bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3643. Ms. MURKOWSKI submitted an amendment intended to be proposed by her to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3644. Mr. HATCH (for himself, Mr. COBURN, and Mr. CRAPO) proposed an amendment to the bill H.R. 4872, supra.

SA 3645. Mr. RISCH (for himself and Mr. CRAPO) proposed an amendment to the bill H.R. 4872, supra.

SA 3646. Mr. RISCH submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3647. Ms. COLLINS submitted an amendment intended to be proposed by her to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3648. Mr. COBURN submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3649. Mr. COBURN submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3650. Mr. COBURN submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3651. Mr. GREGG proposed an amendment to the bill H.R. 4872, supra.

SA 3652. Mr. BURR (for himself, Mr. GRAHAM, Mr. CRAPO, Mr. BARRASSO, Mr. MCCAIN, and Mr. BROWN of Massachusetts) proposed an amendment to the bill H.R. 4872, supra.

SA 3653. Mr. BROWNBACK submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3654. Mr. BARRASSO submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3655. Mr. BARRASSO submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3656. Mr. BARRASSO submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3657. Mr. BARRASSO submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3658. Mr. BARRASSO submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3659. Mr. BARRASSO submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3660. Mr. BARRASSO submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3661. Mr. BARRASSO submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3662. Mr. BARRASSO submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3663. Mr. BARRASSO submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3664. Mr. VITTER submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3665. Mr. VITTER submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3666. Mr. VITTER submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3667. Mr. VITTER submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3668. Mr. VITTER proposed an amendment to the bill H.R. 4872, supra.

SA 3669. Mr. VITTER submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3670. Mr. ENZI submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3671. Mr. ENZI (for himself and Mr. COBURN) submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3672. Mr. ENZI submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3673. Mr. ENZI submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3674. Mr. HATCH submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3675. Mr. HATCH submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3676. Ms. COLLINS submitted an amendment intended to be proposed by her to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3677. Mr. LEMIEUX submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3678. Mr. LEMIEUX submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3679. Mr. LEMIEUX submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3680. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3681. Mr. BUNNING proposed an amendment to the bill H.R. 4872, supra.

SA 3682. Mr. MCCAIN (for himself and Mr. KYL) submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3683. Mr. THUNE submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3684. Mr. BROWNBACK submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3685. Mr. BROWNBACK (for himself and Mr. ROBERTS) submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3686. Mr. BROWNBACK submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3687. Mr. COBURN submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3688. Ms. SNOWE (for herself, Mr. MCCAIN, Mr. VITTER, Mr. THUNE, Mr. GRASSLEY, and Ms. COLLINS) submitted an amendment intended to be proposed by her to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3689. Mr. COBURN submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3690. Mr. BROWNBACK submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3691. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3692. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3693. Ms. MURKOWSKI submitted an amendment intended to be proposed by her to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3694. Mr. GRAHAM submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3695. Mr. ALEXANDER submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3696. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3697. Mr. BROWNBACK submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3698. Mr. CORNYN submitted an amendment intended to be proposed by him to the bill H.R. 4872, supra; which was ordered to lie on the table.

SA 3699. Mr. GRASSLEY proposed an amendment to the bill H.R. 4872, supra.

TEXT OF AMENDMENTS

SA 3586. Mr. LEMIEUX submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

At the end of subtitle C of title I, add the following:

SEC. 1207. MEMBERS OF CONGRESS REQUIRED TO HAVE COVERAGE UNDER MEDICAID INSTEAD OF THROUGH FEHBP.

(a) IN GENERAL.—Notwithstanding chapter 89 of title 5, United States Code, title XIX of the Social Security Act, or any provision of this Act, effective on the date of enactment of this Act—

(1) each Member of Congress shall be eligible for medical assistance under the Medicaid plan of the State in which the Member resides; and

(2) any employer contribution under chapter 89 of title 5 of such Code on behalf of the Member may be paid only to the State agency responsible for administering the Medicaid plan in which the Member enrolls and not to the offeror of a plan offered through the Federal employees health benefit program under such chapter.

(b) PAYMENTS BY FEDERAL GOVERNMENT.—The Secretary of Health and Human Services, in consultation with the Director of the Office of Personnel Management, shall establish procedures under which the employer contributions that would otherwise be made on behalf of a Member of Congress if the

Member were enrolled in a plan offered through the Federal employees health benefit program may be made directly to the State agencies described in subsection (a).

(c) INELIGIBLE FOR FEHBP.—Effective on the date of enactment of this Act, no Member of Congress shall be eligible to obtain health insurance coverage under the program chapter 89 of title 5, United States Code.

(d) DEFINITION.—In this section, the term ''Member of Congress'' means any member of the House of Representatives or the Senate.

SA 3587. Mr. BROWNBACK (for himself and Mr. VITTER) submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

Strike section 1107.

SA 3588. Mr. INHOFE submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

On page 99, between lines 9 and 10, insert the following:

(e) EXCLUSION OF MEDICAL DEVICES FOR PEDIATRIC USE AND PERSONS WITH DISABILITIES.—

(1) IN GENERAL.—For purposes of section 4191(b)(1) of the Internal Revenue Code of 1986, as added by subsection (a), the term ''taxable medical device'' shall not include any device which is primarily designed—

(A) to be used by or for pediatric patients, or

(B) to assist persons with disabilities with tasks of daily life.

(2) EXPANSION OF AFFORDABILITY EXCEPTION TO INDIVIDUAL MANDATE.—Section 5000A(e)(1)(A) of the Internal Revenue Code of 1986, as added by section 1501(b) of the Patient Protection and Affordable Care Act and amended by section 10106 of such Act, is amended by striking ''8 percent'' and inserting ''5 percent''.

(3) APPLICATION OF PROVISION.—The amendment made by paragraph (2) shall apply as if included in the Patient Protection and Affordable Care Act.

SA 3589. Ms. SNOWE submitted an amendment intended to be proposed by her to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

On page 64, between lines 4 and 5, insert the following:

SEC. 1201A. TRANSITIONAL STATE SHARE FOR COVERAGE OF PARENTS BY EXPANSION STATES.

Section 1905(z) of the Social Security Act (42 U.S.C. 1396d(z)), as amended by section 1201, is amended by adding at the end the following:

''(4) In the case of an expansion State described in paragraph (3), the State percentage with respect to amounts expended for medical assistance for individuals who are parents described in subclause (VIII) of section 1902(a)(10)(A)(i) whose income (as determined under section 1902(e)(14)) exceeds 67 percent, but does not exceed 133 percent, of the poverty line (as defined in section 2110(c)(5)) applicable to a family of the size involved, and who are not newly eligible (as defined in subsection (y)(2)), shall be reduced as follows:

''(A) In the case of such expenditures for 2014, by 50 percent.

''(B) In the case of such expenditures for 2015, by 60 percent.

''(C) In the case of such expenditures for 2016, by 70 percent.

''(D) In the case of such expenditures for 2017, by 80 percent.

''(E) In the case of such expenditures for 2018, by 90 percent.''.

SA 3590. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle A of title I, add the following:

SEC. 1110. SPECIAL RULES TO ENSURE CITIZENS AND NATIONALS OF THE UNITED STATES HAVE THE SAME HEALTH CARE CHOICES AS LEGAL IMMIGRANTS.

Section 36B(c)(1) of the Internal Revenue Code of 1986, as added by section 1401 of the Patient Protection and Affordable Care Act and amended by section 10105 of such Act, is amended by adding at the end the following:

''(E) SPECIAL RULES TO ENSURE CITIZENS AND NATIONALS OF THE UNITED STATES HAVE THE SAME HEALTH CARE CHOICES AS LEGAL IMMIGRANTS.—

''(i) IN GENERAL.—Notwithstanding any other provision of this Code, the Patient Protection and Affordable Care Act, or any amendment made by that Act, any taxpayer who—

''(I) is a citizen or national of the United States; and

''(II) has a household income which is not greater than 133 percent of an amount equal to the poverty line for a family of the size involved,

may elect to enroll in a qualified health plan through the Exchange established by the State under section 1311 of the Patient Protection and Affordable Care Act instead of enrolling in the State Medicaid plan under title XIX of the Social Security, or under a waiver of such plan.

''(ii) SPECIAL RULES.—

''(I) An individual making an election under clause (i) shall waive being provided with medical assistance under the State Medicaid plan under title XIX of the Social Security, or under a waiver of such plan while enrolled in a qualified health plan.

''(II) In the case of an individual who is a child, the child's parent or legal guardian may make such an election on behalf of the child.

''(III) Any individual making such an election, or on whose behalf such an election is made, shall—

''(aa) 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 the percentage determined under subsection (b)(3)(A)(i); and

''(bb) for purposes of reduced cost-sharing under section 1402 of the Patient Protection and Affordable Care Act, be treated as an eligible individual whose household income is in the category described in subsection (c)(2)(A) of such section.''.

SA 3591. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle B of title II, add the following:

SEC. 23___. TREATMENT OF HIGH DEDUCTIBLE HEALTH PLANS AS QUALIFIED HEALTH PLANS.

Subparagraph (B) of section 1301(a)(1) of the Patient Protection and Affordable Care Act is amended by inserting ''or meets the requirements for a high deductible health plan under section 223(c)(2) of the Internal Revenue Code of 1986'' after ''section 1302(a)''.

SA 3592. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle F of title I, add the following:

SEC. 1___. PROTECTION OF ACCESS TO QUALITY HEALTH CARE THROUGH THE DEPARTMENT OF VETERANS AFFAIRS AND THE DEPARTMENT OF DEFENSE.

(a) HEALTH CARE THROUGH DEPARTMENT OF VETERANS AFFAIRS.—Nothing in this Act or the Patient Protection and Affordable Care Act (or any amendment made by either such Act) shall be construed to prohibit, limit, or otherwise penalize veterans and dependents eligible for health care through the Department of Veterans Affairs under the laws administered by the Secretary of Veterans Affairs from receiving timely access to quality health care in any facility of the Department or from any non-Department health care provider through which the Secretary provides health care.

(b) HEALTH CARE THROUGH DEPARTMENT OF DEFENSE.—

(1) IN GENERAL.—Nothing in this Act or the Patient Protection and Affordable Care Act (or any amendment made by either such Act) shall be construed to prohibit, limit, or otherwise penalize eligible beneficiaries from receiving timely access to quality health care in any military medical treatment facility or under the TRICARE program.

(2) DEFINITIONS.—In this subsection:

(A) The term ''eligible beneficiaries'' means covered beneficiaries (as defined in section 1072(5) of title 10, United States Code) for purposes of eligibility for mental and dental care under chapter 55 of title 10, United States Code.

(B) The term ''TRICARE program'' has the meaning given that term in section 1072(7) of title 10, United States Code.

SA 3593. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle B of title II, insert the following:

SEC. 2___. HEALTH CARE SAFETY NET ENHANCEMENT.

(a) LIMITATION ON LIABILITY.—Notwithstanding any other provision of law, a health care professional shall not be liable in any medical malpractice lawsuit for a cause of

action arising out of the provision of, or the failure to provide, any medical service to a medically underserved or indigent individual while engaging in the provision of pro bono medical services.

(b) REQUIREMENTS.—Subsection (a) shall not apply—

(1) to any act or omission by a health care professional that is outside the scope of the services for which such professional is deemed to be licensed or certified to provide, unless such act or omission can reasonably be determined to be necessary to prevent serious bodily harm or preserve the life of the individual being treated;

(2) if the services on which the medical malpractice claim is based did not arise out of the rendering of pro bono care for a medically underserved or indigent individual; or

(3) to an act or omission by a health care professional that constitutes willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious, flagrant indifference to the rights or safety of the individual harmed by such professional.

(c) DEFINITION.—In this section—

(1) the term ''medically underserved individual'' means an individual who does not have health care coverage under a group health plan, health insurance coverage, or any other health care coverage program; and

(2) the term ''indigent individual'' means and individual who is unable to pay for the health care services that are provided to the individual.

SA 3594. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle F of title I, add the following:

SEC. 15___. EQUIVALENT BANKRUPTCY PROTECTIONS FOR HEALTH SAVINGS ACCOUNTS AS RETIREMENT FUNDS.

(a) IN GENERAL.—Section 522 of title 11, United States Code, is amended by adding at the end the following new subsection:

''(r) TREATMENT OF HEALTH SAVINGS ACCOUNTS.—For purposes of this section, any health savings account (as described in section 223 of the Internal Revenue Code of 1986) shall be treated in the same manner as an individual retirement account described in section 408 of such Code.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to cases commencing under title 11, United States Code, after the date of the enactment of this Act.

SA 3595. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle B of title II, insert the following:

SEC. 2304. APPLICATION OF WELLNESS PROGRAMS PROVISIONS TO CARRIERS PROVIDING FEDERAL EMPLOYEE HEALTH BENEFITS PLANS.

(a) IN GENERAL.—Notwithstanding section 8906 of title 5, United States Code (including subsections (b)(1) and (b)(2) of such section), section 2705(j) of the Public Health Service Act (relating to wellness programs) shall apply to carriers entering into contracts under section 8902 of title 5, United States Code.

(b) PROPOSALS.—Carriers may submit separate proposals relating to voluntary wellness program offerings as part of the annual call for benefit and rate proposals to the Office of Personnel Management.

(c) EFFECTIVE DATE.—This section shall take effect on the date of enactment of this Act and shall apply to contracts entered into under section 8902 of title 5, United States Code, that take effect with respect to calendar years that begin more than 1 year after that date.

SA 3596. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle C of title I, add the following:

SEC. 1207. STATE OPTION TO OPT-OUT OF MEDICAID COVERAGE EXPANSION TO AVOID ASSUMING UNFUNDED FEDERAL MANDATE.

Notwithstanding any provision of the Patient Protection and Affordable Care Act (or any amendment made by such Act), the Governor of a State shall have the authority to opt out of any provision under such Act or any amendment made by such Act that requires the State to expand coverage under the Medicaid program if the State agency responsible for administering the State plan under title XIX certifies that such expansion would result in an increase of at least 1 percent in the total amount of expenditures by the State for providing medical assistance to all individuals enrolled under the State plan, when compared to the total amount of such expenditures for the most recently ended State fiscal year.

SA 3597. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle B of title II, add the following:

SEC. 23___. SOCIAL SECURITY NUMBER REQUIREMENT FOR PARTICIPATION IN EXCHANGES.

Section 1411(b)(2) of the Patient Protection and Affordable Care Act is amended by adding at the end the following new flush sentence:

''For purposes of this section, the term 'social security number' means a social security number issued to an individual by the Social Security Administration. Such term shall not include a taxpayer identification number or TIN issued by the Internal Revenue Service.''.

SA 3598. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle B of title I, add the following:

SEC. ___. ENSURING MEDICARE SAVINGS ARE KEPT IN THE MEDICARE PROGRAM.

No reduction in outlays under the Medicare program under title XVIII of the Social Security Act under the provisions of, and amendments made by, this Act or the Patient Protection and Affordable Care Act may be utilized to offset any outlays under any other program or activity of the Federal government.

SA 3599. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. PROHIBITION ON USING MEDICARE SAVINGS TO OFFSET PROGRAMS UNRELATED TO MEDICARE.

Title III of the Congressional Budget Act of 1974 (2 U.S.C. 621 et seq.) is amended by adding at the end the following:

''SEC. 316. PROHIBITION ON USING MEDICARE SAVINGS TO OFFSET PROGRAMS UNRELATED TO MEDICARE.

''For purposes of this title and title IV, a reduction in outlays under title XVIII of the Social Security Act may not be counted as an offset to any outlays under any other program or activity of the Federal Government.''.

SA 3600. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. PROHIBITION ON USING MEDICARE SAVINGS TO OFFSET PROGRAMS UNRELATED TO MEDICARE.

Title III of the Congressional Budget Act of 1974 (2 U.S.C. 621 et seq.) is amended by adding at the end the following:

''SEC. 316. PROHIBITION ON USING MEDICARE SAVINGS TO OFFSET PROGRAMS UNRELATED TO MEDICARE.

''(a) IN GENERAL.—For purposes of this title and title IV, a reduction in outlays under title XVIII of the Social Security Act or an increase in revenues resulting from an increase in taxes assessed for purposes of such title may not be counted as an offset to any outlays under any other program or activity of the Federal Government.

''(b) POINT OF ORDER.—

''(1) IN GENERAL.—It shall not be in order to consider any bill, resolution, amendment, conference report, or motion that violates subsection (a).

''(2) WAIVER AND APPEAL.—

''(A) WAIVER.—This subsection may be waived or suspended in the Senate only by the affirmative vote of three-fifths of the Members, duly chosen and sworn.

''(B) APPEALS.—Appeals in the Senate from the decisions of the Chair relating to any provision of this subsection shall be limited to 1 hour, to be equally divided between, and controlled by, the appellant and the manager of the bill or joint resolution, as the case may be. An affirmative vote of three-fifths of the Members of the Senate, duly chosen and sworn, shall be required to sustain an appeal of the ruling of the Chair on a point of order raised under this subsection.''.

SA 3601. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for

reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of section 1002, add the following:

(c) LIMITATION ON LIENS AND LEVIES.—Section 5000A(g)(2) of the Internal Revenue Code of 1986, as added by the Patient Protection and Affordable Care Act, is amended by striking subparagraphs (A) and (B) and inserting the following:

''(A) WAIVER OF CRIMINAL AND CIVIL PENALTIES AND INTEREST.—In the case of any failure by a taxpayer to timely pay any penalty imposed by this section—

''(i) such taxpayer shall not be subject to any criminal prosecution or penalty with respect to such failure, and

''(ii) no penalty, addition to tax, or interest shall be imposed with respect to such failure or such penalty.

''(B) LIMITED COLLECTION ACTIONS PERMITTED.—In the case of the assessment of any penalty imposed by this section, the Secretary shall not take any action with respect to the collection of such penalty other than—

''(i) giving notice and demand for such penalty under section 6303,

''(ii) crediting under section 6402(a) the amount of any overpayment of the taxpayer against such penalty, and

''(iii) offsetting any payment owed by any Federal agency to the taxpayer against such penalty under the Treasury offset program.''.

SA 3602. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle E of title I, add the following:

SEC. 14___. REPEAL OF ADDITIONAL TAX FROM DISTRIBUTIONS FROM HSAS AND MSAS.

(a) HSAs.—Section 223(f)(4)(A) of the Internal Revenue Code of 1986, as amended by section 9004 of the Patient Protection and Affordable Care Act, is amended by striking ''20 percent'' and inserting ''10 percent''.

(b) ARCHER MSAs.—Section 220(f)(4)(A) of the Internal Revenue Code of 1986, as amended by section 9004 of the Patient Protection and Affordable Care Act, is amended by striking ''20 percent'' and inserting ''15 percent''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to distributions made after December 31, 2010.

SA 3603. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

Strike section 1403 and insert the following:

SEC. 1403. ELIMINATION OF LIMITATION ON HEALTH FLEXIBLE SPENDING ARRANGEMENTS UNDER CAFETERIA PLANS.

(a) IN GENERAL.—Section 125 of the Internal Revenue Code of 1986, as amended by sections 9005 and 10902 of the Patient Protection and Affordable Care Act, is amended by striking subsection (i).

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 2010.

SA 3604. Mr. BENNETT submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle E of title I, add the following:

SEC. 1412. SUNSET FOR EXPANSIONS OF ENTITLEMENT SPENDING.

(a) IN GENERAL.—Notwithstanding any other provision of this Act or the Patient Protection and Affordable Care Act (or any amendments made by such Acts), any establishment or expansion of entitlement authority (as defined in subsection (b)) that is provided for under this Act or the Patient Protection and Affordable Care Act (or any amendments made by such Acts) that would draw from the general funds of the Treasury, the Federal Hospital Insurance Trust Fund (as established under section 1817 of the Social Security Act (42 U.S.C. 1395i)), the Federal Supplementary Medical Insurance Trust Fund (as established under section 1841 of such Act (42 U.S.C. 1395t)), or any other such trust fund, shall terminate at the end of fiscal year 2020.

