

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. INOUE, 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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Affordable Health Care Act”.

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

Sec. 1. Short title; table of contents.

TITLE I—MAKING PRESCRIPTION DRUGS MORE SAFE AND
AFFORDABLE

Subtitle A—Access to Prescription Drugs

- Sec. 101. Findings.
 Sec. 102. Repeal of certain section regarding importation of prescription drugs.
 Sec. 103. Importation of prescription drugs; waiver of certain import restrictions.
 Sec. 104. Additional waivers regarding personal importation; enforcement policies of Secretary.
 Sec. 105. Disposition of certain drugs denied admission into United States.
 Sec. 106. Civil actions regarding property.
 Sec. 107. Wholesale distribution of drugs; Statements regarding prior sale, purchase, or trade.
 Sec. 108. Repeal of importation exemption under Controlled Substances Import and Export Act.
 Sec. 109. Effect on administration practices.

Subtitle B—Ensuring Drug Safety

- Sec. 121. Drug safety.
 Sec. 122. Report by GAO on drug safety.

TITLE II—MODERNIZING THE HEALTH CARE SYSTEM

- Sec. 201. Amendment to the Public Health Service Act.
 Sec. 202. Standardized measures of quality health care and data collection.

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

Subtitle A—Covering all Children

- Sec. 300. Findings.

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.
 Sec. 302. Elimination of cap on SCHIP funding for States that expand eligibility for children.

CHAPTER 2—STATE OPTIONS FOR INCREMENTAL CHILD COVERAGE
EXPANSIONS

- Sec. 311. State option to enroll low-income children of State employees in SCHIP.
 Sec. 312. State option for passive renewal of eligibility for children under medicaid and SCHIP.

CHAPTER 3—TAX INCENTIVES FOR HEALTH INSURANCE COVERAGE OF
CHILDREN

- Sec. 321. Refundable credit for health insurance coverage of children.
 Sec. 322. Forfeiture of personal exemption for any child not covered by health insurance.

CHAPTER 4—MISCELLANEOUS

Sec. 331. Requirement for group market health insurers to offer dependent coverage option for workers with children.

Sec. 332. Effective 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.

Sec. 352. Optional coverage of legal immigrants under the medicaid program and SCHIP.

Sec. 353. Promoting cessation of tobacco use under the medicaid program.

Sec. 354. Promoting cessation of tobacco use under the maternal and child health services block grant program.

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.

Sec. 356. State option to extend the postpartum period for provision of family planning services and supplies.

Sec. 357. State option to provide wrap-around SCHIP coverage to children who have other health coverage.

Sec. 358. Innovative outreach programs.

Subtitle C—Affirming the Importance of Medicaid

Sec. 361. Sense of the Senate.

TITLE IV—REDUCING HEALTH CARE COSTS FOR SMALL EMPLOYERS

Subtitle A—Tax Relief

Sec. 401. Refundable credit for small business employee health insurance expenses.

Subtitle B—Three-Share Program

Sec. 421. Three-share programs.

1 **TITLE I—MAKING PRESCRIP-**
 2 **TION DRUGS MORE SAFE AND**
 3 **AFFORDABLE**

4 **Subtitle A—Access to Prescription**
 5 **Drugs**

6 **SEC. 101. FINDINGS.**

7 Congress finds that—

1 (1) Americans unjustly pay up to 5 times more
2 to fill their prescriptions than consumers in other
3 countries;

4 (2) the United States is the largest market for
5 pharmaceuticals in the world, yet American con-
6 sumers pay the highest prices for brand pharma-
7 ceuticals in the world;

8 (3) a prescription drug is neither safe nor effec-
9 tive to an individual who cannot afford it;

10 (4) allowing and structuring the importation of
11 prescription drugs to ensure access to safe and af-
12 fordable drugs approved by the Food and Drug Ad-
13 ministration will provide a level of safety to Amer-
14 ican consumers that they do not currently enjoy;

15 (5) American seniors alone will spend
16 \$1,800,000,000,000 on pharmaceuticals over the
17 next 10 years; and

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

21 **SEC. 102. REPEAL OF CERTAIN SECTION REGARDING IM-**
22 **PORTATION OF PRESCRIPTION DRUGS.**

23 Chapter VIII of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 381 et seq.) is amended by striking
25 section 804.

1 **SEC. 103. IMPORTATION OF PRESCRIPTION DRUGS; WAIVER**
2 **OF CERTAIN IMPORT RESTRICTIONS.**

3 (a) IN GENERAL.—Chapter VIII of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.),
5 as amended by section 102, is further amended by insert-
6 ing after section 803 the following:

7 **“SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF**
8 **PRESCRIPTION DRUGS.**

9 “(a) IMPORTATION OF PRESCRIPTION DRUGS.—

10 “(1) IN GENERAL.—The Secretary shall in ac-
11 cordance with this section provide by regulation
12 that, in the case of qualifying drugs imported or of-
13 fered for import into the United States from reg-
14 istered exporters or by registered importers—

15 “(A) the limitation on importation that is
16 established in section 801(d)(1) is waived; and

17 “(B) the standards referred to in section
18 801(a) regarding admission of the drugs are
19 subject to subsection (g) of this section (includ-
20 ing with respect to qualifying drugs to which
21 section 801(d)(1) does not apply).

22 “(2) IMPORTERS.—A qualifying drug may not
23 be imported under paragraph (1) unless—

24 “(A) the drug is imported by a pharmacy
25 or a wholesaler that is a registered importer; or

1 “(B) the drug is imported by an individual
2 for personal use or for the use of a family mem-
3 ber of the individual (not for resale) from a reg-
4 istered exporter.

5 “(3) RULE OF CONSTRUCTION.—This section
6 shall apply only with respect to a drug that is im-
7 ported or offered for import into the United
8 States—

9 “(A) by a registered importer; or

10 “(B) from a registered exporter to an indi-
11 vidual.

12 “(4) DEFINITIONS.—

13 “(A) REGISTERED EXPORTER; REG-
14 ISTERED IMPORTER.—For purposes of this sec-
15 tion:

16 “(i) The term ‘registered exporter’
17 means an exporter for which a registration
18 under subsection (b) has been approved
19 and is in effect.

