendant unless such individual—

(A) except as required under paragraph (2), is a health care professional who—

(i) is appropriately credentialed or licensed in 1 or more States to deliver health care services; and

(ii) typically treats the diagnosis or condition or provides the type of treatment under review; and

(B) can demonstrate by competent evidence that, as a result of training, education, knowledge, and experience in the evaluation, diagnosis, and treatment of the disease or injury which is the subject matter of the lawsuit against the defendant, the individual was substantially familiar with applicable standards of care and practice as they relate to the act or omission which is the subject of the lawsuit on the date of the incident.

(2) PHYSICIAN REVIEW.—In a health care lawsuit, if the claim of the plaintiff involved treatment that is recommended or provided by a physician (allopathic or osteopathic), an individual shall not be qualified to be an expert witness under this subsection with respect to issues of negligence concerning such treatment unless such individual is a physician.

(3) SPECIALTIES AND SUBSPECIALTIES.—With respect to a lawsuit described in paragraph (1), a court shall not permit an expert in one medical specialty or subspecialty to testify against a defendant in another medical specialty or subspecialty unless, in addition to a showing of substantial familiarity in accordance with paragraph (1)(B), there is a showing that the standards of care and practice in the two specialty or subspecialty fields are similar.

(4) LIMITATION.—The limitations in this subsection shall not apply to expert witnesses testifying as to the degree or permanency of medical or physical impairment.

SEC. __107. ADDITIONAL HEALTH BENEFITS.

(a) IN GENERAL.—The amount of any damages received by a claimant in any health care lawsuit shall be reduced by the court by the amount of any collateral source benefits to which the claimant is entitled, less any insurance premiums or other payments made by the claimant (or by the spouse, parent, child, or legal guardian of the claimant) to obtain or secure such benefits.

(b) PRESERVATION OF CURRENT LAW.—Where a payor of collateral source benefits has a right of recovery by reimbursement or subrogation and such right is permitted under Federal or State law, subsection (a) shall not apply.

(c) APPLICATION OF PROVISION.—This section shall apply to any health care lawsuit that is settled or resolved by a fact finder.

SEC. __108. PUNITIVE DAMAGES.

(a) PUNITIVE DAMAGES PERMITTED.—

(1) IN GENERAL.—Punitive damages may, if otherwise available under applicable State or Federal law, be awarded against any person in a health care lawsuit only if it is proven by clear and convincing evidence that such person acted with malicious intent to injure the claimant, or that such person deliberately failed to avoid unnecessary injury that such person knew the claimant was substantially certain to suffer.

(2) FILING OF LAWSUIT.—No demand for punitive damages shall be included in a health care lawsuit as initially filed. A court may allow a claimant to file an amended pleading for punitive damages only upon a motion by the claimant and after a finding by the court, upon review of supporting and opposing affidavits or after a hearing, after weighing the evidence, that the claimant has established by a substantial probability that the claimant will prevail on the claim for punitive damages.

(3) SEPARATE PROCEEDING.—At the request of any party in a health care lawsuit, the trier of fact shall consider in a separate proceeding—

(A) whether punitive damages are to be awarded and the amount of such award; and

(B) the amount of punitive damages following a determination of punitive liability. If a separate proceeding is requested, evidence relevant only to the claim for punitive damages, as determined by applicable State law, shall be inadmissible in any proceeding to determine whether compensatory damages are to be awarded.

(4) LIMITATION WHERE NO COMPENSATORY DAMAGES ARE AWARDED.—In any health care lawsuit where no judgment for compensatory damages is rendered against a person, no punitive damages may be awarded with respect to the claim in such lawsuit against such person.

(b) DETERMINING AMOUNT OF PUNITIVE DAMAGES.—

(1) FACTORS CONSIDERED.—In determining the amount of punitive damages under this section, the trier of fact shall consider only the following:

(A) the severity of the harm caused by the conduct of such party;

(B) the duration of the conduct or any concealment of it by such party;

(C) the profitability of the conduct to such party;

(D) the number of products sold or medical procedures rendered for compensation, as the case may be, by such party, of the kind causing the harm complained of by the claimant;

(E) any criminal penalties imposed on such party, as a result of the conduct complained of by the claimant; and

(F) the amount of any civil fines assessed against such party as a result of the conduct complained of by the claimant.

