109TH CONGRESS
1ST SESSION

S. 16

To reduce to the cost of quality health care coverage and improve the availability of health care coverage for all Americans.

IN THE SENATE OF THE UNITED STATES

JANUARY 24, 2005

Mr. KENNEDY (for himself, Mr. REID, Ms. STABENOW, Mr. CORZINE, Mr. SCHUMER, Ms. MIKULSKI, Mr. AKAKA, Mr. INOUYE, Mr. LEVIN, Mr. KERRY, Mr. LAUTENBERG, Mr. ROCKEFELLER, Mr. DODD, Mr. PRYOR, and Mr. DURBIN) introduced the following bill; which was read twice and referred to the Committee on Finance

---

A BILL

To reduce to the cost of quality health care coverage and improve the availability of health care coverage for all Americans.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Affordable Health Care Act''.

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

TITLE I—MAKING PRESCRIPTION DRUGS MORE SAFE AND AFFORDABLE

Subtitle A—Access to Prescription Drugs

SEC. 101. 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 seniors alone will spend $1,800,000,000,000 on pharmaceuticals over the next 10 years; and

(6) allowing open pharmaceutical markets could save American consumers at least $38,000,000,000 each year.

SEC. 102. 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. 103. 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 102, 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.—The Secretary shall in accordance with this section provide by regulation that, 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 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 prescription drug, other than any of the following:

''(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).

''(iii) An infused drug, including a peritoneal dialysis solution.

''(iv) An intravenously injected drug.

''(v) A drug that is inhaled during surgery.

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

''(i) The term 'exporter' means a person that is in the business of exporting a drug from Canada to individuals in the United States or that, pursuant to submit-

ting a registration under subsection (b), seeks to be in such business.

''(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).

"(D) PERMITTED COUNTRY.—The term 'permitted country' means—

"(i) Australia;

"(ii) Canada;

"(iii) a member country of the European Union as of January 1, 2003;

"(iv) Japan;

"(v) New Zealand; and

"(vi) Switzerland.

"(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) The name of the registrant and an 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) 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 exported 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 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 from Canada; 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 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 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 if, after opportunity for an informal hearing, the Secretary determines that the exporter has exported a drug to the United States that is not a qualifying drug or that is not in compliance with subsections (g) or (i), 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.

''(J) Such other provisions as the Secretary may require to protect the public health while permitting—

''(i) the importation by pharmacies, groups of pharmacies, 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 sub-

mits 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)(G) 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, 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 accordingly.

''(4) SUSPENSION AND TERMINATION.—

''(A) SUSPENSION.—With respect to the effectiveness of a registration submitted under paragraph (1):

''(i) Subject to clause (ii), if the Secretary determines, after notice and opportunity for a hearing, that the registrant 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 exporter has exported a drug or the importer has imported a drug that is not a qualifying drug, or a drug that does not meet the criteria under subsection (g)(2)(A), or has exported a qualifying drug to an individual in violation of subsection (i)(1)(F), 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.

''(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 to 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; or

''(B) inspected by the Secretary as provided by this section.

''(2) The establishment is located in the United States or in any foreign 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 was 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 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) The foreign country from which the importer will import the drug is a permitted country.

"(5) The foreign country from which the exporter will export the drug is Canada.

"(6) 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.

"(7) The exporter or importer retains a sample of each lot of the drug sufficient 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 not less than every 3 weeks 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—

''(A) shall be designed to prevent affixation of the markings to any shipping container that is not authorized to bear the markings; and

''(B) may include anti-counterfeiting or track-and-trace technologies.

''(3) CERTAIN DUTIES RELATING TO EXPORTERS.—Duties of the Secretary with respect to an exporter include the following:

''(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 may be accomplished by the use of anticounterfeiting or track-and-trace technologies, if available.

''(B) 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.

''(C) Monitoring the affixing of markings under paragraph (2).

''(D) Inspect as the Secretary determines is necessary the warehouses and other facilities of other parties in the chain of custody of qualifying drugs.

''(E) Determine whether the exporter is in compliance with all other registration conditions.

''(4) CERTAIN DUTIES RELATING TO IMPORTERS.—Duties of the Secretary with respect to an importer include the following:

''(A) As authorized under section 704, inspect not less than every 3 weeks, the places of business of the importer that relate to the receipt and distribution of a qualifying drug, including each warehouse or other facility owned

or controlled by, or operated for, the importer at which qualifying drugs are received or from which they are distributed to pharmacies.

''(B) During the inspections under subparagraph (A), verify 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 may be accomplished by the use of anticounterfeiting or track-and-trace technologies, if available.

''(C) Inspect as the Secretary determines is necessary the warehouses and other facilities of other parties in the chain of custody of qualifying drugs.

''(D) Determine 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 to the Sec-

retary in accordance with this subsection a fee on a semiannual basis, with the first fee due on the date that is 6 months after the date on which the registration of the importer under subsection (b) is first approved by the Secretary.

''(3) AMOUNT OF INSPECTION FEE.—

''(A) AGGREGATE TOTAL OF FEES.—The Secretary shall ensure that the aggregate total of fees collected under paragraph (2) for a fiscal year from all importers is sufficient, and no more than necessary, to pay the costs of administering this section with respect to registered importers for a fiscal year, including—

''(i) inspection of the facilities of importers under subsection (d)(4);

''(ii) reviewing qualifying drugs offered for import to importers; and

''(iii) determining the compliance of importers with registration conditions.

''(B) LIMITATION.—The aggregate total of fees collected under paragraph (2) shall not exceed 1 percent of the total price of drugs imported annually to the United States by registered importers under this section.

"(C) INDIVIDUAL IMPORTER FEE.—Subject to the limitation described in subparagraph (B), a fee under paragraph (2) for an importer shall be an amount that is a reasonable estimate by the Secretary of the semiannual share of the importer of the volume of drugs imported by importers under this section.

"(D) ADJUSTMENT OF FEE.—The Secretary shall annually adjust the fees under paragraph (2) to ensure that the fees accurately reflect the actual costs referred to in subparagraph (A) and do not exceed, in the aggregate, 1 percent of the total price of drugs imported annually to the United States under this section.

"(4) USE OF FEES.—Subject to appropriations Acts, fees collected by the Secretary under paragraphs (1) and (2) are available only to the Secretary and are for the sole purpose of paying the costs referred to in paragraph (3)(A).

"(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 to the Secretary in accordance with this subsection a fee on a semiannual basis, with the first fee due on the date that is 6 months after the date on which the registration of the exporter under subsection (b) is first approved by the Secretary.

''(3) AMOUNT OF INSPECTION FEE.—

''(A) AGGREGATE TOTAL OF FEES.—The Secretary shall ensure that the aggregate total of fees collected under paragraph (2) for a fiscal year from all exporters is sufficient, and not more than necessary, to pay the costs of administering this section with respect to registered exporters for a fiscal year, including—

''(i) monitoring foreign facilities under subsection (d);

''(ii) developing, implementing, and maintaining under such subsection a system to mark shipments to indicate compliance with all registration conditions; and

''(iii) conducting under such subsection inspections within the United

States to determine compliance with conditions under subsections (h) and (i).

''(B) LIMITATION.—The aggregate total of fees collected under paragraph (2) shall not exceed 1 percent of the total price of drugs imported annually to the United States by registered exporters under this section.

''(C) INDIVIDUAL EXPORTER FEE.—Subject to the limitation described in subparagraph (B), a fee under paragraph (2) for an exporter shall be an amount that is a reasonable estimate by the Secretary of the semiannual share of the exporter of the volume of drugs exported by exporters under this section.

''(D) ADJUSTMENT OF FEE.—The Secretary shall annually adjust the fees under paragraph (2) to ensure that the fees accurately reflect the actual costs referred to in subparagraph (A) and do not exceed, in the aggregate, 1 percent of the total price of drugs imported annually to the United States under this section.

''(4) USE OF FEES.—Subject to appropriations Acts, fees collected by the Secretary under paragraphs (1) and (2) are only available to the Sec-

retary and are for the sole purpose of paying the costs referred to in paragraph (3)(A).

''(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.—For purposes of administrative and judicial procedure, there is a presumption that a drug proposed for export or import under subsection (a) is an approved drug under section 505(b) if the following criteria are met:

''(i) The drug proposed for export or import is in compliance with subsection (c).

''(ii) The drug proposed for export or import has the same active ingredient or ingredients, route of administration, dosage form, and strength, according to infor-

mation provided by the labeling of the drug proposed for export or import, as a drug (referred to in this subsection as a 'U.S. label drug') that—

"(I) is manufactured by or for the person that manufactures the drug proposed for export or import; and

"(II) is approved under section 505(b).

"(B) IMPORTATION.—Subject to subparagraphs (D) and (E), a drug meeting the criteria described in subparagraph (A) may, in accordance with the other subsections of this section, be imported into the United States.

"(C) NOTICE BY MANUFACTURER; GENERAL PROVISIONS.—

"(i) IN GENERAL.—The person that manufactures a drug that may be imported under subsection (a) shall in accordance with this paragraph submit to the Secretary a notice that—

"(I) includes each difference in the drug from a condition established in the approved application for the

U.S. label drug beyond the variations provided for in the application, any difference in labeling, the date on which the drug with such difference was, or will be, introduced for commercial distribution in a permitted country, and such additional information as the Secretary may require; or

''(II) states that there is no difference in the drug from a condition established in the approved application for the U.S. label drug beyond the variations provided for in the application and differences in labeling.

''(ii) INFORMATION REGARDING FOREIGN GOVERNMENT.—A notice under clause (i)(I) shall with respect to the permitted country that approved the drug for commercial distribution, or with respect to which such approval is sought, include the following:

''(I) 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 drug from a condition established in the approved application for the U.S. label drug.

''(II) 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 Assistant Attorney General in charge of the Antitrust Division of the Department of Justice (referred to in this subsection as the 'Assistant Attorney General').

"(iv) FEE.—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). Subject to appropriations Acts, 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).

"(v) TIMING OF SUBMISSION OF NOTICES.—

"(I) PRIOR APPROVAL NOTICES.—A notice under clause (i) to which subparagraph (D) applies shall be submitted to the Secretary not later than 120 days before the drug with the difference is introduced for commercial distribution in a permitted country, unless the country requires that distribution of the 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 (E) applies shall be submitted to the Secretary not later than the day on which the drug with the difference is introduced for commercial distribution in a permitted country.

"(III) OTHER NOTICES.—A notice under clause (i) to which subparagraph (F) applies shall be submitted to the Secretary on the date that the drug is first introduced for commer-

cial distribution in a permitted country and annually thereafter.

''(vi) REVIEW BY SECRETARY.—

''(I) IN GENERAL.—In this paragraph, the difference in a drug that may be imported under subsection (a) from the U.S. label drug shall be treated by the Secretary as if it was a manufacturing change to the U.S. label drug under section 506A.

''(II) 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.

''(III) ESTABLISHMENT INSPECTION.—If review of such difference would require an inspection by the Secretary of the establishment in which the drug is manufactured, such inspection shall be authorized by section 704.

"(vii) PUBLICATION OF INFORMATION ON NOTICES.—

"(I) IN GENERAL.—Through the Internet website of the Food and Drug Administration, 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 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.

"(D) NOTICE; DRUG DIFFERENCE REQUIRING PRIOR APPROVAL.—In the case of a notice under subparagraph (C)(i) that includes a difference that would, under section 506A(c) or (d)(3)(B)(i), 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 Assistant Attorney General that the notice has been submitted with respect to the drug involved.

"(ii) If the Secretary has not made a determination whether a supplemental application regarding the U.S. label drug would be approved or disapproved by the date on which the drug involved is to be introduced for commercial distribution in a permitted country, the Secretary shall—

"(I) order that the importation of the drug involved from the permitted country cease for the period in which

the Secretary completes review of the notice; and

''(II) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the Attorney 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 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 drug for commercial distribution of the determination; and

''(III) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the Assistant Attorney 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 vacate the order under clause (ii), if any, permit importation of the drug under subsection (a), and promptly notify registered exporters, registered importers, the Federal Trade Commission, and the Assistant Attorney General of the determination.

''(E) NOTICE; DRUG DIFFERENCE NOT REQUIRING PRIOR APPROVAL.—In the case of a notice under subparagraph (C)(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 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 order that the importation of the drug involved from the permitted country cease, shall notify the permitted country that approved the drug for commercial distribution of the determination, and shall promptly notify registered exporters, registered importers, the Federal Trade Commission, and the Assistant Attorney General of the determination.

"(F) NOTICE; DRUG DIFFERENCE NOT REQUIRING APPROVAL; NO DIFFERENCE.—In the case of a notice under subparagraph (C)(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) may not order that the importation of the drug involved cease; and

"(ii) shall promptly notify registered exporters and registered importers.

"(G) DIFFERENCES IN ACTIVE INGREDIENT, ROUTE OF ADMINISTRATION, DOSAGE FORM, OR STRENGTH.—

"(i) IN GENERAL.—A person who manufactures a U.S. label drug shall submit an application under section 505(b) for a drug that is manufactured for distribution in a permitted country by or for the person that manufactures the U.S. label drug if—

"(I) there is no drug for export from at least half of the permitted countries with the same active ingredient or ingredients, route of administration, dosage form, and strength as the U.S. label drug; and

"(II) each active ingredient of the drug is related to an active ingredient of the U.S. label drug, 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 drug for the indication or indications for which the U.S. label drug is approved under section 505;

"(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 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 under section 505(b) for the U.S. label drug; 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 Assistant Attorney 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 if the drug bears—

"(I) a copy of the labeling approved for the drug under section

505, without regard to whether the copy bears the trademark involved;

"(II) the name of the manufacturer and location of the manufacturer;

"(III) the lot number assigned by the manufacturer; and

"(IV) the name, location, and registration number of the importer.

"(ii) REQUEST FOR COPY OF THE LABELING.—The Secretary shall provide such copy to the registered importer involved, upon request of the importer.

"(B) IMPORTATION BY INDIVIDUAL.—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 if the drug bears a label providing the directions for use by the consumer, and bears a copy of any special labeling that would be required by the Secretary had the drug been dispensed by a pharmacist in the United States, without regard to whether the special labeling bears the trademark involved. The Secretary shall provide to the reg-

istered exporter involved a copy of the special labeling, upon request of the exporter.

''(4) SECTION 501; STANDARDS FOR REFUSING ADMISSION.—

''(A) IN GENERAL.—For purposes of administrative and judicial procedure, there is a presumption that a drug proposed for export or import under subsection (a) is in compliance with section 501 if the drug is in compliance with subsection (c).

''(B) STANDARDS FOR REFUSING ADMISSION.—A qualifying 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:

''(i) The shipping container appears damaged in a way that may affect the strength, quality, or purity of the drug.

''(ii) 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.

"(iii) The Secretary has obtained an injunction under section 302 that prohibits the distribution of the drug in interstate commerce.

"(iv) The Secretary has under section 505(e) withdrawn approval of the drug.

"(v) The manufacturer of the drug has instituted a recall of the drug.

"(vi) If the qualifying drug is exported 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) LICENSING AS PHARMACIST.—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 Canadian law to dispense prescription drugs; and

''(2) the exporter employs persons that are licensed under Canadian law to dispense prescription drugs in sufficient number to dispense safely the qualifying drugs exported by the exporter to individuals, and the exporter assigns to those persons responsibility for dispensing such qualifying drugs to individuals.

''(i) INDIVIDUALS; CONDITIONS FOR IMPORTATION FROM CANADA.—

''(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 Canada 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 Canada, 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.—A registration condition is that the importer or exporter involved shall—

''(1) maintain records required under this section for not less than 2 years; and

''(2) maintain samples of each lot of a drug required under this section for not less than 2 years.

''(k) DRUG RECALLS.—

''(1) MANUFACTURERS.—A person that manufactures a prescription 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 prescription drugs in the country; or

''(B) monitor recalls and withdrawals of prescription 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 prescription drug in a permitted country.''.

(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)(C) or in an application required under section 804(g)(2)(G), or the failure to submit such a notice or application.

''(4) The importation of a drug in violation of a requirement under section 804.''; 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(aa) (3) or (4) shall be imprisoned not more than 10 years, or fined in accordance with title 18, United States Code, or both.''.

(c) IMPLEMENTATION.—

(1) RULEMAKING.—

(A) IN GENERAL.—

(i) PROMULGATION BY SECRETARY.—Not later than 90 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate an interim rule for implementing section 804 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a) of this section. Such rule shall be developed and promulgated by the Secretary without providing general notice of proposed rulemaking. Not later than 1 year

after the date on which the interim rule is promulgated, 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, to the extent that such provisions are not modified.

(ii) EFFECT OF RULES.—The rules promulgated under clause (i) shall permit the importation of prescription drugs—

(I) from registered exporters by individuals effective on the date of the promulgation of the interim rule;

(II) from Canada by registered importers effective on the date of the promulgation of the interim rule; and

(III) from Australia, a member country of the European Union as of January 1, 2003, Japan, New Zealand, or Switzerland by registered importers on the date that is 1 year after the date of the enactment of this Act.