20 “(ii) The term ‘registered importer’
21 means a pharmacy, group of pharmacies,
22 or a wholesaler for which a registration
23 under subsection (b) has been approved
24 and is in effect.

1 “(iii) The term ‘registration condition’
2 means a condition that must exist for a
3 registration under subsection (b) to be ap-
4 proved.

5 “(B) QUALIFYING DRUG.—For purposes of
6 this section, the term ‘qualifying drug’ means a
7 prescription drug, other than any of the fol-
8 lowing:

9 “(i) A controlled substance, as defined
10 in section 102 of the Controlled Sub-
11 stances Act (21 U.S.C. 802).

12 “(ii) A biological product, as defined
13 in section 351 of the Public Health Service
14 Act (42 U.S.C. 262).

15 “(iii) An infused drug, including a
16 peritoneal dialysis solution.

17 “(iv) An intravenously injected drug.

18 “(v) A drug that is inhaled during
19 surgery.

20 “(C) OTHER DEFINITIONS.—For purposes
21 of this section:

22 “(i) The term ‘exporter’ means a per-
23 son that is in the business of exporting a
24 drug from Canada to individuals in the
25 United States or that, pursuant to submit-

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

3 “(ii) The term ‘importer’ means a
4 pharmacy, a group of pharmacies, or a
5 wholesaler that is in the business of im-
6 porting a drug into the United States or
7 that, pursuant to submitting a registration
8 under subsection (b), seeks to be in such
9 business.

10 “(iii) The term ‘pharmacist’ means a
11 person licensed by a State to practice
12 pharmacy, including the dispensing and
13 selling of prescription drugs.

14 “(iv) The term ‘pharmacy’ means a
15 person that—

16 “(I) is licensed by a State to en-
17 gage in the business of selling pre-
18 scription drugs at retail; and

19 “(II) employs 1 or more phar-
20 macists.

21 “(v) The term ‘prescription drug’
22 means a drug that is described in section
23 503(b)(1).

24 “(vi) The term ‘wholesaler’—

1 “(I) means a person licensed as a
2 wholesaler or distributor of prescrip-
3 tion drugs in the United States under
4 section 503(e)(2)(A); and

5 “(II) does not include a person
6 authorized to import drugs under sec-
7 tion 801(d)(1).

8 “(D) PERMITTED COUNTRY.—The term
9 ‘permitted country’ means—

10 “(i) Australia;

11 “(ii) Canada;

12 “(iii) a member country of the Euro-
13 pean Union as of January 1, 2003;

14 “(iv) Japan;

15 “(v) New Zealand; and

16 “(vi) Switzerland.

17 “(b) REGISTRATION OF IMPORTERS AND EXPORT-
18 ERS.—

19 “(1) REGISTRATION OF IMPORTERS AND EX-
20 PORTERS.—A registration condition is that the im-
21 porter or exporter involved (referred to in this sub-
22 section as a ‘registrant’) submits to the Secretary a
23 registration containing the following:

24 “(A) The name of the registrant and an
25 identification of all places of business of the

1 registrant that relate to qualifying drugs, in-
2 cluding each warehouse or other facility owned
3 or controlled by, or operated for, the registrant.

4 “(B) Such information as the Secretary
5 determines to be necessary to demonstrate that
6 the registrant is in compliance with registration
7 conditions under—

8 “(i) in the case of an importer, sub-
9 sections (c), (d), (e), (g), and (j) (relating
10 to the sources of exported drugs; the in-
11 spection of facilities of the importer; the
12 payment of fees; compliance with the
13 standards referred to in section 801(a);
14 and maintenance of records and samples);
15 or

16 “(ii) in the case of an exporter, sub-
17 sections (c), (d), (f), (g), (h), (i), and (j)
18 (relating to the sources of exported drugs;
19 the inspection of facilities of the exporter
20 and the marking of compliant shipments;
21 the payment of fees; and compliance with
22 the standards referred to in section 801(a);
23 being licensed as a pharmacist; conditions
24 for individual importation from Canada;
25 and maintenance of records and samples).

1 “(C) An agreement by the registrant that
2 the registrant will not under subsection (a) im-
3 port or export any drug that is not a qualifying
4 drug.

5 “(D) An agreement by the registrant to—

6 “(i) notify the Secretary of a recall or
7 withdrawal of a drug distributed in a per-
8 mitted country that the registrant has ex-
9 ported or imported, or intends to export or
10 import, to the United States under sub-
11 section (a);

12 “(ii) provide for the return to the reg-
13 istrant of such drug; and

14 “(iii) cease, or not begin, the expor-
15 tation or importation of such drug unless
16 the Secretary has notified the registrant
17 that exportation or importation of such
18 drug may proceed.

19 “(E) An agreement by the registrant to
20 ensure and monitor compliance with each reg-
21 istration condition, to promptly correct any
22 noncompliance with such a condition, and to
23 promptly report to the Secretary any such non-
24 compliance.

1 “(F) A plan describing the manner in
2 which the registrant will comply with the agree-
3 ment under subparagraph (E).

4 “(G) An agreement by the registrant to
5 enforce a contract under subsection (c)(3)(B)
6 against a party in the chain of custody of a
7 qualifying drug with respect to the authority of
8 the Secretary under clauses (ii) and (iii) of that
9 subsection.

10 “(H) An agreement by the registrant to
11 notify the Secretary of—

12 “(i) any change that the registrant in-
13 tends to make regarding information pro-
14 vided under subparagraph (A) or (B); and

15 “(ii) any change that the registrant
16 intends to make in the compliance plan
17 under subparagraph (F).

18 “(I) In the case of an exporter—

19 “(i) An agreement by the exporter
20 that a qualifying drug will not under sub-
21 section (a) be exported to any individual
22 not authorized pursuant to subsection
23 (a)(2)(B) to be an importer of such drug.

24 “(ii) An agreement to post a bond,
25 payable to the Treasury of the United

1 States if, after opportunity for an informal
2 hearing, the Secretary determines that the
3 exporter has exported a drug to the United
4 States that is not a qualifying drug or that
5 is not in compliance with subsections (g)
6 or (i), that is equal in value to the lesser
7 of—

8 “(I) the value of drugs exported
9 by the exporter to the United States
10 in a typical 4-week period over the
11 course of a year under this section; or

12 “(II) \$1,000,000.