(b) ENTITLEMENT AUTHORITY.—In this section, the term ''entitlement authority'' means the authority to make payments (including loans and grants), the budget authority for which is not provided for in advance by appropriation Acts, to any person or government if, under the provisions of the law containing that authority, the United States is obligated to make such payments to persons or government who meet the requirements established by that law.

SA 3605. Mr. BENNETT submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle C of title I, add the following:

SEC. 1207. STATE EXEMPTION FROM MEDICAID EXPANSION TO PREVENT REDUCTION IN MEDICAL SERVICES.

Notwithstanding any other provision of law, no State shall be required to expand coverage under the Medicaid program on or after the date of enactment of the Patient Protection and Affordable Care Act if the State agency responsible for administering the State Medicaid plan under title XIX of the Social Security Act certifies that such expansion would require the State to reduce or eliminate care or services provided to individuals who are eligible for medical assistance under such State plan on the date of enactment of the Patient Protection and Affordable Care Act.

SA 3606. Mr. BENNETT submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

On page 61, between lines 3 and 4, insert the following:

SEC. 1110. APPLICATION OF UNUSED STIMULUS FUNDS FOR UPDATING OF THE MEDICARE PHYSICIAN FEE SCHEDULE.

(a) RESCISSION IN ARRA.—Effective as the date of enactment of this Act, 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.

(b) UPDATE OF MEDICARE PHYSICIAN FEE SCHEDULE.—The Secretary of Health and Human Services shall increase the update to the conversion factor under section 1848 of the Social Security Act (42 U.S.C. 1395w-4) for physicians' services so that the estimated total amount of payments for such services furnished during fiscal years 2010 through 2019 is equal to the estimated total amount of payments for such services that would have been made in such fiscal years if this section did not apply plus an amount equal to the total funds rescinded under subsection (a).

SA 3607. Mr. BENNETT submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

On page 113, after line 21, insert the following:

SEC. 1502. STATE OPTION TO OPT-OUT OF NEW FEDERAL PROGRAM AND REQUIREMENTS.

(a) IN GENERAL.—In accordance with this section, a State may elect for the provisions of the Patient Protection and Affordable Care Act to not apply within such State to the extent that such provisions violate the protections described in subsection (b).

(b) EFFECT OF OPT-OUT.—In the case of a State that makes an election under subsection (a)—

(1) the residents of such State shall not be subject to any requirement under such Act, including tax provisions or penalties, that would otherwise require such residents to purchase health insurance;

(2) the employers located in such State shall not be subject to any requirement under such Act, including tax provisions or penalties, that would otherwise require such employers to provide health insurance to their employees or make contributions relating to health insurance;

(3) the residents of such State shall not be prohibited under such Act from receiving health care services from any provider of health care services under terms and conditions subject to the laws of such State and mutually acceptable to the patient and the provider;

(4) the residents of such State shall not be prohibited under such Act from entering into a contract subject to the laws of such State with any group health plan, health insurance issuer, or other business, for the provision of, or payment to other parties for, health care services;

(5) the eligibility of residents of such State for any program operated by or funded wholly or partly by the Federal Government shall not be adversely affected as a result of having received services in a manner consistent with paragraphs (3) and (4);

(6) the health care providers within such State shall not be denied participation in or payment from a Federal program for which they would otherwise be eligible as a result of having provided services in a manner consistent with paragraphs (3) and (4); and

(7) such State shall not be subject to the taxes and fees enumerated in the amendments made by title IX of such Act.

(c) PROCESS.—A State shall be treated as making an election under subsection (a) if—

(1) the Governor of such State provides timely and appropriate notice, at least 180 days before the election is to become effective, to the Secretary of Health and Human Services notifying the Secretary that the State is making such election; or

(2) the legislature of such State enacts a law to provide for such election.

SA 3608. Mrs. HUTCHISON (for herself, Mr. ENZI, Mr. COBURN, Mr. BURR, Mr. BROWN of Massachusetts, and Mr. CRAPO) proposed an amendment to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

At the end of section 1002, insert the following:

(c) RIGHT OF STATES TO OPT OUT OF FEDERAL HEALTH CARE TAKEOVER.—Section 1321(d) of the Patient Protection and Affordable Care Act is amended—

(1) by striking ''Nothing'' and inserting:

''(1) IN GENERAL.—Except as provided in paragraph (2), nothing''; and

(2) by adding at the end the following:

''(2) EXCEPTION FOR OPT OUT OF HEALTH CARE REFORM.—The provisions of, and the amendments made by, this Act shall not preempt any State law enacted after the date of enactment of this Act that exempts the State from such provisions or amendments, including, but not limited to, provisions and amendments relating to the individual mandate, the employer mandate, taxes on prescription drugs, taxes on medical devices, taxes on high value health plans, Medicare cuts, and the unfunded expansion of Medicaid.''.

SA 3609. Mr. JOHANNS submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle B of title I, insert the following:

SEC. _____. DISCLOSURE OF AGREEMENTS WITH COMPANIES, UNIONS, AND ASSOCIATIONS.

Not later than 30 days after the date of enactment of this Act, the President shall disclose any agreement made between the White House or any of its designees and a company, union, or association on the Patient Protection and Affordable Care Act or this Act.

SA 3610. Mr. JOHANNS submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

On page 144, between lines 2 and 3, insert the following:

SEC. 2214. ONGOING RECORD OF JOBS LOST.

The Secretary of Labor shall keep an ongoing record of jobs lost due to the termination of the Robert T. Stafford Federal Student Loan Program.

SA 3611. Mr. JOHANNS submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle B of title I, add the following:

SEC. ____. DELAYED IMPLEMENTATION.

Notwithstanding any other provision of this Act or the Patient Protection and Affordable Care Act, or the amendments made by this Act or the Patient Protection and Affordable Care Act, such provisions and amendments shall not take effect before the date that the Board of Trustees of the Federal Hospital Insurance Trust Fund under section 1817 of the Social Security Act (42 U.S.C. 1395i) submits an annual report to Congress under subsection (b)(2) of such section that includes a statement that such Trust Fund is projected to be solvent through 2037.

SA 3612. Mr. JOHANNS submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle B of title I, insert the following:

SEC. _____. STATE OPT OUT.

A State may opt out of the application of the Patient Protection and Affordable Care Act and this Act effective upon notice by the Governor of that State to the President.

SA 3613. Mr. JOHANNS submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle B of title I, insert the following:

SEC. _____. PROHIBITING IRS HIRING.

The Internal Revenue Service shall not hire any additional staff for the purpose of enforcing, implementing, or administering the Patient Protection and Affordable Care Act and this Act.

SA 3614. Mr. JOHANNS submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle B of title I, insert the following:

SEC. _____. JOB LOSS RECORDS DUE TO HEALTH CARE BILL.

The Director of the Office of Management and Budget, in coordination with the Secretary of Labor, shall submit a semiannual public report to Congress detailing the record of jobs lost due to additional taxes, fees, and mandates contained in the Patient Protection and Affordable Care Act and this Act.

SA 3615. Mr. JOHANNS submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle C of title I, add the following:

SEC. 1207. NONAPPLICATION OF ANY MEDICAID ELIGIBILITY EXPANSION UNTIL REDUCTION IN MEDICAID FRAUD RATE.

Notwithstanding any other provision of law, with respect to a State, any provision of law that imposes on or after the date of enactment of this Act a federally-mandated expansion of eligibility for Medicaid shall not apply to the State before the date on which the State Medicaid Director certifies to the Secretary of Health and Human Services that the Medicaid payment error rate measurement (commonly referred to as ''PERM'') for the State does not exceed 5 percent.

SA 3616. Mr. JOHANNS submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle B of title I, add the following:

SEC. ____. EXEMPTING CRITICAL ACCESS HOSPITALS FROM RECOMMENDATIONS OF THE INDEPENDENT PAYMENT ADVISORY BOARD.

Section 1899A(c)(2)(A) of the Social Security Act, as added by section 3403 of the Patient Protection and Affordable Care Act and amended by section 10320 of such Act, is amended by adding at the end the following new clause:

''(vii) The proposal shall not include any recommendation that would reduce payment rates for items and services furnished by a critical access hospital (as defined in section 1861(mm)(1)).''.

SA 3617. Mr. JOHANNS submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

On page 144, between lines 2 and 3, insert the following:

SEC. 2214. PROHIBITION REGARDING SPENDING FOR ADDITIONAL EDUCATION EMPLOYEES AND FOR IMPLEMENTING THE GOVERNMENT TAKEOVER OF THE STUDENT LOAN INDUSTRY.

Notwithstanding any other provision of this subtitle, none of the funds made available under this subtitle or the amendments made by this subtitle shall be available to hire additional employees at the Department of Education who are responsible for implementing, or to implement, the provisions of this subtitle or the amendments made by this subtitle related to the termination of the Robert T. Stafford Federal Student Loan Program.

SA 3618. Mr. CRAPO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

Strike section 1403 and insert the following:

SECTION 1403. REPEAL OF LIMITATION ON FLEXIBLE SPENDING ARRANGEMENTS UNDER CAFETERIA PLANS.

Sections 9005 and 10902 of the Patient Protection and Affordable Care Act are hereby repealed effective as of the date of the enactment of such Act and any provisions of law amended by such sections are amended to read as such provisions would read if such sections had never been enacted.

SA 3619. Mr. CRAPO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

Strike section 1105 and insert the following:

SEC. 1105. REPEAL OF THE PRODUCTIVITY AND OTHER MARKET BASKET ADJUSTMENTS.

Effective as if included in the enactment of the Patient Protection and Affordable Care Act, sections 3401 and 10319 of such Act (and the amendments made by such sections) are repealed.

SA 3620. Mr. CRAPO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of section 1003, add the following:

(e) INCREASE IN SIZE OF APPLICABLE LARGE EMPLOYER.—Section 4980H(d)(2) of the Internal Revenue Code of 1986, as added by the Patient Protection and Affordable Care Act, is amended by striking ''50'' each place it appears and inserting ''499''.

SA 3621. Mr. CRAPO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle E of title I, add the following:

SECTION 14___. REPEAL OF LIMITATION ON DEDUCTIONS FOR OVER-THE-COUNTER MEDICINE.

Section 9003 of the Patient Protection and Affordable Care Act is hereby repealed effective as of the date of the enactment of such Act and any provisions of law amended by such section is amended to read as such provision would read if such section had never been enacted.

SA 3622. Mr. CRAPO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle E of title I, add the following:

SEC. 14___. REPEAL OF ADDITIONAL TAX FROM DISTRIBUTIONS FROM HSAS AND MSAS.

(a) HSAs.—Section 223(f)(4)(A) of the Internal Revenue Code of 1986, as amended by section 9004 of the Patient Protection and Affordable Care Act, is amended by striking ''20 percent'' and inserting ''10 percent''.

(b) ARCHER MSAs.—Section 220(f)(4)(A) of the Internal Revenue Code of 1986, as amended by section 9004 of the Patient Protection and Affordable Care Act, is amended by striking ''20 percent'' and inserting ''15 percent''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to distributions made after December 31, 2010.

SA 3623. Mr. CRAPO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

Strike section 1402 and insert the following:

SECTION 1402. REPEAL OF ADDITIONAL HOSPITAL INSURANCE TAX AND UNEARNED INCOME MEDICARE CONTRIBUTION.

Sections 9015 and 10906 of the Patient Protection and Affordable Care Act are hereby repealed effective as of the date of the enactment of such Act and any provisions of law amended by such sections are amended to read as such provisions would read if such sections had never been enacted.

SA 3624. Mr. CRAPO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle E of title I, add the following:

SECTION 14___. REPEAL OF MODIFICATION OF ITEMIZED DEDUCTION FOR MEDICAL EXPENSES.

Section 9013 of the Patient Protection and Affordable Care Act is hereby repealed effective as of the date of the enactment of such Act and any provisions of law amended by such section is amended to read as such provision would read if such section had never been enacted.

SA 3625. Mr. CRAPO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

Strike section 1401 and insert the following:

SECTION 1401. REPEAL OF EXCISE TAX ON HIGH COST EMPLOYER-SPONSORED HEALTH COVERAGE.

Sections 9001 and 10901 of the Patient Protection and Affordable Care Act are hereby repealed effective as of the date of the enactment of such Act and any provisions of law amended by such sections are amended to read as such provisions would read if such sections had never been enacted.

SA 3626. Mr. CRAPO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle F of title I, add the following::

SEC. 15___. NON-APPLICATION OF PROVISIONS TO CERTAIN INDIVIDUALS.

(a) IN GENERAL.—Notwithstanding any provision of, or amendment made by, this Act or the Patient Protection and Affordable Care Act, no such provision or amendment which, directly or indirectly, results in an increase in Federal tax liability with respect to any taxpayer for any taxable year described in subsection (b) shall be administered in such a manner as to impose such an increase on such taxpayer.

(b) FEDERAL TAX INCREASE.—An increase in Federal tax liability with respect to any taxpayer for any taxable year is described in this subsection if the amount of Federal taxes owed for such taxable year is in excess of the amount of Federal taxes which would be owed by such taxpayer for such taxable year under the Internal Revenue Code of 1986 as in effect for taxable years beginning in 1999.

SA 3627. Mr. CRAPO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle E of title I, add the following:

SEC. 14___. NO FEDERAL TAX INCREASE IMPOSED ON MIDDLE INCOME INDIVIDUALS AND FAMILIES.

(a) IN GENERAL.—Notwithstanding any provision of, or amendment made by, this Act or the Patient Protection and Affordable Care Act, no such provision or amendment which, directly or indirectly, results in a Federal tax increase shall be administered in such manner as to impose such an increase on any middle income taxpayer.

(b) MIDDLE INCOME TAXPAYER.—For purposes of this section, the term ''middle income taxpayer'' means, for any taxable year, any taxpayer with adjusted gross income (as defined in section 62 of the Internal Revenue Code of 1986) of less than $200,000 ($250,000 in the case of a joint return of tax).

SA 3628. Mr. CRAPO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle B of title I, add the following:

SEC. ___. REPEAL OF THE CENTER FOR MEDICARE AND MEDICAID INNOVATION.

(a) IN GENERAL.—Effective as if included in the enactment of the Patient Protection and Affordable Care Act, sections 3021 and 10306 of such Act (and the amendments made by such sections) are repealed.

(b) CONFORMING AMENDMENTS.—

(1) Section 2705 of the Patient Protection and Affordable Care Act is amended—

(A) in subsection (a), by striking ''shall, in coordination'' and that follows through ''establish'' and inserting ''shall establish''; and

(B) in subsection (d)(2), by striking ''section 1115A(b)(3) of the Social Security Act (as so added)'' and inserting ''the Social Security Act''.

(2) Section 1899(b)(4) of the Social Security Act, as added by section 3022 of the Patient Protection and Affordable Care Act, is amended by striking ''any of the following''

and all that follows through the period at the end of subparagraph (B) and inserting ''the independence at home medical practice pilot program under section 1866E.''.

(3) Section 933 of the Public Health Service Act, as added by section 3501 of the Patient Protection and Affordable Care Act, is amended by striking subsection (f).

(4) Section 10328(b) of the Patient Protection and Affordable Care Act is amended by striking ''or to study'' and all that follows through ''3021''.

(5) EFFECTIVE DATE.—The amendments made by this subsection shall take effect as if included in the enactment of the Patient Protection and Affordable Care Act.

SA 3629. Mr. CRAPO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle B of title I, add the following:

SEC. ___. REPEAL OF THE INDEPENDENT PAYMENT ADVISORY BOARD.

Effective as if included in the enactment of the Patient Protection and Affordable Care Act, sections 3403 and 10320 of such Act (and the amendments made by such sections) are repealed.

SA 3630. Mr. CRAPO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

Beginning on page 30, strike line 17 and all that follows through page 50, line 11.

SA 3631. Mr. CRAPO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle B of title I, insert the following:

SEC. ___. REPEALING PAYMENT ADJUSTMENTS FOR HOME HEALTH CARE.

Effective as if included in the enactment of the Patient Protection and Affordable Care Act, sections 3131 and 3401(e) of such Act (and the amendments made by such sections) are repealed.

SA 3632. Mr. CRAPO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle B of title I, insert the following:

SEC. ___. REPEALING PAYMENT ADJUSTMENTS FOR HOSPICE CARE.

Effective as if included in the enactment of the Patient Protection and Affordable Care Act, sections 3004(c), 3132, and 3401(g) of such Act (and the amendments made by such sections) are repealed.

SA 3633. Mr. CRAPO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

Strike section 1104 and insert the following:

SEC. 1104. REPEALING CUTS TO MEDICARE DISPROPORTIONATE SHARE HOSPITAL PAYMENTS.

Effective as if included in the enactment of the Patient Protection and Affordable Care Act, sections 3133 and 10316 of such Act (and the amendments made by such sections) are repealed.

SA 3634. Mrs. HUTCHISON submitted an amendment intended to be proposed by her to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

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

SEC. 1006. REPEAL OF TAXABLE YEAR LIMITATION ON SMALL BUSINESS TAX CREDIT.

(a) IN GENERAL.—Section 45R of the Internal Revenue Code of 1986, as added by section 1421 of the Patient Protection and Affordable Care Act and amended by section 10105(e) of such Act, is amended—

(1) by striking ''in the credit period'' in subsection (a),

(2) in subsection (e), by striking paragraph (2) and redesignating paragraphs (3), (4), and (5) as paragraphs (2), (3), and (4), respectively,

(3) in subsection (g), by striking paragraph (1) and redesignating paragraphs (2) and (3) as paragraphs (1) and (2), respectively, and

(4) by striking ''to prevent the avoidance of the 2-year limit on the credit period through the use of successor entities and'' in subsection (i).

(b) EFFECTIVE DATE.—The amendments made by this section shall take effect as if included in the provisions of the Patient Protection and Affordable Care Act to which the amendments relate.

SA 3635. Mrs. HUTCHISON submitted an amendment intended to be proposed by her to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle F of title I, add the following:

SEC. 15___. PERMANENT TAX RELIEF PROVISIONS.

(a) REPEAL OF SUNSET ON MARRIAGE PENALTY RELIEF.—Title IX of the Economic Growth and Tax Relief Reconciliation Act of 2001 (relating to sunset of provisions of such Act) shall not apply to sections 301, 302, and 303(a) of such Act (relating to marriage penalty relief).

(b) PERMANENT EXTENSION OF ELECTION TO DEDUCT STATE AND LOCAL SALES TAXES.—Subparagraph (I) of section 164(b)(5) of the Internal Revenue Code of 1986 is amended by striking '', and before January 1, 2010''.

(c) RESCISSION OF STIMULUS FUNDS.—Any amounts appropriated or made available and remaining unobligated under division A of the American Recovery and Reinvestment Act of 2009 (Public Law 111–5; 123 Stat. 115) (other than under title X of such division A), are hereby rescinded.

SA 3636. Mr. BROWNBACK submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

On page 113, after line 21, add the following:

SEC. 1502. CIVIL ACTIONS.

For purposes of any civil action in which a State challenges any provision of this Act, or an amendment made by this Act, the State shall be—

(1) deemed to be a party for purposes of section 2412(d) of title 28, United States Code; and

(2) entitled to an award of attorney's fees under section 2412(d)(1)(A) of title 28, United States Code, if the State is a prevailing party, without regard to whether the position of the United States was substantially justified or whether there are special circumstances.

SA 3637. Mr. BROWNBACK submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

On page 113, after line 21, add the following:

SEC. 1502. OPEN FUEL STANDARD.

(a) SHORT TITLE.—This section may be cited as the ''Open Fuel Standard Act of 2009'' or the ''OFS Act''.