(B) CERTAIN EXPORTERS.—The interim rule under subparagraph (A) shall provide that, in the review of registrations submitted under subsection (b) of the section 804 referred to in such subparagraph, registrations submitted by entities in Canada that are significant exporters of prescription drugs to individuals in the United States as of the date of the enactment of this Act will have priority during the period in which the interim rule under subparagraph (A) is in effect. During such 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) DRUGS FOR IMPORT FROM CANADA.—The notices with respect to drugs to be imported from Canada that are required under subsection (g)(2)(C)(i)(I) of such section 804 and that require approval under subsection (g)(2)(D) or (E) of such section 804 shall be submitted to the Secretary not later than 30 days after the date of enactment of this Act. The notices with respect to drugs to be imported from Canada that are required under

subsection (g)(2)(C)(i) of such section 804 and that do not require approval under subsection (g)(2)(D) or (E) of such section 804 shall be submitted to the Secretary not later than 90 days after the date of enactment of this Act.

(D) DRUGS FOR IMPORT FROM OTHER COUNTRIES.—The notices with respect to drugs to be imported from Australia, a member country of the European Union as of January 1, 2003, Japan, New Zealand, or Switzerland that are required under subsection (g)(2)(C)(i)(I) of such section 804 and that require approval under subsection (g)(2)(D) or (E) of such section 804 shall be submitted to the Secretary not later than 180 days after the date of enactment of this Act. The notices with respect to drugs to be imported from such countries that are required under subsection (g)(2)(C)(i)(II) of such section 804 and that do not require approval under subsection (g)(2)(D) or (E) of such section 804 shall be submitted to the Secretary not later than 270 days after the date of enactment of this Act.

(2) PERSONAL IMPORTATION FROM CANADA.—Until the expiration of the 60-day period beginning

on the date on which the interim rule under paragraph (1)(A) is promulgated, an individual may import a prescription drug from Canada for personal use or for the use of a family member of the individual (rather than for resale), subject to compliance with the following conditions:

(A) The drug 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);

(iii) an infused drug, including a peritoneal dialysis solution;

(iv) an intravenously injected drug;

(v) a drug that is inhaled during surgery; or

(vi) a drug 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.

(B) The drug is dispensed by a person licensed in Canada to dispense such drugs.

(C) The drug is accompanied by a copy of the 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.

(D) The drug is accompanied by a copy of the document that was required in Canada as a condition of dispensing the drug to the individual.

(E) The copies referred to in subparagraphs (C) and (D) are marked in a manner sufficient—

(i) to indicate that the prescription, and the equivalent document in Canada, have been filled; and

(ii) to prevent a duplicative filling by another pharmacist.

(F) The quantity of the drug does not exceed a 90-day supply.

(3) FACILITATION OF CANADIAN IMPORTS.—Not less than 15 days after the enactment of this Act and until the expiration of the 60-day period that begins on the date on which the interim rule under paragraph (1)(A) is promulgated, the Secretary shall, through the Internet website of the Food and Drug Administration, make readily available to the public a list of persons licensed in Canada to dispense prescription drugs who are willing to export drugs under paragraph (2) to individuals in the United States.

(4) EFFECT OF PROVISIONS.—The amendments made in subsection (d), section 6, and section 7 of this Act shall have no effect with respect to imports made under paragraph (2).

(d) AMENDMENT OF CERTAIN PROVISION.—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 Canadian exporters registered with the Secretary; 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.''.

(e) ANTICOMPETITIVE PRACTICES RELATING TO IMPORTING AND EXPORTING DRUGS TO THE UNITED STATES.—

(1) IN GENERAL.—The Clayton Act (15 U.S.C. 12 et seq.) is amended by adding at the end the following:

''SEC. 27. RESTRAINT OF TRADE REGARDING PRESCRIPTION DRUGS.

''(a) IN GENERAL.—It shall be unlawful for any person engaged in commerce, directly or indirectly to—

''(1) charge a higher price for prescription drugs sold to a registered exporter or other person that exports prescription drugs to the United States under section 804 of the Federal Food, Drug, and Cosmetic Act than the price that is charged to another person that is in the same country and that does not export prescription drugs into the United States under section 804 of such Act;

''(2) charge a higher price for prescription drugs sold to a registered importer or other person that distributes, sells, or uses prescription drugs imported to the United States under section 804 of such Act than the price that is charged to another person in the United States that does not import prescription drugs under section 804 of such Act, or that does not distribute, sell, or use such drugs;

''(3) deny supplies of prescription drugs to a registered exporter or other person that exports prescription drugs to the United States under section 804 of such Act or to a registered importer or other person that distributes, sells, or uses prescription drugs imported to the United States under section 804 of such Act;

''(4) publicly, privately, or otherwise refuse to do business with a registered exporter or other per-

son that exports prescription drugs to the United States under section 804 of such Act or with a registered importer or other person that distributes, sells, or uses prescription drugs imported to the United States under section 804 of such Act;

''(5) specifically restrict supplies of prescription drugs to a registered exporter or other person that exports prescription drugs to the United States under section 804 of such Act or to a registered importer or other person that distributes, sells, or uses prescription drugs imported to the United States under section 804 of such Act;

''(6) fail to submit a notice under subsection (g)(2)(C)(i) of section 804 of such Act, fail to submit such a notice on or before the date specified in subsection (g)(2)(C)(v) of section 804 of such Act, submit such a notice that makes a materially false, fictitious, or fraudulent statement, or fail to provide promptly any information requested by the Secretary of Health and Human Services to review such a notice;

''(7) fail to submit an application required under subsection (g)(2)(G) of section 804 of such Act, fail to submit such an application on or before the date specified in subsection (g)(2)(G)(ii) of sec-

tion 804 of such Act, submit such an application that makes a materially false, fictitious, or fraudulent statement, or fail to provide promptly any information requested by the Secretary of Health and Human Services to review such an application;

''(8) 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 a prescription drug for distribution in Australia, Canada, a member country of the European Union as of January 1, 2003, Japan, New Zealand, or Switzerland for the purpose of restricting importation of the drug to the United States under section 804 of such Act;

''(9) refuse to allow an inspection authorized under section 804 of such Act of an establishment that manufactures a prescription drug that is offered for import under such section;

''(10) fail to conform to the methods used in, or the facilities used for, the manufacturing, processing, packing, or holding of a prescription drug of-

fered for import under section 804 to good manufacturing practice under such Act; or

''(11) engage in any other action that the Federal Trade Commission determines to unfairly restrict competition under section 804 of such Act.

''(b) 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) between a prescription drug for distribution in the United States and a prescription drug for distribution in Australia, Canada, a member country of the European Union as of January 1, 2003, Japan, New Zealand, or Switzerland made after January 1, 2004, shall be presumed to be for the purpose of restricting importation of the drug to the United States under section 804 of the Federal Food, Drug, and Cosmetic Act unless—

''(1) the person manufacturing the drug for distribution in the United States proves that the difference was required by the country in which the drug is distributed;

''(2) the Secretary of Health and Human Services, acting through the Commissioner of Food and Drug, determines that the difference was necessary to improve the safety or efficacy of the drug; or

''(3) the person manufacturing the drug for distribution in the United States has given notice to the Secretary of Health and Human Services under subsection (g)(2)(C)(i) of section 804 of such Act that the drug for distribution in the United States is not different from a drug for distribution in not fewer than half of those countries.

''(c) AFFIRMATIVE DEFENSE.—It shall be an affirmative defense to a charge that a person has violated paragraph (1), (2), (3), (4), or (5) of subsection (a) that the higher prices charged for prescription drugs sold to a person, the denial of supplies of prescription drugs 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—

''(1) the person exporting or importing prescription drugs to the United States under section 804 of the Federal Food, Drug, and Cosmetic Act; or

''(2) the person distributing, selling, or using prescription drugs imported to the United States under section 804 of such Act.

''(d) DEFINITIONS.—In this section:

''(1) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug that is described in

section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)).

''(2) REGISTERED IMPORTER.—The term 'registered importer' has the meaning given such term in section 804 of the Federal Food, Drug, and Cosmetic Act.

''(3) REGISTERED EXPORTER.—The term 'registered exporter' has the same meaning as in section 804 of the Federal Food, Drug, and Cosmetic Act.''.

(2) APPLICABILITY OF AMENDMENTS TO IMPORTATION UNDER THE PHARMACEUTICAL MARKET ACCESS AND FAIR TRADE ACT OF 2004.—

(A) PERSONAL IMPORTATION FROM CANADA.—Paragraphs (1) through (5) and (11) of subsection (a) of section 27 of the Clayton Act (15 U.S.C. et seq.) (as amended by paragraph (1)) shall apply with respect to the importation of drugs from Canada under subsection (c)(2).

(B) NOTICES RESPECTING DRUG FOR IMPORT.—Paragraph (6) of subsection (a) of section 27 of the Clayton Act (15 U.S.C. et seq.) (as amended by paragraph (1)) shall apply with respect to notices required under section 804(g)(2)(C)(i) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 384(g)(2)(C)(i)) that

are not submitted by the dates required under subsections (c)(1)(C) and (D).

(f) 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.

SEC. 104. ADDITIONAL WAIVERS REGARDING PERSONAL IMPORTATION; ENFORCEMENT POLICIES OF SECRETARY.

(a) IN GENERAL.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by adding at the end the following:

''(p)(1) Waivers under this subsection are in addition to, and independent of, the waiver pursuant to section 804(a)(2)(B).

''(2) With respect to the standards referred to in subsection (d)(1), the Secretary shall establish by regulation a waiver of such standards in the case of the importation by an individual of a drug into the United States in the following circumstances:

''(A) The drug was dispensed to the individual while the individual was in the United States, the drug was dispensed by a pharmacist or by a practitioner licensed by law to administer the drug, and the individual traveled from the United States with the drug.

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

''(C) The drug does not appear to the Secretary to be adulterated.

''(D) The quantity of the drug does not exceed a 90-day supply.

''(E) The drug is accompanied by a statement that the individual seeks to import the drug into the United States under a personal importation waiver.

''(F) Such additional standards as the Secretary determines to be appropriate to protect the public health.

''(3) With respect to the standards referred to in subsections (a) and (d)(1), the Secretary shall establish by regulation a waiver of such standards in the case of the importation by an individual of a drug into the United States in the following circumstances:

''(A) The drug was dispensed to the individual while the individual was in a foreign 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 foreign country in which the drug was obtained.

''(D) The drug does not appear to the Secretary to be adulterated.

''(E) The quantity of the drug does not exceed—

''(i) a 90-day supply if the drug is dispensed in Australia, Canada, a member country of the European Union as of January 1, 2003, Japan, New Zealand, or Switzerland; or

''(ii) a 14-day supply otherwise.

''(F) The drug is accompanied by a statement that the individual seeks to import the drug into the United States under a personal importation waiver.

''(G) Such additional standards as the Secretary determines to be appropriate to protect the public health.

''(q) The Secretary may not administer any enforcement policy that has the effect of permitting the importation of a prescription drug into the United States in violation of this Act or section 351 of the Public Health Service Act.''.

(b) ADDITIONAL WAIVER.—This Act and the amendments made by this Act shall not be construed as limiting the authority of the Secretary of Health and Human Services to establish a waiver of the standards referred to in section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) with respect to the importation by an individual of a drug into the United States that does

not meet such standards, provided that such waiver is no more permissive than the guidance, as in effect on January 1, 2004, that is provided in the item numbered 2 (relating to a specific situation, consisting of conditions (a) through (d)) under the heading ''Drugs, Biologics, and Devices'' in chapter 9 of the FDA/ORA Regulatory Procedures Manual (relating to import operations/actions), in the subchapter relating to coverage of personal importations.

SEC. 105. 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 102, 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 refuse admission to a shipment of drugs that is imported or offered for import into the United States if the shipment has a declared value of less than $10,000 and the drugs are in violation of any standard referred to in section 801(a) or 801(d)(1), including any drugs imported or offered for import under enforcement policies prohibited under section 801(q).

''(b) IMPORTATION UNDER SECTION 804.—In the case of a drug that under section 804 is imported or offered for import from a registered exporter, the reference in subsection (a) to standards referred to in section 801(a) or 801(d)(1) shall be considered a reference to standards referred to in section 804(g)(4)(B).

''(c) DESTRUCTION OF VIOLATIVE SHIPMENTS.—Drugs refused admission under subsection (a) or (b) shall be destroyed, subject to subsection (e). Section 801(b) does not authorize the delivery of the drugs pursuant to the execution of a bond, and the drugs may not be exported.

''(d) CERTAIN PROCEDURES.—

''(1) IN GENERAL.—The refusal of admission 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 subsection (a) or (b) are identified and refused admission 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.

SEC. 106. CIVIL ACTIONS REGARDING PROPERTY.

Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following subsection:

''(g)(1) If a person is alienating or disposing of property, or intends to alienate or dispose of property, that is obtained as a result of or is traceable to a drug imported in violation of section 801(a) or 801(d), the Attorney General may commence a civil action in any Federal court—

''(A) to enjoin such alienation or disposition of property; or

''(B) for a restraining order to—

''(i) prohibit any person from withdrawing, transferring, removing, dissipating, or disposing of any such property or property of equivalent value; and

''(ii) appoint a temporary receiver to administer such restraining order.

''(2) Proceedings under paragraph (1) shall be carried out in the same manner as applies under section 1345 of title 18, United States Code.''.

SEC. 107. 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 may 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 anti-counterfeiting or track-and-trace technologies, will identify such chain of custody or the identity of the drug with equal certainty to the requirements of subparagraph (A), and that the alternative requirements are economically and technically feasible.

''(ii) If the Secretary promulgates a final rule to establish such alternative requirements, the final rule in addition shall, with respect to the registration condition es-

tablished in clause (i) of section 804(c)(3)(B), establish a condition equivalent to the alternative requirements, and such equivalent condition supersedes 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.''.

SEC. 108. REPEAL OF IMPORTATION EXEMPTION UNDER CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT.

Section 1006 of the Controlled Substances Import and Export Act (21 U.S.C. 956) is repealed.

SEC. 109. EFFECT ON ADMINISTRATION PRACTICES.

Notwithstanding any provision of this Act (and the amendments made by this Act), nothing in this Act (or the amendments made by this Act) shall be construed to change, limit, or restrict the practices of the Food and Drug Administration or the 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.

Subtitle B—Ensuring Drug Safety

SEC. 121. DRUG SAFETY.

(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 506C the following:

"SEC. 507. DRUG SAFETY.

"(a) PHASE IV STUDIES.—

"(1) IN GENERAL.—The Secretary may require that the sponsor of a drug that is approved or licensed under section 505(c) or under section 351 of the Public Health Service Act conduct one or more

studies, to be completed by a date after approval or licensing of such drug specified by the Secretary, that confirms or refutes an empirical or theoretical hypothesis of a significant safety issue with the drug, raised with respect to the drug or the class of the drug, found in—

''(A) the MedWatch post-market surveillance system;

''(B) a clinical or epidemiological study; or

''(C) the scientific literature.

''(b) SUPPLEMENTS.—The sponsor of a drug that is approved or licensed under section 505(c) or under section 351 of the Public Health Service Act shall promptly submit the results of a study required under subsection (a) as a supplement to the application for the drug.

''(c) PUBLIC DISCLOSURE.—The Secretary shall, not less than every quarter, make public each study required under subsection (a), including a description of, and the reason for, the study, the required completion date, and whether the study has been completed, through—

''(1) a notice in the Federal Register; and

''(2) a database that shall be readily accessible to the public through the Internet site of the Food and Drug Administration.

''(d) CIVIL PENALTIES.—

''(1) IN GENERAL.—The Secretary may order the sponsor of a drug that is approved or licensed under section 505(c) or under section 351 of the Public Health Service Act to pay a civil penalty, subject to paragraph (2), if, after providing an opportunity for an informal hearing, the Secretary determines that—

''(A) the sponsor has failed to complete a study required under subsection (a) by the date specified by the Secretary; and

''(B) there is no legitimate reason for such failure.

''(2) AMOUNT OF PENALTIES.—The civil penalty order under paragraph (1) may be assessed for each day the completion of a required study of a drug is delayed in an amount that is not more than 3 times the gross revenue received by the sponsor for the average sales of the drug in a day.

''(3) RECORDS RELATING TO GROSS REVENUE.—When provided an opportunity for an informal hearing under paragraph (1), a drug sponsor shall provide to the Secretary all records relating to the gross revenues received by the sponsor for average sales of the drug in a day.

''(4) PROCEDURE.—The provisions of paragraphs (3) (other than subparagraph (A)), (4), and (5) of section 303(f) shall apply to a violation under subsection (a) in the same manner as such provisions apply to a violation of a requirement of this Act that relates to devices.''.