13 “(J) Such other provisions as the Sec-
14 retary may require to protect the public health
15 while permitting—

16 “(i) the importation by pharmacies,
17 groups of pharmacies, wholesalers as reg-
18 istered importers of qualifying drugs under
19 subsection (a); and

20 “(ii) importation by individuals of
21 qualifying drugs under subsection (a).

22 “(2) APPROVAL OR DISAPPROVAL OF REGISTRA-
23 TION.—

24 “(A) IN GENERAL.—Not later than 90
25 days after the date on which a registrant sub-

1 mits to the Secretary a registration under para-
2 graph (1), the Secretary shall notify the reg-
3 istrant whether the registration is approved or
4 is disapproved. The Secretary shall disapprove
5 a registration if there is reason to believe that
6 the registrant is not in compliance with one or
7 more registration conditions, and shall notify
8 the registrant of such reason. In the case of a
9 disapproved registration, the Secretary shall
10 subsequently notify the registrant that the reg-
11 istration is approved if the Secretary deter-
12 mines that the registrant is in compliance with
13 such conditions.

14 “(B) CHANGES IN REGISTRATION INFOR-
15 MATION.—Not later than 30 days after receiv-
16 ing a notice under paragraph (1)(G) from a
17 registrant, the Secretary shall determine wheth-
18 er the change involved affects the approval of
19 the registration of the registrant under para-
20 graph (1), and shall inform the registrant of
21 the determination.

22 “(3) PUBLICATION OF CONTACT INFORMATION
23 FOR REGISTERED EXPORTERS.—Through the Inter-
24 net website of the Food and Drug Administration,
25 the Secretary shall make readily available to the

1 public a list of registered exporters, including con-
2 tact information for the exporters. Promptly after
3 the approval of a registration submitted under para-
4 graph (1), the Secretary shall update the Internet
5 website accordingly.

6 “(4) SUSPENSION AND TERMINATION.—

7 “(A) SUSPENSION.—With respect to the
8 effectiveness of a registration submitted under
9 paragraph (1):

10 “(i) Subject to clause (ii), if the Sec-
11 retary determines, after notice and oppor-
12 tunity for a hearing, that the registrant
13 has failed to maintain substantial compli-
14 ance with all registration conditions, the
15 Secretary may suspend the registration.

16 “(ii) If the Secretary determines that,
17 under color of the registration, the ex-
18 porter has exported a drug or the importer
19 has imported a drug that is not a quali-
20 fying drug, or a drug that does not meet
21 the criteria under subsection (g)(2)(A), or
22 has exported a qualifying drug to an indi-
23 vidual in violation of subsection (i)(1)(F),
24 the Secretary shall immediately suspend
25 the registration. A suspension under the

1 preceding sentence is not subject to the
2 provision by the Secretary of prior notice,
3 and the Secretary shall provide to the reg-
4 istrant an opportunity for a hearing not
5 later than 10 days after the date on which
6 the registration is suspended.

7 “(iii) The Secretary may reinstate the
8 registration, whether suspended under
9 clause (i) or (ii), if the Secretary deter-
10 mines that the registrant has demonstrated
11 that further violations of registration con-
12 ditions will not occur.

13 “(B) TERMINATION.—The Secretary, after
14 notice and opportunity for a hearing, may ter-
15 minate the registration under paragraph (1) of
16 a registrant if the Secretary determines that
17 the registrant has engaged in a pattern or prac-
18 tice of violating 1 or more registration condi-
19 tions, or if on 1 or more occasions the Secretary
20 has under subparagraph (A)(ii) suspended the
21 registration of the registrant. The Secretary
22 may make the termination permanent, or for a
23 fixed period of not less than 1 year. During the
24 period in which the registration is terminated,
25 any registration submitted under paragraph (1)

1 by the registrant, or a person that is a partner
2 in the export or import enterprise, or a principal
3 officer in such enterprise, and any registration
4 prepared with the assistance of the registrant or
5 such a person, has no legal effect under this sec-
6 tion.

7 “(c) SOURCES OF QUALIFYING DRUGS.—A registra-
8 tion condition is that the exporter or importer involved
9 agrees that a qualifying drug will under subsection (a) be
10 exported or imported to the United States only if there
11 is compliance with the following:

12 “(1) The drug was manufactured in an estab-
13 lishment—

14 “(A) required to register under subsection
15 (h) or (i) of section 510; or

16 “(B) inspected by the Secretary as pro-
17 vided by this section.

18 “(2) The establishment is located in the United
19 States or in any foreign country, and the establish-
20 ment manufactured the drug for distribution in the
21 United States or for distribution in 1 or more of the
22 permitted countries (without regard to whether in
23 addition the drug was manufactured for distribution
24 in a foreign country that is not a permitted coun-
25 try).

1 “(3) The exporter or importer obtained the
2 drug—

3 “(A) directly from the establishment; or

4 “(B) directly from an entity that, by con-
5 tract with the exporter or importer—

6 “(i) provides to the exporter or im-
7 porter a statement (in such form and con-
8 taining such information as the Secretary
9 may require) that, for the chain of custody
10 from the establishment, identifies each
11 prior sale, purchase, or trade of the drug
12 (including the date of the transaction and
13 the names and addresses of all parties to
14 the transaction);

15 “(ii) agrees to permit the Secretary to
16 inspect such statements and related
17 records to determine their accuracy;

18 “(iii) agrees, with respect to the quali-
19 fying drugs involved, to permit the Sec-
20 retary to inspect warehouses and other fa-
21 cilities of the entity for purposes of deter-
22 mining whether the facilities are in compli-
23 ance with any standards under this Act
24 that are applicable to facilities of that type
25 in the United States; and

1 “(iv) has ensured, through such con-
2 tractual relationships as may be necessary,
3 that the Secretary has the same authority
4 regarding other parties in the chain of cus-
5 tody from the establishment that the Sec-
6 retary has under clauses (ii) and (iii) re-
7 garding such entity.

8 “(4) The foreign country from which the im-
9 porter will import the drug is a permitted country.

10 “(5) The foreign country from which the ex-
11 porter will export the drug is Canada.