(b) FINDINGS.—Congress makes the following findings:

(1) The status of oil as a strategic commodity, which derives from its domination of the transportation sector, presents a clear and present danger to the United States;

(2) in a prior era, when salt was a strategic commodity, salt mines conferred national power and wars were fought over the control of such mines;

(3) technology, in the form of electricity and refrigeration, decisively ended salt's monopoly of meat preservation and greatly reduced its strategic importance;

(4) fuel competition and consumer choice would similarly serve to end oil's monopoly in the transportation sector and strip oil of its strategic status;

(5) the current closed fuel market has allowed a cartel of petroleum exporting countries to inflate fuel prices, effectively imposing a harmful tax on the economy of the United States;

(6) much of the inflated petroleum revenues the oil cartel earns at the expense of the people of the United States are used for purposes antithetical to the interests of the United States and its allies;

(7) alcohol fuels, including ethanol and methanol, could potentially provide significant supplies of additional fuels that could be produced in the United States and in many other countries in the Western Hemisphere that are friendly to the United States;

(8) alcohol fuels can only play a major role in securing the energy independence of the United States if a substantial portion of vehicles in the United States are capable of operating on such fuels;

(9) it is not in the best interest of United States consumers or the United States Government to be constrained to depend solely upon petroleum resources for vehicle fuels if alcohol fuels are potentially available;

(10) existing technology, in the form of flexible fuel vehicles, allows internal combustion engine cars and trucks to be produced at little or no additional cost, which are capable of operating on conventional gasoline, alcohol fuels, or any combination of such fuels, as availability or cost advantage dictates, providing a platform on which fuels can compete;

(11) the necessary distribution system for such alcohol fuels will not be developed in the United States until a substantial fraction of the vehicles in the United States are capable of operating on such fuels;

(12) the establishment of such a vehicle fleet and distribution system would provide a large market that would mobilize private resources to substantially advance the technology and expand the production of alcohol fuels in the United States and abroad;

(13) the United States has an urgent national security interest to develop alcohol fuels technology, production, and distribution systems as rapidly as possible;

(14) new cars sold in the United States that are equipped with an internal combustion engine should allow for fuel competition by being flexible fuel vehicles, and new diesel cars should be capable of operating on biodiesel; and

(15) such an open fuel standard would help to protect the United States economy from high and volatile oil prices and from the threats caused by global instability, terrorism, and natural disaster.

(c) OPEN FUEL STANDARD FOR TRANSPORTATION.—

(1) IN GENERAL.—Chapter 329 of title 49, United States Code, is amended by adding at the end the following:

''§ 32920. Open fuel standard for transportation

''(a) DEFINITIONS.—In this section:

''(1) E85.—The term 'E85' means a fuel mixture containing 85 percent ethanol and 15 percent gasoline by volume.

''(2) FLEXIBLE FUEL AUTOMOBILE.—The term 'flexible fuel automobile' means an automobile that has been warranted by its manufacturer to operate on gasoline, E85, and M85.

''(3) FUEL CHOICE-ENABLING AUTOMOBILE.—The term 'fuel choice-enabling automobile' means—

''(A) a flexible fuel automobile; or

''(B) an automobile that has been warranted by its manufacturer to operate on biodiesel.

''(4) LIGHT-DUTY AUTOMOBILE.—The term 'light-duty automobile' means—

''(A) a passenger automobile; or

''(B) a non-passenger automobile.

''(5) LIGHT-DUTY AUTOMOBILE MANUFACTURER'S ANNUAL COVERED INVENTORY.—The term 'light-duty automobile manufacturer's annual covered inventory' means the number of light-duty automobiles powered by an internal combustion engine that a manufacturer, during a given calendar year, manufactures in the United States or imports from outside of the United States for sale in the United States.

''(6) M85.—The term 'M85' means a fuel mixture containing 85 percent methanol and 15 percent gasoline by volume.

''(b) OPEN FUEL STANDARD FOR TRANSPORTATION.—

''(1) IN GENERAL.—Except as provided in paragraph (2), each light-duty automobile manufacturer's annual covered inventory shall be comprised of—

''(A) not less than 50 percent fuel choice-enabling automobiles in 2012, 2013, and 2014; and

''(B) not less than 80 percent fuel choice-enabling automobiles in 2015, and in each subsequent year.

''(2) TEMPORARY EXEMPTION FROM REQUIREMENTS.—

''(A) APPLICATION.—A manufacturer may request an exemption from the requirement described in paragraph (1) by submitting an application to the Secretary, at such time, in such manner, and containing such information as the Secretary may require by regulation. Each such application shall specify the models, lines, and types of automobiles affected.

''(B) EVALUATION.—After evaluating an application received from a manufacturer, the Secretary may at any time, under such terms and conditions, and to such extent as the Secretary considers appropriate, temporarily exempt, or renew the exemption of, a light-duty automobile from the requirement described in paragraph (1) if the Secretary determines that unavoidable events that are not under the control of the manufacturer prevent the manufacturer of such automobile from meeting its required production volume of fuel choice-enabling automobiles, including—

''(i) a disruption in the supply of any component required for compliance with the regulations;

''(ii) a disruption in the use and installation by the manufacturer of such component; or

''(iii) the failure for plug-in hybrid electric automobiles to meet State air quality requirements as a result of the requirement described in paragraph (1).

''(C) CONSOLIDATION.—The Secretary may consolidate applications received from multiple manufactures under subparagraph (A) if they are of a similar nature.

''(D) CONDITIONS.—Any exemption granted under subparagraph (B) shall be conditioned upon the manufacturer's commitment to recall the exempted automobiles for installation of the omitted components within a reasonable time proposed by the manufacturer and approved by the Secretary after such components become available in sufficient quantities to satisfy both anticipated production and recall volume requirements.

''(E) NOTICE.—The Secretary shall publish in the Federal Register—

''(i) notice of each application received from a manufacturer;

''(ii) notice of each decision to grant or deny a temporary exemption; and

''(iii) the reasons for granting or denying such exemptions.

''(c) LIMITED LIABILITY PROTECTION FOR RENEWABLE FUEL AND ETHANOL MANUFACTURE, USE, OR DISTRIBUTION.—

''(1) IN GENERAL.—Notwithstanding any other provision of Federal or State law, any fuel containing ethanol or a renewable fuel (as defined in section 211(o)(1) of the Clean Air Act) that is used or intended to be used to operate an internal combustion engine shall not be deemed to be a defective product or subject to a failure to warn due to such ethanol or renewable fuel content unless such fuel violates a control or prohibition imposed by the Administrator under section 211 of the Clean Air Act (42 U.S.C. 7545).

''(2) SAVINGS PROVISION.—Nothing in this subsection may be construed to affect the liability of any person other than liability based upon a claim of defective product and failure to warn described in paragraph (1).

''(d) RULEMAKING.—Not later than 1 year after the date of the enactment of this section, the Secretary of Transportation shall promulgate regulations to carry out this section.''.

(2) CLERICAL AMENDMENT.—The table of sections for chapter 329 of title 49, United States Code, is amended by adding at the end the following:

''32920. Open fuel standard for transportation.''.

SA 3638. Ms. COLLINS proposed an amendment to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

At the end of section 1003, add the following:

(e) UNEMPLOYED INDIVIDUAL NOT TAKEN INTO ACCOUNT.—Paragraph (5) of section 4980H(d) of the Internal Revenue Code of 1986, as added by the Patient Protection and Affordable Care Act, is amended by adding at the end the following new subparagraph:

''(C) EXCEPTION FOR PREVIOUSLY UNEMPLOYED INDIVIDUALS.—

''(i) IN GENERAL.—The term 'full-time employee' shall not include any individual who certifies by signed affidavit, under penalties of perjury, that such individual has not been employed from more than 40 hours during the 60-day period ending on the date such individual begins such employment.

''(ii) EXCEPTION FOR REPLACEMENT WORKERS.—Clause (i) shall not apply to an individual who is employed by the employer to replace another employee of such employer unless such other employee separated from employment voluntarily or for cause.''.

SA 3639. Mr. THUNE proposed an amendment to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

Beginning on page 123, strike line 10 and all that follows through page 124, line 10, and insert the following:

SEC. 2201. TERMINATION OF FEDERAL FAMILY EDUCATION LOAN APPROPRIATIONS.

Section 421 (20 U.S.C. 1071) is amended—

(1) in subsection (b), in the first sentence of the matter following paragraph (6), by inserting '', except that no sums may be expended after June 30, 2010, with respect to loans under this part for which the first disbursement is after such date if the Secretary certifies that no State will experience a net job loss as a result of the enactment of the SAFRA Act'' after ''expended''; and

(2) by adding at the end the following new subsection:

''(d) TERMINATION OF AUTHORITY TO MAKE OR INSURE NEW LOANS.—Notwithstanding paragraphs (1) through (6) of subsection (b) or any other provision of law—

''(1) no new loans (including consolidation loans) may be made or insured under this part after June 30, 2010 if the Secretary certifies that no State will experience a net job loss as a result of the enactment of the SAFRA Act; and

''(2) no funds are authorized to be appropriated, or may be expended, under this Act or any other Act to make or insure loans under this part (including consolidation loans) for which the first disbursement is after June 30, 2010 if the Secretary certifies that no State will experience a net job loss as a result of the enactment of the SAFRA Act,

except as expressly authorized by an Act of Congress enacted after the date of enactment of the SAFRA Act.''.

SA 3640. Mr. THUNE (for himself, Mr. COBURN, and Mr. CRAPO) proposed an amendment to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

At the end of subtitle B of title II, add the following:

SEC. 2304. REPEAL OF THE CLASS ACT.

Title VIII of the Patient Protection and Affordable Care Act and the amendments made by that title are repealed.

SA 3641. Mr. DEMINT submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. SECRET BALLOT PROTECTION.

(a) SHORT TITLE.—This section may be cited as the ''Secret Ballot Protection Act of 2010''.

(b) FINDINGS.—Congress makes the following findings:

(1) The right of employees under the National Labor Relations Act (29 U.S.C. 151 et seq.) to choose whether to be represented by a labor organization by way of secret ballot election conducted by the National Labor Relations Board is among the most important protections afforded under Federal labor law.

(2) The right of employees to choose by secret ballot is the only method that ensures a choice free of coercion, intimidation, irregularity, or illegality.

(3) The recognition of a labor organization by using a private agreement, rather than a secret ballot election overseen by the National Labor Relations Board, threatens the freedom of employees to choose whether to be represented by a labor organization, and severely limits the ability of the National Labor Relations Board to ensure the protection of workers.

(c) NATIONAL LABOR RELATIONS ACT.—

(1) RECOGNITION OF REPRESENTATIVE.—

(A) IN GENERAL.—Section 8(a)(2) of the National Labor Relations Act (29 U.S.C. 158(a)(2)) is amended by inserting before the colon the following: ''or to recognize or bargain collectively with a labor organization that has not been selected by a majority of such employees in a secret ballot election conducted by the Board in accordance with section 9''.

(B) APPLICATION.—The amendment made by subparagraph (A) shall not apply to collective bargaining relationships in which a labor organization with majority support was lawfully recognized prior to the date of enactment of this Act.

(2) ELECTION REQUIRED.—

(A) IN GENERAL.—Section 8(b) of the National Labor Relations Act (29 U.S.C. 158(b)) is amended—

(i) in paragraph (6), by striking ''and'' at the end;

(ii) in paragraph (7), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following:

''(8) to cause or attempt to cause an employer to recognize or bargain collectively with a representative of a labor organization that has not been selected by a majority of such employees in a secret ballot election conducted by the Board in accordance with section 9.''.

(B) APPLICATION.—The amendment made by subparagraph (A) shall not apply to collective bargaining relationships that were recognized prior to the date of enactment of this Act.

(3) SECRET BALLOT ELECTION.—Section 9(a) of the National Labor Relations Act (29 U.S.C. 159(a)) is amended—

(A) by striking ''Representatives'' and inserting ''(1) Representatives'';

(B) by inserting after ''designated or selected'' the following: ''by a secret ballot election conducted by the Board in accordance with this section''; and

(C) by adding at the end the following:

''(2) The secret ballot election requirement under paragraph (1) shall not apply to collective bargaining relationships that were recognized before the date of the enactment of the Health Care and Education Reconciliation Act of 2010.''.

(d) REGULATIONS AND AUTHORITY.—

(1) REGULATIONS.—Not later than 6 months after the date of enactment of this Act, the National Labor Relations Board shall review and revise all regulations promulgated prior to such date of enactment to implement the amendments made by this section.

(2) AUTHORITY.—Nothing in this section (or the amendments made by this section) shall be construed to limit or otherwise diminish the remedial authority of the National Labor Relations Board.

SA 3642. Mr. DEMINT submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle B of title I, add the following:

SEC. ___. ALLOWING INDIVIDUALS TO CHOOSE TO OPT OUT OF THE MEDICARE PART A BENEFIT.

Notwithstanding any other provision of law, in the case of an individual who elects to opt-out of benefits under part A of title XVIII of the Social Security Act, such individual shall not be required to—

(1) opt-out of benefits under title II of such Act as a condition for making such election; and

(2) repay any amount paid under such part A for items and services furnished prior to making such election.

SA 3643. Ms. MURKOWSKI submitted an amendment intended to be proposed by her to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle B of title I, insert the following:

SEC. ___. ALLOWING INDIVIDUALS TO CHOOSE TO OPT OUT OF THE MEDICARE PART A BENEFIT.

Notwithstanding any other provision of law, in the case of an individual who elects to opt-out of benefits under part A of title XVIII of the Social Security Act, such individual shall not be required to—

(1) opt-out of benefits under title II of such Act as a condition for making such election; and

(2) repay any amount paid under such part A for items and services furnished prior to making such election.

SA 3644. Mr. HATCH (for himself, Mr. COBURN, and Mr. CRAPO) proposed an amendment to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

On page 99, between lines 9 and 10, insert the following:

(e) EXCLUSION OF MEDICAL DEVICES SOLD UNDER THE TRICARE FOR LIFE PROGRAM OR VETERAN'S HEALTH CARE PROGRAMS.—

(1) IN GENERAL.—For purposes of section 4191(b)(1) of the Internal Revenue Code of 1986, as added by subsection (a), the term ''taxable medical device'' shall not include any device which is sold to individuals covered under the TRICARE for Life program or the veteran's health care program under chapter 17 of title 38, United States Code, any portion of the cost of which is paid or reimbursed under either such program.

(2) EXPANSION OF AFFORDABILITY EXCEPTION TO INDIVIDUAL MANDATE.—Section 5000A(e)(1)(A) of the Internal Revenue Code of 1986, as added by section 1501(b) of the Patient Protection and Affordable Care Act and amended by section 10106 of such Act, is amended by striking ''8 percent'' and inserting ''5 percent''.

(3) APPLICATION OF PROVISION.—The amendment made by paragraph (2) shall apply as if included in the Patient Protection and Affordable Care Act.

SA 3645. Mr. RISCH (for himself and Mr. CRAPO) submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

At the end of subtitle E of title I, insert the following:

SECTION—.REPEAL OF LIMITATION ON ITEMIZED DEDUCTIONS FOR MEDICAL EXPENSES.

(a) IN GENERAL.—Section 9013 of the Patient Protection and Affordable Care Act is hereby repealed effective as of the date of the enactment of such Act and any provisions of law amended by such section are amended to read as such provisions would read if such section had never been enacted.

(b) EXPANSION OF AFFORDABILITY EXCEPTION TO INDIVIDUAL MANDATE.—Section 5000A(e)(1)(A) of the Internal Revenue Code of 1986, as added by section 1501(b) of the Patient Protection and Affordable Care Act and amended by section 10106 of such Act, is amended by striking ''8 percent'' and inserting ''5 percent''.

(c) APPLICATION OF PROVISION.—The amendment made by subsection (b) shall apply as if included in the Patient Protection and Affordable Care Act.

SA 3646. Mr. RISCH submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

At the end of subtitle C of title I, add the following:

SEC. 1207. REQUIREMENT FOR ALL MEDICAID AND CHIP APPLICANTS TO PRESENT AN IDENTIFICATION DOCUMENT.

(a) IN GENERAL.—Section 1902 of the Social Security Act (42 U.S.C. 1396a), as amended by section 211(a)(1)(A)(i) of Public Law 111–3, section 2303(a)(2) of the Patient Protection and Affordable Care Act, and section 1202 of this Act, is amended—

(1) in subsection (a)(46), —

(A) in subparagraph (A), by striking ''and'' after the semicolon;

(B) in subparagraph (B), by adding ''and'' after the semicolon; and

(C) by adding at the end the following:

''(C) provide that each applicant for medical assistance (or the parent or guardian of an applicant who has not attained age 18), regardless of whether the applicant is described in paragraph (2) of section 1903(x), shall present an identification document described in subsection (kk) when applying for

medical assistance (and shall be provided with at least the reasonable opportunity to present such identification as is provided under clauses (i) and (ii) of section 1137(d)(4)(A) to an individual for the submittal to the State of evidence indicating a satisfactory immigration status;''; and

(2) by adding at the end the following:

''(kk) For purposes of subsection (a)(46)(C), a document described in this subsection is—

''(1) in the case of an individual who is a national of the United States—

''(A) a United States passport, or passport card issued pursuant to the Secretary of State's authority under the first section of the Act of July 3, 1926 (44 Stat. 887, Chapter 772; 22 U.S.C. 211a); or

''(B) a driver's license or identity card issued by a State, the Commonwealth of the Northern Mariana Islands, or an outlying possession of the United States that—

''(i) contains a photograph of the individual and other identifying information, including the individual's name, date of birth, gender, and address; and

''(ii) contains security features to make the license or card resistant to tampering, counterfeiting, and fraudulent use;

''(2) in the case of an alien lawfully admitted for permanent residence in the United States, a permanent resident card, as specified by the Secretary of Homeland Security that meets the requirements of clauses (i) and (ii) of paragraph (1)(B);

''(3) in the case of an alien who is authorized to be employed in the United States, an employment authorization card, as specified by the Secretary of Homeland Security that meets the requirements of clauses (i) and (ii) of paragraph (1)(B); or

''(4) in the case of an individual who is unable to obtain a document described in paragraph (1), (2), or (3), a document designated by the Secretary of Homeland Security that meets the requirements of clauses (i) and (ii) of paragraph (1)(B).''.

(b) APPLICATION TO CHIP.—Section 2105(c)(9)(A) (42 U.S.C. 1397ee(c)(9)(A)) is amended by striking ''section 1902(a)(46)(B)'' and inserting ''subparagraphs (B) and (C) of subsection (a)(46) and subsection (kk) of section 1902''.

SA 3647. Mr. COLLINS submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

At the end of section 1001, insert the following:

(c) BEREAVEMENT EXCEPTION IN DETERMINING FAMILY SIZE.—

(1) IN GENERAL.—Section 36B(d)(1) of the Internal Revenue Code of 1986, as added by section 1401 of the Patient Protection and Affordable Care Act and amended by section 10105 of such Act is amended by adding at the end the following new sentence: ''If an individual taken into account under the preceding sentence for any taxable year dies during such taxable year, such individual shall be taken into account in determining family size for the following taxable year unless the family size for the taxable year of death was only one.''

(2) EFFECTIVE DATE.—The amendment made by this section shall take effect as if included in the provision of the Patient Protection and Affordable Care Act to which the amendment relates.

SA 3648. Mr. COBURN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

On page 144, between lines 2 and 3, insert the following:

SEC. 2214. DIRECT LOAN ORIGINATION FEE REDETERMINATION.

Notwithstanding section 455(c) of the Higher Education Act of 1965 (20 U.S.C. 1087e(c)), the Secretary of Education shall determine under such section an increase to the origination fee charged to a borrower of a loan made under part D of title IV of such Act (20 U.S.C. 1087a et seq.) for the subsequent award year to take into account any increase in actual program costs for the Federal Direct Loan Program under such part D, as determined by the Office of Management and Budget in the program re-estimate contained in the President's current fiscal year budget.

SA 3649. Mr. COBURN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

On page 144, between lines 2 and 3, insert the following:

SEC. 2214. QUALIFICATION REQUIREMENT FOR DEPARTMENT OF EDUCATION STAFF.