(2) MAXIMUM AWARD.—The amount of punitive damages awarded in a health care lawsuit may not exceed an amount equal to two times the amount of economic damages awarded in the lawsuit or $250,000, whichever is greater. The jury shall not be informed of the limitation under the preceding sentence.

(c) LIABILITY OF HEALTH CARE PROVIDERS.—

(1) IN GENERAL.—A health care provider who prescribes, or who dispenses pursuant to a prescription, a drug, biological product, or medical device approved by the Food and Drug Administration, for an approved indication of the drug, biological product, or medical device, shall not be named as a party to a product liability lawsuit invoking such drug, biological product, or medical device and shall not be liable to a claimant in a class action lawsuit against the manufacturer, distributor, or product seller of such drug, biological product, or medical device.

(2) MEDICAL PRODUCT.—The term ''medical product'' means a drug or device intended for humans. The terms ''drug'' and ''device'' have the meanings given such terms in sections 201(g)(1) and 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321), respectively, including any component or raw material used therein, but excluding health care services.

SEC. __109. AUTHORIZATION OF PAYMENT OF FUTURE DAMAGES TO CLAIMANTS IN HEALTH CARE LAWSUITS.

(a) IN GENERAL.—In any health care lawsuit, if an award of future damages, without reduction to present value, equaling or exceeding $50,000 is made against a party with sufficient insurance or other assets to fund a periodic payment of such a judgment, the court shall, at the request of any party, enter a judgment ordering that the future damages be paid by periodic payments in accordance with the Uniform Periodic Payment of Judgments Act promulgated by the National Conference of Commissioners on Uniform State Laws.

(b) APPLICABILITY.—This section applies to all actions which have not been first set for trial or retrial before the effective date of this subtitle.

SEC. __110. EFFECT ON OTHER LAWS.

(a) GENERAL VACCINE INJURY.—

(1) IN GENERAL.—To the extent that title XXI of the Public Health Service Act establishes a Federal rule of law applicable to a civil action brought for a vaccine-related injury or death—

(A) this subtitle shall not affect the application of the rule of law to such an action; and

(B) any rule of law prescribed by this subtitle in conflict with a rule of law of such title XXI shall not apply to such action.

(2) EXCEPTION.—If there is an aspect of a civil action brought for a vaccine-related injury or death to which a Federal rule of law

under title XXI of the Public Health Service Act does not apply, then this subtitle or otherwise applicable law (as determined under this subtitle) will apply to such aspect of such action.

(b) SMALLPOX VACCINE INJURY.—

(1) IN GENERAL.—To the extent that part C of title II of the Public Health Service Act establishes a Federal rule of law applicable to a civil action brought for a smallpox vaccine-related injury or death—

(A) this subtitle shall not affect the application of the rule of law to such an action; and

(B) any rule of law prescribed by this subtitle in conflict with a rule of law of such part C shall not apply to such action.

(2) EXCEPTION.—If there is an aspect of a civil action brought for a smallpox vaccine-related injury or death to which a Federal rule of law under part C of title II of the Public Health Service Act does not apply, then this subtitle or otherwise applicable law (as determined under this subtitle) will apply to such aspect of such action.

(c) OTHER FEDERAL LAW.—Except as provided in this section, nothing in this subtitle shall be deemed to affect any defense available, or any limitation on liability that applies to, a defendant in a health care lawsuit or action under any other provision of Federal law.

SEC. __111. STATE FLEXIBILITY AND PROTECTION OF STATES' RIGHTS.

(a) HEALTH CARE LAWSUITS.—The provisions governing health care lawsuits set forth in this subtitle shall preempt, subject to subsections (b) and (c), State law to the extent that State law prevents the application of any provisions of law established by or under this subtitle. The provisions governing health care lawsuits set forth in this subtitle supersede chapter 171 of title 28, United States Code, to the extent that such chapter—

(1) provides for a greater amount of damages or contingent fees, a longer period in which a health care lawsuit may be commenced, or a reduced applicability or scope of periodic payment of future damages, than provided in this subtitle; or

(2) prohibits the introduction of evidence regarding collateral source benefits.