12 “(6) During any period in which the drug was
13 not in the control of the manufacturer of the drug,
14 the drug did not enter any country that is not a per-
15 mitted country.

16 “(7) The exporter or importer retains a sample
17 of each lot of the drug sufficient for testing by the
18 Secretary.

19 “(d) INSPECTION OF FACILITIES; MARKING OF SHIP-
20 MENTS.—

21 “(1) INSPECTION OF FACILITIES.—A registra-
22 tion condition is that, for the purpose of assisting
23 the Secretary in determining whether the exporter
24 involved is in compliance with all other registration
25 conditions—

1 “(A) the exporter agrees to permit the Sec-
2 retary—

3 “(i) to conduct onsite inspections, in-
4 cluding monitoring on a day-to-day basis,
5 of places of business of the exporter that
6 relate to qualifying drugs, including each
7 warehouse or other facility owned or con-
8 trolled by, or operated for, the exporter;

9 “(ii) to have access, including on a
10 day-to-day basis, to—

11 “(I) records of the exporter that
12 relate to the export of such drugs, in-
13 cluding financial records; and

14 “(II) samples of such drugs;

15 “(iii) to carry out the duties described
16 in paragraph (3); and

17 “(iv) to carry out any other functions
18 determined by the Secretary to be nec-
19 essary regarding the compliance of the ex-
20 porter; and

21 “(B) the Secretary has assigned 1 or more
22 employees of the Secretary to carry out the
23 functions described in this subsection for the
24 Secretary not less than every 3 weeks on the
25 premises of places of businesses referred to in

1 subparagraph (A)(i), and such an assignment
2 remains in effect on a continuous basis.

3 “(2) MARKING OF COMPLIANT SHIPMENTS.—A
4 registration condition is that the exporter involved
5 agrees to affix to each shipping container of quali-
6 fying drugs exported under subsection (a) such
7 markings as the Secretary determines to be nec-
8 essary to identify the shipment as being in compli-
9 ance with all registration conditions. Markings under
10 the preceding sentence—

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

14 “(B) may include anti-counterfeiting or
15 track-and-trace technologies.

16 “(3) CERTAIN DUTIES RELATING TO EXPORT-
17 ERS.—Duties of the Secretary with respect to an ex-
18 porter include the following:

19 “(A) Verifying the chain of custody of a
20 statistically significant sample of qualifying
21 drugs from the establishment in which the drug
22 was manufactured to the exporter, which may
23 be accomplished by the use of anticounterfeiting
24 or track-and-trace technologies, if available.

1 “(B) Randomly reviewing records of ex-
2 ports to individuals for the purpose of deter-
3 mining whether the drugs are being imported
4 by the individuals in accordance with the condi-
5 tions under subsection (i). Such reviews shall be
6 conducted in a manner that will result in a sta-
7 tistically significant determination of compli-
8 ance with all such conditions.

9 “(C) Monitoring the affixing of markings
10 under paragraph (2).

11 “(D) Inspect as the Secretary determines
12 is necessary the warehouses and other facilities
13 of other parties in the chain of custody of quali-
14 fying drugs.

15 “(E) Determine whether the exporter is in
16 compliance with all other registration condi-
17 tions.

18 “(4) CERTAIN DUTIES RELATING TO IMPORT-
19 ERS.—Duties of the Secretary with respect to an im-
20 porter include the following:

21 “(A) As authorized under section 704, in-
22 spect not less than every 3 weeks, the places of
23 business of the importer that relate to the re-
24 ceipt and distribution of a qualifying drug, in-
25 cluding each warehouse or other facility owned

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

4 “(B) During the inspections under sub-
5 paragraph (A), verify the chain of custody of a
6 statistically significant sample of qualifying
7 drugs from the establishment in which the drug
8 was manufactured to the importer, which may
9 be accomplished by the use of anticounterfeiting
10 or track-and-trace technologies, if available.

11 “(C) Inspect as the Secretary determines
12 is necessary the warehouses and other facilities
13 of other parties in the chain of custody of quali-
14 fying drugs.

15 “(D) Determine whether the importer is in
16 compliance with all other registration condi-
17 tions.

18 “(e) IMPORTER FEES.—

19 “(1) REGISTRATION FEE.—A registration con-
20 dition is that the importer involved pays to the Sec-
21 retary a fee of \$10,000 due on the date on which
22 the importer first submits the registration to the
23 Secretary under subsection (b).

24 “(2) INSPECTION FEE.—A registration condi-
25 tion is that the importer involved pays to the Sec-

1 retary in accordance with this subsection a fee on a
2 semiannual basis, with the first fee due on the date
3 that is 6 months after the date on which the reg-
4 istration of the importer under subsection (b) is first
5 approved by the Secretary.

6 “(3) AMOUNT OF INSPECTION FEE.—

7 “(A) AGGREGATE TOTAL OF FEES.—The
8 Secretary shall ensure that the aggregate total
9 of fees collected under paragraph (2) for a fis-
10 cal year from all importers is sufficient, and no
11 more than necessary, to pay the costs of admin-
12 istering this section with respect to registered
13 importers for a fiscal year, including—

14 “(i) inspection of the facilities of im-
15 porters under subsection (d)(4);

16 “(ii) reviewing qualifying drugs of-
17 fered for import to importers; and

18 “(iii) determining the compliance of
19 importers with registration conditions.

20 “(B) LIMITATION.—The aggregate total of
21 fees collected under paragraph (2) shall not ex-
22 ceed 1 percent of the total price of drugs im-
23 ported annually to the United States by reg-
24 istered importers under this section.

1 “(C) INDIVIDUAL IMPORTER FEE.—Sub-
2 ject to the limitation described in subparagraph
3 (B), a fee under paragraph (2) for an importer
4 shall be an amount that is a reasonable esti-
5 mate by the Secretary of the semiannual share
6 of the importer of the volume of drugs imported
7 by importers under this section.

8 “(D) ADJUSTMENT OF FEE.—The Sec-
9 retary shall annually adjust the fees under
10 paragraph (2) to ensure that the fees accurately
11 reflect the actual costs referred to in subpara-
12 graph (A) and do not exceed, in the aggregate,
13 1 percent of the total price of drugs imported
14 annually to the United States under this sec-
15 tion.