Not later than 6 years after the date of enactment of this Act, each employee of the Department of Education Office of Federal Student Aid shall become highly qualified in fiscal management by earning a bachelor's degree in finance or business management/administration.

SA 3650. Mr. COBURN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

On page 144, between lines 2 and 3, insert the following:

SEC. 2214. REDUCTION OF FEDERAL PELL GRANT ADD ON.

Notwithstanding any other provision of law, the additional funds amount provided under section 401(b)(8) of the Higher Education Act of 1965 (20 U.S.C. 1070a(b)(8)) for Federal Pell Grants for a fiscal year shall be reduced for such fiscal year by the amount that reflects any increase in actual program costs for the Federal Direct Loan Program under part D of title IV of the Higher Education Act of 1965 (20 U.S.C. 1087a et seq.), as determined by the Office of Management and Budget in the program re-estimate contained in the President's current fiscal year budget.

SA 3651. Mr. GREGG proposed an amendment to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

On page 61, between lines 3 and 4, insert the following:

SEC. ___. INCREASE IN THE MEDICARE PHYSICIAN PAYMENT UPDATE FOR THE LAST 9 MONTHS OF 2010 AND ALL OF 2011 THROUGH 2013.

Paragraph (1) of section 1848(d) of the Social Security Act, as added by section 1011(a) of the Department of Defense Appropriations Act, 2010 (Public Law 111–118) and as amended by section 5 of the Temporary Extension Act of 2010 (Public Law 111–144), is amended to read as follows:

''(10) UPDATE FOR 2010 THROUGH 2013.—

''(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, 2012, and 2013, the update to the single conversion factor shall be 0 percent for such years.

''(B) NO EFFECT ON COMPUTATION OF CONVERSION FACTOR FOR 2014 AND SUBSEQUENT YEARS.—The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2014 and subsequent years as if subparagraph (A) had never applied.''.

SA 3652. Mr. BURR (for himself, Mr. GRAHAM, Mr. CRAPO, Mr. BARRASSO, Mr. MCCAIN and Mr. BROWN of Massachusetts) proposed an amendment to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

At the end of subtitle F of title I, insert the following:

SEC. 1___. TREATMENT OF DEPARTMENT OF VETERANS AFFAIRS AND DEPARTMENT OF DEFENSE HEALTH PROGRAMS.

Subtitle G of title I of the Patient Protection and Affordable Care Act is amended by adding at the end the following new section:

''SEC. 1564. DEPARTMENT OF VETERANS AFFAIRS AND DEPARTMENT OF DEFENSE HEALTH PROGRAMS.

''(a) CLARIFICATIONS WITH RESPECT TO CERTAIN PROGRAMS AND AUTHORITIES.—Nothing in this Act or in the amendments made by this Act shall be construed as affecting any of the following:

''(1) Any authority under title 38, United States Code.

''(2) Any authority under chapter 55 of title 10, United States Code.

''(3) Any health care or health care benefit provided under the TRICARE program under chapter 55 of title 10, United States Code, or by the Secretary of Veterans Affairs under the laws administered by such Secretary.

''(b) CLARIFICATION WITH RESPECT TO MINIMUM ESSENTIAL COVERAGE.—For purposes of this Act and the amendments made by this Act, the term 'minimum essential coverage' includes the following:

''(1) Coverage provided under chapter 55 of title 10, United States Code.

''(2) Eligibility for health care provided by the Secretary of Veterans Affairs under title 38, United States Code.''.

SA 3653. Mr. BROWNBACK submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

At the end of subtitle F of title I, add the following:

SEC. 15___. RENEWABLE FUEL.

(a) DEFINITION OF RENEWABLE FUEL.—Section 211(o)(1)(J) of the Clean Air Act (42 U.S.C. 7545(o)(1)(J)) is amended by striking ''fuel that is produced'' and inserting ''a blend of fuel at least 85 percent of the content of which is derived''.

(b) LIABILITY PROTECTION FOR RENEWABLE FUEL OR ETHANOL MANUFACTURE, USE, OR DISTRIBUTION.—

(1) IN GENERAL.—Section 211(o) of the Clean Air Act (42 U.S.C. 7545(o)) is amended by adding at the end the following:

''(13) LIABILITY PROTECTION FOR RENEWABLE FUEL OR ETHANOL MANUFACTURE, USE, OR DISTRIBUTION.—

''(A) IN GENERAL.—Notwithstanding any other provision of Federal or State law, no renewable fuel or ethanol used or intended to be used as a motor vehicle fuel, nor any motor vehicle fuel containing renewable fuel or ethanol, shall be considered a defective product or subject to a failure to warn by virtue of the fact that the renewable fuel or ethanol is, or contains, the renewable fuel or ethanol, if the renewable fuel or ethanol does not violate a control or prohibition imposed by the Administrator under this section.

''(B) EFFECT ON LIABILITY.—Nothing in this paragraph affects the liability of any person other than liability based on a claim of a defective product and failure to warn of the defect.''.

(2) EFFECTIVE DATE; APPLICATION.—The amendment made by paragraph (1) shall—

(A) be effective on the earlier of—

(i) the date of enactment of this Act; or

(ii) the date on which the Administrator of the Environmental Protection Agency approves for use fuel blends with greater than 10 percent ethanol by volume; and

(B) apply with respect to all claims filed on or after the earlier date described in subparagraph (A).

SA 3654. Mr. BARRASSO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

At the end of subtitle A of title I, add the following:

SEC. 1006. SUNSET IF PREMIUMS INCREASE TOO RAPIDLY.

(a) IN GENERAL.—The following requirements of the Patient Protection and Affordable Care Act 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 such Act, section 2707 of the Public Health Service Act, or any other provision of, or amendment made by, such Act that a health plan provide an essential health benefits package described in section 1302(a) of such Act, including any requirement that the plan provide—

(A) for essential health benefits described in section 1302(b) of such Act;

(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) of such Act; and

(C) a level of coverage described in section 1302(d) of such Act.

(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 of health and Human Services 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 of the Patient Protection and Affordable Care Act 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 3655. Mr. BARRASSO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

In subtitle A of title I, add at the end the following:

SEC. 1___. EXEMPTION FROM MANDATE.

Section 5000A of the Internal Revenue Code of 1986, as added by section 1501(b) of the Patient Protection and Affordable Care Act, is amended—

(1) by redesignating subsection (g) as subsection (h); and

(2) by inserting after subsection (f), 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 3656. Mr. BARRASSO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

At the end of section 1002, insert the following:

(c) HIGH DEDUCTIBLE HEALTH PLANS TREATED AS MINIMUM ESSENTIAL COVERAGE.—Section 5000A(f) of the Internal Revenue Code of 1986, as so added and amended, is amended by redesignating paragraph (5) as paragraph (6) and by inserting after paragraph (4) 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 3657. Mr. BARRASSO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

At the end of section 1002, insert the following:

(c) INDIVIDUAL MANDATE PENALTIES CREDITED TO INDIVIDUAL ACCOUNTS AND USED FOR PREMIUMS.—Section 5000A of the Internal Revenue Code of 1986, as so added and amended, is amended by adding at the end the following:

''(h) 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 3658. Mr. BARRASSO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

On page 61, between lines 3 and 4, insert the following:

SEC. ___. USE OF PRIVATE CONTRACTS BY MEDICARE BENEFICIARIES FOR PROFESSIONAL SERVICES.

(a) IN GENERAL.—Section 1802(b) of the Social Security Act (42 U.S.C. 1395a) is amended to read as follows:

''(b) CLARIFICATION OF USE OF PRIVATE CONTRACTS BY MEDICARE BENEFICIARIES FOR PROFESSIONAL SERVICES.—

''(1) IN GENERAL.—Nothing in this title shall prohibit a medicare beneficiary from

entering into a private contract with a physician or health care practitioner for the provision of medicare covered professional services (as defined in paragraph (5)(C)) if—

''(A) the services are covered under a private contract that is between the beneficiary and the physician or practitioner and meets the requirements of paragraph (2);

''(B) under the private contract no claim for payment for services covered under the contract is to be submitted (and no payment made) under part A or B, under a contract under section 1876, or under an MA plan (other than an MSA plan); and

''(C)(i) the Secretary has been provided with the minimum information necessary to avoid any payment under part A or B for services covered under the contract, or

''(ii) in the case of an individual enrolled under a contract under section 1876 or an MA plan (other than an MSA plan) under part C, the eligible organization under the contract or the MA organization offering the plan has been provided the minimum information necessary to avoid any payment under such contract or plan for services covered under the contract.

''(2) REQUIREMENTS FOR PRIVATE CONTRACTS.—The requirements in this paragraph for a private contract between a medicare beneficiary and a physician or health care practitioner are as follows:

''(A) GENERAL FORM OF CONTRACT.—The contract is in writing and is signed by the medicare beneficiary.

''(B) NO CLAIMS TO BE SUBMITTED FOR COVERED SERVICES.—The contract provides that no party to the contract (and no entity on behalf of any party to the contract) shall submit any claim for (or request) payment for services covered under the contract under part A or B, under a contract under section 1876, or under an MA plan (other than an MSA plan).

''(C) SCOPE OF SERVICES.—The contract identifies the medicare covered professional services and the period (if any) to be covered under the contract, but does not cover any services furnished—

''(i) before the contract is entered into; or

''(ii) for the treatment of an emergency medical condition (as defined in section 1867(e)(1)(A)), unless the contract was entered into before the onset of the emergency medical condition.

''(D) CLEAR DISCLOSURE OF TERMS.—The contract clearly indicates that by signing the contract the medicare beneficiary—

''(i) agrees not to submit a claim (or to request that anyone submit a claim) under part A or B (or under section 1876 or under an MA plan, other than an MSA plan) for services covered under the contract;

''(ii) agrees to be responsible, whether through insurance or otherwise, for payment for such services and understands that no reimbursement will be provided under such part, contract, or plan for such services;

''(iii) acknowledges that no limits under this title (including limits under paragraphs (1) and (3) of section 1848(g)) will apply to amounts that may be charged for such services;

''(iv) acknowledges that medicare supplemental policies under section 1882 do not, and other supplemental health plans and policies may elect not to, make payments for such services because payment is not made under this title; and

''(v) acknowledges that the beneficiary has the right to have such services provided by (or under the supervision of) other physicians or health care practitioners for whom payment would be made under such part, contract, or plan.

Such contract shall also clearly indicate whether the physician or practitioner involved is excluded from participation under this title.

''(3) MODIFICATIONS.—The parties to a private contract may mutually agree at any time to modify or terminate the contract on a prospective basis, consistent with the provisions of paragraphs (1) and (2).

''(4) NO REQUIREMENTS FOR SERVICES FURNISHED TO MSA PLAN ENROLLEES.—The requirements of paragraphs (1) and (2) do not apply to any contract or arrangement for the provision of services to a medicare beneficiary enrolled in an MSA plan under part C.

''(5) DEFINITIONS.—In this subsection:

''(A) HEALTH CARE PRACTITIONER.—The term 'health care practitioner' means a practitioner described in section 1842(b)(18)(C).

''(B) MEDICARE BENEFICIARY.—The term 'medicare beneficiary' means an individual who is enrolled under part B.

''(C) MEDICARE COVERED PROFESSIONAL SERVICES.—The term 'medicare covered professional services' means—

''(i) physicians' services (as defined in section 1861(q), and including services described in section 1861(s)(2)(A)), and

''(ii) professional services of health care practitioners, including services described in section 1842(b)(18)(D),

for which payment may be made under part A or B, under a contract under section 1876, or under a Medicare Advantage plan but for the provisions of a private contract that meets the requirements of paragraph (2).

''(D) MA PLAN; MSA PLAN.—The terms 'MA plan' and 'MSA plan' have the meanings given such terms in section 1859.

''(E) PHYSICIAN.—The term 'physician' has the meaning given such term in section 1861(r).''.

(b) CONFORMING AMENDMENTS CLARIFYING EXEMPTION FROM LIMITING CHARGE AND FROM REQUIREMENT FOR SUBMISSION OF CLAIMS.—Section 1848(g) of the Social Security Act (42 U.S.C. 1395w–4(g)) is amended—

(1) in paragraph (1)(A), by striking ''In'' and inserting ''Subject to paragraph (8), in'';

(2) in paragraph (3)(A), by striking ''Payment'' and inserting ''Subject to paragraph (8), payment'';

(3) in paragraph (4)(A), by striking ''For'' and inserting ''Subject to paragraph (8), for''; and

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

''(8) EXEMPTION FROM REQUIREMENTS FOR SERVICES FURNISHED UNDER PRIVATE CONTRACTS.—

''(A) IN GENERAL.—Pursuant to section 1802(b)(1), paragraphs (1), (3), and (4) do not apply with respect to physicians' services (and services described in section 1861(s)(2)(A)) furnished to an individual by (or under the supervision of) a physician if the conditions described in section 1802(b)(1) are met with respect to the services.

''(B) NO RESTRICTIONS FOR ENROLLEES IN MSA PLANS.—Such paragraphs do not apply with respect to services furnished to individuals enrolled with MSA plans under part C, without regard to whether the conditions described in subparagraphs (A) through (C) of section 1802(b)(1) are met.

''(C) APPLICATION TO ENROLLEES IN OTHER PLANS.—Subject to subparagraph (B) and section 1852(k)(2), the provisions of subparagraph (A) shall apply in the case of an individual enrolled under a contract under section 1876 or under an MA plan (other than an MSA plan) under part C, in the same manner as they apply to individuals not enrolled under such a contract or plan.''.

(c) CONFORMING AMENDMENTS.—(1) Section 1842(b)(18) of the Social Security Act (42 U.S.C. 1395u(b)(18)) is amended by adding at the end the following:

''(E) The provisions of section 1848(g)(8) shall apply with respect to exemption from limitations on charges and from billing requirements for services of health care practitioners described in this paragraph in the same manner as such provisions apply to exemption from the requirements referred to in section 1848(g)(8)(A) for physicians' services.''.

(2) Section 1866(a)(1)(O) of such Act (42 U.S.C. 1395cc(a)(1)(O)) is amended by striking ''enrolled with a Medicare Advantage organization under part C'' and inserting ''enrolled with an MA organization under part C (other than under an MSA plan)''.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date that is 6 months after the date of the enactment of this Act and apply to contracts entered into on or after that date.

SA 3659. Mr. BARRASSO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle F of title I, insert the following:

SEC. 1____. CONTINUED ABILITY TO PAY FOR HEALTH CARE.

Title I of the Patient Protection and Affordable Care Act is amended by adding at the end the following:

''SEC. 1564. CONTINUED ABILITY TO PAY FOR HEALTH CARE.

''Nothing in this title (or an amendment made by this title) shall be construed to prohibit an individual from purchasing or otherwise paying for health care items or services on an out-of-pocket basis.''.

SA 3660. Mr. BARRASSO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle F of title I, insert the following:

SEC. 1____. PROTECTING THE TAXPAYERS.

Title I of the Patient Protection and Affordable Care Act is amended by adding at the end the following:

''SEC. 1564. PROTECTING THE TAXPAYERS.

''The provisions of this title (and the amendments made by this title) shall not apply with respect to a fiscal year if the Director of the Office of Management and Budget fails to certify to Congress that the application of such provisions (and amendments) in such fiscal year will not increase the Federal budget deficit.''.

SA 3661. Mr. BARRASSO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

In subtitle A of title I, add at the end the following:

SEC. 1____. EXEMPTION FROM MANDATE.

Section 5000A of the Internal Revenue Code of 1986, as added by section 1501(b) of the Patient Protection and Affordable Care Act, is amended—

(1) by redesignating subsection (g) as subsection (h); and

(2) by inserting after subsection (f), 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 3662. Mr. BARRASSO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle E of title I, add the following:

SEC. 14___. REPEAL OF ADDITIONAL TAX FROM DISTRIBUTIONS FROM HSAS AND MSAS.

(a) HSAS.—Section 223(f)(4)(A) of the Internal Revenue Code of 1986, as amended by section 9004 of the Patient Protection and Affordable Care Act, is amended by striking ''20 percent'' and inserting ''10 percent''.

(b) ARCHER MSAS.—Section 220(f)(4)(A) of the Internal Revenue Code of 1986, as amended by section 9004 of the Patient Protection and Affordable Care Act, is amended by striking ''20 percent'' and inserting ''15 percent''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to distributions made after December 31, 2010.

SA 3663. Mr. BARRASSO submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

On page 56, between lines 20 and 21, insert the following:

(f) BUDGET-NEUTRAL EXEMPTION OF CERTAIN PROVIDERS.—Notwithstanding the provisions of, and amendments made by, the preceding subsections of this section and sections 3401 and 10319 of the Patient Protection and Affordable Care Act—

(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 3664. Mr. VITTER submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle F of title I, add the following:

SEC. 1502. VERIFICATION OF IDENTITY.

No individual may receive assistance of any kind provided by the Federal Government to obtain health insurance coverage unless the individual provides to the appropriate agency or department of the Federal Government an appropriate identification that was issued by a governmental entity and that includes a photograph and the name, date of birth, and social security number of the individual.

SA 3665. Mr. VITTER submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle B of title I, insert the following:

SEC. _____. SUSPENSION OF THE ACT.

If at the beginning of any fiscal year OMB determines that the deficit targets set forth in the CBO report of March 20, 2010 will not be met, the provisions of this Act and the Patient Protection and Affordable Care Act shall be suspended for that year.

SA 3666. Mr. VITTER submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle F of title I, add the following:

SEC. 1502. ELIMINATION OF AUTOMATIC PAY ADJUSTMENTS FOR MEMBERS OF CONGRESS.

(a) IN GENERAL.—Paragraph (2) of section 601(a) of the Legislative Reorganization Act of 1946 (2 U.S.C. 31) is repealed.

(b) TECHNICAL AND CONFORMING AMENDMENTS.—Section 601(a)(1) of such Act is amended—

(1) by striking ''(a)(1)'' and inserting ''(a)'';

(2) by redesignating subparagraphs (A), (B), and (C) as paragraphs (1), (2), and (3), respectively; and

(3) by striking ''as adjusted by paragraph (2) of this subsection'' and inserting ''adjusted as provided by law''.

(c) EFFECTIVE DATE.—This section shall take effect on December 31, 2011.

SA 3667. Mr. VITTER submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle F of title I, add the following:

SEC. 1502. ELIMINATION OF SPECIAL HEALTH CARE PRIVILEGES FOR MEMBERS OF CONGRESS.

Section 1312(d)(3) of the Patient Protection and Affordable Care Act is amended by striking subparagraph (D) and inserting the following:

''(D) REQUIREMENT OF MEMBERS OF CONGRESS TO ENROLL IN AN EXCHANGE.—

''(i) REQUIREMENT.—Notwithstanding any other provision of law, all Members of Congress shall be enrolled in an Exchange when established under section 1321.

''(ii) INELIGIBLE FOR FEHBP.—Effective on the date on which an Exchange is established under section 1321, no Member of Congress shall be eligible to participate in a health benefits plan under chapter 89 of title 5, United States Code.

''(iii) EMPLOYER CONTRIBUTION.—

''(I) IN GENERAL.—The Secretary of the Senate or the Chief Administrative Officer of the House of Representatives shall pay the amount determined under subclause (II) to the appropriate Exchange.

''(II) AMOUNT OF EMPLOYER CONTRIBUTION.—The Director of the Office Of Personnel Management shall determine the amount of the employer contribution for each Member of Congress enrolled in an Exchange. The amount shall be equal to the employer contribution for the health benefits plan under chapter 89 of title 5, United States Code, with the greatest number of enrollees, except that the contribution shall be actuarially adjusted for age.

''(iv) MILITARY MEDICAL TREATMENT FACILITIES AND THE OFFICE OF THE ATTENDING PHYSICIAN.—

''(I) IN GENERAL.—Notwithstanding any other provision of law, a Member of Congress may not receive health care or medical treatment at any military medical treatment facility or at the Office of the Attending Physician.