(b) RESOURCES.—In addition to fees that may be available to the Office of Drug Safety under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g and 379h), there is authorized to be appropriated for the Office of Drug Safety within the Center for Drug Evaluation and Research of the Food and Drug Administration—

(1) $30,000,000 for fiscal year 2006;

(2) $40,000,0000 for fiscal year 2007;

(3) $50,000,000 for fiscal year 2008;

(4) $60,000,000 for fiscal year 2009; and

(5) $70,00,000 for fiscal year 2010.

SEC. 122. REPORT BY GAO ON DRUG SAFETY.

(a) IN GENERAL.—The Government Accountability Office shall provide for the conduct of a study concerning measures to increase the safety of prescription drugs, including—

(1) whether Federal funding levels are adequate to ensure drug safety and whether the uncertainty

associated with the Federal budgetary process hampers planning;

(2) whether the lack of permanent leadership at the Food and Drug Administration has contributed to problems in decisionmaking and in transmitting information to the public concerning the safety of drugs;

(3) whether prolonged and rampant vacancies within the Food and Drug Administration have contributed to the ability of the Food and Drug Administration to properly examine drug safety;

(4) whether conflicts of interest exist that unduly bias approvals or later reviews of drug safety;

(5) whether employees of the Food and Drug Administration have been improperly threatened or face any barriers to raising concerns about drug safety;

(6) whether the procedure of the Food and Drug Administration for notifying the public of possible drug safety issues is appropriate and complied with;

(7) whether further measures or authorities are necessary to ensure the safety of drugs; and

(8) other matters determined appropriate.

(b) REPORT.—Not later than 90 days after the date of enactment of this Act, the Government Accountability Office shall prepare and submit to the appropriate committees of Congress a report concerning the results of the study conducted under subsection (a). Such report shall include a proposal (including legislative language) for improving the safety of prescription drugs.

TITLE II—MODERNIZING THE HEALTH CARE SYSTEM

SEC. 201. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended by adding at the end thereof the following:

"TITLE XXIX—HEALTH CARE INFORMATION TECHNOLOGY

"SEC. 2901. DEFINITIONS.

''In this title:

''(1) COVERAGE AREA.—The term 'coverage area' means the boundaries of a local health information infrastructure.

''(2) DIRECTOR.—The term 'Director' means the Director of the Office of Health Information Technology.

''(3) HEALTH CARE PROVIDER.—The term 'health care provider' means a hospital, skilled nursing facility, home health entity, health care clinic, community health center, group practice (as defined in section 1877(h)(4) of the Social Security Act, including practices with only 1 physician), and any other facility or clinician determined appropriate by the Director.

''(4) HEALTH INFORMATION TECHNOLOGY.—The term 'health information technology' means a computerized system that—

''(A) is consistent with the standards developed pursuant to section 2903;

''(B) permits the secure electronic transmission of information to other health care providers and public health entities; and

''(C) includes—

''(i) an electronic health record (EHR) that provides access in real-time to the patient's complete medical record;

''(ii) a personal health record (PHR) through which an individual (and anyone authorized by such individual) can maintain and manage their health information;

''(iii) computerized provider order entry (CPOE) technology that permits the electronic ordering of diagnostic and treatment services, including prescription drugs;

''(iv) decision support to assist physicians in making clinical decisions by providing electronic alerts and reminders to improve compliance with best practices, promote regular screenings and other preventive practices, and facilitate diagnoses and treatments;

''(v) error notification procedures so that a warning is generated if an order is entered that is likely to lead to a significant adverse outcome for the patient; and

''(vi) tools to allow for the collection, analysis, and reporting of data on adverse events, near misses, and the quality of care provided to the patient.

''(5) LOCAL HEALTH INFORMATION INFRASTRUCTURES.—The term 'local health information infrastructure' means an independent organization of health care entities established for the purpose of linking health information systems to electronically

shared information. A local health information infrastructure may not be a single business entity.

''(6) OFFICE.—The term 'Office' means the Office of Health Information Technology established under section 2902.

"SEC. 2902. OFFICE OF HEALTH INFORMATION TECHNOLOGY.

''(a) ESTABLISHMENT.—There is established within the executive office of the President an Office of Health Information Technology. The Office shall be headed by a Director to be appointed by the President. The Director shall report directly to the President.

''(b) PURPOSE.—It shall be the purpose of the Office to—

''(1) improve the quality and increase the efficiency of health care delivery through the use of health information technology;

''(2) provide national leadership relating to, and encourage the adoption of, health information technology;

''(3) direct all health information technology activities within the Federal Government; and

''(4) facilitate the interaction between the Federal Government and the private sector relating to health information technology development and use.

''(c) DUTIES AND RESPONSIBILITIES.—The Office shall be responsible for the following:

''(1) NATIONAL STRATEGY.—The Office shall develop a national strategy for improving the quality and enhancing the efficiency of health care through the improved use of health information technology and the creation of a National Health Information Infrastructure.

''(2) FEDERAL LEADERSHIP.—The Office shall—

''(A) serve as the principle advisor to the President concerning health information technology;

''(B) direct all health information technology activity within the Federal Government, including approving or disapproving agency policies submitted under paragraph (3);

''(C) work with public and private health information technology stakeholders to implement the national strategy described in paragraph (1); and

''(D) ensure that health information technology is utilized as fully as practicable in carrying out health surveillance efforts.

''(3) AGENCY POLICIES.—

"(A) IN GENERAL.—The Office shall, in accordance with this paragraph, approve or disapprove the policies of Federal departments or agencies with respect to any policy proposed to be implemented by such agency or department that would significantly affect that agency or department's use of health information technology.

"(B) SUBMISSION OF PROPOSAL.—The head of any Federal Government agency or department that desires to implement any policy with respect to such agency or department that would significantly affect that agency or department's use of health information technology shall submit an implementation proposal to the Office at least 60 days prior to the proposed date of the implementation of such policy.

"(C) APPROVAL OR DISAPPROVAL.—Not later than 60 days after the date on which a proposal is received under subparagraph (B), the Office shall determine whether to approve the implementation of such proposal. In making such determination, the Office shall consider whether the proposal is consistent with the national strategy described in paragraph (1). If

the Office fails to make a determination within such 60-day period, such proposal shall be deemed to be approved.

''(D) FAILURE TO APPROVE.—Except as otherwise provided for by law, a proposal submitted under subparagraph (B) may not be implemented unless such proposal is approved or deemed to be approved under subparagraph (C).

''(4) COORDINATION.—The Office shall—

''(A) encourage the development and adoption of clinical, messaging, and decision support health information data standards, pursuant to the requirements of section 2903;

''(B) ensure the maintenance and implementation of the data standards described in subparagraph (A);

''(C) oversee and coordinate the health information technology efforts of the Federal Government;

''(D) ensure the compliance of the Federal Government with Federally adopted health information technology data standards;

''(E) ensure that the Federal Government consults and collaborates on decision making

with respect to health information technology with the private sector and other interested parties; and

''(F) in consultation with private sector, adopt certification and testing criteria to determine if electronic health information systems interoperate.

''(5) COMMUNICATION.—The Office shall—

''(A) act as the point of contact for the private sector with respect to the use of health information technology; and

''(B) work with the private sector to collect and disseminate best health information technology practices.

''(6) EVALUATION AND DISSEMINATION.—The Office shall coordinate with the Agency for Health Research and Quality and other Federal agencies to—

''(A) evaluate and disseminate information relating to evidence of the costs and benefits of health information technology and to whom those costs and benefits accrue;

''(B) evaluate and disseminate information on the impact of health information technology

on the quality and efficiency of patient care; and

''(C) review Federal payment structures and differentials for health care providers that utilize health information technology systems.

''(7) TECHNICAL ASSISTANCE.—The Office shall utilize existing private sector quality improvement organizations to—

''(A) promote the adoption of health information technology among healthcare providers; and

''(B) provide technical assistance concerning the implementation of health information technology to healthcare providers.

''(8) FEDERAL REIMBURSEMENT.—

''(A) IN GENERAL.—Not later than 6 months after the date of enactment of this title, the Office shall make recommendations to the President and the Secretary of Health and Human Services on changes to Federal reimbursement and payment structures that would encourage the adoption of information technology (IT) to improve health care quality and safety.

''(B) PLAN.—Not later than 90 days after receiving recommendations under subparagraph (A), the Secretary shall provide to the relevant Committees of Congress a report that provides, with respect to each recommendation, a plan for the implementation, or an explanation as to why implementation is inadvisable, of such recommendations. The Office shall continue to monitor federally funded and supported information technology and quality initiatives (including the initiatives authorized in this title), and periodically update recommendations to the President and the Secretary.

''(d) RESOURCES.—The President shall make available to the Office, the resources, both financial and otherwise, necessary to enable the Director to carry out the purposes of, and perform the duties and responsibilities of the Office under, this section.

''(e) DETAIL OF FEDERAL EMPLOYEES.—Upon the request of the Director, the head of any Federal agency is authorized to detail, without reimbursement from the Office, any of the personnel of such agency to the Office to assist it in carrying out its duties under this section. Any such detail shall not interrupt or otherwise affect the civil service status or privileges of the Federal employee.

"SEC. 2903. PROMOTING THE INTEROPERABILITY OF HEALTH CARE INFORMATION TECHNOLOGY SYSTEMS.

"(a) DEVELOPMENT, AND FEDERAL GOVERNMENT ADOPTION, OF STANDARDS.—

"(1) ADOPTION.—

"(A) IN GENERAL.—Not later than 2 years after the date of the enactment of this title, the Director, in collaboration with the Consolidated Health Informatics Initiative (or a successor organization to such Initiative), shall provide for the adoption by the Federal Government of national data and communication health information technology standards that promote the efficient exchange of data between varieties of provider health information technology systems. In carrying out the preceding sentence, the Director may adopt existing standards. Except as otherwise provided for in this title, standards adopted under this section shall be voluntary for private sector entities.

"(B) GRANTS OR CONTRACTS.—The Director may utilize grants or contracts to provide for the private sector development of standards for adoption by the Federal Government under subparagraph (A).

"(C) DEFINITION.—In this paragraph, the term 'provide for' means that the Director shall promulgate, and each Federal agency or department shall adopt, regulations to ensure that each such agency or department complies with the requirements of subsection (b).

"(2) REQUIREMENTS.—The standards developed and adopted under paragraph (1) shall be designed to—

"(A) enable health information technology to be used for the collection and use of clinically specific data;

"(B) promote the interoperability of health care information across health care settings;

"(C) facilitate clinical decision support through the use of health information technology; and

"(D) ensure the privacy and confidentiality of medical records.

"(3) PUBLIC PRIVATE PARTNERSHIP.—Consistent with activities being carried out on the date of enactment of this title, including the Consolidated Health Informatics Initiative (or a successor organization to such Initiative), health information technology standards shall be adopted by the Director

under paragraph (1) at the conclusion of a collaborative process that includes consultation between the Federal Government and private sector health care and information technology stakeholders.

''(4) PRIVACY AND SECURITY.—The regulations promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and sections 261, 262, 263, and 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) with respect to the privacy, confidentiality, and security of health information shall apply to the implementation of programs and activities under this title.

''(5) PILOT TESTS.—To the extent practical, the Director shall pilot test the health information technology data standards developed under paragraph (1) prior to their implementation under this section.

''(6) DISSEMINATION.—

''(A) IN GENERAL.—The Director shall ensure that the standards adopted under paragraph (1) are widely disseminated to interested stakeholders.

''(B) LICENSING.—To facilitate the dissemination and implementation of the stand-

ards developed and adopted under paragraph (1), the Director may license such standards, or utilize other means, to ensure the widespread use of such standards.

''(b) IMPLEMENTATION OF STANDARDS.—

''(1) PURCHASE OF SYSTEMS BY THE SECRETARY.—Effective beginning on the date that is 1 year after the adoption of the technology standards pursuant to subsection (a), the Secretary shall not purchase any health care information technology system unless such system is in compliance with the standards adopted under subsection (a), nor shall the Director approve any proposal pursuant to section 2902(c)(3) unless such proposal utilizes systems that are in compliance with the standards adopted under subsection (a).

''(2) RECIPIENTS OF FEDERAL FUNDS.—Effective on the date described in paragraph (1), no appropriated funds may be used to purchase a health care information technology system unless such system is in compliance with applicable standards adopted under subsection (a).

''(c) MODIFICATION OF STANDARDS.—The Director shall provide for ongoing oversight of the health informa-

tion technology standards developed under subsection (a) to—

''(1) identify gaps or other shortcomings in such standards; and

''(2) modify such standards when determined appropriate or develop additional standards, in collaboration with standard setting organizations.

''SEC. 2904. LOAN GUARANTEES FOR THE ADOPTION OF HEALTH INFORMATION TECHNOLOGY.

''(a) IN GENERAL.—The Director shall guarantee payment of the principal of and the interest on loans made to eligible entities to enable such entities—

''(1) to implement local health information infrastructures to facilitate the development of interoperability across health care settings to improve quality and efficiency; or

''(2) to facilitate the purchase and adoption of health information technology to improve quality and efficiency.

''(b) ELIGIBILITY.—To be eligible to receive a loan guarantee under subsection (a) an entity shall—

''(1) with respect to an entity desiring a loan guarantee—

''(A) under subsection (a)(1), be a coalition of entities that represent an independent con-

sortium of health care stakeholders within a community that—

"(i) includes—

"(I) physicians (as defined in section 1881(r)(1) of the Social Security Act);

"(II) hospitals; and

"(III) group health plans or other health insurance issuers (as such terms are defined in section 2791); and

"(ii) may include any other health care providers; or

"(B) under subsection (a)(2) be a health care provider;

"(2) to the extent practicable, adopt the national health information technology standards adopted under section 2903;

"(3) provide assurances that the entity shall submit to the Director regular reports on the activities carried out under the loan guarantee, including—

"(A) a description of the financial costs and benefits of the project involved and of the entities to which such costs and benefits accrue;

"(B) a description of the impact of the project on health care quality and safety; and

"(C) a description of any reduction in duplicative or unnecessary care as a result of the project involved;

"(4) provide assurances that not later than 30 days after the development of the standard quality measures pursuant to section 2906, the entity shall submit to the Director regular reports on such measures, including provider level data and analysis of the impact of information technology on such measures;

"(5) prepare and submit to the Director an application at such time, in such manner, and containing such information as the Director may require.

"(c) USE OF FUNDS.—Amounts received under a loan guarantee under subsection (a) shall be used—

"(1) with respect to a loan guarantee described in subsection (a)(1)—

"(A) to develop a plan for the implementation of a local health information infrastructure under this section;

"(B) to establish systems for the sharing of data in accordance with the national health

information technology standards developed under section 2903;

''(C) to purchase directly related integrated hardware and software to establish an interoperable health information technology system that is capable of linking to a local health care information infrastructure; and

''(D) to train staff, maintain health information technology systems, and maintain adequate security and privacy protocols;

''(2) with respect to a loan guarantee described in subsection (a)(2)—

''(A) to develop a plan for the purchase and installation of health information technology;

''(B) to purchase directly related integrated hardware and software to establish an interoperable health information technology system that is capable of linking to a national or local health care information infrastructure; and

''(C) to train staff, maintain health information technology systems, and maintain adequate security and privacy protocols; and

''(3) to carry out any other activities determined appropriate by the Director.

''(d) SPECIAL CONSIDERATIONS FOR CERTAIN ENTITIES.—In awarding loan guarantees under this section, the Director shall give special consideration to eligible entities that—

''(1) provide service to low-income and underserved populations; and

''(2) agree to electronically submit the information described in paragraphs (3) and (4) of subsection (b) on a daily basis.

''(e) SPECIAL CONSIDERATIONS FOR LOCAL HEALTH INFORMATION INFRASTRUCTURES.—In awarding loan guarantees under this section to local health information infrastructures, the Director shall give special consideration to eligible entities that—

''(1) include at least 50 percent of the patients living in the designated coverage area;

''(2) incorporate public health surveillance and reporting into the overall architecture of the proposed infrastructure; and

''(3) link local health information infrastructures.

''(f) AREAS OF SPECIFIC INTEREST.—In awarding loan guarantees under this section, the Director shall include—

''(1) entities with a coverage area that includes an entire State; and

''(2) entities with a multi-state coverage area.

''(g) ADMINISTRATIVE PROVISIONS.—

''(1) AGGREGATE AMOUNT.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the aggregate amount of principal of loans guaranteed under subsection (a) with respect to an eligible entity may not exceed $5,000,000. In any 12-month period the amount disbursed to an eligible entity under this section (by a lender under a guaranteed loan) may not exceed $5,000,000.

''(B) EXCEPTION.—The cumulative total of the principal of the loans outstanding at any time to which guarantees have been issued under subsection (a) may not exceed such limitations as may be specified in appropriation Acts.