16 “(4) USE OF FEES.—Subject to appropriations
17 Acts, fees collected by the Secretary under para-
18 graphs (1) and (2) are available only to the Sec-
19 retary and are for the sole purpose of paying the
20 costs referred to in paragraph (3)(A).

21 “(f) EXPORTER FEES.—

22 “(1) REGISTRATION FEE.—A registration con-
23 dition is that the exporter involved pays to the Sec-
24 retary a fee of \$10,000 due on the date on which

1 the exporter first submits that registration to the
2 Secretary under subsection (b).

3 “(2) INSPECTION FEE.—A registration condi-
4 tion is that the exporter involved pays to the Sec-
5 retary in accordance with this subsection a fee on a
6 semiannual basis, with the first fee due on the date
7 that is 6 months after the date on which the reg-
8 istration of the exporter under subsection (b) is first
9 approved by the Secretary.

10 “(3) AMOUNT OF INSPECTION FEE.—

11 “(A) AGGREGATE TOTAL OF FEES.—The
12 Secretary shall ensure that the aggregate total
13 of fees collected under paragraph (2) for a fis-
14 cal year from all exporters is sufficient, and not
15 more than necessary, to pay the costs of admin-
16 istering this section with respect to registered
17 exporters for a fiscal year, including—

18 “(i) monitoring foreign facilities under
19 subsection (d);

20 “(ii) developing, implementing, and
21 maintaining under such subsection a sys-
22 tem to mark shipments to indicate compli-
23 ance with all registration conditions; and

24 “(iii) conducting under such sub-
25 section inspections within the United

1 States to determine compliance with condi-
2 tions under subsections (h) and (i).

3 “(B) LIMITATION.—The aggregate total of
4 fees collected under paragraph (2) shall not ex-
5 ceed 1 percent of the total price of drugs im-
6 ported annually to the United States by reg-
7 istered exporters under this section.

8 “(C) INDIVIDUAL EXPORTER FEE.—Sub-
9 ject to the limitation described in subparagraph
10 (B), a fee under paragraph (2) for an exporter
11 shall be an amount that is a reasonable esti-
12 mate by the Secretary of the semiannual share
13 of the exporter of the volume of drugs exported
14 by exporters under this section.

15 “(D) ADJUSTMENT OF FEE.—The Sec-
16 retary shall annually adjust the fees under
17 paragraph (2) to ensure that the fees accurately
18 reflect the actual costs referred to in subpara-
19 graph (A) and do not exceed, in the aggregate,
20 1 percent of the total price of drugs imported
21 annually to the United States under this sec-
22 tion.

23 “(4) USE OF FEES.—Subject to appropriations
24 Acts, fees collected by the Secretary under para-
25 graphs (1) and (2) are only available to the Sec-

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

3 “(g) COMPLIANCE WITH SECTION 801(a).—

4 “(1) IN GENERAL.—A registration condition is
5 that each qualifying drug exported under subsection
6 (a) by the registered exporter involved or imported
7 under subsection (a) by the registered importer in-
8 volved is in compliance with the standards referred
9 to in section 801(a) regarding admission of the drug
10 into the United States, subject to paragraphs (2),
11 (3), and (4).

12 “(2) SECTION 505; APPROVAL STATUS.—

13 “(A) IN GENERAL.—For purposes of ad-
14 ministrative and judicial procedure, there is a
15 presumption that a drug proposed for export or
16 import under subsection (a) is an approved
17 drug under section 505(b) if the following cri-
18 teria are met:

19 “(i) The drug proposed for export or
20 import is in compliance with subsection
21 (c).

22 “(ii) The drug proposed for export or
23 import has the same active ingredient or
24 ingredients, route of administration, dos-
25 age form, and strength, according to infor-

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

5 “(I) is manufactured by or for
6 the person that manufactures the
7 drug proposed for export or import;
8 and

9 “(II) is approved under section
10 505(b).

11 “(B) IMPORTATION.—Subject to subpara-
12 graphs (D) and (E), a drug meeting the criteria
13 described in subparagraph (A) may, in accord-
14 ance with the other subsections of this section,
15 be imported into the United States.

16 “(C) NOTICE BY MANUFACTURER; GEN-
17 ERAL PROVISIONS.—

18 “(i) IN GENERAL.—The person that
19 manufactures a drug that may be imported
20 under subsection (a) shall in accordance
21 with this paragraph submit to the Sec-
22 retary a notice that—

23 “(I) includes each difference in
24 the drug from a condition established
25 in the approved application for the

1 U.S. label drug beyond the variations
2 provided for in the application, any
3 difference in labeling, the date on
4 which the drug with such difference
5 was, or will be, introduced for com-
6 mercial distribution in a permitted
7 country, and such additional informa-
8 tion as the Secretary may require; or

9 “(II) states that there is no dif-
10 ference in the drug from a condition
11 established in the approved applica-
12 tion for the U.S. label drug beyond
13 the variations provided for in the ap-
14 plication and differences in labeling.

15 “(ii) INFORMATION REGARDING FOR-
16 EIGN GOVERNMENT.—A notice under
17 clause (i)(I) shall with respect to the per-
18 mitted country that approved the drug for
19 commercial distribution, or with respect to
20 which such approval is sought, include the
21 following:

22 “(I) Information demonstrating
23 that the person submitting the notice
24 has also notified the government of
25 the permitted country in writing that

1 the person is submitting to the Sec-
2 retary a notice under clause (i)(I),
3 which notice describes the difference
4 in the drug from a condition estab-
5 lished in the approved application for
6 the U.S. label drug.

7 “(II) The information that the
8 person submitted or will submit to the
9 government of the permitted country
10 for purposes of obtaining approval for
11 commercial distribution of the drug in
12 the country which, if in a language
13 other than English, shall be accom-
14 panied by an English translation
15 verified to be complete and accurate,
16 with the name, address, and a brief
17 statement of the qualifications of the
18 person that made the translation.