''(II) EXCEPTION.—Subclause (I) shall not apply to any case of a medical emergency in which the life of a Member of Congress is in immediate danger.

''(v) DEFINITIONS.—In this subparagraph:

''(I) EXCHANGE.—The term 'Exchange' means an Exchange established under section 1321.

''(II) MEMBER OF CONGRESS.—The term 'Member of Congress' means any member of the House of Representatives or the Senate.''.

SA 3668. Mr. VITTER submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle F of title I, add the following:

SEC. 15___. REFUNDS OF FEDERAL MOTOR FUEL EXCISE TAXES FOR FUEL USED IN MOBILE MAMMOGRAPHY VEHICLES.

(a) REFUNDS.—Section 6427 of the Internal Revenue Code of 1986 (relating to fuels not used for taxable purposes) is amended by inserting after subsection (f) the following new subsection:

''(g) FUELS USED IN MOBILE MAMMOGRAPHY VEHICLES.—Except as provided in subsection (k), if any fuel on which tax was imposed by section 4041 or 4081 is used in any highway vehicle designed exclusively to provide mobile mammography services to patients within such vehicle, the Secretary shall pay (without interest) to the ultimate purchaser of such fuel an amount equal to the aggregate amount of the tax imposed on such fuel.''.

(b) EXEMPTION FROM RETAIL TAX.—Section 4041 of such Code is amended by adding at the end the following new subsection:

''(n) FUELS USED IN MOBILE MAMMOGRAPHY VEHICLES.—No tax shall be imposed under this section on any liquid sold for use in, or used in, any highway vehicle designed exclusively to provide mobile mammography services to patients within such vehicle.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of the enactment of this Act.

SA 3669. Mr. VITTER submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13);

which was ordered to lie on the table; as follows:

At the end, add the following:

TITLE III—IMPORTATION OF PRESCRIPTION DRUGS

SEC. 3001. SHORT TITLE.

This title may be cited as the ''Pharmaceutical Market Access Act of 2010''.

SEC. 3002. FINDINGS.

Congress finds as follows:

(1) Americans unjustly pay up to 1,000 percent more to fill their prescriptions than consumers in other countries.

(2) The United States is the world's largest market for pharmaceuticals yet consumers still pay the world's highest prices.

(3) An unaffordable drug is neither safe nor effective. Allowing and structuring the importation of prescription drugs ensures access to affordable drugs, thus providing a level of safety to American consumers they do not currently enjoy.

(4) Prescription drugs are a leading cost of the growth in health care spending in the United States, which is projected to reach $2,600,000,000,000 in 2009, according to the Congressional Budget Office.

(5) According to the Congressional Budget Office, American seniors alone will spend $1,800,000,000,000 on pharmaceuticals over the next 10 years.

(6) Allowing open pharmaceutical markets could save American consumers at least $635,000,000,000 of their own money.

SEC. 3003. PURPOSES.

The purposes of this title are to—

(1) give all Americans immediate relief from the outrageously high cost of pharmaceuticals;

(2) reverse the perverse economics of the American pharmaceutical market;

(3) allow the importation of prescription drugs only if the drugs and facilities where such drugs are manufactured are approved by the Food and Drug Administration, and to exclude pharmaceutical narcotics; and

(4) ensure continued integrity to the prescription drug supply of the United States by—

(A) requiring that imported prescription drugs be packaged and shipped using counterfeit-resistant technologies;

(B) requiring Internet pharmacies to register with the United States Government for Americans to verify authenticity before purchases over the Internet;

(C) requiring all foreign sellers to register with United States Government and submit to facility inspections by the Government without prior notice; and

(D) limiting the eligible countries from which prescription drugs may be imported to Canada, member countries of the European Union, and other highly industrialized nations with safe pharmaceutical infrastructures.

SEC. 3004. AMENDMENTS TO SECTION 804 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) DEFINITIONS.—Section 804(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(a)) is amended to read as follows:

''(a) DEFINITIONS.—In this section:

''(1) IMPORTER.—The term 'importer' means a pharmacy, group of pharmacies, pharmacist, or wholesaler.

''(2) PERMITTED COUNTRY.—The term 'permitted country' means Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxemburg, Netherlands, Portugal, Spain, Sweden, the United Kingdom, Iceland, Liechtenstein, and Norway, except that the Secretary—

''(A) may add a country, union, or economic area as a permitted country for purposes of this section if the Secretary determines that the country, union, or economic area has a pharmaceutical infrastructure that is substantially equivalent or superior to the pharmaceutical infrastructure of the United States, taking into consideration pharmacist qualifications, pharmacy storage procedures, the drug distribution system, the drug dispensing system, and market regulation; and

''(B) may remove a country, union, or economic area as a permitted country for purposes of this section if the Secretary determines that the country, union, or economic area does not have such a pharmaceutical infrastructure.

''(3) PHARMACIST.—The term 'pharmacist' means a person licensed by the relevant governmental authority to practice pharmacy, including the dispensing and selling of prescription drugs.

''(4) PHARMACY.—The term 'pharmacy' means a person that is licensed by the relevant governmental authority to engage in the business of selling prescription drugs that employs 1 or more pharmacists.

''(5) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug subject to section 503(b), other than—

''(A) a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

''(B) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

''(C) an infused drug (including a peritoneal dialysis solution);

''(D) an intravenously injected drug;

''(E) a drug that is inhaled during surgery; or

''(F) a drug which is a parenteral drug, the importation of which pursuant to subsection (b) is determined by the Secretary to pose a threat to the public health, in which case section 801(d)(1) shall continue to apply.

''(6) QUALIFYING DRUG.—The term 'qualifying drug' means a prescription drug that—

''(A) is approved pursuant to an application submitted under section 505(b)(1); and

''(B) is not—

''(i) a drug manufactured through 1 or more biotechnology processes;

''(ii) a drug that is required to be refrigerated; or

''(iii) a photoreactive drug.

''(7) QUALIFYING INTERNET PHARMACY.—The term 'qualifying Internet pharmacy' means a registered exporter that dispenses qualifying drugs to individuals over an Internet Web site.

''(8) QUALIFYING LABORATORY.—The term 'qualifying laboratory' means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

''(9) REGISTERED EXPORTER.—The term 'registered exporter' means a person that is in the business of exporting a drug to persons in the United States (or that seeks to be in such business), for which a registration under this section has been approved and is in effect.

''(10) WHOLESALER.—

''(A) IN GENERAL.—The term 'wholesaler' means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A).

''(B) EXCLUSION.—The term 'wholesaler' does not include a person authorized to import drugs under section 801(d)(1).''.

(b) REGULATIONS.—Section 804(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(b)) is amended to read as follows:

''(b) REGULATIONS.—Not later than 180 days after the date of enactment of the Pharmaceutical Market Access Act of 2010, the Secretary, after consultation with the United States Trade Representative and the Commissioner of the U.S. Customs and Border Protection, shall promulgate regulations permitting pharmacists, pharmacies, and wholesalers to import qualifying drugs from permitted countries into the United States.''.

(c) LIMITATION.—Section 804(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(c)) is amended by striking ''prescription drug'' each place it appears and inserting ''qualifying drug''.

(d) INFORMATION AND RECORDS.—Section 804(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(d)(1)) is amended—

(1) by striking subparagraph (G) and redesignating subparagraphs (H) through (N) as subparagraphs (G) through (M), respectively;

(2) in subparagraph (H) (as so redesignated), by striking ''telephone number, and professional license number (if any)'' and inserting ''and telephone number''; and

(3) in subparagraph (L) (as so redesignated), by striking ''(J) and (L)'' and inserting ''(I) and (K)''.

(e) TESTING.—Section 804(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(e)) is amended to read as follows:

''(e) TESTING.—The regulations under subsection (b) shall require that the testing described under subparagraphs (I) and (K) of subsection (d)(1) be conducted by the importer of the qualifying drug, unless the qualifying drug is subject to the requirements under section 505E for counterfeit-resistant technologies.''.

(f) REGISTRATION OF EXPORTERS; INSPECTIONS.—Section 804(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(f)) is amended to read as follows:

''(f) REGISTRATION OF EXPORTERS; INSPECTIONS.—

''(1) IN GENERAL.—Any person that seeks to be a registered exporter (referred to in this subsection as the 'registrant') shall submit to the Secretary a registration that includes the following:

''(A) The name of the registrant and identification of all places of business of the registrant that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the registrant.

''(B) An agreement by the registrant to—

''(i) make its places of business that relate to qualifying drugs (including warehouses and other facilities owned or controlled by, or operated for, the exporter) and records available to the Secretary for on-site inspections, without prior notice, for the purpose of determining whether the registrant is in compliance with this Act's requirements;

''(ii) export only qualifying drugs;

''(iii) export only to persons authorized to import the drugs;

''(iv) notify the Secretary of a recall or withdrawal of a qualifying drug distributed in a permitted country to or from which the registrant has exported or imported, or intends to export or import, to the United States;

''(v) monitor compliance with registration conditions and report any noncompliance promptly;

''(vi) submit a compliance plan showing how the registrant will correct violations, if any; and

''(vii) promptly notify the Secretary of changes in the registration information of the registrant.

''(2) NOTICE OF APPROVAL OR DISAPPROVAL.—

''(A) IN GENERAL.—Not later than 90 days after receiving a completed registration from a registrant, the Secretary shall—

''(i) notify such registrant of receipt of the registration;

''(ii) assign such registrant a registration number; and

''(iii) approve or disapprove the application.

''(B) DISAPPROVAL OF APPLICATION.—

''(i) IN GENERAL.—The Secretary shall disapprove a registration, and notify the registrant of such disapproval, if the Secretary has reason to believe that such registrant is not in compliance with a registration condition.

''(ii) SUBSEQUENT APPROVAL.—The Secretary may subsequently approve a registration that was denied under clause (i) if the Secretary finds that the registrant is in compliance with all registration conditions.

''(3) LIST.—The Secretary shall—

''(A) maintain an up-to-date list of registered exporters (including qualifying Internet pharmacies that sell qualifying drugs to individuals);

''(B) make such list available to the public on the Internet Web site of the Food and Drug Administration and via a toll-free telephone number; and

''(C) update such list promptly after the approval of a registration under this subsection.

''(4) EDUCATION OF CONSUMERS.—The Secretary shall carry out activities, by use of the Internet Web site and toll-free telephone number under paragraph (3), that educate consumers with regard to the availability of qualifying drugs for import for personal use under this section, including information on how to verify whether an exporter is registered.

''(5) INSPECTION OF IMPORTERS AND REGISTERED EXPORTERS.—The Secretary shall inspect the warehouses, other facilities, and records of importers and registered exporters as often as the Secretary determines necessary to ensure that such importers and registered exporters are in compliance with this section.''.

(g) SUSPENSION OF IMPORTATION.—Section 804(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(g)) is amended by—

(1) striking ''and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b)''; and

(2) by adding after the period at the end the following: ''The Secretary shall reinstate the importation by a specific importer upon a determination by the Secretary that the violation has been corrected and that the importer has demonstrated that further violations will not occur. This subsection shall not apply to a prescription drug imported by an individual, or to a prescription drug shipped to an individual by a qualifying Internet pharmacy.''.

(h) WAIVER AUTHORITY FOR INDIVIDUALS.—Section 804(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(j)) is amended to read as follows:

''(j) IMPORTATION BY INDIVIDUALS.—

''(1) IN GENERAL.—Not later than 180 days after the enactment of the Pharmaceutical Market Access Act of 2010, the Secretary shall by regulation permit an individual to import a drug from a permitted country to the United States if the drug is—

''(A) a qualifying drug;

''(B) imported from a licensed pharmacy or qualifying Internet pharmacy;

''(C) for personal use by an individual, or family member of the individual, not for resale;

''(D) in a quantity that does not exceed a 90-day supply during any 90-day period; and

''(E) accompanied by a copy of a prescription for the drug, which—

''(i) is valid under applicable Federal and State laws; and

''(ii) was issued by a practitioner who is authorized to administer prescription drugs.

''(2) DRUGS DISPENSED OUTSIDE THE UNITED STATES.—An individual may import a drug from a country that is not a permitted country if—

''(A) the drug was dispensed to the individual while the individual was in such country, and the drug was dispensed in accordance with the laws and regulations of such country;

''(B) the individual is entering the United States and the drug accompanies the individual at the time of entry;

''(C) the drug is approved for commercial distribution in the country in which the drug was obtained;

''(D) the drug does not appear to be adulterated; and

''(E) the quantity of the drug does not exceed a 14-day supply.''.

(i) REPEAL OF CERTAIN PROVISIONS.—Section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384) is amended by striking subsections (l) and (m).

SEC. 3005. REGISTRATION FEES.

Subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is amended by adding at the end the following:

''PART 6—FEES RELATING TO PRESCRIPTION DRUG IMPORTATION

''SEC. 743. FEES RELATING TO PRESCRIPTION DRUG IMPORTATION.

''(a) REGISTRATION FEE.—The Secretary shall establish a registration fee program under which a registered exporter under section 804 shall be required to pay an annual fee to the Secretary in accordance with this subsection.

''(b) COLLECTION.—

''(1) COLLECTION ON INITIAL REGISTRATION.—A fee under this section shall be payable for the fiscal year in which the registered exporter first submits a registration under section 804 (or reregisters under that section if that person has withdrawn its registration and subsequently reregisters) in a amount of $10,000, due on the date the exporter first submits a registration to the Secretary under section 804.

''(2) COLLECTION IN SUBSEQUENT YEARS.—After the fee is paid for the first fiscal year, the fee described under this subsection shall be payable on or before October 1 of each year.

''(3) ONE FEE PER FACILITY.—The fee shall be paid only once for each registered exporter for a fiscal year in which the fee is payable.

''(c) FEE AMOUNT.—

''(1) IN GENERAL.—Subject to subsection (b)(1), the amount of the fee shall be determined each year by the Secretary and shall be based on the anticipated costs to the Secretary of enforcing the amendments made by the Pharmaceutical Market Access Act of 2010 in the subsequent fiscal year.

''(2) LIMITATION.—

''(A) IN GENERAL.—The aggregate total of fees collected under this section shall not exceed 1 percent of the total price of drugs exported annually to the United States by registered exporters under this section.

''(B) REASONABLE ESTIMATE.—Subject to the limitation described in subparagraph (A), a fee under this subsection for an exporter shall be an amount that is a reasonable estimate by the Secretary of the annual share of the exporter of the volume of drugs exported by exporters under this section.

''(d) USE OF FEES.—The fees collected under this section shall be used for the sole purpose of administering this section with respect to registered exporters, including the costs associated with—

''(1) inspecting the facilities of registered exporters, and of other entities in the chain of custody of a qualifying drug;

''(2) developing, implementing, and maintaining a system to determine registered exporters' compliance with the registration conditions under the Pharmaceutical Market Access Act of 2010, including when shipments of qualifying drugs are offered for import into the United States; and

''(3) inspecting such shipments, as necessary, when offered for import into the United States to determine if any such shipment should be refused admission.

''(e) ANNUAL FEE SETTING.—The Secretary shall establish, 60 days before the beginning of each fiscal year beginning after September 30, 2009, for that fiscal year, registration fees.

''(f) EFFECT OF FAILURE TO PAY FEES.—

''(1) DUE DATE.—A fee payable under this section shall be paid by the date that is 30 days after the date on which the fee is due.

''(2) FAILURE TO PAY.—If a registered exporter subject to a fee under this section fails to pay the fee, the Secretary shall not permit the registered exporter to engage in exportation to the United States or offering for exportation prescription drugs under this Act until all such fees owed by that person are paid.

''(g) REPORTS.—

''(1) FEE ESTABLISHMENT.—Not later than 60 days before the beginning of each fiscal year, the Secretary shall—

''(A) publish registration fees under this section for that fiscal year;

''(B) hold a meeting at which the public may comment on the recommendations; and

''(C) provide for a period of 30 days for the public to provide written comments on the recommendations.

''(2) PERFORMANCE AND FISCAL REPORT.—Beginning with fiscal year 2009, not later than 60 days after the end of each fiscal year during which fees are collected under this section, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes—

''(A) implementation of the registration fee authority during the fiscal year; and

''(B) the use by the Secretary of the fees collected during the fiscal year for which the report is made.''.

SEC. 3006. COUNTERFEIT-RESISTANT TECHNOLOGY.

(a) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352; deeming drugs and devices to be misbranded) is amended by adding at the end the following:

''(aa) If it is a drug subject to section 503(b), unless the packaging of such drug complies with the requirements of section 505E for counterfeit-resistant technologies.''.

(b) REQUIREMENTS.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505D the following:

''SEC. 505E. COUNTERFEIT-RESISTANT TECHNOLOGIES.

''(a) INCORPORATION OF COUNTERFEIT-RESISTANT TECHNOLOGIES INTO PRESCRIPTION DRUG PACKAGING.—The Secretary shall require that the packaging of any drug subject to section 503(b) incorporate—

''(1) overt optically variable counterfeit-resistant technologies that are described in subsection (b) and comply with the standards of subsection (c); or

''(2) technologies that have an equivalent function of security, as determined by the Secretary.

''(b) ELIGIBLE TECHNOLOGIES.—Technologies described in this subsection—

''(1) shall be visible to the naked eye, providing for visual identification of product authenticity without the need for readers, microscopes, lighting devices, or scanners;

''(2) shall be similar to that used by the Bureau of Engraving and Printing to secure United States currency;

''(3) shall be manufactured and distributed in a highly secure, tightly controlled environment; and

''(4) should incorporate additional layers of non-visible covert security features up to and including forensic capability.

''(c) STANDARDS FOR PACKAGING.—

''(1) MULTIPLE ELEMENTS.—For the purpose of making it more difficult to counterfeit the packaging of drugs subject to section 503(b), manufacturers of the drugs shall incorporate the technologies described in subsection (b) into multiple elements of the physical packaging of the drugs, including blister packs, shrink wrap, package labels, package seals, bottles, and boxes.

''(2) LABELING OF SHIPPING CONTAINER.—Shipments of drugs described in subsection (a) shall include a label on the shipping container that incorporates the technologies described in subsection (b), so that officials inspecting the packages will be able to determine the authenticity of the shipment. Chain of custody procedures shall apply to such labels and shall include procedures applicable to contractual agreements for the use and distribution of the labels, methods to audit the use of the labels, and database access for the relevant governmental agencies for audit or verification of the use and distribution of the labels.

''(d) EFFECTIVE DATE.—This section shall take effect 180 days after the date of enactment of the Pharmaceutical Market Access Act of 2010.''.

SEC. 3007. PROHIBITED ACTS.

Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by inserting after subsection (k) the following:

''(l) The failure to register in accordance with section 804(f) or to import or offer to import a prescription drug in violation of a suspension order under section 804(g).''.

SEC. 3008. PATENTS.

Section 271 of title 35, United States Code, is amended—

(1) by redesignating subsections (h) and (i) as subsections (i) and (j), respectively; and

(2) 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 (21 U.S.C. 384) that was first sold abroad by or under authority of the owner or licensee of such patent.''.

SEC. 3009. OTHER ENFORCEMENT ACTIONS.