''(2) PROTECTION OF FEDERAL GOVERNMENT.—

"(A) IN GENERAL.—The Director may not approve an application for a loan guarantee under this section unless the Director determines that—

"(i) the terms, conditions, security (if any), and schedule and amount of repayments with respect to the loan are sufficient to protect the financial interests of the United States and are otherwise reasonable, including a determination that the rate of interest does not exceed such percent per annum on the principal obligation outstanding as the Director determines to be reasonable, taking into account the range of interest rates prevailing in the private market for loans with similar maturities, terms, conditions, and security and the risks assumed by the United States; and

"(ii) the loan would not be available on reasonable terms and conditions without the enactment of this section.

"(B) RECOVERY.—

"(i) IN GENERAL.—The United States shall be entitled to recover from the appli-

cant for a loan guarantee under this section the amount of any payment made pursuant to such loan guarantee, unless the Director for good cause waives such right of recovery, and, upon making any such payment, the United States shall be subrogated to all of the rights of the recipient of the payments with respect to which the loan was made.

''(ii) MODIFICATION OF TERMS.—Any terms and conditions applicable to a loan guarantee under this section may be modified by the Director to the extent the Director determines it to be consistent with the financial interest of the United States.

''(3) DEFAULTS.—The Director may take such action as the Director deems appropriate to protect the interest of the United States in the event of a default on a loan guaranteed under this section, including taking possession of, holding, and using real property pledged as security for such a loan guarantee.

''(h) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—There is authorized to be appropriated to carry out this section, such sums as

may be necessary for each of fiscal years 2006 through 2011.

''(2) AVAILABILITY.—Amounts appropriated under subparagraph (A) shall remain available for obligation until expended.

''SEC. 2905. GRANTS FOR THE PURCHASE OF HEALTH INFORMATION TECHNOLOGY.

''(a) IN GENERAL.—The Director may award competitive grants to eligible entities—

''(1) to implement local health information infrastructures to facilitate the development of interoperability across health care settings; or

''(2) to facilitate the purchase and adoption of health information technology.

''(b) ELIGIBILITY.—To be eligible to receive a grant under subsection (a) an entity shall—

''(1) demonstrate financial need to the Director;

''(2) with respect to an entity desiring a grant—

''(A) under subsection (a)(1), represent an independent consortium of health care stakeholders within a community that—

''(i) includes—

''(I) physicians (as defined in section 1881(r)(1) of the Social Security Act);

''(II) hospitals; and

''(III) group health plans or other health insurance issuers (as such terms are defined in section 2791); and

''(ii) may include any other health care providers; or

''(B) under subsection (a)(2) be a health care provider that provides health care services to low-income and underserved populations;

''(3) adopt the national health information technology standards developed under section 2903;

''(4) provide assurances that the entity shall submit to the Director regular reports on the activities carried out under the loan guarantee, including—

''(A) a description of the financial costs and benefits of the project involved and of the entities to which such costs and benefits accrue;

''(B) a description of the impact of the project on health care quality and safety; and

''(C) a description of any reduction in duplicative or unnecessary care as a result of the project involved;

''(5) provide assurances that not later than 30 days after the development of the standard quality measures pursuant to section 2906, the entity shall submit to the Director regular reports on such measures, including provider level data and analysis of the impact of information technology on such measures;

''(6) prepare and submit to the Director an application at such time, in such manner, and containing such information as the Director may require; and

''(7) agree to provide matching funds in accordance with subsection (g).

''(c) USE OF FUNDS.—Amounts received under a grant under subsection (a) shall be used to—

''(1) with respect to a grant described in subsection (a)(1)—

''(A) to develop a plan for the implementation of a local health information infrastructure under this section;

''(B) to establish systems for the sharing of data in accordance with the national health

information technology standards developed under section 2903;

''(C) to implement, enhance, or upgrade a comprehensive, electronic health information technology system; and

''(D) to maintain adequate security and privacy protocols;

''(2) with respect to a grant described in subsection (a)(2)—

''(A) to develop a plan for the purchase and installation of health information technology;

''(B) to purchase directly related integrated hardware and software to establish an interoperable health information technology system that is capable of linking to a national or local health care information infrastructure; and

''(C) to train staff, maintain health information technology systems, and maintain adequate security and privacy protocols;

''(3) maintain adequate security and privacy protocols; and

''(4) carry out any other activities determined appropriate by the Director.

''(d) SPECIAL CONSIDERATIONS FOR CERTAIN ENTITIES.—In awarding grants under this section, the Director shall give special consideration to eligible entities that—

''(1) provide service to low-income and underserved populations; and

''(2) agree to electronically submit the information described in paragraphs (4) and (5) of subsection (b).

''(e) SPECIAL CONSIDERATIONS FOR LOCAL HEALTH INFORMATION INFRASTRUCTURES.—In awarding grants under this section to local health information infrastructures, the Director shall give special consideration to eligible entities that—

''(1) include at least 50 percent of the patients living in the designated coverage area;

''(2) incorporate public health surveillance and reporting into the overall architecture of the proposed infrastructure; and

''(3) link local health information infrastructures;

''(f) AREAS OF SPECIFIC INTEREST.—In awarding grants under this section, the Director shall include—

''(1) entities with a coverage area that includes an entire State; and

''(2) entities with a multi-state coverage area.

''(g) MATCHING REQUIREMENT.—

''(1) IN GENERAL.—The Director may not make a grant under this section to an entity unless the entity agrees that, with respect to the costs to be incurred by the entity in carrying out the infrastructure program for which the grant was awarded, the entity will make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount equal to not less than 20 percent of such costs ($1 for each $5 of Federal funds provided under the grant).

''(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required under paragraph (1) may be in cash or in kind, fairly evaluated, including equipment, technology, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

''(h) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—There is authorized to be appropriated to carry out this section, such sums as

may be necessary for each of fiscal years 2006 through 2011.

''(2) AVAILABILITY.—Amounts appropriated under paragraph (1) shall remain available for obligation until expended.''.

SEC. 202. STANDARDIZED MEASURES OF QUALITY HEALTH CARE AND DATA COLLECTION.

Title XXIX of the Public Health Service Act, as added by section 201, is amended by adding at the end the following:

''SEC. 2906. STANDARDIZED MEASURES OF QUALITY HEALTH CARE.

''(a) IN GENERAL.—

''(1) COLLABORATION.—The Secretary of Health and Human Services, the Secretary of Defense, and the Secretary of Veterans Affairs (referred to in this section as the 'Secretaries'), in consultation with the Quality Interagency Coordination Taskforce (as established by Executive Order on March 13, 1998), the Institute of Medicine, the Joint Commission on Accreditation of Healthcare Organizations, the National Committee for Quality Assurance, the American Health Quality Association, the National Quality Forum, the Medicare Payment Advisory Committee, and other individuals and

organizations determined appropriate by the Secretaries, shall establish uniform health care quality measures to assess the effectiveness, timeliness, patient-centeredness, efficiency, equity, and safety of care delivered across all federally supported health delivery programs.

''(2) DEVELOPMENT OF MEASURES.—Not later than 18 months after the date of enactment of this title, the Secretaries shall develop standardized sets of quality measures for each of the 20 priority areas for improvement in health care quality as identified by the Institute of Medicine in their report entitled 'Priority Areas for National Action' in 2003, or other such areas as identified by the Secretaries in order to assist beneficiaries in making informed choices about health plans or care delivery systems. The selection of appropriate quality indicators under this subsection shall include the evaluation criteria formulated by clinical professionals, consumers, and data collection experts.

''(3) PILOT TESTING.—Each federally supported health delivery program may conduct a pilot test of the quality measures developed under paragraph (2) that shall include a collection of patient-

level data and a public release of comparative performance reports.

''(b) PUBLIC REPORTING REQUIREMENTS.—The Secretaries, working collaboratively, shall establish public reporting requirements for clinicians, institutional providers, and health plans in each of the federally supported health delivery program described in subsection (a). Such requirements shall provide that the entities described in the preceding sentence shall report to the appropriate Secretary on the measures developed under subsection (a).

''(c) FULL IMPLEMENTATION.—The Secretaries, working collaboratively, shall implement all sets of quality measures and reporting systems developed under subsections (a) and (b) by not later than the date that is 1 year after the date on which the measures are developed under subsection (a)(2).

''(d) REPORTS.—Not later than 1 year after the date of enactment of this title, and annually thereafter, the Secretary shall—

''(1) submit to Congress a report that details the collaborative efforts carried out under subsection (a), the progress made on standardizing quality indicators throughout the Federal Government, and the state of quality measurement for priority areas that

links data to the report submitted under paragraph (2) for the year involved; and

''(2) submit to Congress a report that details areas of clinical care requiring further research necessary to establish effective clinical treatments that will serve as a basis for additional quality indicators.

''(e) COMPARATIVE QUALITY REPORTS.—Beginning not later than 3 years after the date of enactment of this title, in order to make comparative quality information available to health care consumers, including members of health disparity populations, health professionals, public health officials, researchers, and other appropriate individuals and entities, the Secretaries shall provide for the pooling, analysis, and dissemination of quality measures collected under this section. Nothing in this section shall be construed as modifying the privacy standards under the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191).

''(f) ONGOING EVALUATION OF USE.—The Secretary of Health and Human Services shall ensure the ongoing evaluation of the use of the health care quality measures established under this section.

''(g) EVALUATION AND REGULATIONS.—

''(1) EVALUATION.—

"(A) IN GENERAL.—The Secretary shall, directly or indirectly through a contract with another entity, conduct an evaluation of the collaborative efforts of the Secretaries to establish uniform health care quality measures and reporting requirements for federally supported health care delivery programs as required under this section.

"(B) REPORT.—Not later than 1 year after the date of enactment of this title, the Secretary of Health and Human Services shall submit a report to the appropriate committees of Congress concerning the results of the evaluation under subparagraph (A).

"(2) REGULATIONS.—

"(A) PROPOSED.—Not later than 6 months after the date on which the report is submitted under paragraph (1)(B), the Secretary shall publish proposed regulations regarding the application of the uniform health care quality measures and reporting requirements described in this section to federally supported health delivery programs.

"(B) FINAL REGULATIONS.—Not later than 1 year after the date on which the report

is submitted under paragraph (1)(B), the Secretary shall publish final regulations regarding the uniform health care quality measures and reporting requirements described in this section.

''(h) DEFINITIONS.—In this section, the term 'federally supported health delivery program' means a program that is funded by the Federal Government under which health care items or services are delivered directly to patients.''.

TITLE III—MAKING HEALTH CARE MORE AFFORDABLE FOR CHILDREN AND PREGNANT WOMEN

Subtitle A—Covering all Children

SEC. 300. FINDINGS.

Congress makes the following findings:

(1) NEED FOR UNIVERSAL COVERAGE.—

(A) Currently, there are 9,000,000 children under the age of 19 that are uninsured. One out of every 8 children are uninsured while 1 in 5 Hispanic children and 1 in 7 African American children are uninsured. Three-quarters, approximately 6,800,000, of these children are eligible but not enrolled in the medicaid program or the State children's health insur-

ance program (SCHIP). Long-range studies found that 1 in 3 children went without health insurance for all or part of 2002 and 2003.

(B) Low-income children are 3 times as likely as children in higher income families to be uninsured. It is estimated that 65 percent of uninsured children have at least 1 parent working full time over the course of the year.

(C) It is estimated that 50 percent of all legal immigrant children in families with income that is less than 200 percent of the Federal poverty line are uninsured. In States without programs to cover immigrant children, 57 percent of non-citizen children are uninsured.

(D) Children in the Southern and Western parts of the United States were nearly 1.7 times more likely to be uninsured than children in the Northeast. In the Northeast, 9.4 percent of children are uninsured while in the Midwest, 8.3 percent are uninsured. The South's rate of uninsured children is 14.3 percent while the West has an uninsured rate of 13 percent.

(E) Children's health care needs are neglected in the United States. One-quarter of young children in the United States are not

fully up to date on their basic immunizations. One-third of children with chronic asthma do not get a prescription for the necessary medications to manage the disease.

(F) According to the Centers for Disease Control and Prevention, nearly ½ of all uninsured children have not had a well-child visit in the past year. One out of every 5 children has problems accessing needed care, and 1 out of every 4 children do not receive annual dental exams. One in 6 uninsured children had a delayed or unmet medical need in the past year. Minority children are less likely to receive proven treatments such as prescription medications to treat chronic disease.

(G) There are 7,600,000 young adults between the ages of 19 and 20. In the United States, approximately 28 percent, or 2,100,000 individuals, of this group are uninsured.

(H) Chronic illness and disability among children are on the rise. Children most at risk for chronic illness and disability are children who are most likely to be poor and uninsured.

(2) ROLE OF THE MEDICAID AND STATE CHILDREN'S HEALTH INSURANCE PROGRAMS.—

(A) The medicaid program and SCHIP serve as a crucial health safety net for 30,000,000 children. During the recent economic downturn and the highest number of uninsured individuals ever recorded in the United States, the medicaid program and SCHIP offset losses in employer-sponsored coverage. While the number of children living in low-income families increased by 2,000,000 between 2000 and 2003, the number of uninsured children fell due to the medicaid program and SCHIP.

(B) In 2003, 25,000,000 children were enrolled in the medicaid program, accounting for ½ of all enrollees and only 19 percent of total program costs.

(C) The medicaid program and SCHIP do more than just fill in the gaps. Gains in public coverage have reduced the percentage of low-income uninsured by a ⅓ from 1997 to 2003. In addition, a recent study found that publicly-insured children are more likely to obtain medical care, preventive care and dental care than similar low-income privately-insured children.

(D) Publicly funded programs such as the medicaid program and SCHIP actually improve children's health. Children who are currently insured by public programs are in better health than they were a year ago. Expansion of coverage for children and pregnant women under the medicaid program and SCHIP reduces rates of avoidable hospitalizations by 22 percent.

(E) Studies have found that children enrolled in public insurance programs experienced a 68 percent improvement in measures of school performance.

(F) Despite the success of expansions in general under the medicaid program and SCHIP, due to current budget constraints, many States have stopped doing aggressive outreach and have raised premiums and cost-sharing requirements on families under these programs. In addition, 8 States stopped enrollment in SCHIP for a period of time between April 2003 and July 2004. As a result, SCHIP enrollment fell by 200,000 children for the first time in the program's history.

(G) It is estimated that nearly 50 percent of children covered through SCHIP do not remain in the program due to reenrollment barriers. A recent study found that between 10 and 40 percent of these children are ''lost'' in the system. Difficult renewal policies and reenrollment barriers make seamless coverage in SCHIP unattainable. Studies indicate that as many as 67 percent of children who were eligible but not enrolled for SCHIP had applied for coverage but were denied due to procedural issues.

(H) While the medicaid program and SCHIP expansions to date have done much to offset what otherwise would have been a significant loss of coverage among children because of declining access to employer coverage, the shortcomings of previous expansions, such as the failure to enroll all eligible children and caps on enrollment in SCHIP because of underfunding, also are clear.

CHAPTER 1—EXPANDED COVERAGE OF CHILDREN UNDER MEDICAID AND SCHIP

SEC. 301. STATE OPTION TO RECEIVE 100 PERCENT FMAP FOR MEDICAL ASSISTANCE FOR CHILDREN IN POVERTY IN EXCHANGE FOR EXPANDED COVERAGE OF CHILDREN IN WORKING POOR FAMILIES UNDER TITLE XXI.

(a) STATE OPTION.—Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended by redesignating section 1936 as section 1937, and by inserting after section 1935 the following:

''STATE OPTION FOR INCREASED FMAP FOR MEDICAL ASSISTANCE FOR CHILDREN IN POVERTY IN EXCHANGE FOR EXPANDED COVERAGE OF CHILDREN IN WORKING POOR FAMILIES UNDER TITLE XXI

''SEC. 1936. (a) 100 PERCENT FMAP.—

''(1) IN GENERAL.—Notwithstanding any other provision of this title, in the case of a State that, through an amendment to each of its State plans under this title and title XXI (or to a waiver of either such plan), agrees to satisfy the conditions described in subsections (b), (c), and (d) the Federal medical assistance percentage shall be 100 percent with respect to the total amount expended by the State for providing medical assistance under this title for each fiscal year quarter beginning on or

after the date described in subsection (e) for children whose family income does not exceed 100 percent of the poverty line.

''(2) LIMITATION ON SCOPE OF APPLICATION OF INCREASE.—The increase in the Federal medical assistance percentage for a State under this section shall apply only with respect to the total amount expended for providing medical assistance under this title for a fiscal year quarter for children described in paragraph (1) and shall not apply with respect to—

''(A) any other payments made under this title, including disproportionate share hospital payments described in section 1923;

''(B) payments under title IV or XXI; or

''(C) any payments made under this title or title XXI that are based on the enhanced FMAP described in section 2105(b).

''(b) ELIGIBILITY EXPANSIONS.—The condition described in this subsection is that the State agrees to do the following:

''(1) COVERAGE UNDER MEDICAID OR SCHIP FOR CHILDREN IN FAMILIES WHOSE INCOME DOES NOT EXCEED 300 PERCENT OF THE POVERTY LINE.—

''(A) IN GENERAL.—The State agrees to provide medical assistance under this title or child health assistance under title XXI to children whose family income exceeds the medicaid applicable income level (as defined in section 2110(b)(4) but by substituting 'January 1, 2005' for 'March 31, 1997'), but does not exceed 300 percent of the poverty line.