19 “(iii) CERTIFICATIONS.—The chief ex-
20 ecutive officer and the chief medical officer
21 of the manufacturer involved shall each
22 certify in the notice under clause (i) that—

23 “(I) the information provided in
24 the notice is complete and true; and

1 “(II) a copy of the notice has
2 been provided to the Federal Trade
3 Commission and to the Assistant At-
4 torney General in charge of the Anti-
5 trust Division of the Department of
6 Justice (referred to in this subsection
7 as the ‘Assistant Attorney General’).

8 “(iv) FEE.—If a notice submitted
9 under clause (i) includes a difference that
10 would, under section 506A, require the
11 submission of a supplemental application if
12 made as a change to the U.S. label drug,
13 the person that submits the notice shall
14 pay to the Secretary a fee in the same
15 amount as would apply if the person were
16 paying a fee pursuant to section
17 736(a)(1)(A)(ii). Subject to appropriations
18 Acts, fees collected by the Secretary under
19 the preceding sentence are available only to
20 the Secretary and are for the sole purpose
21 of paying the costs of reviewing notices
22 submitted under clause (i).

23 “(v) TIMING OF SUBMISSION OF NO-
24 TICES.—

1 “(I) PRIOR APPROVAL NO-
2 TICES.—A notice under clause (i) to
3 which subparagraph (D) applies shall
4 be submitted to the Secretary not
5 later than 120 days before the drug
6 with the difference is introduced for
7 commercial distribution in a permitted
8 country, unless the country requires
9 that distribution of the drug with the
10 difference begin less than 120 days
11 after the country requires the dif-
12 ference.

13 “(II) OTHER APPROVAL NO-
14 TICES.—A notice under clause (i) to
15 which subparagraph (E) applies shall
16 be submitted to the Secretary not
17 later than the day on which the drug
18 with the difference is introduced for
19 commercial distribution in a permitted
20 country.

21 “(III) OTHER NOTICES.—A no-
22 tice under clause (i) to which subpara-
23 graph (F) applies shall be submitted
24 to the Secretary on the date that the
25 drug is first introduced for commer-

1 cial distribution in a permitted coun-
2 try and annually thereafter.

3 “(vi) REVIEW BY SECRETARY.—

4 “(I) IN GENERAL.—In this para-
5 graph, the difference in a drug that
6 may be imported under subsection (a)
7 from the U.S. label drug shall be
8 treated by the Secretary as if it was
9 a manufacturing change to the U.S.
10 label drug under section 506A.

11 “(II) REVIEW BY THE SEC-
12 RETARY.—The Secretary shall review
13 and approve or disapprove the dif-
14 ference in a notice submitted under
15 clause (i), if required under section
16 506A, not later than 120 days after
17 the date on which the notice is sub-
18 mitted.

19 “(III) ESTABLISHMENT INSPEC-
20 TION.—If review of such difference
21 would require an inspection by the
22 Secretary of the establishment in
23 which the drug is manufactured, such
24 inspection shall be authorized by sec-
25 tion 704.

1 “(vii) PUBLICATION OF INFORMATION
2 ON NOTICES.—

3 “(I) IN GENERAL.—Through the
4 Internet website of the Food and
5 Drug Administration, the Secretary
6 shall readily make available to the
7 public a list of notices submitted
8 under clause (i).

9 “(II) CONTENTS.—The list under
10 subclause (I) shall include the date on
11 which a notice is submitted and
12 whether—

13 “(aa) a notice is under re-
14 view;

15 “(bb) the Secretary has or-
16 dered that importation of the
17 drug from a permitted country
18 cease; or

19 “(cc) the importation of the
20 drug is permitted under sub-
21 section (a).

22 “(III) UPDATE.—The Secretary
23 shall promptly update the Internet
24 website with any changes to the list.

1 “(D) NOTICE; DRUG DIFFERENCE REQUIR-
2 ING PRIOR APPROVAL.—In the case of a notice
3 under subparagraph (C)(i) that includes a dif-
4 ference that would, under section 506A(c) or
5 (d)(3)(B)(i), require the approval of a supple-
6 mental application before the difference could
7 be made to the U.S. label drug the following
8 shall occur:

9 “(i) Promptly after the notice is sub-
10 mitted, the Secretary shall notify reg-
11 istered exporters, registered importers, the
12 Federal Trade Commission, and the As-
13 sistant Attorney General that the notice
14 has been submitted with respect to the
15 drug involved.

16 “(ii) If the Secretary has not made a
17 determination whether a supplemental ap-
18 plication regarding the U.S. label drug
19 would be approved or disapproved by the
20 date on which the drug involved is to be in-
21 troduced for commercial distribution in a
22 permitted country, the Secretary shall—

23 “(I) order that the importation of
24 the drug involved from the permitted
25 country cease for the period in which

1 the Secretary completes review of the
2 notice; and

3 “(II) promptly notify registered
4 exporters, registered importers, the
5 Federal Trade Commission, and the
6 Attorney General of the order.

7 “(iii) If the Secretary determines that
8 such a supplemental application regarding
9 the U.S. label drug would not be approved,
10 the Secretary shall—

11 “(I) order that the importation of
12 the drug involved from the permitted
13 country cease, or provide that an
14 order under clause (ii), if any, re-
15 mains in effect;

16 “(II) notify the permitted coun-
17 try that approved the drug for com-
18 mercial distribution of the determina-
19 tion; and

20 “(III) promptly notify registered
21 exporters, registered importers, the
22 Federal Trade Commission, and the
23 Assistant Attorney General of the de-
24 termination.

1 “(iv) If the Secretary determines that
2 such a supplemental application regarding
3 the U.S. label drug would be approved, the
4 Secretary shall vacate the order under
5 clause (ii), if any, permit importation of
6 the drug under subsection (a), and
7 promptly notify registered exporters, reg-
8 istered importers, the Federal Trade Com-
9 mission, and the Assistant Attorney Gen-
10 eral of the determination.

11 “(E) NOTICE; DRUG DIFFERENCE NOT RE-
12 QUIRING PRIOR APPROVAL.—In the case of a
13 notice under subparagraph (C)(i) that includes
14 a difference that would, under section
15 506A(d)(3)(B)(ii), not require the approval of a
16 supplemental application before the difference
17 could be made to the U.S. label drug the fol-
18 lowing shall occur:

19 “(i) During the period in which the
20 notice is being reviewed by the Secretary,
21 the authority under this subsection to im-
22 port the drug involved continues in effect.