(b) PREEMPTION OF CERTAIN STATE LAWS.—No provision of this subtitle shall be construed to preempt any State law (whether effective before, on, or after the date of the enactment of this Act) that specifies a particular monetary amount of compensatory or punitive damages (or the total amount of damages) that may be awarded in a health care lawsuit, regardless of whether such monetary amount is greater or lesser than is provided for under this subtitle, notwithstanding section __105(a).

(c) PROTECTION OF STATE'S RIGHTS AND OTHER LAWS.—

(1) IN GENERAL.—Any issue that is not governed by a provision of law established by or under this subtitle (including the State standards of negligence) shall be governed by otherwise applicable Federal or State law.

(2) RULE OF CONSTRUCTION.—Nothing in this subtitle shall be construed to—

(A) preempt or supersede any Federal or State law that imposes greater procedural or substantive protections (such as a shorter statute of limitations) for a health care provider or health care institution from liability, loss, or damages than those provided by this subtitle;

(B) preempt or supercede any State law that permits and provides for the enforcement of any arbitration agreement related to a health care liability claim whether enacted prior to or after the date of enactment of this Act;

(C) create a cause of action that is not otherwise available under Federal or State law; or

(D) affect the scope of preemption of any other Federal law.

SEC. __112. APPLICABILITY; EFFECTIVE DATE.

This subtitle shall apply to any health care lawsuit brought in a Federal or State court, or subject to an alternative dispute resolution system, that is initiated on or after the date of the enactment of this Act, except that any health care lawsuit arising from an injury occurring prior to the date of enactment of this Act shall be governed by the applicable statute of limitations provisions in effect at the time the injury occurred.

SA 3160. Mr. BEGICH submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

At the end of subtitle C of title IV, insert the following:

SEC. 4208. INTERAGENCY TASK FORCE TO ASSESS AND IMPROVE ACCESS TO HEALTH CARE IN THE STATE OF ALASKA.

(a) ESTABLISHMENT.—There is established a task force to be known as the ''Interagency Access to Health Care in Alaska Task Force'' (referred to in this section as the ''Task Force'').

(b) DUTIES.—The Task Force shall—

(1) assess access to health care for beneficiaries of Federal health care systems in Alaska; and

(2) develop a strategy for the Federal Government to improve delivery of health care to Federal beneficiaries in the State of Alaska.

(c) MEMBERSHIP.—The Task Force shall be comprised of Federal members who shall be appointed, not later than 45 days after the date of enactment of this Act, as follows:

(1) The Secretary of Health and Human Services shall appoint one representative of each of the following:

(A) The Department of Health and Human Services.

(B) The Centers for Medicare and Medicaid Services.

(C) The Indian Health Service.

(2) The Secretary of Defense shall appoint one representative of the TRICARE Management Activity.

(3) The Secretary of the Army shall appoint one representative of the Army Medical Department.

(4) The Secretary of the Air Force shall appoint one representative of the Air Force, from among officers at the Air Force performing medical service functions.

(5) The Secretary of Veterans Affairs shall appoint one representative of each of the following:

(A) The Department of Veterans Affairs.

(B) The Veterans Health Administration.

(6) The Secretary of Homeland Security shall appoint one representative of the United States Coast Guard.

(d) CHAIRPERSON.—One chairperson of the Task Force shall be appointed by the Secretary at the time of appointment of members under subsection (c), selected from among the members appointed under paragraph (1).

(e) MEETINGS.—The Task Force shall meet at the call of the chairperson.

(f) REPORT.—Not later than 180 days after the date of enactment of this Act, the Task Force shall submit to Congress a report detailing the activities of the Task Force and containing the findings, strategies, recommendations, policies, and initiatives developed pursuant to the duty described in subsection (b)(2). In preparing such report, the Task Force shall consider completed and ongoing efforts by Federal agencies to improve access to health care in the State of Alaska.

(g) TERMINATION.—The Task Force shall be terminated on the date of submission of the report described in subsection (f).