''(B) STATE OPTION TO EXPAND COVERAGE THROUGH SUBSIDIZED PURCHASE OF FAMILY COVERAGE.—A State may elect to carry out subparagraph (A) through the provision of assistance for the purchase of dependent coverage under a group health plan or health insurance coverage if—

''(i) the dependent coverage is consistent with the benefit standards under this title or title XXI, as approved by the Secretary; and

''(ii) the State provides 'wrap-around' coverage under this title or title XXI.

''(C) DEEMED SATISFACTION FOR CERTAIN STATES.—A State that, as of January 1, 2005, provides medical assistance under this title or child health assistance under title XXI to chil-

dren whose family income is 300 percent of the poverty line shall be deemed to satisfy this paragraph.

''(2) COVERAGE FOR CHILDREN UNDER AGE 21.—The State agrees to define a child for purposes of this title and title XXI as an individual who has not attained 21 years of age.

''(3) OPPORTUNITY FOR HIGHER INCOME CHILDREN TO PURCHASE SCHIP COVERAGE.—The State agrees to permit any child whose family income exceeds 300 percent of the poverty line to purchase full or 'wrap-around' coverage under title XXI at the full cost of providing such coverage, as determined by the State.

''(4) COVERAGE FOR LEGAL IMMIGRANT CHILDREN.—The State agrees to—

''(A) provide medical assistance under this title and child health assistance under title XXI for alien children who are lawfully residing in the United States (including battered aliens described in section 431(c) of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996) and who are otherwise eligible for such assistance in accordance with section 1903(v)(4) and 2107(e)(1)(E); and

"(B) not establish or enforce barriers that deter applications by such aliens, including through the application of the removal of the barriers described in subsection (c).

"(c) REMOVAL OF ENROLLMENT AND ACCESS BARRIERS.—The condition described in this subsection is that the State agrees to do the following:

"(1) PRESUMPTIVE ELIGIBILITY FOR CHILDREN.—The State agrees to—

"(A) provide presumptive eligibility for children under this title and title XXI in accordance with section 1920A;

"(B) treat any items or services that are provided to an uncovered child (as defined in section 2110(c)(8)) who is determined ineligible for medical assistance under this title as child health assistance for purposes of paying a provider of such items or services, so long as such items or services would be considered child health assistance for a targeted low-income child under title XXI.

"(2) ADOPTION OF 12-MONTH CONTINUOUS ENROLLMENT.—The State agrees to provide that eligibility for assistance under this title and title XXI

shall not be regularly redetermined more often than once every year for children.

''(3) ACCEPTANCE OF SELF-DECLARATION OF INCOME.—The State agrees to permit the family of a child applying for medical assistance under this title or child health assistance under title XXI to declare and certify by signature under penalty of perjury family income for purposes of collecting financial eligibility information.

''(4) ADOPTION OF ACCEPTANCE OF ELIGIBILITY DETERMINATIONS FOR OTHER ASSISTANCE PROGRAMS.—The State agrees to accept determinations (made within a reasonable period, as found by the State, before its use for this purpose) of an individual's family or household income made by a Federal or State agency (or a public or private entity making such determination on behalf of such agency), including the agencies administering the Food Stamp Act of 1977, the Richard B. Russell National School Lunch Act, and the Child Nutrition Act of 1966, notwithstanding any differences in budget unit, disregard, deeming, or other methodology, but only if—

''(A) such agency has fiscal liabilities or responsibilities affected or potentially affected by such determinations; and

''(B) any information furnished by such agency pursuant to this subparagraph is used solely for purposes of determining eligibility for medical assistance under this title or for child health assistance under title XXI.

''(5) NO ASSETS TEST.—The State agrees to not (or demonstrates that it does not) apply any assets or resources test for eligibility under this title or title XXI with respect to children.

''(6) ELIGIBILITY DETERMINATIONS AND REDETERMINATIONS.—

''(A) IN GENERAL.—The State agrees for purposes of initial eligibility determinations and redeterminations of children under this title and title XXI not to require a face-to-face interview and to permit applications and renewals by mail, telephone, and the Internet.

''(B) NONDUPLICATION OF INFORMATION.—

''(i) IN GENERAL.—For purposes of redeterminations of eligibility for currently or previously enrolled children under this

title and title XXI, the State agrees to use all information in its possession (including information available to the State under other Federal or State programs) to determine eligibility or redetermine continued eligibility before seeking similar information from parents.

''(ii) RULE OF CONSTRUCTION.—Nothing in clause (i) shall be construed as limiting any obligation of a State to provide notice and a fair hearing before denying, terminating, or reducing a child's coverage based on such information in the possession of the State.

''(7) NO WAITING LIST FOR CHILDREN UNDER SCHIP.—The State agrees to not impose any numerical limitation, waiting list, waiting period, or similar limitation on the eligibility of children for child health assistance under title XXI or to establish or enforce other barriers to the enrollment of eligible children based on the date of their application for coverage.

''(8) ADEQUATE PROVIDER PAYMENT RATES.—The State agrees to—

"(A) establish payment rates for children's health care providers under this title that are no less than the average of payment rates for similar services for such providers provided under the benchmark benefit packages described in section 2103(b);

"(B) establish such rates in amounts that are sufficient to ensure that children enrolled under this title or title XXI have adequate access to comprehensive care, in accordance with the requirements of section 1902(a)(30)(A); and

"(C) include provisions in its contracts with providers under this title guaranteeing compliance with these requirements.

"(d) MAINTENANCE OF MEDICAID ELIGIBILITY LEVELS FOR CHILDREN.—

"(1) IN GENERAL.—The condition described in this subsection is that the State agrees to maintain eligibility income, resources, and methodologies applied under this title (including under a waiver of such title or under section 1115) with respect to children that are no more restrictive than the eligibility income, resources, and methodologies applied

with respect to children under this title (including under such a waiver) as of January 1, 2005.

''(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as implying that a State does not have to comply with the minimum income levels required for children under section 1902(l)(2).

''(e) DATE DESCRIBED.—The date described in this subsection is the date on which, with respect to a State, a plan amendment that satisfies the requirements of subsections (b), (c), and (d) is approved by the Secretary.

''(f) DEFINITION OF POVERTY LINE.—In this section, the term 'poverty line' has the meaning given that term in section 2110(c)(5).''.

(b) CONFORMING AMENDMENTS.—

(1) The third sentence of section 1905(b) of the Social Security Act (42 U.S.C. 1396d(b)) is amended by inserting before the period the following: '', and with respect to amounts expended for medical assistance for children on or after the date described in subsection (d) of section 1936, in the case of a State that has, in accordance with such section, an approved plan amendment under this title and title XXI''.

(2) Section 1903(f)(4) of the Social Security Act (42 U.S.C. 1396b(f)(4)) is amended—

(A) in subparagraph (C), by adding ''or'' after ''section 1611(b)(1),''; and

(B) by inserting after subparagraph (C), the following:

''(D) who would not receive such medical assistance but for State electing the option under section 1936 and satisfying the conditions described in subsections (b), (c), and (d) of such section,''.

SEC. 302. ELIMINATION OF CAP ON SCHIP FUNDING FOR STATES THAT EXPAND ELIGIBILITY FOR CHILDREN.

(a) IN GENERAL.—Section 2105 of the Social Security Act (42 U.S.C. 1397dd) is amended by adding at the end the following:

''(h) GUARANTEED FUNDING FOR CHILD HEALTH ASSISTANCE FOR COVERAGE EXPANSION STATES.—

''(1) IN GENERAL.—Only in the case of a State that has, in accordance with section 1936, an approved plan amendment under this title and title XIX, any payment cap that would otherwise apply to the State under this title as a result of having expended all allotments available for expenditure by the State with respect to a fiscal year shall not apply

with respect to amounts expended by the State on or after the date described in section 1936(d).

''(2) APPROPRIATION.—There is appropriated, out of any money in the Treasury not otherwise appropriated, such sums as may be necessary for the purpose of paying a State described in paragraph (1) for each quarter beginning on or after the date described in section 1936(d), an amount equal to the enhanced FMAP of expenditures described in paragraph (1) and incurred during such quarter.''.

(b) CONFORMING AMENDMENTS.—Section 2104 of the Social Security Act (42 U.S.C. 1397dd) is amended—

(1) in subsection (a), by inserting ''subject to section 2105(h),'' after ''under this section,'';

(2) in subsection (b)(1), by inserting ''and section 2105(h)'' after ''Subject to paragraph (4)''; and

(3) in subsection (c)(1), by inserting ''subject to section 2105(h),'' after ''for a fiscal year,''.

CHAPTER 2—STATE OPTIONS FOR INCREMENTAL CHILD COVERAGE EXPANSIONS

SEC. 311. STATE OPTION TO ENROLL LOW-INCOME CHILDREN OF STATE EMPLOYEES IN SCHIP.

Section 2110(b)(2) of the Social Security Act (42 U.S.C. 1397jj(b)(2)) is amended—

(1) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively and realigning the left margins of such clauses appropriately;

(2) by striking ''Such term'' and inserting the following:

''(A) IN GENERAL.—Such term''; and

(3) by adding at the end the following:

''(B) STATE OPTION TO ENROLL LOW-INCOME CHILDREN OF STATE EMPLOYEES.—At the option of a State, subparagraph (A)(ii) shall not apply to any low-income child who would otherwise be eligible for child health assistance under this title but for such subparagraph.''.

SEC. 312. STATE OPTION FOR PASSIVE RENEWAL OF ELIGIBILITY FOR CHILDREN UNDER MEDICAID AND SCHIP.

(a) IN GENERAL.—Section 1902(l) of the Social Security Act (42 U.S.C. 1396a(l)) is amended by adding at the end the following:

''(5) Notwithstanding any other provision of this title, a State may provide that an individual who has not attained 21 years of age who has been determined eligible for medical assistance under this title shall remain eligible for medical assistance until such time as the State has

information demonstrating that the individual is no longer so eligible.''.

(b) APPLICATION UNDER TITLE XXI.—Section 2107(e)(1) of the Social Security Act (42 U.S.C. 1397gg(e)) is amended—

(1) by redesignating subparagraphs (B) through (D) as subparagraphs (C) through (E), respectively; and

(2) by inserting after subparagraph (A), the following:

''(B) Section 1902(l)(5) (relating to passive renewal of eligibility for children).''.

CHAPTER 3—TAX INCENTIVES FOR HEALTH INSURANCE COVERAGE OF CHILDREN

SEC. 321. REFUNDABLE CREDIT FOR HEALTH INSURANCE COVERAGE OF CHILDREN.

(a) IN GENERAL.—Subpart C of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 (relating to refundable credits) is amended by redesignating section 36 as section 37 and by inserting after section 35 the following new section:

''SEC. 36. HEALTH INSURANCE COVERAGE OF CHILDREN.

''(a) IN GENERAL.—In the case of an individual, there shall be allowed as a credit against the tax imposed

by this subtitle an amount equal to so much of the amount paid during the taxable year, not compensated for by insurance or otherwise, for qualified health insurance for each dependent child of the taxpayer, as exceeds 5 percent of the adjusted gross income of such taxpayer for such taxable year.

''(b) DEPENDENT CHILD.—For purposes of this section, the term 'dependent child' means any child (as defined in section 152(f)(1)) who has not attained the age of 19 as of the close of the calendar year in which the taxable year of the taxpayer begins and with respect to whom a deduction under section 151 is allowable to the taxpayer.

''(c) QUALIFIED HEALTH INSURANCE.—For purposes of this section—

''(1) IN GENERAL.—The term 'qualified health insurance' means insurance, either employer-provided or made available under title XIX or XXI of the Social Security Act, which constitutes medical care as defined in section 213(d) without regard to—

''(A) paragraph (1)(C) thereof, and

''(B) so much of paragraph (1)(D) thereof as relates to qualified long-term care insurance contracts.

''(2) EXCLUSION OF CERTAIN OTHER CONTRACTS.—Such term shall not include insurance if a substantial portion of its benefits are excepted benefits (as defined in section 9832(c)).

''(d) MEDICAL SAVINGS ACCOUNT AND HEALTH SAVINGS ACCOUNT CONTRIBUTIONS.—

''(1) IN GENERAL.—If a deduction would (but for paragraph (2)) be allowed under section 220 or 223 to the taxpayer for a payment for the taxable year to the medical savings account or health savings account of an individual, subsection (a) shall be applied by treating such payment as a payment for qualified health insurance for such individual.

''(2) DENIAL OF DOUBLE BENEFIT.—No deduction shall be allowed under section 220 or 223 for that portion of the payments otherwise allowable as a deduction under section 220 or 223 for the taxable year which is equal to the amount of credit allowed for such taxable year by reason of this subsection.

''(e) SPECIAL RULES.—

''(1) DETERMINATION OF INSURANCE COSTS.—The Secretary shall provide rules for the allocation of the cost of any qualified health insurance for family coverage to the coverage of any dependent child under such insurance.

''(2) COORDINATION WITH DEDUCTION FOR HEALTH INSURANCE COSTS OF SELF-EMPLOYED INDIVIDUALS.—In the case of a taxpayer who is eligible to deduct any amount under section 162(l) for the taxable year, this section shall apply only if the taxpayer elects not to claim any amount as a deduction under such section for such year.

''(3) COORDINATION WITH MEDICAL EXPENSE AND HIGH DEDUCTIBLE HEALTH PLAN DEDUCTIONS.—The amount which would (but for this paragraph) be taken into account by the taxpayer under section 213 or 224 for the taxable year shall be reduced by the credit (if any) allowed by this section to the taxpayer for such year.

''(4) DENIAL OF CREDIT TO DEPENDENTS.—No credit shall be allowed under this section to any individual with respect to whom a deduction under section 151 is allowable to another taxpayer for a taxable year beginning in the calendar year in which such individual's taxable year begins.

''(5) DENIAL OF DOUBLE BENEFIT.—No credit shall be allowed under subsection (a) if the credit under section 35 is allowed and no credit shall be allowed under 35 if a credit is allowed under this section.

''(6) ELECTION NOT TO CLAIM CREDIT.—This section shall not apply to a taxpayer for any taxable year if such taxpayer elects to have this section not apply for such taxable year.''.

(b) INFORMATION REPORTING.—

(1) IN GENERAL.—Subpart B of part III of subchapter A of chapter 61 of the Internal Revenue Code of 1986 (relating to information concerning transactions with other persons) is amended by inserting after section 6050T the following new section:

''SEC. 6050U. RETURNS RELATING TO PAYMENTS FOR QUALIFIED HEALTH INSURANCE.

''(a) IN GENERAL.—Any governmental unit or any person who, in connection with a trade or business conducted by such person, receives payments during any calendar year from any individual for coverage of a dependent child (as defined in section 36(b)) of such individual under creditable health insurance, shall make the return described in subsection (b) (at such time as the Secretary may by regulations prescribe) with respect to each individual from whom such payments were received.

''(b) FORM AND MANNER OF RETURNS.—A return is described in this subsection if such return—

''(1) is in such form as the Secretary may prescribe, and

''(2) contains—

''(A) the name, address, and TIN of the individual from whom payments described in subsection (a) were received,

''(B) the name, address, and TIN of each dependent child (as so defined) who was provided by such person with coverage under creditable health insurance by reason of such payments and the period of such coverage, and

''(C) such other information as the Secretary may reasonably prescribe.

''(c) CREDITABLE HEALTH INSURANCE.—For purposes of this section, the term 'creditable health insurance' means qualified health insurance (as defined in section 36(c)).

''(d) STATEMENTS TO BE FURNISHED TO INDIVIDUALS WITH RESPECT TO WHOM INFORMATION IS REQUIRED.—Every person required to make a return under subsection (a) shall furnish to each individual whose name is required under subsection (b)(2)(A) to be set forth in such return a written statement showing—

''(1) the name and address of the person required to make such return and the phone number of the information contact for such person,

''(2) the aggregate amount of payments described in subsection (a) received by the person required to make such return from the individual to whom the statement is required to be furnished, and

''(3) the information required under subsection (b)(2)(B) with respect to such payments.

The written statement required under the preceding sentence shall be furnished on or before January 31 of the year following the calendar year for which the return under subsection (a) is required to be made.

''(e) RETURNS WHICH WOULD BE REQUIRED TO BE MADE BY 2 OR MORE PERSONS.—Except to the extent provided in regulations prescribed by the Secretary, in the case of any amount received by any person on behalf of another person, only the person first receiving such amount shall be required to make the return under subsection (a).''.

(2) ASSESSABLE PENALTIES.—

(A) Subparagraph (B) of section 6724(d)(1) of such Code (relating to definitions) is amended by redesignating clauses (xiii) through (xviii) as clauses (xiv) through (xix),

respectively, and by inserting after clause (xii) the following new clause:

"(xiii) section 6050U (relating to returns relating to payments for qualified health insurance),".