23 “(ii) If the Secretary determines that
24 such a supplemental application regarding
25 the U.S. label drug would not be approved,

1 the Secretary shall order that the importa-
2 tion of the drug involved from the per-
3 mitted country cease, shall notify the per-
4 mitted country that approved the drug for
5 commercial distribution of the determina-
6 tion, and shall promptly notify registered
7 exporters, registered importers, the Fed-
8 eral Trade Commission, and the Assistant
9 Attorney General of the determination.

10 “(F) NOTICE; DRUG DIFFERENCE NOT RE-
11 QUIRING APPROVAL; NO DIFFERENCE.—In the
12 case of a notice under subparagraph (C)(i) that
13 includes a difference for which, under section
14 506A(d)(1)(A), a supplemental application
15 would not be required for the difference to be
16 made to the U.S. label drug, or that states that
17 there is no difference, the Secretary—

18 “(i) may not order that the importa-
19 tion of the drug involved cease; and

20 “(ii) shall promptly notify registered
21 exporters and registered importers.

22 “(G) DIFFERENCES IN ACTIVE INGRE-
23 DIENT, ROUTE OF ADMINISTRATION, DOSAGE
24 FORM, OR STRENGTH.—

1 “(i) IN GENERAL.—A person who
2 manufactures a U.S. label drug shall sub-
3 mit an application under section 505(b) for
4 a drug that is manufactured for distribu-
5 tion in a permitted country by or for the
6 person that manufactures the U.S. label
7 drug if—

8 “(I) there is no drug for export
9 from at least half of the permitted
10 countries with the same active ingre-
11 dient or ingredients, route of adminis-
12 tration, dosage form, and strength as
13 the U.S. label drug; and

14 “(II) each active ingredient of
15 the drug is related to an active ingre-
16 dient of the U.S. label drug, as de-
17 fined in clause (v).

18 “(ii) APPLICATION UNDER SECTION
19 505(b).—The application under section
20 505(b) required under clause (i) shall—

21 “(I) request approval of the drug
22 for the indication or indications for
23 which the U.S. label drug is approved
24 under section 505;

1 “(II) include the information that
2 the person submitted to the govern-
3 ment of the permitted country for
4 purposes of obtaining approval for
5 commercial distribution of the drug in
6 that country, which if in a language
7 other than English, shall be accom-
8 panied by an English translation
9 verified to be complete and accurate,
10 with the name, address, and a brief
11 statement of the qualifications of the
12 person that made the translation;

13 “(III) include a right of reference
14 to the application under section
15 505(b) for the U.S. label drug; and

16 “(IV) include such additional in-
17 formation as the Secretary may re-
18 quire.

19 “(iii) TIMING OF SUBMISSION OF AP-
20 PLICATION.—An application under section
21 505(b) required under clause (i) shall be
22 submitted to the Secretary not later than
23 the day on which the information referred
24 to in clause (ii)(II) is submitted to the gov-
25 ernment of the permitted country.

1 “(iv) NOTICE OF DECISION ON APPLI-
2 CATION.—The Secretary shall promptly no-
3 tify registered exporters, registered import-
4 ers, the Federal Trade Commission, and
5 the Assistant Attorney General of a deter-
6 mination to approve or to disapprove an
7 application under section 505(b) required
8 under clause (i).

9 “(v) RELATED ACTIVE INGREDI-
10 ENTS.—For purposes of clause (i)(II), 2
11 active ingredients are related if they are—

12 “(I) the same; or

13 “(II) different salts, esters, or
14 complexes of the same moiety.

15 “(3) SECTION 502; LABELING.—

16 “(A) IMPORTATION BY REGISTERED IM-
17 PORTER.—

18 “(i) IN GENERAL.—In the case of a
19 qualifying drug that is imported or offered
20 for import by a registered importer, such
21 drug shall be considered to be in compli-
22 ance with section 502 if the drug bears—

23 “(I) a copy of the labeling ap-
24 proved for the drug under section

1 505, without regard to whether the
2 copy bears the trademark involved;

3 “(II) the name of the manufac-
4 turer and location of the manufac-
5 turer;

6 “(III) the lot number assigned by
7 the manufacturer; and

8 “(IV) the name, location, and
9 registration number of the importer.

10 “(ii) REQUEST FOR COPY OF THE LA-
11 BELING.—The Secretary shall provide such
12 copy to the registered importer involved,
13 upon request of the importer.

14 “(B) IMPORTATION BY INDIVIDUAL.—In
15 the case of a qualifying drug that is imported
16 or offered for import by a registered exporter to
17 an individual, such drug shall be considered to
18 be in compliance with section 502 if the drug
19 bears a label providing the directions for use by
20 the consumer, and bears a copy of any special
21 labeling that would be required by the Secretary
22 had the drug been dispensed by a pharmacist in
23 the United States, without regard to whether
24 the special labeling bears the trademark in-
25 volved. The Secretary shall provide to the reg-

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

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

5 “(A) IN GENERAL.—For purposes of ad-
6 ministrative and judicial procedure, there is a
7 presumption that a drug proposed for export or
8 import under subsection (a) is in compliance
9 with section 501 if the drug is in compliance
10 with subsection (c).

11 “(B) STANDARDS FOR REFUSING ADMIS-
12 SION.—A qualifying drug exported under sub-
13 section (a) from a registered exporter or im-
14 ported by a registered importer may be refused
15 admission into the United States if 1 or more
16 of the following applies:

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

20 “(ii) The Secretary becomes aware
21 that—

22 “(I) the drug may be counterfeit;

23 “(II) the drug may have been
24 prepared, packed, or held under in-
25 sanitary conditions; or

1 “(III) the methods used in, or
2 the facilities or controls used for, the
3 manufacturing, processing, packing,
4 or holding of the drug do not conform
5 to good manufacturing practice.

6 “(iii) The Secretary has obtained an
7 injunction under section 302 that prohibits
8 the distribution of the drug in interstate
9 commerce.

10 “(iv) The Secretary has under section
11 505(e) withdrawn approval of the drug.

12 “(v) The manufacturer of the drug
13 has instituted a recall of the drug.