SA 3161. Mr. THUNE submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 101, between lines 19 and 20, insert the following:

(3) INCLUSION OF HIGH DEDUCTIBLE HEALTH PLANS IN CERTAIN STATES.—

(A) IN GENERAL.—If a State is described in subparagraph (B) with respect to health plans offered in the individual or small group market, then, on and after the certification date—

(i) a health plan described in subparagraph (C) shall be treated as a qualified health plan under this section, and as minimum essential coverage under section 5000A of such Code, for purposes of this Act and the amendments made by this Act; and

(ii) no requirement imposed by any provision of, or any amendment made by, this Act shall apply with respect to such plan or issuer thereof.

(B) STATE DESCRIBED.—For purposes of this paragraph—

(i) IN GENERAL.—A State is described in this subparagraph with respect to the individual or small group market within the State if the applicable State authority determines for any calendar year after 2013 that the percentage increase in average annual premiums for health insurance coverage in such market for the calendar year over the preceding calendar year exceeds the percentage increase for such period in the Consumer Price Index for all urban consumers published by the Department of Labor.

(ii) CERTIFICATION DATE.—The term ''certification date'' means the first date on which the applicable State authority certifies a determination described in clause (i).

(iii) APPLICABLE STATE AUTHORITY.—The term ''applicable State authority'' has the meaning given such term by section 2791(d)(1) of the Public Health Service Act.

(C) HIGH DEDUCTIBLE HEALTH PLAN.—A health plan is described in this subparagraph if the plan is a high deductible health plan (as defined in section 223(c)(2) of the Internal Revenue Code of 1986) that meets all requirements under such section to be offered in connection with a health savings account.

SA 3162. Mr. SPECTER (for himself and Mrs. HAGAN) submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain

other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 1925, between lines 14 and 15, insert the following:

Subtitle C—Provisions Relating to the Safety of Drugs and Biological Products

SEC. 7201. ENSURING THE SAFETY OF DRUGS AND BIOLOGICAL PRODUCTS CONTAINING BLOOD, BLOOD COMPONENTS, AND BLOOD DERIVATIVES.

Section 351 of the Public Health Service Act (42 U.S.C. 262), as amended by section 7002, is further amended by adding at the end the following:

''(m) BLOOD, BLOOD COMPONENTS, AND BLOOD DERIVATIVES.—

''(1) REGULATION AND LICENSURE.—The Secretary shall issue regulations that—

''(A) require a person seeking approval of any drug or licensure of a biological product that contains blood, blood components, or blood derivatives to—

''(i) submit an application for licensure pursuant to this section; and

''(ii) demonstrate the clinical safety, purity, and potency of such drug or product; and

''(B) provide analytical methods and standards to evaluate the quality of the blood, blood components, or blood derivatives contained in the new drug or biological product throughout the manufacturing process.

''(2) BIOLOGICAL PRODUCTS AND DRUG PRODUCTS CONTAINING BLOOD, BLOOD COMPONENTS, OR BLOOD DERIVATIVES.—A drug or biological product described in paragraph (1) that contains blood, blood components, or blood derivatives shall include any drug or biological product that includes an active or inactive ingredient that—

''(A) contains blood, blood components, or blood derivatives and has the potential to—

''(i) transmit infectious agents, such as of a prion or a microbial origin; or

''(ii) cause an adverse immune reaction due to the presence of blood, blood components, or blood derivatives; and

''(B) is—

''(i) essential to the manufacture of the drug or product;

''(ii) determinate of the absorption and distribution of the drug or product when administered; and

''(iii) essential to the safety and efficacy of the drug or product.

''(3) OTHER PRODUCTS CONTAINING BLOOD, BLOOD PRODUCTS, OR BLOOD DERIVATIVES.—In addition to the drugs and biological products that meet the criteria described in paragraph (2), the Secretary may issue regulations to include other products containing blood, blood products, or blood derivatives as biological products subject to paragraph (1).

''(4) CONSISTENCY OF DEFINITIONS.—Notwithstanding any other provision of this Act or the Federal Food, Drug, and Cosmetic Act, after the date of enactment of the Patient Protection and Affordable Care Act, a drug or biological product that has been approved under section 505 of the Federal Food, Drug, and Cosmetic Act and that meets the criteria described in paragraph (2) shall be treated by the Secretary as a biological product approved under a biologics license application under this section.''.