(B) Paragraph (2) of section 6724(d) of such Code is amended by striking "or" at the end of the next to last subparagraph, by striking the period at the end of the last subparagraph and inserting ", or", and by adding at the end the following new subparagraph:

"(CC) section 6050U(d) (relating to returns relating to payments for qualified health insurance).".

(3) CLERICAL AMENDMENT.—The table of sections for subpart B of part III of subchapter A of chapter 61 of such Code is amended by inserting after the item relating to section 6050T the following new item:

"Sec. 6050U. Returns relating to payments for qualified health insurance.".

(c) CONFORMING AMENDMENTS.—

(1) Paragraph (2) of section 1324(b) of title 31, United States Code, is amended by inserting before the period ", or from section 36 of such Code".

(2) The table of sections for subpart C of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 is amended by striking the last item and inserting the following new items:

"Sec. 36. Health insurance coverage of children.
"Sec. 37. Overpayments of tax.".

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2004.

SEC. 322. FORFEITURE OF PERSONAL EXEMPTION FOR ANY CHILD NOT COVERED BY HEALTH INSURANCE.

(a) IN GENERAL.—Section 151(d) of the Internal Revenue Code of 1986 (relating to exemption amount) is amended by adding at the end the following new paragraph:

"(5) REDUCTION OF EXEMPTION AMOUNT FOR ANY CHILD NOT COVERED BY HEALTH INSURANCE.—

"(A) IN GENERAL.—Except as otherwise provided in this paragraph, the exemption amount otherwise determined under this subsection for any dependent child (as defined in section 36(b)) for any taxable year shall be reduced by the same percentage as the percentage of such taxable year during which such depend-

ent child was not covered by qualified health insurance (as defined in section 36(c)).

''(B) FULL REDUCTION IF NO PROOF OF COVERAGE IS PROVIDED.—For purposes of subparagraph (A), in the case of any taxpayer who fails to attach to the return of tax for any taxable year a copy of the statement furnished to such taxpayer under section 6050U, the percentage reduction under such subparagraph shall be deemed to be 100 percent.

''(C) NONAPPLICATION OF PARAGRAPH TO TAXPAYERS IN LOWEST TAX BRACKET.—This paragraph shall not apply to any taxpayer whose taxable income for the taxable year does not exceed the initial bracket amount determined under section 1(i)(1)(B).''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 2004.

CHAPTER 4—MISCELLANEOUS

SEC. 331. REQUIREMENT FOR GROUP MARKET HEALTH INSURERS TO OFFER DEPENDENT COVERAGE OPTION FOR WORKERS WITH CHILDREN.

(a) ERISA.—

(1) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185 et seq.) is amended by adding at the end the following:

"SEC. 714. REQUIREMENT TO OFFER OPTION TO PURCHASE DEPENDENT COVERAGE FOR CHILDREN.

''(a) REQUIREMENTS FOR COVERAGE.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, shall offer an individual who is enrolled in such coverage the option to purchase dependent coverage for a child of the individual.

''(b) NO EMPLOYER CONTRIBUTION REQUIRED.—An employer shall not be required to contribute to the cost of purchasing dependent coverage for a child by an individual who is an employee of such employer.

''(c) DEFINITION OF CHILD.—In this section, the term 'child' means an individual who has not attained 21 years of age.''.

(2) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001) is amended by inserting after the item relating to section 713 the following:

''Sec. 714. Requirement to offer option to purchase dependent coverage for children.''.

(b) PUBLIC HEALTH SERVICE ACT.—Subpart 2 of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–4 et seq.) is amended by adding at the end the following:

"SEC. 2707. REQUIREMENT TO OFFER OPTION TO PURCHASE DEPENDENT COVERAGE FOR CHILDREN.

''(a) REQUIREMENTS FOR COVERAGE.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, shall offer an individual who is enrolled in such coverage the option to purchase dependent coverage for a child of the individual.

''(b) NO EMPLOYER CONTRIBUTION REQUIRED.—An employer shall not be required to contribute to the cost of purchasing dependent coverage for a child by an individual who is an employee of such employer.

''(c) DEFINITION OF CHILD.—In this section, the term 'child' means an individual who has not attained 21 years of age.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan years beginning on or after January 1, 2006.

SEC. 332. EFFECTIVE DATE.

Unless otherwise provided, the amendments made by this subtitle shall take effect on October 1, 2005, and shall apply to child health assistance and medical assistance provided on or after that date without regard to whether or not final regulations to carry out such amendments have been promulgated by such date.

Subtitle B—Covering Pregnant Women

SEC. 351. STATE OPTION TO EXPAND OR ADD COVERAGE OF PREGNANT WOMEN UNDER THE MEDICAID PROGRAM AND STATE CHILDREN'S HEALTH INSURANCE PROGRAM.

(a) MEDICAID.—

(1) AUTHORITY TO EXPAND COVERAGE.—Section 1902(l)(2)(A)(i) of the Social Security Act (42 U.S.C. 1396a(l)(2)(A)(i)) is amended by inserting ''(or such higher percentage as the State may elect for purposes of expenditures for medical assistance for pregnant women described in section 1905(u)(4)(A))'' after ''185 percent''.

(2) ENHANCED MATCHING FUNDS AVAILABLE IF CERTAIN CONDITIONS MET.—Section 1905 of the Social Security Act (42 U.S.C. 1396d), as amended by section 311(b)(2), is amended—

(A) in the fourth sentence of subsection (b), by striking ''or (u)(4)'' and inserting '', (u)(4), or (u)(5)''; and

(B) in subsection (u)—

(i) by redesignating paragraph (5) as paragraph (6); and

(ii) by inserting after paragraph (4) the following new paragraph:

''(5) For purposes of the fourth sentence of subsection (b) and section 2105(a), the expenditures described in this paragraph are the following:

''(A) CERTAIN PREGNANT WOMEN.—If the conditions described in subparagraph (B) are met, expenditures for medical assistance for pregnant women described in subsection (n) or under section 1902(l)(1)(A) in a family the income of which exceeds 185 percent of the poverty line, but does not exceed the income eligibility level established under title XXI for a targeted low-income child.

''(B) CONDITIONS.—The conditions described in this subparagraph are the following:

''(i) The State plans under this title and title XXI do not provide coverage for pregnant women described in subparagraph (A) with

higher family income without covering such pregnant women with a lower family income.

''(ii) The State does not apply an effective income level for pregnant women that is lower than the effective income level (expressed as a percent of the poverty line and considering applicable income disregards) that has been specified under the State plan under subsection (a)(10)(A)(i)(III) or (l)(2)(A) of section 1902, as of January 1, 2005, to be eligible for medical assistance as a pregnant woman.

''(C) DEFINITION OF POVERTY LINE.—In this subsection, the term 'poverty line' has the meaning given such term in section 2110(c)(5).''.

(3) PAYMENT FROM TITLE XXI ALLOTMENT FOR MEDICAID EXPANSION COSTS; ELIMINATION OF COUNTING MEDICAID CHILD PRESUMPTIVE ELIGIBILITY COSTS AGAINST TITLE XXI ALLOTMENT.—Section 2105(a)(1) of the Social Security Act (42 U.S.C. 1397ee(a)(1)) is amended—

(A) in the matter preceding subparagraph (A), by striking ''(or, in the case of expenditures described in subparagraph (B), the Federal medical assistance percentage (as defined in the first sentence of section 1905(b)))''; and

(B) by striking subparagraph (B) and inserting the following new subparagraph:

''(B) for the provision of medical assistance that is attributable to expenditures described in section 1905(u)(5)(A);''.

(b) SCHIP.—

(1) COVERAGE.—Title XXI of the Social Security Act (42 U.S.C. 1397aa et seq.) is amended by adding at the end the following new section:

''SEC. 2111. OPTIONAL COVERAGE OF TARGETED LOW-INCOME PREGNANT WOMEN.

''(a) OPTIONAL COVERAGE.—Notwithstanding any other provision of this title, a State may provide for coverage, through an amendment to its State child health plan under section 2102, of pregnancy-related assistance for targeted low-income pregnant women in accordance with this section, but only if—

''(1) the State has established an income eligibility level for pregnant women under subsection (a)(10)(A)(i)(III) or (l)(2)(A) of section 1902 that is at least 185 percent of the income official poverty line; and

''(2) the State meets the conditions described in section 1905(u)(5)(B).

''(b) DEFINITIONS.—For purposes of this title:

''(1) PREGNANCY-RELATED ASSISTANCE.—The term 'pregnancy-related assistance' has the meaning given the term child health assistance in section 2110(a) as if any reference to targeted low-income children were a reference to targeted low-income pregnant women, except that the assistance shall be limited to services related to pregnancy (which include prenatal, delivery, and postpartum services and services described in section 1905(a)(4)(C)) and to other conditions that may complicate pregnancy.

''(2) TARGETED LOW-INCOME PREGNANT WOMAN.—The term 'targeted low-income pregnant woman' means a woman—

''(A) during pregnancy and through the end of the month in which the 60-day period (beginning on the last day of her pregnancy) ends;

''(B) whose family income exceeds the effective income level (expressed as a percent of the poverty line and considering applicable income disregards) that has been specified under subsection (a)(10)(A)(i)(III) or (l)(2)(A) of section 1902, as of January 1, 2005, to be eligible for medical assistance as a pregnant woman under title XIX but does not exceed the income

eligibility level established under the State child health plan under this title for a targeted low-income child; and

"(C) who satisfies the requirements of paragraphs (1)(A), (1)(C), (2), and (3) of section 2110(b).

"(c) REFERENCES TO TERMS AND SPECIAL RULES.—In the case of, and with respect to, a State providing for coverage of pregnancy-related assistance to targeted low-income pregnant women under subsection (a), the following special rules apply:

"(1) Any reference in this title (other than in subsection (b)) to a targeted low-income child is deemed to include a reference to a targeted low-income pregnant woman.

"(2) Any such reference to child health assistance with respect to such women is deemed a reference to pregnancy-related assistance.

"(3) Any such reference to a child is deemed a reference to a woman during pregnancy and the period described in subsection (b)(2)(A).

"(4) In applying section 2102(b)(3)(B), any reference to children found through screening to be eligible for medical assistance under the State med-

icaid plan under title XIX is deemed a reference to pregnant women.

''(5) There shall be no exclusion of benefits for services described in subsection (b)(1) based on any preexisting condition and no waiting period (including any waiting period imposed to carry out section 2102(b)(3)(C)) shall apply.

''(6) Subsection (a) of section 2103 (relating to required scope of health insurance coverage) shall not apply insofar as a State limits coverage to services described in subsection (b)(1) and the reference to such section in section 2105(a)(1)(C) is deemed not to require, in such case, compliance with the requirements of section 2103(a).

''(7) In applying section 2103(e)(3)(B) in the case of a pregnant woman provided coverage under this section, the limitation on total annual aggregate cost-sharing shall be applied to such pregnant woman.

''(8) The reference in section 2107(e)(1)(D) to section 1920A (relating to presumptive eligibility for children) is deemed a reference to section 1920 (relating to presumptive eligibility for pregnant women).

"(d) AUTOMATIC ENROLLMENT FOR CHILDREN BORN TO WOMEN RECEIVING PREGNANCY-RELATED ASSISTANCE.—If a child is born to a targeted low-income pregnant woman who was receiving pregnancy-related assistance under this section on the date of the child's birth, the child shall be deemed to have applied for child health assistance under the State child health plan and to have been found eligible for such assistance under such plan or to have applied for medical assistance under title XIX and to have been found eligible for such assistance under such title, as appropriate, on the date of such birth and to remain eligible for such assistance until the child attains 1 year of age. During the period in which a child is deemed under the preceding sentence to be eligible for child health or medical assistance, the child health or medical assistance eligibility identification number of the mother shall also serve as the identification number of the child, and all claims shall be submitted and paid under such number (unless the State issues a separate identification number for the child before such period expires).".

(2) ADDITIONAL ALLOTMENTS FOR PROVIDING COVERAGE OF PREGNANT WOMEN.—

(A) IN GENERAL.—Section 2104 of the Social Security Act (42 U.S.C. 1397dd) is amend-

ed by inserting after subsection (c) the following new subsection:

"(d) ADDITIONAL ALLOTMENTS FOR PROVIDING COVERAGE OF PREGNANT WOMEN.—

"(1) APPROPRIATION; TOTAL ALLOTMENT.—For the purpose of providing additional allotments to States under this title, there is appropriated, out of any money in the Treasury not otherwise appropriated, for each of fiscal years 2006 through 2009, $200,000,000.

"(2) STATE AND TERRITORIAL ALLOTMENTS.—In addition to the allotments provided under subsections (b) and (c), subject to paragraphs (3) and (4), of the amount available for the additional allotments under paragraph (1) for a fiscal year, the Secretary shall allot to each State with a State child health plan approved under this title—

"(A) in the case of such a State other than a commonwealth or territory described in subparagraph (B), the same proportion as the proportion of the State's allotment under subsection (b) (determined without regard to subsection (f)) to the total amount of the allotments under subsection (b) for such States eli-

gible for an allotment under this paragraph for such fiscal year; and

''(B) in the case of a commonwealth or territory described in subsection (c)(3), the same proportion as the proportion of the commonwealth's or territory's allotment under subsection (c) (determined without regard to subsection (f)) to the total amount of the allotments under subsection (c) for commonwealths and territories eligible for an allotment under this paragraph for such fiscal year.

''(3) USE OF ADDITIONAL ALLOTMENT.—Additional allotments provided under this subsection are not available for amounts expended before October 1, 2005. Such amounts are available for amounts expended on or after such date for child health assistance for targeted low-income children, as well as for pregnancy-related assistance for targeted low-income pregnant women.

''(4) NO PAYMENTS UNLESS ELECTION TO EXPAND COVERAGE OF PREGNANT WOMEN.—No payments may be made to a State under this title from an allotment provided under this subsection unless the State provides pregnancy-related assistance for targeted low-income pregnant women under this

title, or provides medical assistance for pregnant women under title XIX, whose family income exceeds the effective income level applicable under subsection (a)(10)(A)(i)(III) or (l)(2)(A) of section 1902 to a family of the size involved as of January 1, 2005.''.

(B) CONFORMING AMENDMENTS.—Section 2104 of the Social Security Act (42 U.S.C. 1397dd), as amended by section 302(b), is amended—

(i) in subsection (a), in the matter preceding paragraph (1), by inserting ''subsection (d) and'' before ''section 2105(h)'';

(ii) in subsection (b)(1), by inserting '', subsection (d),'' after ''Subject to paragraph (4)''; and

(iii) in subsection (c)(1), by inserting ''subsection (d) and'' after ''section 2105(h)''.

(3) ADDITIONAL CONFORMING AMENDMENTS.—

(A) NO COST-SHARING FOR PREGNANCY-RELATED BENEFITS.—Section 2103(e)(2) of the Social Security Act (42 U.S.C. 1397cc(e)(2)) is amended—

(i) in the heading, by inserting ''OR PREGNANCY-RELATED SERVICES'' after ''PREVENTIVE SERVICES''; and

(ii) by inserting before the period at the end the following: ''or for pregnancy-related services''.

(B) NO WAITING PERIOD.—Section 2102(b)(1)(B) (42 U.S.C. 1397bb(b)(1)(B)) is amended—

(i) in clause (i), by striking '', and'' at the end and inserting a semicolon;

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

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

''(iii) may not apply a waiting period (including a waiting period to carry out paragraph (3)(C)) in the case of a targeted low-income pregnant woman.''.

(c) AUTHORITY FOR STATES THAT PROVIDE MEDICAID OR SCHIP COVERAGE FOR PREGNANT WOMEN WITH INCOME ABOVE 185 PERCENT OF THE POVERTY LINE TO USE PORTION OF SCHIP FUNDS FOR MEDICAID EXPENDITURES.—Section 2105(g) of the Social Security Act (42 U.S.C. 1397ee(g)) is amended—

(1) in the subsection heading, by inserting ''AND CERTAIN PREGNANCY COVERAGE EXPANSION STATES'' after ''QUALIFYING STATES'';

(2) by adding at the end the following:

''(4) SPECIAL AUTHORITY FOR CERTAIN PREGNANCY COVERAGE EXPANSION STATES.—

''(A) IN GENERAL.—In the case of a State that, as of the date of enactment of the Affordable Health Care Act of 2005, has an income eligibility standard under title XIX or this title (under section 1902(a)(10)(A) or under a statewide waiver in effect under section 1115 with respect to title XIX or this title) that is at least 185 percent of the poverty line with respect to pregnant women, the State may elect to use not more than 20 percent of any allotment under section 2104 for any fiscal year (insofar as it is available under subsections (e) and (g) of such section) for payments under title XIX in accordance with subparagraph (B), instead of for expenditures under this title.