(a) IN GENERAL.—Section 804 of the Federal Food, Drug, and Cosmetic Act, as amended by section 3004, is amended by adding at the end the following:

''(l) UNFAIR OR DISCRIMINATORY ACTS AND PRACTICES.—

''(1) IN GENERAL.—It is unlawful for a manufacturer, directly or indirectly (including by being a party to a licensing or other agreement) to—

''(A) discriminate by charging a higher price for a prescription drug sold to a person in a permitted country that exports a prescription drug to the United States under this section than the price that is charged to another person that is in the same country and that does not export a prescription drug into the United States under this section;

''(B) discriminate by charging a higher price for a prescription drug sold to a person that distributes, sells, or uses a prescription 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 prescription drug under this section, or that does not distribute, sell, or use such a drug;

''(C) discriminate by denying supplies of a prescription drug to a person in a permitted country that exports a prescription drug to the United States under this section or distributes, sells, or uses a prescription drug imported into the United States under this section;

''(D) discriminate by publicly, privately, or otherwise refusing to do business with a person in a permitted country that exports a prescription drug to the United States under this section or distributes, sells, or uses a prescription drug imported into the United States under this section;

''(E) discriminate by specifically restricting or delaying the supply of a prescription drug to a person in a permitted country that exports a prescription drug to the United States under this section or distributes, sells, or uses a prescription drug imported into the United States under this section;

''(F) 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 for the purpose of restricting importation of the drug into the United States under this section;

''(G) refuse to allow an inspection authorized under this section of an establishment that manufactures a prescription drug that may be imported or offered for import under this section;

''(H) fail to conform to the methods used in, or the facilities used for, the manufacturing, processing, packing, or holding of a prescription drug that may be imported or offered for import under this section to good manufacturing practice under this Act;

''(I) become a party to a licensing or other agreement related to a prescription drug that fails to provide for compliance with all requirements of this section with respect to such prescription drug or that has the effect of prohibiting importation of the drug under this section; or

''(J) engage in any other action that the Federal Trade Commission determines to discriminate against a person that engages in, or to impede, delay, or block the process for, the importation of a prescription drug under this section.

''(2) AFFIRMATIVE DEFENSE.—It shall be an affirmative defense to a charge that a person has discriminated under subparagraph (A), (B), (C), (D), or (E) of paragraph (1) that the higher price charged for a prescription drug sold to a person, the denial of supplies of a prescription drug to a person, the refusal to do business with a person, or the specific restriction or delay of supplies to a person is not based, in whole or in part, on—

''(A) the person exporting or importing a prescription drug into the United States under this section; or

''(B) the person distributing, selling, or using a prescription drug imported into the United States under this section.

''(3) PRESUMPTION AND AFFIRMATIVE DEFENSE.—

''(A) PRESUMPTION.—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) created after January 1, 2009, between a prescription drug for distribution in the United States and the drug for distribution in a permitted country shall be presumed under paragraph (1)(F) to be for the purpose of restricting importation of the drug into the United States under this section.

''(B) AFFIRMATIVE DEFENSE.—It shall be an affirmative defense to the presumption under subparagraph (A) that—

''(i) the difference was required by the country in which the drug is distributed; or

''(ii) the Secretary has determined that the difference was necessary to improve the safety or effectiveness of the drug.

''(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.

''(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 were incorporated into and made a part of this section; and

''(ii) may seek monetary relief threefold the damages sustained.

''(6) ACTIONS BY STATES.—

''(A) IN GENERAL.—

''(i) CIVIL ACTIONS.—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 for a violation of paragraph (1) 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 Commission shall have the right to intervene in the action that is the subject of the notice.

''(ii) EFFECT OF INTERVENTION.—If the 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.—

''(i) IN GENERAL.—In any case in which an action is instituted by or on behalf of the 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.

''(ii) INTERVENTION.—An attorney general of a State may intervene, on behalf of the residents of that State, in an action instituted by the Commission.

''(iii) EFFECT OF INTERVENTION.—If an attorney general of a State intervenes in an action instituted by the Commission, such attorney general 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.

''(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) LIMITATION OF ACTIONS.—Any action under this paragraph to enforce a cause of action under this subsection by the Federal Trade Commission or the attorney general of a State shall be forever barred unless commenced within 5 years after the Federal Trade Commission, or the attorney general, as the case may be, knew or should have known that the cause of action accrued. No cause of action barred under existing law on the effective date of the Pharmaceutical Market Access Act of 2010 shall be revived by such Act.

''(H) 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.

''(I) 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) REGULATIONS.—The Federal Trade Commission shall promulgate regulations to carry out the enforcement program under section 804(l) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)).

(c) SUSPENSION AND TERMINATION OF EXPORTERS.—Section 804(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(g)), as amended by section 3004(g), is amended by—

(1) striking ''SUSPENSION OF IMPORTATION.—The Secretary'' and inserting ''SUSPENSION OF IMPORTATION.—

''(1) IN GENERAL.—The Secretary''; and

(2) adding at the end the following:

''(2) SUSPENSION AND TERMINATION OF EXPORTERS.—

''(A) SUSPENSION.—With respect to the effectiveness of a registration submitted under subsection (f) by a registered exporter:

''(i) Subject to clause (ii), if the Secretary determines, after notice and opportunity for a hearing, that the registered exporter has failed to maintain substantial compliance with all registration conditions, the Secretary may suspend the registration.

''(ii) If the Secretary determines that, under color of the registration, the registered exporter has exported a drug that is not a qualifying drug, or a drug that does not meet the criteria under this section, or has exported a qualifying drug to an individual in violation of this section, 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 registered exporter involved 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 registered exporter 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 subsection (f) of a registered exporter if the Secretary determines that the registered exporter 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 registered exporter. 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 of a registered exporter is terminated, any registration submitted under subsection (f) by such exporter or a person who is a partner in the export enterprise or a principal officer in such enterprise, and any registration prepared with the assistance of such exporter or such a person, has no legal effect under this section.''.

SEC. 3010. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated such sums as may be necessary to carry out this title (and the amendments made by this title).

SA 3670. Mr. ENZI submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

On page 143, between lines 17 and 18, insert the following:

SEC. 2213. DIRECT LENDING ADMINISTRATIVE EXPENSES.

Section 458(a) (20 U.S.C. 1087h(a)) (as amended by section 2212(b)(1)) is amended—

(1) by striking paragraph (3) and inserting the following:

''(2) MANDATORY FUNDS FOR ADMINISTRATIVE COSTS IN FISCAL YEARS 2010 THROUGH 2019.—For each of the fiscal years 2010 through 2019, there shall be available to the Secretary, from funds not otherwise appropriated, such sums as may be necessary for the administrative costs under this part and part B, including the costs of the direct student loan programs under this part, in each such fiscal year.'';

(2) in paragraph (4), by striking ''through 2014'' and inserting ''through 2019''.

SA 3671. Mr. ENZI (for himself and Mr. COBURN) submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

On page 114, between lines 12 and 13, insert the following:

SEC. 2002. ELIMINATION OF SPENDING IN ORDER TO REDUCE THE PUBLIC DEBT.

Notwithstanding any other provision of this title, sections 2101, 2102, 2103, and 2213, and the amendments made by such sections, shall have no force and effect, and the resulting savings shall be used to reduce the public debt.

SA 3672. Mr. ENZI submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

Beginning on page 114, strike line 13 and all that follows through line 8 on page 123 and insert the following:

PART I—EXTENSION OF ECASLA

SEC. 2101. EXTENSION OF STUDENT LOAN PURCHASE AUTHORITY.

Section 459A (20 U.S.C. 1087i–1) is amended—

(1) in subsections (a)(1), (a)(3)(A), and (f), by striking ''July 1, 2010'' and inserting ''July 1, 2011''; and

(2) in subsection (e)—

(A) in the matter preceding clause (i) of paragraph (1)(A) and the matter preceding subparagraph (A) of paragraph (2), by striking ''September 30, 2010'' and inserting ''September 30, 2011'';

(B) in paragraph (2), by striking ''February 15, 2011'' and inserting ''February 15, 2012''; and

(C) in paragraph (3), by striking ''2010, and 2011'' and inserting ''2010, 2011, and 2012''.

SEC. 2102. EXTENSION OF AUTHORITY TO DESIGNATE LENDERS FOR LENDER-OF-LAST-RESORT PROGRAM.

Section 428(j) (20 U.S.C. 1078(j)) is amended—

(1) in paragraph (6), by striking ''June 30, 2010'' and inserting ''June 30, 2011'';

(2) in paragraph (7), by striking ''June 30, 2010'' and inserting ''June 30, 2011''; and

(3) in paragraph (9)(A)—

(A) in the matter preceding subclause (I) of clause (ii), by striking ''June 30, 2011'' and inserting ''June 30, 2012'';

(B) in subclause (III) of clause (ii), by striking ''June 30, 2010'' and inserting ''June 30, 2011''; and

(C) in the matter preceding subclause (I) of clause (iii), by striking ''July 1, 2011'' and inserting ''July 1, 2012''.

SEC. 2103. ONE-YEAR DELAY OF FFEL TERMINATION.

(a) ONE-YEAR DELAY.—Title IV (as amended by part II) (20 U.S.C. 1070 et seq.) is further amended—

(1) in section 427A(l)(4), by inserting the following:

''(D) For a loan for which the first disbursement is made on or after July 1, 2010, and before July 1, 2011, 4.5 percent on the unpaid principal balance of the loan.'';

(2) in section 438(c)(2)(B)—

(A) in clause (iii), by striking ''; and'' and inserting a semicolon;

(B) in clause (iv), by striking the period and inserting ''; and''; and

(C) by adding at the end the following:

''(v) by substituting '0.0 percent' for '3.0 percent' with respect to loans for which the first disbursement of principal is made on or after July 1, 2010 and before July 1, 2011.'';

(3) in section 456(a)(4)(A)(iii), by striking ''2014'' and inserting ''2015''; and

(4) in section 458(a)(2), by striking ''2010 through 2019'' and inserting ''2011 through 2019'';

(5) in sections 458(a)(7)(B) and 459B(a)(3), by striking ''2011'' and inserting ''2012'';

(6) in the headings of sections 427A(l), 438(b)(2)(I), and 438(b)(2)(I)(vi), by striking ''2010'' and inserting ''2011'';

(7) in sections 421(b), 428B(a)(1), 458(a)(6)(B), and 459B(a)(3), subsections (f) and (j)(1) of section 428, subsections (c)(2)(B)(6) and (d)(2)(B) of section 438, and subsections (a)(1) and (g) of section 455, by striking ''2010'' and inserting ''2011'';

(8) in sections 421(d), 424(a), 427A(l), 428B(a)(1), 428C, 428H, 438(b)(2)(I), and 458(a)(7), and subsections (a) and (b)(1) of section 428, by striking ''2010'' each place the term appears and inserting ''2011''; and

(9) in sections 424(a) and 456(c)(1)(B), by striking ''2009'' each place the term appears and inserting ''2010''.

(b) DELAYED IMPLEMENTATION.—Notwithstanding section 2209(b)(2), 2210(b), or 2211(b) or any other provision of this title—

(1) subsection (a) and part II, and the amendments made by such subsection and part, shall not be effective until the day that is one year after the date of enactment of this Act; and

(2) sections 2210(b) and 2211(b) shall be applied, beginning on the date described in paragraph (1), by striking ''July 1, 2010'' and inserting ''July 1, 2011''.

SEC. 2104. ELIMINATION OF INCOME-BASED REPAYMENT CHANGES.

Notwithstanding any other provision of this title, section 2213 and the amendments made by such section shall have no force and effect.

SA 3673. Mr. ENZI submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of part II of subtitle A of title II, add the following:

SEC. 2214. GRANT PROHIBITION.

For fiscal year 2012 and succeeding fiscal years, and notwithstanding any other provision of law, the Secretary of Education, the Secretary of Health and Human Services, and the Secretary of Labor shall not award a grant to an institution of higher education that increases the tuition and fees charged for attendance at the institution at a rate that is greater than the annual increase in the Consumer Price Index prepared by the Department of Labor.

SA 3674. Mr. HATCH submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle B of title II, insert the following:

SEC. 2___. EXEMPTION RELATING TO EXCHANGE REQUIREMENTS.

Section 1311 of the Patient Protection and Affordable Care Act is amended by adding at the end the following:

''(l) EXEMPTION.—The provisions of this section shall not apply to any State that has a State exchange in operation on the date of enactment of this Act. Such exchange shall be deemed to meet all requirements applicable to Exchanges under this section.''.

SA 3675. Mr. HATCH submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

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

SEC. 1___. REPEAL OF INDIVIDUAL MANDATE.

Section 5000A of the Internal Revenue Code of 1986, as added by section 1501(b) of the Patient Protection and Affordable Care Act, is repealed.

SA 3676. Ms. COLLINS submitted an amendment intended to be proposed by her to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle E of title I, insert the following:

SECTION ___. HEALTH CARE COST INCREASE TAX CREDIT.

(a) IN GENERAL.—Subpart A of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 is amended by inserting after section 25D the following new section:

''SEC. 25E. HEALTH CARE COST INCREASE TAX CREDIT.

''(a) IN GENERAL.—In the case of an eligible taxpayer, there shall be allowed a credit against the tax imposed by this chapter for the taxable year in an amount equal to the lesser of—

''(1) the health care cost increase amount for such taxable year, or

''(2) the eligible taxpayer's premium increase amount for such taxable year.

''(b) ELIGIBLE TAXPAYER.—For purposes of this section, the term 'eligible taxpayer' means an individual who purchases self-only or family health insurance coverage which is a qualified health plan within the meaning of section 36B(c)(3)(A) for all months in the taxable year.

''(c) HEALTH CARE COST INCREASE AMOUNT.—

''(1) IN GENERAL.—For purposes of this section, with respect to taxable years beginning in any calendar year after 2009, the health care cost increase amount is the amount, as determined by the Secretary of Health and Human Services, by which the average national premium cost for a plan in the silver level of coverage (within the meaning of section 1302(d)(1)(B) of the Patient Protection and Affordable Care Act) for such calendar year exceeds the average national premium cost for such a plan as of March 23, 2010.

''(2) PUBLICATION OF DETERMINATION.—The Secretary of Health and Human Services shall publish the health care cost increase amount determined under paragraph (1) for each calendar year not later than December 31 of such calendar year.

''(d) PREMIUM INCREASE AMOUNT.—

''(1) IN GENERAL.—For purposes of this section, with respect to an eligible taxpayer, the premium increase amount is the amount by which the total premiums paid by such taxpayer for months during the taxable year for coverage described in subsection (b) exceed the total premiums paid by such taxpayer for such coverage for the last plan year ending before March 23, 2010, except that such amount—

''(A) shall be adjusted to reflect any changes in coverage under the taxpayer's plan or in the family size of the taxpayer, and

''(B) shall be reduced by the amount of any credit under section 36B and any Federal cost sharing subsidy with respect to such coverage.

''(2) REGULATORY AUTHORITY.—The Secretary of Health and Human Services shall prescribe regulations for determining the adjustments required under paragraph (1)(A).

''(e) CREDIT ALLOWED AGAINST ALTERNATIVE MINIMUM TAX.—In the case of a taxable year to which section 26(a)(2) does not apply, the credit allowed under subsection (a) for any taxable year shall not exceed the excess of—

''(1) the sum of the regular tax liability (as defined in section 26(b)) plus the tax imposed by section 55, over

''(2) the sum of the credits allowable under this subpart (other than this section and sections 23, 25D, and 30D) and section 27 for the taxable year.''.

(b) CLERICAL AMENDMENT.—The table of sections for subpart A of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 is amended by inserting after the item relating to section 25D the following new item:

''Sec. 25E. Health care cost increase credit.''.

(c) CONFORMING AMENDMENTS.—

(1) Section 24(b)(3)(B) of the Internal Revenue Code of 1986 is amended by inserting ''25E,'' after ''25D,''.

(2) Section 25(e)(1)(C)(ii) of such Code is amended by inserting ''25E,'' after ''25D,''.

(3) Section 26(a)(1) of such Code is amended by inserting ''25E,'' after ''25D,''.

(4) Section 25B(g)(2) of such Code is amended by inserting ''25E,'' after ''25D,''.

(5) Section 904(i) of such Code is amended by inserting ''25E,'' after ''25B,''.

(6) Section 1400C(d)(2) of such Code is amended by inserting ''25E,'' after ''25D,''.

(d) APPLICATION OF EGGTRA SUNSET.—The amendment made by subsection (c)(1) shall be subject to title IX of the Economic Growth and Tax Relief Reconciliation Act of 2001 in the same manner as the provision of such Act to which such amendment relates.

(e) EFFECTIVE DATE.—The amendments made by subsections (a), (b), and (c) shall apply to taxable years ending after March 23, 2010.

SA 3677. Mr. LEMIEUX submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle D of title I, add the following:

SEC. 1305. HEALTH CARE FRAUD PREVENTION SYSTEM.

(a) HEALTH CARE FRAUD PREVENTION SYSTEM.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall establish a fraud prevention system which shall be designed as follows:

(A) IN GENERAL.—The fraud prevention system shall—

(i) be holistic;

(ii) be able to view all provider and patient activities across all Federal health program payers;

(iii) be able to integrate into the existing health care claims flow with minimal effort, time, and cost;

(iv) be modeled after systems used in the Financial Services industry; and

(v) utilize integrated real-time transaction risk scoring and referral strategy capabilities to identify claims that are statistically unusual.

(B) MODULARIZED ARCHITECTURE.—The fraud prevention system shall be designed from an end-to-end modularized perspective to allow for ease of integration into multiple points along a health care claim flow (pre- or post-adjudication), which shall—

(i) utilize a single entity to host, support, manage, and maintain software-based services, predictive models, and solutions from a central location for the customers who access the fraud prevention system;

(ii) allow access through a secure private data connection rather than the installation of software in multiple information technology infrastructures (and data facilities);

(iii) provide access to the best and latest software without the need for upgrades, data security, and costly installations;

(iv) permit modifications to the software and system edits in a rapid and timely manner;

(v) ensure that all technology and decision components reside within the module; and

(vi) ensure that the third party host of the modular solution is not a party, payer, or stakeholder that reports claims data, accesses the results of the fraud prevention systems analysis, or is otherwise required under this section to verify, research, or investigate the risk of claims.

(C) PROCESSING, SCORING, AND STORAGE.—The platform of the fraud prevention system shall be a high volume, rapid, real-time information technology solution, which includes data pooling, data storage, and scoring capabilities to quickly and accurately capture and evaluate data from millions of claims per day. Such platform shall be secure and have (at a minimum) data centers that comply with Federal and State privacy laws.

(D) DATA CONSORTIUM.—The fraud prevention system shall provide for the establishment of a centralized data file (referred to as a ''consortium'') that accumulates data from all government health insurance claims data sources. Notwithstanding any other provision of law, Federal health care payers shall provide to the consortium existing claims data, such as Medicare's ''Common Working File'' and Medicaid claims data, for the purpose of fraud and abuse prevention. Such accumulated data shall be transmitted and stored in an industry standard secure data environment that complies with applicable Federal privacy laws for use in building medical waste, fraud, and abuse prevention predictive models that have a comprehensive view of provider activity across all payers (and markets).

(E) MARKET VIEW.—The fraud prevention system shall ensure that claims data from Federal health programs and all markets flows through a central source so the waste, fraud, and abuse system can look across all markets and geographies in health care to identify fraud and abuse in Medicare, Medicaid, the State Children's Health Program, TRICARE, and the Department of Veterans Affairs, holistically. Such cross-market visibility shall identify unusual provider and patient behavior patterns and fraud and abuse schemes that may not be identified by looking independently at one Federal payer's transactions.

(F) BEHAVIOR ENGINE.—The fraud prevention system shall ensure that the technology used provides real-time ability to identify high-risk behavior patterns across markets, geographies, and specialty group providers to detect waste, fraud, and abuse, and to identify providers that exhibit unusual behavior patterns. Behavior pattern technology that provides the capability to compare a provider's current behavior to their own past behavior and to compare a provider's current behavior to that of other providers in the same specialty group and geographic location shall be used in order to provide a comprehensive waste, fraud, and abuse prevention solution.

(G) PREDICTIVE MODEL.—The fraud prevention system shall involve the implementation of a statistically sound, empirically derived predictive modeling technology that is designed to prevent (versus post-payment detect) waste, fraud, and abuse. Such prevention system shall utilize historical transaction data, from across all Federal health programs and markets, to build and re-develop scoring models, have the capability to incorporate external data and external models from other sources into the health care predictive waste, fraud, and abuse model, and provide for a feedback loop to provide outcome information on verified claims so future system enhancements can be developed based on previous claims experience.