SA 3163. Mr. SPECTER submitted an amendment intended to be proposed to amendment SA 2786 proposed by Mr. REID (for himself, Mr. BAUCUS, Mr. DODD, and Mr. HARKIN) to the bill H.R. 3590, to amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes; which was ordered to lie on the table; as follows:

On page 869, between lines 14 and 15, insert the following:

SEC. 3143. REVISION TO PAYMENT FOR CONSULTATION CODES.

(a) TEMPORARY DELAY OF ELIMINATION OF PAYMENT FOR CONSULTATION CODES.—Notwithstanding any other provision of law, the Secretary of Health and Human Services shall not, prior to January 1, 2011, implement any provision contained in a final rule that eliminates or discontinues payment for consultation codes under the physician fee schedule and part B of title XVIII of the Social Security Act.

(b) EVALUATION PERIOD.—During the period prior to January 1, 2011, the Secretary of Health and Human Services shall consult with the Current Procedural Terminology Editorial Panel of the American Medical Association for the purpose of developing proposals to—

(1) modify existing consultation codes or establish new consultation codes to more accurately reflect the value provided through such consultation services; and

(2) minimize coding errors.

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON BANKING, HOUSING, AND URBAN AFFAIRS

Mr. BAUCUS. Mr. President, I ask unanimous consent that the Committee on Banking, Housing, and Urban Affairs, Subcommittee on Housing, Transportation, and Community Development, be authorized to meet during the session on the Senate on December 10, 2009 at 9:30 a.m., to conduct a hearing entitled ''Examining the Federal Role in Overseeing the Safety of Public Transportation Systems.''

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

COMMITTEE ON ENERGY AND NATURAL RESOURCES

Mr. BAUCUS. Mr. President, I ask unanimous consent that the Committee on Energy and Natural Resources be authorized to meet during the session of the Senate on December 10, at 10 a.m., in room SD–366 of the Dirksen Senate Office Building.

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

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

Mr. BAUCUS. Mr. President, I ask unanimous consent that the Committee on Environment and Public Works be authorized to meet during the session of the Senate on December 10, 2009, at 9:30 a.m. in room 406 of the Dirksen Senate Office Building.

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

COMMITTEE ON FOREIGN RELATIONS

Mr. BAUCUS. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on December 10, 2009, at 10 a.m.

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

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

Mr. BAUCUS. Mr. President, I ask unanimous consent that the Committee on Health, Education, Labor, and Pensions be authorized to meet during the session of the Senate on December 10, 2009.

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

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

Mr. BAUCUS. Mr. President, I ask unanimous consent that the Committee on Homeland Security and Governmental Affairs be authorized to meet during the session of the Senate on December 10, 2009, at 10 a.m.

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

COMMITTEE ON THE JUDICIARY

Mr. BAUCUS. Mr. President, I ask unanimous consent that the Committee on the Judiciary be authorized to meet during the session of the Senate on December 10, 2009, at 10 a.m., in SD–226 of the Dirksen Senate Office Building, to conduct an executive business meeting.

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

AD HOC SUBCOMMITTEE ON DISASTER RECOVERY

Mr. BAUCUS. Mr. President, I ask unanimous consent that the Ad Hoc Subcommittee on Disaster Recovery of the Committee on Homeland Security and Governmental Affairs be authorized to meet during the session of the Senate on December 10, 2009, at 2:30 p.m. to conduct a hearing entitled, ''Children and Disasters: A Progress Report on Addressing Needs.''

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

SELECT COMMITTEE ON INTELLIGENCE

Mr. BAUCUS. Mr. President, I ask unanimous consent that the Select Committee on Intelligence be authorized to meet during the session of the Senate on December 10, 2009, at 2:30 p.m.

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

SUBCOMMITTEE ON AVIATION OPERATIONS, SAFETY, AND SECURITY

Mr. BAUCUS. Mr. President, I ask unanimous consent that the Subcommittee on Aviation Operations, Safety, and Security of the Committee on Commerce, Science, and Transportation be authorized to meet during the session of the Senate on December 10, 2009, at 10 a.m. in room 253 of the Russell Senate Office Building.

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

PRIVILEGES OF THE FLOOR

Mr. BAUCUS. Mr. President, I ask unanimous consent that the following staff of the Finance Committee be permitted the privileges of the floor during debate on the health care bill: Angela Franklin, Kaitlin Guarascio, and Scott Allen.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.