''(B) PAYMENTS TO STATES.—

''(i) IN GENERAL.—In the case of a State described in subparagraph (A) that has elected the option described in that

subparagraph, subject to the availability of funds under such subparagraph and, if applicable, paragraph (1)(A), with respect to the State, the Secretary shall pay the State an amount each quarter equal to the additional amount that would have been paid to the State under title XIX with respect to expenditures described in clause (ii) if the enhanced FMAP (as determined under subsection (b)) had been substituted for the Federal medical assistance percentage (as defined in section 1905(b)).

''(ii) EXPENDITURES DESCRIBED.—For purposes of this subparagraph, the expenditures described in this clause are expenditures, made after the date of the enactment of this paragraph and during the period in which funds are available to the State for use under subparagraph (A), for medical assistance under title XIX for pregnant women whose family income is at least 185 percent of the poverty line.

''(iii) NO IMPACT ON DETERMINATION OF BUDGET NEUTRALITY FOR WAIVERS.—In the case of a State described in sub-

paragraph (A) that uses amounts paid under this paragraph for expenditures described in clause (ii) that are incurred under a waiver approved for the State, any budget neutrality determinations with respect to such waiver shall be determined without regard to such amounts paid.''; and

(3) in paragraph (3), by striking ''and (2)'' and inserting ''(2), and (4)''.

(d) OTHER AMENDMENTS TO MEDICAID.—

(1) ELIGIBILITY OF A NEWBORN.—Section 1902(e)(4) of the Social Security Act (42 U.S.C. 1396a(e)(4)) is amended in the first sentence by striking ''so long as the child is a member of the woman's household and the woman remains (or would remain if pregnant) eligible for such assistance''.

(2) APPLICATION OF QUALIFIED ENTITIES TO PRESUMPTIVE ELIGIBILITY FOR PREGNANT WOMEN UNDER MEDICAID.—Section 1920(b) of the Social Security Act (42 U.S.C. 1396r–1(b)) is amended by adding after paragraph (2) the following flush sentence:

''The term 'qualified provider' includes a qualified entity as defined in section 1920A(b)(3).''.

(e) EFFECTIVE DATE.—The amendments made by this section apply to items and services furnished on or after October 1, 2005, without regard to whether regulations implementing such amendments have been promulgated.

SEC. 352. OPTIONAL COVERAGE OF LEGAL IMMIGRANTS UNDER THE MEDICAID PROGRAM AND SCHIP.

(a) MEDICAID PROGRAM.—Section 1903(v) of the Social Security Act (42 U.S.C. 1396b(v)) is amended—

(1) in paragraph (1), by striking ''paragraph (2)'' and inserting ''paragraphs (2) and (4)''; and

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

''(4)(A) A State may elect (in a plan amendment under this title) to provide medical assistance under this title for aliens who are lawfully residing in the United States (including battered aliens described in section 431(c) of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996) and who are otherwise eligible for such assistance, within any of the following eligibility categories:

''(i) PREGNANT WOMEN.—Women during pregnancy (and during the 60-day period beginning on the last day of the pregnancy).

''(ii) CHILDREN.—Children (as defined under such plan), including optional targeted low-income children described in section 1905(u)(2)(B).

''(B)(i) In the case of a State that has elected to provide medical assistance to a category of aliens under subparagraph (A), no debt shall accrue under an affidavit of support against any sponsor of such an alien on the basis of provision of assistance to such category and the cost of such assistance shall not be considered as an unreimbursed cost.

''(ii) The provisions of sections 401(a), 402(b), 403, and 421 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 shall not apply to a State that makes an election under subparagraph (A).''.

(b) TITLE XXI.—Section 2107(e)(1) of the Social Security Act (42 U.S.C. 1397gg(e)(1)) is amended by adding at the end the following new subparagraph:

''(E) Section 1903(v)(4) (relating to optional coverage of permanent resident alien pregnant women and children), but only with respect to an eligibility category under this title,

if the same eligibility category has been elected under such section for purposes of title XIX.''.

(c) EFFECTIVE DATE.—The amendments made by this section take effect on October 1, 2005, and apply to medical assistance and child health assistance furnished on or after such date.

SEC. 353. PROMOTING CESSATION OF TOBACCO USE UNDER THE MEDICAID PROGRAM.

(a) DROPPING EXCEPTION FROM MEDICAID PRESCRIPTION DRUG COVERAGE FOR TOBACCO CESSATION MEDICATIONS.—Section 1927(d)(2) of the Social Security Act (42 U.S.C. 1396r–8(d)(2)) is amended—

(1) by striking subparagraph (E);

(2) by redesignating subparagraphs (F) through (J) as subparagraphs (E) through (I), respectively; and

(3) in subparagraph (F) (as redesignated by paragraph (2)), by inserting before the period at the end the following: '', except agents approved by the Food and Drug Administration for purposes of promoting, and when used to promote, tobacco cessation''.

(b) REQUIRING COVERAGE OF TOBACCO CESSATION COUNSELING SERVICES FOR PREGNANT WOMEN.—Sec-

tion 1905 of the Social Security Act (42 U.S.C. 1396d(a)(4)) is amended—

(1) in subsection (a)(4)—

(A) by striking ''and'' before ''(C)''; and

(B) by inserting before the semicolon at the end the following new subparagraph: ''; and

(D) counseling for cessation of tobacco use (as defined in subsection (x)) for pregnant women''; and

(2) by adding at the end the following:

''(y)(1) For purposes of this title, the term 'counseling for cessation of tobacco use' means therapy and counseling for cessation of tobacco use for pregnant women who use tobacco products or who are being treated for tobacco use that is furnished—

''(A) by or under the supervision of a physician; or

''(B) by any other health care professional who—

''(i) is legally authorized to furnish such services under State law (or the State regulatory mechanism provided by State law) of the State in which the services are furnished; and

''(ii) is authorized to receive payment for other services under this title or is designated by the Secretary for this purpose.

''(2) Subject to paragraph (3), such term is limited to—

''(A) therapy and counseling services recommended in 'Treating Tobacco Use and Dependence: A Clinical Practice Guideline', published by the Public Health Service in June 2000, or any subsequent modification of such Guideline; and

''(B) such other therapy and counseling services that the Secretary recognizes to be effective.

''(3) Such term shall not include coverage for drugs or biologicals that are not otherwise covered under this title.''.

(c) REMOVAL OF COST-SHARING FOR TOBACCO CESSATION COUNSELING SERVICES FOR PREGNANT WOMEN.—Section 1916 of the Social Security Act (42 U.S.C. 1396o) is amended in each of subsections (a)(2)(B) and (b)(2)(B) by inserting '', and counseling for cessation of tobacco use (as defined in section 1905(x))'' after ''complicate the pregnancy''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after

the date that is 1 year after the date of enactment of this Act.

SEC. 354. PROMOTING CESSATION OF TOBACCO USE UNDER THE MATERNAL AND CHILD HEALTH SERVICES BLOCK GRANT PROGRAM.

(a) QUALITY MATERNAL AND CHILD HEALTH SERVICES INCLUDES TOBACCO CESSATION COUNSELING AND MEDICATIONS.—

(1) IN GENERAL.—Section 501 of the Social Security Act (42 U.S.C. 701) is amended by adding at the end the following new subsection:

''(c) For purposes of this title, counseling for cessation of tobacco use (as defined in section 1905(y)), drugs and biologicals used to promote smoking cessation, and the inclusion of antitobacco messages in health promotion counseling shall be considered to be part of quality maternal and child health services.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date that is 1 year after the date of enactment of this Act.

(b) EVALUATION OF NATIONAL CORE PERFORMANCE MEASURES.—

(1) IN GENERAL.—The Administrator of the Health Resources and Services Administration shall assess the current national core performance meas-

ures and national core outcome measures utilized under the Maternal and Child Health Block Grant under title V of the Social Security Act (42 U.S.C. 701 et seq.) for purposes of expanding such measures to include some of the known causes of low birthweight and prematurity, including the percentage of infants born to pregnant women who smoked during pregnancy.

(2) REPORT.—Not later than 1 year after the date of enactment of this Act, the Administrator of the Health Resources and Services Administration shall submit to the appropriate committees of Congress a report concerning the results of the evaluation conducted under paragraph (1).

SEC. 355. STATE OPTION TO PROVIDE FAMILY PLANNING SERVICES AND SUPPLIES TO INDIVIDUALS WITH INCOMES THAT DO NOT EXCEED A STATE'S INCOME ELIGIBILITY LEVEL FOR MEDICAL ASSISTANCE.

(a) IN GENERAL.—Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), as amended by section 301(a), is amended—

(1) by redesignating section 1937 as section 1938; and

(2) by inserting after section 1936 the following new section:

''STATE OPTION TO PROVIDE FAMILY PLANNING SERVICES AND SUPPLIES

''SEC. 1937. (a) IN GENERAL.—Subject to subsections (b) and (c), a State may elect (through a State plan amendment) to make medical assistance described in section 1905(a)(4)(C) available to any individual whose family income does not exceed the greater of—

''(1) 185 percent of the income official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved; or

''(2) the eligibility income level (expressed as a percentage of such poverty line) that has been specified under a waiver authorized by the Secretary or under section 1902(r)(2)), as of January 1, 2005, for an individual to be eligible for medical assistance under the State plan.

''(b) COMPARABILITY.—Medical assistance described in section 1905(a)(4)(C) that is made available under a State plan amendment under subsection (a) shall—

''(1) not be less in amount, duration, or scope than the medical assistance described in that section

that is made available to any other individual under the State plan; and

''(2) be provided in accordance with the restrictions on deductions, cost sharing, or similar charges imposed under section 1916(a)(2)(D).

''(c) OPTION TO EXTEND COVERAGE DURING A POST-ELIGIBILITY PERIOD.—

''(1) INITIAL PERIOD.—A State plan amendment made under subsection (a) may provide that any individual who was receiving medical assistance described in section 1905(a)(4)(C) as a result of such amendment, and who becomes ineligible for such assistance because of hours of, or income from, employment, may remain eligible for such medical assistance through the end of the 6-month period that begins on the first day the individual becomes so ineligible.

''(2) ADDITIONAL EXTENSION.—A State plan amendment made under subsection (a) may provide that any individual who has received medical assistance described in section 1905(a)(4)(C) during the entire 6-month period described in paragraph (1) may be extended coverage for such assistance for a succeeding 6-month period.''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) apply to medical assistance provided on and after October 1, 2005.

SEC. 356. STATE OPTION TO EXTEND THE POSTPARTUM PERIOD FOR PROVISION OF FAMILY PLANNING SERVICES AND SUPPLIES.

(a) IN GENERAL.—Section 1902(e)(5) of the Social Security Act (42 U.S.C. 1396a(e)(5)) is amended—

(1) by striking ''eligible under the plan, as though'' and inserting ''eligible under the plan—

''(A) as though'';

(2) by striking the period and inserting ''; and''; and

(3) by adding at the end the following new subparagraph:

''(B) for medical assistance described in section 1905(a)(4)(C) for so long as the family income of such woman does not exceed the maximum income level established by the State for the woman to be eligible for medical assistance under the State plan (as a result of pregnancy or otherwise).''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) apply to medical assistance provided on and after October 1, 2005.

SEC. 357. STATE OPTION TO PROVIDE WRAP-AROUND SCHIP COVERAGE TO CHILDREN WHO HAVE OTHER HEALTH COVERAGE.

(a) IN GENERAL.—

(1) SCHIP.—

(A) STATE OPTION TO PROVIDE WRAP-AROUND COVERAGE.—Section 2110(b) of the Social Security Act (42 U.S.C. 1397jj(b)) is amended—

(i) in paragraph (1)(C), by inserting ", subject to paragraph (5)," after "under title XIX or"; and

(ii) by adding at the end the following:

"(5) STATE OPTION TO PROVIDE WRAP-AROUND COVERAGE.—A State may waive the requirement of paragraph (1)(C) that a targeted low-income child may not be covered under a group health plan or under health insurance coverage, if the State satisfies the conditions described in subsection (c)(8). The State may waive such requirement in order to provide—

"(A) services for a child with special health care needs; or

"(B) all services.

In waiving such requirement, a State may limit the application of the waiver to children whose family income does not exceed a level specified by the State, so long as the level so specified does not exceed the maximum income level otherwise established for other children under the State child health plan.''.

(B) CONDITIONS DESCRIBED.—Section 2105(c) of the Social Security Act (42 U.S.C. 1397ee(c)) is amended by adding at the end the following:

''(8) CONDITIONS FOR PROVISION OF WRAP-AROUND COVERAGE.—For purposes of section 2110(b)(5), the conditions described in this paragraph are the following:

''(A) INCOME ELIGIBILITY.—The State child health plan (whether implemented under title XIX or this XXI)—

''(i) has the highest income eligibility standard permitted under this title as of January 1, 2005;

''(ii) subject to subparagraph (B), does not limit the acceptance of applications for children; and

"(iii) provides benefits to all children in the State who apply for and meet eligibility standards.

"(B) NO WAITING LIST IMPOSED.—With respect to children whose family income is at or below 200 percent of the poverty line, the State does not impose any numerical limitation, waiting list, or similar limitation on the eligibility of such children for child health assistance under such State plan.

"(C) NO MORE FAVORABLE TREATMENT.—The State child health plan may not provide more favorable coverage of dental services to the children covered under section 2110(b)(5) than to children otherwise covered under this title.".

(C) STATE OPTION TO WAIVE WAITING PERIOD.—Section 2102(b)(1)(B) of the Social Security Act (42 U.S.C. 1397bb(b)(1)(B)), as amended by section 2(b)(3)(B), is amended—

(i) in clause (ii), by striking ", and" at the end and inserting a semicolon;

(ii) in clause (iii), by striking the period at the end and inserting "; and"; and

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

"(iv) at State option, may not apply a waiting period in the case of a child described in section 2110(b)(5), if the State satisfies the requirements of section 2105(c)(8).".

(2) APPLICATION OF ENHANCED MATCH UNDER MEDICAID.—Section 1905 of the Social Security Act (42 U.S.C. 1396d), as amended by section 2(a)(2), is amended—

(A) in subsection (b), in the fourth sentence, by striking "or (u)(4)" and inserting "(u)(4), or (u)(5)"; and

(B) in subsection (u)—

(i) by redesignating paragraph (5) as paragraph (6); and

(ii) by inserting after paragraph (4) the following:

"(5) For purposes of subsection (b), the expenditures described in this paragraph are expenditures for items and services for children described in section 2110(b)(5), but only in the case of a State that satisfies the requirements of section 2105(c)(8).".

(3) APPLICATION OF SECONDARY PAYOR PROVISIONS.—Section 2107(e)(1) of the Social Security Act (42 U.S.C. 1397gg(e)(1)), as amended by section 3(b), is amended by adding at the end the following:

"(F) Section 1902(a)(25) (relating to coordination of benefits and secondary payor provisions) with respect to children covered under a waiver described in section 2110(b)(5).".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect on January 1, 2005, and shall apply to child health assistance and medical assistance provided on or after that date.

SEC. 358. INNOVATIVE OUTREACH PROGRAMS.

Title XXI of the Social Security Act (42 U.S.C. 1397aa et seq.), as amended by section 351(b), is amended by adding at the end the following:

"SEC. 2112. EXPANDED OUTREACH ACTIVITIES.

"(a) IN GENERAL.—Funds made available under subsection (f) for expenditure under this section for a fiscal year shall be used by the Secretary to award grants to eligible entities to conduct innovative outreach and enrollment efforts that are designed to increase the enrollment and participation of eligible children under this title and title XIX.

''(b) PRIORITY FOR GRANTS IN CERTAIN AREAS.—In making grants under subsection (a), the Secretary shall give priority to eligible entities that propose to target geographic areas with high rates of—

''(1) eligible but unenrolled children, including such children who reside in rural areas;

''(2) families for whom English is not their primary language; or

''(3) racial and ethnic minorities and health disparity populations

''(c) APPLICATION.—An eligible entity that desires to receive a grant under this section shall submit an application to the Secretary in such form and manner, and containing such information, as the Secretary may decide. Such application shall include—

''(1) quality and outcomes performance measures to evaluate the effectiveness of activities funded by a grant under this paragraph to ensure that the activities are meeting their goals; and

''(2) an assurance that the entity will—

''(A) collect and report enrollment data; and

''(B) disseminate findings from evaluations of the activities funded under the grant.

''(d) REPORT.—The Secretary shall report to Congress on an annual basis the results of the outreach efforts under grants awarded under this section.

''(e) DEFINITION OF ELIGIBLE ENTITY.—In this section, the term 'eligible entity' means any of the following:

''(1) A State.

''(2) A national, local, or community-based public or nonprofit private organization.

''(f) APPROPRIATION.—For the purpose of awarding grants to eligible entities under this section, there is appropriated, out of any money in the Treasury not otherwise appropriated, $50,000,000 for each of fiscal years 2006 and 2007.''.

Subtitle C—Affirming the Importance of Medicaid

SEC. 361. SENSE OF THE SENATE.

(a) FINDINGS.—The Senate makes the following findings:

(1) The Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) provides essential health care and long-term care coverage to more than 50,000,000 low-income children, pregnant women and families, individuals with disabilities, and senior citizens. It is a Federal guar-

antee that even the most vulnerable will have access to needed medical services.