(H) CHANGE CONTROL.—The fraud prevention system platform shall have the infrastructure to implement new models and attributes in a test environment prior to moving into a production environment. Capabilities shall be developed to quickly make changes to models, attributes, or strategies to react to changing patterns in waste, fraud, and abuse.

(I) SCORING ENGINE.—The fraud prevention system shall identify high-risk claims by scoring all such claims on a real-time capacity prior to payment. Such scores shall then be communicated to the fraud management system provided for under subparagraph (J).

(J) FRAUD MANAGEMENT SYSTEM.—The fraud prevention system shall utilize a fraud management system, that contains workflow management and workstation tools to provide the ability to systematically present scores, reason codes, and treatment actions for high-risk scored transactions. The fraud prevention system shall ensure that analysts who review claims have the capability to access, review, and research claims efficiently, as well as decline or approve claims (payments) in an automated manner. Workflow management under this subparagraph shall be combined with the ability to utilize principles of experimental design to compare and measure prevention and detection rates between test and control strategies. Such strategy testing shall allow for continuous improvement and maximum effectiveness in keeping up with ever changing fraud and abuse patterns. Such system shall provide the capability to test different treatments or actions randomly (typically through use of random digit assignments).

(K) DECISION TECHNOLOGY.—The fraud prevention system shall have the capability to monitor consumer transactions in real-time and monitor provider behavior at different stages within the transaction flow based upon provider, transaction and consumer trends. The fraud prevention system shall provide for the identification of provider and claims excessive usage patterns and trends that differ from similar peer groups, have the capability to trigger on multiple criteria, such as predictive model scores or custom attributes, and be able to segment transaction waste, fraud, and abuse into multiple types for health care categories and business types.

(L) FEEDBACK LOOP.—The fraud prevention system shall have a feedback loop where all Federal health payers provide pre-payment and post-payment information about the eventual status of a claim designated as ''Normal'', ''Waste'', ''Fraud'', ''Abuse'', or ''Education Required''. Such feedback loop shall enable Federal health agencies to measure the actual amount of waste, fraud, and abuse as well as the savings in the system and provide the ability to retrain future, enhanced models. Such feedback loop shall be an industry file that contains information on previous fraud and abuse claims as well as abuse perpetrated by consumers, providers, and fraud rings, to be used to alert other payers, as well as for subsequent fraud and abuse solution development.

(M) TRACKING AND REPORTING.—The fraud prevention system shall ensure that the infrastructure exists to ascertain system, strategy, and predictive model return on investment. Dynamic model validation and strategy validation analysis and reporting shall be made available to ensure a strategy or predictive model has not degraded over time or is no longer effective. Queue reporting shall be established and made available for population estimates of what claims were flagged, what claims received treatment, and ultimately what results occurred. The capability shall exist to complete tracking and reporting for prevention strategies and actions residing farther upstream in the health care payment flow. The fraud prevention system shall establish a reliable metric to measure the dollars that are never paid due to identification of fraud and abuse, as well

as a capability to effectively test and estimate the impact from different actions and treatments utilized to detect and prevent fraud and abuse for legitimate claims. Measuring results shall include waste and abuse.

(N) OPERATING TENET.—The fraud prevention system shall not be designed to deny health care services or to negatively impact prompt-pay laws because assessments are late. The database shall be designed to speed up the payment process. The fraud prevention system shall require the implementation of constant and consistent test and control strategies by stakeholders, with results shared with Federal health program leadership on a quarterly basis to validate improving progress in identifying and preventing waste, fraud, and abuse. Under such implementation, Federal health care payers shall use standard industry waste, fraud, and abuse measures of success.

(2) COORDINATION.—The Secretary shall coordinate the operation of the fraud prevention system with the Department of Justice and other related Federal fraud prevention systems.

(3) OPERATION.—The Secretary shall phase-in the implementation of the system under this subsection beginning not later than 18 months after the date of enactment of this Act, through the analysis of a limited number of Federal health program claims. Not later than 5 years after such date of enactment, the Secretary shall ensure that such system is fully phased-in and applicable to all Federal health program claims.

(4) NON-PAYMENT OF CLAIMS.—The Secretary shall promulgate regulations to prohibit the payment of any health care claim that has been identified as potentially ''fraudulent'', ''wasteful'', or ''abusive'' until such time as the claim has been verified as valid.

(5) APPLICATION.—The system under this section shall only apply to Federal health programs (all such programs), including programs established after the date of enactment of this Act.

(6) REGULATIONS.—The Secretary shall promulgate regulations providing the maximum appropriate protection of personal privacy.

(b) PROTECTING PARTICIPATION IN HEALTH CARE ANTIFRAUD PROGRAMS.—

(1) IN GENERAL.—Notwithstanding any other provision of law, no person providing information to the Secretary under this section shall be held, by reason of having provided such information, to have violated any criminal law, or to be civilly liable under any law of the United States or of any State (or political subdivision thereof) unless such information is false and the person providing it knew, or had reason to believe, that such information was false.

(2) CONFIDENTIALITY.—The Secretary shall, through the promulgation of regulations, establish standards for—

(A) the protection of confidential information submitted or obtained with regard to suspected or actual health care fraud;

(B) the protection of the ability of representatives the Department of Health and Human Services to testify in private civil actions concerning any such information; and

(C) the sharing by the Department of Health and Human Services of any such information related to the medical antifraud programs established under this section.

(c) USE OF SAVINGS.—Notwithstanding any other provision of law, amounts remaining at the end of a fiscal year in the account for any Federal health program to which this section applies that the Secretary of Health and Human Services determines are remaining as a result of the fraud prevention activities applied under this section shall remain in such account and be used for such program for the next fiscal year.

(d) DEFINITION.—In this section, the term ''Federal health program'' means any program that provides Federal payments or reimbursements to providers of health-related items or services, or suppliers of such items, for the provision of such items or services to an individual patient.

(e) RECISSION OF CERTAIN STIMULUS FUNDS.—Notwithstanding section 5 of the American Recovery and Reinvestment Act of 2009 (Public Law 111–5; 123 Stat. 116), from the amounts appropriated or made available under division A of such Act (other than under title X of such division A), there is rescinded, of the remaining unobligated amounts as of the date of the enactment of this Act, funds in the amount as may be necessary to carry out this section. The Director of the Office of Management and Budget shall report to each congressional committee the amounts so rescinded within the jurisdiction of such committee.

SA 3678. Mr. LEMIEUX submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle F of title I, add the following:

SEC. 1___. PRODUCTIVITY AWARD PROGRAM.

Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall establish a Productivity Award Program to recognize employees, work units, and contractors of the Centers for Medicare & Medicaid whose work significantly and measurably increases productivity and promotes innovation to improve the delivery of services and achieving savings for taxpayers. The amount of any such award shall be equal to 10 percent of the amount of the estimated saving to the Federal Government as a result of the action resulting in the award (as determined by the Secretary), but not to exceed $50,000.

SA 3679. Mr. LEMIEUX submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle F of title I, add the following:

SEC. 1___. CONSUMER RIGHT-TO-KNOW.

(a) DEVELOPMENT OF INFORMATION SYSTEM.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall develop a system for the collection of quality and pricing information related to the provision of health care services. Through the use of such information, the Secretary shall, to the extent practicable—

(1) determine the lowest, median, average, and highest charged amount and reimbursed amount for each outpatient and inpatient health care procedure conducted at each facility in the United States;

(2) provide comparisons of such prices with respect to procedures in similar facilities in the same county, city, State and on a national basis; and

(3) develop quality of care data, including data on consumer satisfaction, coordination and continuity of care, infrastructure, the results of accreditation, Medicare-related information, and other survey information, and combine such data with price information to enable consumers to make informed choices.

(b) USE OF EXISTING SOURCES.—To the extent that the information required under subsection (a) is being collected by the Centers for Medicare & Medicaid Services, States, State medical societies, or private sector entities, the Secretary, to the extent practicable, utilize such information to carry out such subsection.

(c) AVAILABILITY OF INFORMATION.—The Secretary, either directly or through contract, shall make the information and data collected and developed under this section available on an Internet website. Such information and data shall be displayed by payer (such as Medicare, Medicaid, health insurance plans, employer-based health plans, and other types of health care coverage).

SA 3680. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); 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. 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 3681. Mr. BUNNING submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle B of title I, add the following:

SEC. ___. ALLOWING INDIVIDUALS TO ELECT TO OPT OUT OF THE MEDICARE PART A BENEFIT.

Notwithstanding any other provision of law, in the case of an individual who elects to opt out of benefits under part A of title XVIII of the Social Security Act, such individual shall not be required to—

(1) opt out of benefits under title II of such Act as a condition for making such election; and

(2) repay any amount paid under such part A for items and services furnished prior to making such election.

SA 3682. Mr. MCCAIN (for himself and Mr. KYL) submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

On page 113, after line 21, insert the following:

SEC. 1502. COMPENSATION TO STATES FOR APPLYING DAVIS-BACON WAGE REQUIREMENTS TO CERTAIN WATER TREATMENT PROJECTS.

(a) IN GENERAL.—The Administrator of the Environmental Protection Agency shall compensate States for any increased administrative and project labor costs incurred by the States as the result of the provisions of title II of the Department of the Interior, Environment, and Related Agencies Appropriations Act, 2010 (Public Law 111–88), that apply the provisions of subchapter IV of chapter 31 of part A of subtitle II of title 40, United States Code (commonly referred to as the ''Davis-Bacon Act''), to any projects carried out, in whole or in part, with assistance made available from the State drinking water treatment revolving loan funds established under section 1452 of the Safe Drinking Water Act (42 U.S.C. 300j–12) or State water pollution control revolving funds established under title VI of the Federal Water Pollution Control Act (33 U.S.C. 1381 et seq.).

(b) OFFSET.—Any amounts otherwise made available to pay the salaries and expenses of the Office of the Administrator of the Environmental Protection Agency shall be reduced by the amount necessary to carry out subsection (a).

SA 3683. Mr. THUNE submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

On page 113, after line 21, insert the following:

SEC. ___. FAIL-SAFE MECHANISM TO PREVENT INCREASE IN FEDERAL BUDGET DEFICIT.

(a) ESTIMATE AND CERTIFICATION OF EFFECT OF PATIENT PROTECTION AND AFFORDABLE CARE ACT AND THIS ACT ON BUDGET DEFICIT.—

(1) IN GENERAL.—The President shall include in the submission under section 1105 of title 31, United States Code, of the budget of the United States Government for fiscal year 2013 and each fiscal year thereafter an estimate of the budgetary effects for the fiscal year of the provisions of (and the amendments made by) the Patient Protection and Affordable Care Act and this Act, based on the information available as of the date of such submission.

(2) CERTIFICATION.—The President shall include with the estimate under paragraph (1) for any fiscal year a certification as to whether the sum of the decreases in revenues and increases in outlays for the fiscal year by reason of the provisions of (and the amendments made by) the Patient Protection and Affordable Care Act and this Act exceed (or do not exceed) the sum of the increases in revenues and decreases in outlays for the fiscal year by reason of the provisions and amendments.

(b) EFFECT OF DEFICIT.—If the President certifies an excess under subsection (a)(2) for any fiscal year—

(1) the President shall include with the certification the percentage by which the credits allowable under section 36B of the Internal Revenue Code of 1986 and the cost-sharing subsidies under section 1402 of the Patient Protection and Affordable Care Act must be reduced for plan years beginning during such fiscal year such that there is an aggregate decrease in the amount of such credits and subsidies equal to the amount of such excess; and

(2) the President shall instruct the Secretary of Health and Human Services and the Secretary of the Treasury to reduce such credits and subsidies for such plan years by such percentage.

(c) EXPANSION OF AFFORDABILITY EXCEPTION TO INDIVIDUAL MANDATE.—Section 5000A(e)(1)(A) of the Internal Revenue Code of 1986, as added by section 1501(b) of the Patient Protection and Affordable Care Act, is amended by striking ''8 percent'' and inserting ''5 percent''.

SA 3684. Mr. BROWNBACK submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

Strike section 1202 and insert the following:

SEC. 1202. PAYMENTS TO PRIMARY CARE PROVIDERS.

(a) GRANTS TO STATES TO INCREASE PAYMENTS.—From the amounts appropriated under subsection (b), the Secretary of Health and Human Services shall award grants to States with an approved State plan amendment under the Medicaid program under title XIX of the Social Security Act to permanently increase payment rates to primary

care providers under the State Medicaid program above the rates applicable under the State Medicaid program on the date of enactment of this Act. Funds paid to a State from such a grant shall only be used for expenditures attributable to the additional amounts paid to such providers as a result of the increase in such rates.

(b) APPROPRIATION.—Out of any funds in the Treasury not otherwise appropriated, there is appropriated to the Secretary of Health and Human Services, $8,000,000,000, to remain available until expended.

(c) EFFECTIVE DATE.—This section shall take effect on January 1, 2013.

SA 3685. Mr. BROWNBACK (for himself and Mr. ROBERTS) submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

On page 61, after line 3, insert the following:

SEC. _____. RESTORING STATE AUTHORITY TO WAIVE THE 35-MILE RULE FOR MEDICARE CRITICAL ACCESS HOSPITAL DESIGNATIONS.

(a) IN GENERAL.—Section 1820(c)(2)(B)(i)(II) of the Social Security Act (42 U.S.C. 1395i–4(c)(2)(B)(i)(II)) is amended by inserting ''or on or after the date of enactment of the Health Care and Education Reconciliation Act of 2010'' after ''January 1, 2006,''.

(b) EXPANSION OF AFFORDABILITY EXCEPTION TO INDIVIDUAL MANDATE.—Section 5000A(e)(1)(A) of the Internal Revenue Code of 1986, as added by section 1501(b) of the Patient Protection and Affordable Care Act, is amended by striking ''8 percent'' and inserting ''5 percent''.

SA 3686. Mr. BROWNBACK submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle C of title I, add the following:

SEC. 1207. INCREASING THE TRANSPARENCY OF INFORMATION ON HOSPITAL CHARGES AND MAKING AVAILABLE INFORMATION ON ESTIMATED OUT-OF-POCKET COSTS FOR HEALTH CARE SERVICES.

(a) IN GENERAL.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)), as amended by section 3021(b) of the Patient Protection and Affordable Care Act, is amended—

(1) by striking ''and'' at the end of paragraph (82);

(2) by striking the period at the end of paragraph (83) and inserting ''; and'';

(3) by inserting after paragraph (83) the following new paragraph:

''(84) provide that the State will establish and maintain laws, in accordance with the requirements of section 1921A, to require disclosure of information on hospital charges, to make such information available to the public, and to provide individuals with information about estimated out-of-pocket costs for health care services.''; and

(4) by inserting after section 1921 the following new section:

''INCREASING THE TRANSPARENCY OF INFORMATION ON HOSPITAL CHARGES AND PROVIDING CONSUMERS WITH ESTIMATES OF OUT-OF-POCKET COSTS FOR HEALTH CARE SERVICES

''SEC. 1921A. (a) IN GENERAL.—The requirements referred to in section 1902(a)(84) are that the laws of a State must—

''(1) in accordance with subsection (b)—

''(A) require the disclosure of information on hospital charges; and

''(B) provide for access to such information; and

''(2) in accordance with subsection (c), require the provision of a statement of the estimated out-of-pocket costs of an individual for anticipated future health care services.

''(b) INFORMATION ON HOSPITAL CHARGES.—The laws of a State must—

''(1) require disclosure, by each hospital located in the State, of information on the charges for certain inpatient and outpatient hospital services (as determined by the State) provided at the hospital; and

''(2) provide for timely access to such information by individuals seeking or requiring such services.

''(c) ESTIMATED OUT-OF-POCKET COSTS.—The laws of a State must require that, upon the request of any individual with health insurance coverage sponsored by a health insurance issuer, the issuer must provide a statement of the estimated out-of-pocket costs that are likely to be incurred by the individual if the individual receives particular health care items and services within a specified period of time.

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

''(1) authorizing or requiring the Secretary to establish uniform standards for the State laws required by subsections (b) and (c);

''(2) requiring any State with a law enacted on or before the date of the enactment of this section that—

''(A) meets the requirements of subsection (b) or subsection (c) to modify or amend such law; or

''(B) meets some but not all of the requirements of subsection (b) or subsection (c) to modify or amend such law except to the extent necessary to address the unmet requirements;

''(3) precluding any State in which a program of voluntary disclosure of information on hospital charges is in effect from adopting a law codifying such program (other than its voluntary nature) to satisfy the requirement of subsection (b)(1); or

''(4) guaranteeing that the out-of-pocket costs of an individual will not exceed the estimate of such costs provided pursuant to subsection (c).

''(e) DEFINITIONS.—For purposes of this section:

''(1) The term 'health insurance coverage' has the meaning given such term in section 2791(b)(1) of the Public Health Service Act.

''(2) The term 'health insurance issuer' has the meaning given such term in section 2791(b)(2) of the Public Health Service Act, except that such term also includes—

''(A) a Medicaid managed care organization (as defined in section 1903(m)); and

''(B) a Medicare Advantage organization (as defined in 1859(a)(1), taking into account the operation of section 201(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003).

Section 1856(b)(3) shall not preclude the application to a Medicare Advantage organization or a Medicare Advantage plan offered by such an organization of any State law adopted to carry out the requirements of subsection (b) or (c).

''(3) The term 'hospital' means an institution that meets the requirements of paragraphs (1) and (7) of section 1861(e) and includes those to which section 1820(c) applies.''.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by subsection (a) shall take effect on October 1, 2010.

(2) EXCEPTION.—In the case of a State plan for medical assistance under title XIX of the Social Security Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirements imposed by the amendment made by subsection (a), the State plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet these additional requirements before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of the enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

SA 3687. Mr. COBURN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. _____. CONDITIONS FOR TREATMENT OF CERTAIN PERSONS AS ADJUDICATED MENTALLY INCOMPETENT FOR CERTAIN PURPOSES.

(a) IN GENERAL.—Chapter 55 of title 38, United States Code, is amended by adding at the end the following new section:

''§ 5511. Conditions for treatment of certain persons as adjudicated mentally incompetent for certain purposes

''In any case arising out of the administration by the Secretary of laws and benefits under this title, a person who is mentally incapacitated, deemed mentally incompetent, or experiencing an extended loss of consciousness shall not be considered adjudicated as a mental defective under subsection (d)(4) or (g)(4) of section 922 of title 18 without the order or finding of a judge, magistrate, or other judicial authority of competent jurisdiction that such person is a danger to himself or herself or others.''.

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 55 of such title is amended by adding at the end the following new item:

''5511. Conditions for treatment of certain persons as adjudicated mentally incompetent for certain purposes.''.

SA 3688. Ms. SNOWE (for herself, Mr. MCCAIN, Mr. VITTER, Mr. THUNE, Mr. GRASSLEY, and Ms. COLLINS) submitted an amendment intended to be proposed by her to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end, add the following:

TITLE III—IMPORTATION OF PRESCRIPTION DRUGS

SEC. 3001. SHORT TITLE.

This title may be cited as the ''Pharmaceutical Market Access and Drug Safety Act of 2010''.

SEC. 3002. 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. 3003. 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. 3004. 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 3003, 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 3004(e) of the Pharmaceutical Market Access and Drug Safety Act of 2010, 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. 3005. 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 3004, 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. 3006. 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 3004.

(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. 3007. 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. 3008. 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. 3009. 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. 3010. 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.

SA 3689. Mr. COBURN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle F of title I, add the following:

SEC. 1502. NO PAY RAISE FOR MEMBERS OF CONGRESS UNTIL THEY BALANCE THE BUDGET.

(a) RESTRICTION ON COLA ADJUSTMENTS.—Notwithstanding any other provision of law, no adjustment shall be made under section 601(a) of the Legislative Reorganization Act of 1946 (2 U.S.C. 31) (relating to cost of living adjustments for Members of Congress) during fiscal year 2011 or any succeeding fiscal year, until the fiscal year following the first fiscal year that the annual Federal budget deficit is $0 as determined in the report submitted under subsection (b).

(b) DETERMINATIONS AND REPORTS.—

(1) IN GENERAL.—Not later than 30 days after the end of each fiscal year, the Secretary of the Treasury shall—

(A) make a determination of whether or not the annual Federal budget deficit was $0 for that fiscal year; and

(B) if the determination is that the annual Federal budget deficit was $0 for that fiscal year, submit a report to Congress of that determination.

(2) RESTRICTION OF COLA ADJUSTMENTS.—Not later than the end of each calendar year, the Secretary of the Treasury shall submit a report to the Secretary of the Senate and the Chief Administrative Officer of the House of Representatives on—

(A) any determination made under paragraph (1); and

(B) whether or not the restriction under subsection (a) shall apply to the succeeding fiscal year.

SA 3690. Mr. BROWNBACK submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

On page 113, after line 21, add the following:

SEC. 1502. RELOCATION OF THE UNITED STATES EMBASSY TO JERUSALEM.

(a) REMOVAL OF WAIVER AUTHORITY.—The Jerusalem Embassy Act of 1995 (Public Law 104–45; 109 Stat. 398) is amended—

(1) by striking section 7; and

(2) by redesignating section 8 as section 7.

(b) TIMETABLE.—Not more than 50 percent of the funds appropriated to the Department of State for fiscal year 2012 for ''Acquisition and Maintenance of Buildings Abroad'' may be obligated until the Secretary of State determines and reports to Congress that the United States Embassy in Jerusalem has officially opened.

(c) FISCAL YEARS 2010 AND 2011 FUNDING.—

(1) FISCAL YEAR 2010.—Of the funds authorized to be appropriated for ''Acquisition and Maintenance of Buildings Abroad'' for the Department of State for fiscal year 2010, such sums as may be necessary shall be made available until expended only for construction and other costs associated with the establishment of the United States Embassy in Israel in the capital of Jerusalem.

(2) FISCAL YEAR 2011.—Of the funds authorized to be appropriated for ''Acquisition and Maintenance of Buildings Abroad'' for the Department of State for fiscal year 2011, such sums as may be necessary shall be made available until expended only for construction and other costs associated with the establishment of the United States Embassy in Israel in the capital of Jerusalem.

(d) DEFINITION.—In this section, the term ''United States Embassy'' means the offices of the United States diplomatic mission and the residence of the United States chief of mission.

SA 3691. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle F of title I, add the following:

SEC. 1502. PAYMENT FOR ILLEGAL UNAPPROVED DRUGS.

(a) LISTING OF DRUGS AND DEVICES.—Section 510 of the Food, Drug and Cosmetic Act (21 U.S.C. 360) is amended—

(1) in subsection (j)(1)(B)—

(A) in clause (i), by inserting ''in the case of a drug, the authority under this Act that does not require such drug to be subject to section 505 and section 512,'' after ''labeling for such drug or device,''; and

(B) in clause (ii), by inserting '', in the case of a drug, the authority under this Act that does not require such drug to be subject to section 505 and section 512,'' after ''for such drug or device''; and

(2) in subsection (f)—

(A) by striking ''(f) The Secretary'' and inserting the following:

''(f) INSPECTION BY PUBLIC OF REGISTRATION.—

''(1) IN GENERAL.—The Secretary''; and

(B) by adding at the end the following:

''(2) LIST OF DRUGS THAT ARE NOT APPROVED UNDER SECTION 505 OR 512.—Not later than January 1, 2011, the Secretary shall make available to the public on the Internet website of the Food and Drug Administration a list that includes, for each drug described in subsection (j)(1)(B)—

''(A) the drug;

''(B) the person who listed such drug; and

''(C) the authority under this Act that does not require such drug to be subject to section 505 and section 512, as provided by such person in such list.''.

(b) PAYMENT FOR COVERED OUTPATIENT DRUGS.—Section 1927 of the Social Security Act (42 U.S.C. 1396r-8) is amended by inserting at the end the following:

''(l) CONDITION.—Beginning January 1, 2011, no State shall make any payment under this section for any covered outpatient drug unless such State first verifies with the Food and Drug Administration that such covered outpatient drug has been approved by the Food and Drug Administration under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or an abbreviated new drug application under section 505(j) of such Act, or that such drug is not subject to such section 505 or section 512 due to the application of section 201(p) of such Act (21 U.S.C. 321(p)). The Secretary shall have the authority to proscribe regulations to create an information sharing protocol to allow States to verify that a covered outpatient drug has been approved by the Food and Drug Administration.''.

SA 3692. Mr. GRASSLEY submitted an amendment intended to be proposed

by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

On page 82, after line 9, insert the following:

SEC. _____. EXTENSION AND EXPANSION OF OVERSIGHT FOR CLAIMS OF DME SUPPLIERS.

Section 1866(j) of the Social Security Act, as amended by section 1304, is further amended—

(1) in paragraph (4)—

(A) in the heading, by striking ''90-DAY'' and inserting ''180-DAY''; and

(B) by striking ''90-day'' and inserting ''180-day'';

(2) by redesignating paragraphs (5) through (8) as paragraphs (6) through (9), respectively; and

(3) by inserting after paragraph (4) the following new paragraph:

''(5) 180-DAY PERIOD OF ENHANCED OVERSIGHT AND ADDITIONAL REVIEW FOR OTHER CLAIMS OF DME SUPPLIERS.—For periods beginning after January 1, 2011, if the Secretary determines that there is a significant risk of fraudulent activity among suppliers of durable medical equipment, in the case of a supplier of durable medical equipment not described in paragraph (4) who is within a category or geographic area under title XVIII identified pursuant to such determination, the Secretary shall, notwithstanding sections 1816(c), 1842(c), and 1869(a)(2)—

''(A) withhold payment under such title with respect to durable medical equipment furnished by such supplier during the 180-day period beginning on the date of such determination; and

''(B) conduct a review of claims for payment under such title with respect to durable medical equipment furnished by such supplier submitted during the 12-month period prior to the date of such determination.''.

SA 3693. Ms. MURKOWSKI submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

In section 1402, strike subsection (a).

SA 3694. Mr. GRAHAM submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

On page 144, between lines 2 and 3, insert the following:

SEC. 2214. SAVINGS TO FUND FEDERAL PELL GRANTS.

Notwithstanding any other provision of this Act, the savings resulting from this subtitle that are spent on healthcare under subtitle B shall instead be used to provide additional funding for the Federal Pell Grant program under section 401 of the Higher Education Act of 1965 (20 U.S.C. 1070a), in order to address budgetary shortfalls for such program for fiscal years 2010 through 2019.

SA 3695. Mr. ALEXANDER submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

On page 143, strike lines 1 through 13 and insert the following:

''(7) INTEREST RATE DISCLOSURE.—

''(A) PROVISION OF ASSISTANCE.—The Secretary shall provide annual disclosures to student and parent borrowers of student loans under this part on the annual and cumulative difference of the interest rate and amounts owed in interest paid by the student, as compared to the interest rate paid by the Department of Education to the Department of the Treasury.

''(B) FUNDS.—There are authorized to be appropriated, and there are appropriated, to carry out this paragraph (in addition to any other amounts appropriated to carry out this paragraph and out of any money in the Treasury not otherwise appropriated), $5,000,000 for each of the fiscal years 2010 through 2019.''.

SA 3696. Mr. ENSIGN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

Strike section 1002 and insert the following:

SEC. 1002. REPEAL OF INDIVIDUAL MANDATE.

Sections 1501 and 1502 and subsections (a), (b), (c), and (d) of section 10106 of the Patient Protection and Affordable Care Act (and the amendments made by such sections and subsections) are repealed and the Internal Revenue Code of 1986 shall be applied and administered as if such provisions and amendments had never been enacted.

SA 3697. Mr. BROWNBACK submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of section 1402(a), insert the following:

(5) INFLATION ADJUSTMENT.—Section 1411 of the Internal Revenue Code of 1986, as added by paragraph (1), is amended by adding at the end the following new subsection:

''(f) ADJUSTMENT FOR INFLATION.—In the case of any taxable year beginning after December 31, 2013, each of the dollar amounts under paragraphs (1) and (3) of subsection (b), subparagraphs (A) and (C) of section 3101(b)(2), and clauses (i) and (iii) of section 1401(b)(2)(A) shall be increased by an amount equal to—

''(1) such amount, multiplied by

''(2) the cost-of-living adjustment determined under section 1(f)(3) for the calendar year in which such taxable year begins by substituting 'calendar year 2012' for 'calendar year 1992' in subparagraph (B) thereof. If any increase determined under this subsection is not a multiple of $1,000, such increase shall be rounded to the next lowest multiple of $1,000.''.

SA 3698. Mr. CORNYN submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); which was ordered to lie on the table; as follows:

At the end of subtitle F of title I, insert the following:

SEC. 1___. LIMITATION ON APPLICATION OF ACTS.

Notwithstanding any other provision of law, the Secretary of Health and Human Services shall not implement the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2011 until the Office of the Actuary at the Centers for Medicare & Medicaid Services certifies to Congress that such Acts will reduce National health expenditures relative to the level of such expenditures under current law.

SA 3699. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill H.R. 4872, to provide for reconciliation pursuant to Title II of the concurrent resolution on the budget for fiscal year 2010 (S. Con. Res. 13); as follows:

At the end of the bill, insert:

TITLE III—TEMPORARY EXTENSION OF CERTAIN PROGRAMS

SEC. 300. SHORT TITLE.

This title may be cited as the ''Continuing Extension Act of 2010''.

SEC. 301. EXTENSION OF UNEMPLOYMENT INSURANCE PROVISIONS.

(a) IN GENERAL.—(1) Section 4007 of the Supplemental Appropriations Act, 2008 (Public Law 110–252; 26 U.S.C. 3304 note) is amended—

(A) by striking ''April 5, 2010'' each place it appears and inserting ''May 5, 2010'';

(B) in the heading for subsection (b)(2), by striking ''APRIL 5, 2010'' and inserting ''MAY 5, 2010''; and

(C) in subsection (b)(3), by striking ''September 4, 2010'' and inserting ''October 2, 2010''.

(2) Section 2002(e) of the Assistance for Unemployed Workers and Struggling Families Act, as contained in Public Law 111–5 (26 U.S.C. 3304 note; 123 Stat. 438), is amended—

(A) in paragraph (1)(B), by striking ''April 5, 2010'' and inserting ''May 5, 2010'';

(B) in the heading for paragraph (2), by striking ''APRIL 5, 2010'' and inserting ''MAY 5, 2010''; and

(C) in paragraph (3), by striking ''October 5, 2010'' and inserting ''November 5, 2010''.

(3) Section 2005 of the Assistance for Unemployed Workers and Struggling Families Act, as contained in Public Law 111–5 (26 U.S.C. 3304 note; 123 Stat. 444), is amended—

(A) by striking ''April 5, 2010'' each place it appears and inserting ''May 5, 2010''; and

(B) in subsection (c), by striking ''September 4, 2010'' and inserting ''October 2, 2010''.

(4) Section 5 of the Unemployment Compensation Extension Act of 2008 (Public Law 110–449; 26 U.S.C. 3304 note) is amended by striking ''September 4, 2010'' and inserting ''October 2, 2010''.

(b) FUNDING.—Section 4004(e)(1) of the Supplemental Appropriations Act, 2008 (Public Law 110–252; 26 U.S.C. 3304 note) is amended—

(1) in subparagraph (C), by striking ''and'' at the end;

(2) by inserting after subparagraph (D) the following new subparagraph:

''(E) the amendments made by section 2(a)(1) of the Continuing Extension Act of 2010; and''.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect as if included in the amendments made by section 2 of the Temporary Extension Act of 2010 (Public Law 111–144).

SEC. 302. EXTENSION AND IMPROVEMENT OF PREMIUM ASSISTANCE FOR COBRA BENEFITS.

Subsection (a)(3)(A) of section 3001 of division B of the American Recovery and Reinvestment Act of 2009 (Public Law 111–5), as amended by section 3(a) of the Temporary Extension Act of 2010 (Public Law 111–144), is amended by striking ''March 31, 2010'' and inserting ''April 30, 2010''.

SEC. 303. INCREASE IN THE MEDICARE PHYSICIAN PAYMENT UPDATE.

Paragraph (10) of section 1848(d) of the Social Security Act, as added by section 1011(a) of the Department of Defense Appropriations Act, 2010 (Public Law 111–118) and as amended by section 5 of the Temporary Extension Act of 2010 (Public Law 111–144), is amended—

(1) in subparagraph (A), by striking ''March 31, 2010'' and inserting ''April 30, 2010''; and

(2) in subparagraph (B), by striking ''April 1, 2010'' and inserting ''May 1, 2010''.

SEC. 304. EHR CLARIFICATION.

(a) QUALIFICATION FOR CLINIC-BASED PHYSICIANS.—

(1) MEDICARE.—Section 1848(o)(1)(C)(ii) of the Social Security Act (42 U.S.C. 1395w–4(o)(1)(C)(ii)) is amended by striking ''setting (whether inpatient or outpatient)'' and inserting ''inpatient or emergency room setting''.

(2) MEDICAID.—Section 1903(t)(3)(D) of the Social Security Act (42 U.S.C. 1396b(t)(3)(D)) is amended by striking ''setting (whether inpatient or outpatient)'' and inserting ''inpatient or emergency room setting''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall be effective as if included in the enactment of the HITECH Act (included in the American Recovery and Reinvestment Act of 2009 (Public Law 111–5)).

(c) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the amendments made by this section by program instruction or otherwise.

SEC. 305. ELIMINATION OF A SWEETHEART DEAL THAT INCREASES MEDICARE REIMBURSEMENT JUST FOR FRONTIER STATES.

Effective as if included in the enactment of the Patient Protection and Affordable Care Act, section 10324 of such Act (and the amendments made by such section) is repealed.

SEC. 306. EXTENSION OF USE OF 2009 POVERTY GUIDELINES.

Section 1012 of the Department of Defense Appropriations Act, 2010 (Public Law 111–118), as amended by section 7 of the Temporary Extension Act of 2010 (Public Law 111–144), is amended by striking ''March 31, 2010'' and inserting ''April 30, 2010''.

SEC. 307. EXTENSION OF NATIONAL FLOOD INSURANCE PROGRAM.

(a) EXTENSION.—Section 129 of the Continuing Appropriations Resolution, 2010 (Public Law 111–68), as amended by section 8 of Public Law 111–144, is amended by striking ''by substituting'' and all that follows through the period at the end and inserting ''by substituting April 30, 2010, for the date specified in each such section.''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall be considered to have taken effect on February 28, 2010.

SEC. 308. SATELLITE TELEVISION EXTENSION.

(a) AMENDMENTS TO SECTION 119 OF TITLE 17, UNITED STATES CODE.—

(1) IN GENERAL.—Section 119 of title 17, United States Code, is amended—

(A) in subsection (c)(1)(E), by striking ''March 28, 2010'' and inserting ''April 30, 2010''; and

(B) in subsection (e), by striking ''March 28, 2010'' and inserting ''April 30, 2010''.

(2) TERMINATION OF LICENSE.—Section 1003(a)(2)(A) of Public Law 111–118 is amended by striking ''March 28, 2010'', and inserting ''April 30, 2010''.

(b) AMENDMENTS TO COMMUNICATIONS ACT OF 1934.—Section 325(b) of the Communications Act of 1934 (47 U.S.C. 325(b)) is amended—

(1) in paragraph (2)(C), by striking ''March 28, 2010'' and inserting ''April 30, 2010''; and

(2) in paragraph (3)(C), by striking ''March 29, 2010'' each place it appears in clauses (ii) and (iii) and inserting ''May 1, 2010''.

SEC. 309. COMPENSATION AND RATIFICATION OF AUTHORITY RELATED TO LAPSE IN HIGHWAY PROGRAMS.

(a) COMPENSATION FOR FEDERAL EMPLOYEES.—Any Federal employees furloughed as a result of the lapse in expenditure authority from the Highway Trust Fund after 11:59 p.m. on February 28, 2010, through March 2, 2010, shall be compensated for the period of that lapse at their standard rates of compensation, as determined under policies established by the Secretary of Transportation.

(b) RATIFICATION OF ESSENTIAL ACTIONS.—All actions taken by Federal employees, contractors, and grantees for the purposes of maintaining the essential level of Government operations, services, and activities to protect life and property and to bring about orderly termination of Government functions during the lapse in expenditure authority from the Highway Trust Fund after 11:59 p.m. on February 28, 2010, through March 2, 2010, are hereby ratified and approved if otherwise in accord with the provisions of the Continuing Appropriations Resolution, 2010 (division B of Public Law 111–68).

(c) FUNDING.—Funds used by the Secretary to compensate employees described in subsection (a) shall be derived from funds previously authorized out of the Highway Trust Fund and made available or limited to the Department of Transportation by the Consolidated Appropriations Act, 2010 (Public Law 111–117) and shall be subject to the obligation limitations established in such Act.

(d) EXPENDITURES FROM HIGHWAY TRUST FUND.—To permit expenditures from the Highway Trust Fund to effectuate the purposes of this section, this section shall be deemed to be a section of the Continuing Appropriations Resolution, 2010 (division B of Public Law 111–68), as in effect on the date of the enactment of the last amendment to such Resolution.

SEC. 310. USE OF STIMULUS FUNDS TO OFFSET SPENDING.

The unobligated balance of each amount appropriated or made available under the American Recovery and Reinvestment Act of 2009 (Public Law 111–5) (other than under title X of division A of such Act) is rescinded pro rata such that the aggregate amount of such rescissions equals $9,200,000,000 in order to offset the net increase in spending resulting from the provisions of, and amendments made by, sections 2 through 10. The Director of the Office of Management and Budget shall report to each congressional committee the amounts so rescinded within the jurisdiction of such committee.

SEC. 311. ELIMINATION OF ADVANCE REFUNDABILITY OF EARNED INCOME CREDIT.

(a) IN GENERAL.—Section 3507, subsection (g) of section 32, and paragraph (7) of section 6051(a) are repealed.

(b) CONFORMING AMENDMENTS.—

(1) Section 6012(a) is amended by striking paragraph (8) and by redesignating paragraph (9) as paragraph (8).

(2) Section 6302 is amended by striking subsection (i).

(c) EFFECTIVE DATE.—The repeals and amendments made by this section shall apply to taxable years beginning after December 31, 2010.

AUTHORITY FOR COMMITTEES TO MEET

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 March 24, 2010, at 10 a.m.

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

SUBCOMMITTEE ON PERSONNEL

Mr. REED. Mr. President, I ask unanimous consent that the Subcommittee on Personnel of the Committee on Armed Services be authorized to meet during the session of the Senate on March 24, 2010, at 10 a.m.

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

PRIVILEGES OF THE FLOOR

Mr. BINGAMAN. Mr. President, I ask unanimous consent that Nassim Zecavati and Jason Ackleson, who are fellows in my office, be granted the privilege of the floor during the pendency of H.R. 4872, the health care reconciliation bill.

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

Mr. GRASSLEY. Mr. President, I ask unanimous consent that Brittney Balduf of my staff be granted floor privileges for the duration of the debate.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

Mr. CASEY. Mr. President, I ask unanimous consent that a fellow in my office, Avni Shridharani, be granted floor privileges for the remainder of the Senate's consideration of H.R. 4872.

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

ORDERS FOR THURSDAY, MARCH 25, 2010

Mr. WHITEHOUSE. Mr. President, I ask unanimous consent that when the Senate completes its business, it adjourn until 9:45 a.m. today, Thursday, March 25; that following the prayer and pledge, the Journal of proceedings be approved to date, the morning hour be deemed expired, the time for the two leaders be reserved for their use later in the day, and the Senate resume consideration of H.R. 4872, as provided for under the previous order.

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

PROGRAM

Mr. WHITEHOUSE. Mr. President, Senators should expect a series of rollcall votes in relation to amendments and motions to the reconciliation bill at approximately 9:45 a.m.