(2) Medicaid provides health insurance for more than ¼ of America's children and is the largest purchaser of maternity care, paying for more than ⅓ of all the births in the United States each year.

(3) Medicaid provides critical help for the elderly and individuals living with disabilities. Medicaid is America's single largest purchaser of nursing home services and other long-term care, covering the majority of nursing home residents.

(4) Medicaid pays for personal care and other supportive services, which are typically not provided by private health insurance, even if individuals could obtain it. These services are necessary to enable individuals with spinal cord injuries, developmental disabilities, neurological degenerative diseases, serious and persistent mental illnesses, HIV/AIDS, and other chronic conditions to remain in the community, to work, and to maintain independence.

(5) Medicaid is an essential supplement to the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) for more than 6,000,000 Medicare beneficiaries who are low-income elderly or disabled, assisting them with their Medi-

care premiums and co-insurance, wrap-around benefits, and, in most States, the costs of nursing home care that Medicare does not cover.

(6) About 42 percent of all Medicaid spending is for those who are elderly or are living with disabilities and are dually eligible for Medicare and Medicaid.

(7) Medicaid faces an ever growing burden as a result of Medicare's gaps. The Medicaid program spent nearly $40,000,000,000 on uncovered Medicare services in 2002. Medicaid payments for low-income Medicare beneficiary cost-sharing are the largest and fastest growing share of Medicaid spending.

(8) The Medicare drug benefit imposes additional costs on States, which will add to the already significant long-term care cost burden. Medicaid spending on Medicare beneficiaries' long-term care costs is expected to double from $25,000,000,000 in 2002 to $51,000,000,000 in 2012.

(9) Medicaid helps ensure access to care for all Americans. Medicaid is the single largest source of revenue for the Nation's safety net hospitals and health centers and is critical to the ability of those providers to serve Medicaid enrollees and uninsured Americans.

(10) Medicaid serves a major role in ensuring that the number of Americans without health insurance, approximately 45,000,000 in 2003, is not substantially higher. Medicaid helps buffer the drop in private coverage during recessions. More than 4,800,000 Americans lost employer sponsored coverage between 2000 and 2003. Medicaid covered an additional 5,800,000 Americans during this period, preventing even greater numbers of uninsured.

(11) Medicaid matters to women in America. More than 16,000,000 women depend on Medicaid for their health care. Women comprise the majority of seniors (71 percent) on Medicaid. Half of non-elderly women with permanent mental or physical disabilities have health coverage through Medicaid. Medicaid provides treatment for low-income women diagnosed with breast or cervical cancer in every State.

(12) Medicaid is critical for children with disabilities. Medicaid covers 78 percent of poor children with disabilities who are under 5 years of age and 70 percent of poor children with disabilities who are between the ages of 5 and 17. Similarly, Medicaid covers a substantial portion of children with disabilities who are near poor, covering 40 percent of chil-

dren with disabilities who are under 5 years of age and 25 percent of children with disabilities who are between the ages of 5 and 17.

(13) Medicaid is the Nation's largest source of payment for mental health services, HIV/AIDS care, and care for children with special needs. Much of this care is either not covered by private insurance or limited in scope or duration. Medicaid is also a critical source of funding for health care for children in foster care and for health services in schools.

(14) The need for Medicaid is greater than ever today, because the number of Americans living in poverty has increased by 8,000,000 over the last 4 years and the number of the uninsured has increased by 5,000,000.

(15) The system of Federal matching for State Medicaid expenditures ensures that Federal funds will grow as State spending increases in response to unmet needs.

(16) Despite the varied population served by the Medicaid program, including those with significant health care needs, Medicaid per capita growth has been consistently about half the rate of growth in private insurance premiums and Medicaid has far lower administrative costs. Medicaid costs less per

person than private coverage for people who have similar health status.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that—

(1) the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is a critical component of the health care system of the United States;

(2) Federal support for the Medicaid program must be adequate to support State spending meeting the essential health needs of the low-income elderly, low-income individuals with disabilities, and low-income children and families, and should not be cut or capped; and

(3) any retreat from the Federal commitment to Medicaid would threaten not only the health care safety net of the United States but the entire health care system

TITLE IV—REDUCING HEALTH CARE COSTS FOR SMALL EMPLOYERS

Subtitle A—Tax Relief

SEC. 401. REFUNDABLE CREDIT FOR SMALL BUSINESS EMPLOYEE HEALTH INSURANCE EXPENSES.

(a) IN GENERAL.—Subpart C of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 (relating to refundable credits) is amended by redesignating section 36 as section 37 and inserting after section 35 the following new section:

"SEC. 36. SMALL BUSINESS EMPLOYEE HEALTH INSURANCE EXPENSES.

"(a) DETERMINATION OF AMOUNT.—In the case of a qualified small employer, there shall be allowed as a credit against the tax imposed by this subtitle for the taxable year an amount equal to the expense amount described in subsection (b) paid by the taxpayer during the taxable year.

"(b) EXPENSE AMOUNT.—For purposes of this section—

"(1) IN GENERAL.—The expense amount described in this subsection is the applicable percentage of the amount of qualified employee health insurance expenses of each qualified employee.

''(2) APPLICABLE PERCENTAGE.—For purposes of paragraph (1), the applicable percentage is equal to—

''(A) for any qualified small employer described in subparagraph (A) of paragraph (4), 50 percent,

''(B) for any qualified small employer described in subparagraph (B) of paragraph (4), 35 percent, and

''(C) for any qualified small employer described in subparagraph (C) of paragraph (4), 25 percent.

''(3) PER EMPLOYEE DOLLAR LIMITATION.—The amount of qualified employee health insurance expenses taken into account under paragraph (1) with respect to any qualified employee for any taxable year shall not exceed—

''(A) $1,500 in the case of self-only coverage; and

''(B) $3,500 in the case of family coverage.

''(4) QUALIFIED SMALL EMPLOYERS DESCRIBED.—A qualified small employer is described in—

''(A) this subparagraph if such employer employed an average of 9 or fewer employees (as determined under subsection (c)(1)(A)(ii)),

''(B) this subparagraph if such employer employed an average of more than 9 but less than 25 employees (as so determined), and

''(C) this subparagraph if such employer employed an average of more than 24 but not more than 50 employees (as so determined).

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

''(1) QUALIFIED SMALL EMPLOYER.—

''(A) IN GENERAL.—The term 'qualified small employer' means, with respect to any calendar year, any employer if—

''(i) such employer pays or incurs at least 75 percent of the qualified employee health insurance expenses of each qualified employee (determined without regard to subsection (b)(3)), and

''(ii) such employer employed an average of 50 or fewer employees on business days during either of the 2 preceding calendar years.

For purposes of clause (ii), a preceding calendar year may be taken into account only if

the employer was in existence throughout such year.

''(B) EMPLOYERS NOT IN EXISTENCE IN PRECEDING YEAR.—In the case of an employer which was not in existence throughout the 1st preceding calendar year, the determination under subparagraph (A)(ii) shall be based on the average number of employees that it is reasonably expected such employer will employ on business days in the current calendar year.

''(2) QUALIFIED EMPLOYEE HEALTH INSURANCE EXPENSES.—

''(A) IN GENERAL.—The term 'qualified employee health insurance expenses' means any amount paid by an employer for health insurance coverage (as defined in section 9832(b)(1)) to the extent such amount is attributable to coverage provided to any employee while such employee is a qualified employee.

''(B) EXCEPTION FOR AMOUNTS PAID UNDER SALARY REDUCTION ARRANGEMENTS.—No amount paid or incurred for health insurance coverage pursuant to a salary reduction arrangement shall be taken into account under subparagraph (A).

''(3) QUALIFIED EMPLOYEE.—

''(A) IN GENERAL.—The term 'qualified employee' means, with respect to any period, an employee of an employer if—

''(i) the annual amount of hours in the employ of such employer by such employee is at least 400 hours,

''(ii) the total amount of wages paid or incurred by such employer to such employee at an annual rate during the taxable year is at least $5,000, and

''(iii) such employee is not eligible for—

''(I) any benefits under title XVIII, XIX, or XXI of the Social Security Act, or

''(II) any other publicly-sponsored health insurance program.

''(B) TREATMENT OF CERTAIN EMPLOYEES.—For purposes of subparagraph (A), the term 'employee'—

''(i) shall not include an employee within the meaning of section 401(c)(1), and

''(ii) shall include a leased employee within the meaning of section 414(n).

''(C) WAGES.—The term 'wages' has the meaning given such term by section 3121(a) (determined without regard to any dollar limitation contained in such section).

''(d) CERTAIN RULES MADE APPLICABLE.—For purposes of this section, rules similar to the rules of section 52 shall apply.

''(e) COORDINATION WITH DEDUCTION FOR HEALTH INSURANCE COSTS OF SELF-EMPLOYED INDIVIDUALS.—In the case of a taxpayer who is eligible to deduct any amount under section 162(l) for the taxable year, this section shall apply only if the taxpayer elects not to claim any amount as a deduction under such section for such year.''.

(b) CONFORMING AMENDMENTS.—

(1) Paragraph (2) of section 1324(b) of title 31, United States Code, is amended by inserting before the period '', or from section 36 of such Code''.

(2) The table of sections for subpart C of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 is amended by striking the last item and inserting the following new items:

''Sec. 36. Small business employee health insurance expenses.
''Sec. 37. Overpayments of tax.''.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to amounts paid or incurred in taxable years beginning after December 31, 2005.

Subtitle B—Three-Share Program

SEC. 421. THREE-SHARE PROGRAMS.

The Social Security Act (42 U.S.C. 301 et seq.) is amended by adding at the end the following:

"TITLE XXII—PROVIDING FOR THE UNINSURED

"SEC. 2201. THREE-SHARE PROGRAMS.

''(a) PILOT PROGRAMS.—The Secretary, acting through the Administrator, shall award grants under this section for the startup and operation of 25 eligible three-share pilot programs for a 5-year period.

''(b) GRANTS FOR THREE-SHARE PROGRAMS.—

''(1) ESTABLISHMENT.—The Administrator may award grants to eligible entities—

''(A) to establish three-share programs;

''(B) to provide for contributions to the premiums assessed for coverage under a three-share program as provided for in subsection (c)(2)(B)(iii); and

''(C) to establish risk pools.

''(2) THREE-SHARE PROGRAM PLAN.—Each entity desiring a grant under this subsection shall de-

velop a plan for the establishment and operation of a three-share program that meets the requirements of paragraphs (2) and (3) of subsection (c).

''(3) APPLICATION.—Each entity desiring a grant under this subsection shall submit an application to the Administrator at such time, in such manner and containing such information as the Administrator may require, including—

''(A) the three-share program plan described in paragraph (2); and

''(B) an assurance that the eligible entity will—

''(i) determine a benefit package;

''(ii) recruit businesses and employees for the three-share program;

''(iii) build and manage a network of health providers or contract with an existing network or licensed insurance provider;

''(iv) manage all administrative needs; and

''(v) establish relationships among community, business, and provider interests.

''(4) PRIORITY.—In awarding grants under this section the Secretary shall give priority to an applicant—

''(A) that is an existing three-share program;

''(B) that is an eligible three-share program that has demonstrated community support; or

''(C) that is located in a State with insurance laws and regulations that permit three-share program expansion.

''(c) GRANT ELIGIBILITY.—

''(1) IN GENERAL.—The Secretary, acting through the Administrator, shall promulgate regulations providing for the eligibility of three-share programs for participation in the pilot program under this section.

''(2) THREE-SHARE PROGRAM REQUIREMENTS.—

''(A) IN GENERAL.—To be determined to be an eligible three-share program for purposes of participation in the pilot program under this section a three-share program shall—

''(i) be either a non-profit or local governmental entity;

"(ii) define the region in which such program will provide services;

"(iii) have the capacity to carry out administrative functions of managing health plans, including monthly billings, verification/enrollment of eligible employers and employees, maintenance of membership rosters, development of member materials (such as handbooks and identification cards), customer service, and claims processing; and

"(iv) have demonstrated community involvement.

"(B) PAYMENT.—To be eligible under paragraph (1), a three-share program shall pay the costs of services provided under subparagraph (A)(ii) by charging a monthly premium for each covered individual to be divided as follows:

"(i) Not more than 30 percent of such premium shall be paid by a qualified employee desiring coverage under the three-share program.

"(ii) Not more than 30 percent of such premium shall be paid by the qualified employer of such a qualified employee.

"(iii) At least 40 percent of such premium shall be paid from amounts provided under a grant under this section.

"(iv) Any remaining amount shall be paid by the three-share program from other public, private, or charitable sources.

"(C) PROGRAM FLEXIBILITY.—A three-share program may set an income eligibility guideline for enrollment purposes.

"(3) COVERAGE.—

"(A) IN GENERAL.—To be an eligible three-share program under this section, the three-share program shall provide at least the following benefits:

"(i) Physicians services.

"(ii) In-patient hospital services.

"(iii) Out-patient services.

"(iv) Emergency room visits.

"(v) Emergency ambulance services.

"(vi) Diagnostic lab fees and x-rays.

"(vii) Prescription drug benefits.

''(B) LIMITATION.—Nothing in subparagraph (A) shall be construed to require that a three-share program provide coverage for services performed outside the region described in paragraph (2)(A)(i).

''(C) PREEXISTING CONDITIONS.—A program described in subparagraph (A) shall not be an eligible three-share program under paragraph (1) if any individual can be excluded from coverage under such program because of a preexisting health condition.

''(d) GRANTS FOR EXISTING THREE-SHARE PROGRAMS TO MEET CERTIFICATION REQUIREMENTS.—

''(1) IN GENERAL.—The Administrator may award grants to three-share programs that are operating on the date of enactment of this section.

''(2) APPLICATION.—Each eligible entity desiring a grant under this subsection shall submit an application to the Administrator at such time, in such manner, and containing such information as the Administrator may require.

''(e) APPLICATION OF STATE LAWS.—Nothing in this section shall be construed to preempt State law.

''(f) DISTRESSED BUSINESS FORMULA.—

''(1) IN GENERAL.—Not later than 60 days after the date of enactment of this section, the Administrator of the Health Resources and Services Administration shall develop a formula to determine which businesses qualify as distressed businesses for purposes of this section.

''(2) EFFECT ON INSURANCE MARKET.—Granting eligibility to a distressed business using the formula under paragraph (1) shall not interfere with the insurance market. Any business found to have reduced benefits to qualify as a distressed business under the formula under paragraph (1) shall not be eligible to be a three-share program for purposes of this section.

''(g) DEFINITIONS.—In this section:

''(1) ADMINISTRATOR.—The term 'Administrator' means the Administrator of the Health Resources and Services Administration.

''(2) COVERED INDIVIDUAL.—The term 'covered individual' means—

''(A) a qualified employee; or

''(B) a child under the age of 23 or a spouse of such qualified employee who—

''(i) lacks access to health care coverage through their employment or employer;

''(ii) lacks access to health coverage through a family member;

''(iii) is not eligible for coverage under the medicare program under title XVIII or the medicaid program under title XIX; and

''(iv) does not qualify for benefits under the State Children's Health Insurance Program under title XXI.

''(3) DISTRESSED BUSINESS.—The term 'distressed business' means a business that—

''(A) in light of economic hardship and rising health care premiums may be forced to discontinue or scale back its health care coverage; and

''(B) qualifies as a distressed business according to the formula under subsection (g).

''(4) ELIGIBLE ENTITY.—The term 'eligible entity' means an entity that meets the requirements of subsection (a)(2)(A).

''(5) QUALIFIED EMPLOYEE.—The term 'qualified employee' means any individual employed by a

qualified employer who meets certain criteria including—

"(A) lacking access to health coverage through a family member or common law partner;

"(B) not being eligible for coverage under the medicare program under title XVIII or the medicaid program under title XIX; and

"(C) agreeing that the share of fees described in subsection (a)(2)(B)(i) shall be paid in the form of payroll deductions from the wages of such individual.

"(6) QUALIFIED EMPLOYER.—The term 'qualified employer' means an employer as defined in section 3(d) of the Fair Labor Standards Act of 1938 (29 U.S.C. 203(d)) who—

"(A) is a small business concern as defined in section 3(a) of the Small Business Act (15 U.S.C. 632);

"(B) is located in the region described in subsection (a)(2)(A)(i); and

"(C) has not contributed to the health care benefits of its employees for at least 12 months consecutively or currently provides insurance but is classified as a distressed business.

''(h) EVALUATION.—Not later than 90 days after the end of the 5-year period during which grants are available under this section, the Government Accountability Office shall submit to the Secretary and the appropriate committees of Congress a report concerning—

''(1) the effectiveness of the programs established under this section;

''(2) the number of individuals covered under such programs;

''(3) any resulting best practices; and

''(4) the level of community involvement.

''(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, such sums as may be necessary for each of fiscal years 2006 through 2011.''.

○