14 “(vi) If the qualifying drug is ex-
15 ported from a registered exporter to an in-
16 dividual and 1 or more of the following ap-
17 plies:

18 “(I) The shipping container for
19 such drug does not bear the markings
20 required under subsection (d)(2).

21 “(II) The markings on the ship-
22 ping container appear to be counter-
23 feit.

1 “(III) The shipping container or
2 markings appear to have been tam-
3 pered with.

4 “(h) LICENSING AS PHARMACIST.—A registration
5 condition is that the exporter involved agrees that a quali-
6 fying drug will be exported to an individual only if the
7 Secretary has verified that—

8 “(1) the exporter is authorized under Canadian
9 law to dispense prescription drugs; and

10 “(2) the exporter employs persons that are li-
11 censed under Canadian law to dispense prescription
12 drugs in sufficient number to dispense safely the
13 qualifying drugs exported by the exporter to individ-
14 uals, and the exporter assigns to those persons re-
15 sponsibility for dispensing such qualifying drugs to
16 individuals.

17 “(i) INDIVIDUALS; CONDITIONS FOR IMPORTATION
18 FROM CANADA.—

19 “(1) IN GENERAL.—For purposes of subsection
20 (a)(2)(B), the importation of a qualifying drug by
21 an individual is in accordance with this subsection if
22 the following conditions are met:

23 “(A) The drug is accompanied by a copy of
24 a prescription for the drug, which prescrip-
25 tion—

1 “(i) is valid under applicable Federal
2 and State laws; and

3 “(ii) was issued by a practitioner who,
4 under the law of a State of which the indi-
5 vidual is a resident, or in which the indi-
6 vidual receives care from the practitioner
7 who issues the prescription, is authorized
8 to administer prescription drugs.

9 “(B) The drug is accompanied by a copy
10 of the documentation that was required under
11 the law or regulations of Canada as a condition
12 of dispensing the drug to the individual.

13 “(C) The copies referred to in subpara-
14 graphs (A)(i) and (B) are marked in a manner
15 sufficient—

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

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

21 “(D) The individual has provided to the
22 registered exporter a complete list of all drugs
23 used by the individual for review by the individ-
24 uals who dispense the drug.

1 “(E) The quantity of the drug does not ex-
2 ceed a 90-day supply.

3 “(F) The drug is not an ineligible subpart
4 H drug. For purposes of this section, a pre-
5 scription drug is an ‘ineligible subpart H drug’
6 if the drug was approved by the Secretary
7 under subpart H of part 314 of title 21, Code
8 of Federal Regulations (relating to accelerated
9 approval), with restrictions under section 520 of
10 such part to assure safe use, and the Secretary
11 has published in the Federal Register a notice
12 that the Secretary has determined that good
13 cause exists to prohibit the drug from being im-
14 ported pursuant to this subsection.

15 “(2) NOTICE REGARDING DRUG REFUSED AD-
16 MISSION.—If a registered exporter ships a drug to
17 an individual pursuant to subsection (a)(2)(B) and
18 the drug is refused admission to the United States,
19 a written notice shall be sent to the individual and
20 to the exporter that informs the individual and the
21 exporter of such refusal and the reason for the re-
22 fusal.

23 “(j) MAINTENANCE OF RECORDS AND SAMPLES.—A
24 registration condition is that the importer or exporter in-
25 volved shall—

1 “(1) maintain records required under this sec-
2 tion for not less than 2 years; and

3 “(2) maintain samples of each lot of a drug re-
4 quired under this section for not less than 2 years.

5 “(k) DRUG RECALLS.—

6 “(1) MANUFACTURERS.—A person that manu-
7 factures a prescription drug imported from a per-
8 mitted country under this section shall promptly in-
9 form the Secretary—

10 “(A) if the drug is recalled or withdrawn
11 from the market in a permitted country;

12 “(B) how the drug may be identified, in-
13 cluding lot number; and

14 “(C) the reason for the recall or with-
15 drawal.

16 “(2) SECRETARY.—With respect to each per-
17 mitted country, the Secretary shall—

18 “(A) enter into an agreement with the gov-
19 ernment of the country to receive information
20 about recalls and withdrawals of prescription
21 drugs in the country; or

22 “(B) monitor recalls and withdrawals of
23 prescription drugs in the country using any in-
24 formation that is available to the public in any
25 media.

1 “(3) NOTICE.—The Secretary may notify, as
2 appropriate, registered exporters, registered import-
3 ers, wholesalers, pharmacies, or the public of a recall
4 or withdrawal of a prescription drug in a permitted
5 country.”.

6 (b) PROHIBITED ACTS.—The Federal Food, Drug,
7 and Cosmetic Act is amended—

8 (1) in section 301 (21 U.S.C. 331), by striking
9 paragraph (aa) and inserting the following:

10 “(aa)(1) The sale or trade by a pharmacist, or by
11 a business organization of which the pharmacist is a part,
12 of a qualifying drug that under section 804(a)(2)(A) was
13 imported by the pharmacist, other than—

14 “(A) a sale at retail made pursuant to dis-
15 pensing the drug to a customer of the pharmacist or
16 organization; or

17 “(B) a sale or trade of the drug to a pharmacy
18 or a wholesaler registered to import drugs under sec-
19 tion 804.

20 “(2) The sale or trade by an individual of a qualifying
21 drug that under section 804(a)(2)(B) was imported by the
22 individual.

23 “(3) The making of a materially false, fictitious, or
24 fraudulent statement or representation, or a material
25 omission, in a notice under clause (i) of section

1 804(g)(2)(C) or in an application required under section
2 804(g)(2)(G), or the failure to submit such a notice or
3 application.

4 “(4) The importation of a drug in violation of a re-
5 quirement under section 804.”; and

6 (2) in section 303(a) (21 U.S.C. 333(a)), by
7 striking paragraph (6) and inserting the following:

8 “(6) Notwithstanding subsection (a), any person that
9 knowingly violates section 301(aa) (3) or (4) shall be im-
10 prisoned not more than 10 years, or fined in accordance
11 with title 18, United States Code, or both.”.

12 (c) IMPLEMENTATION.—

13 (1) RULEMAKING.—

14 (A) IN GENERAL.—

15 (i) PROMULGATION BY SECRETARY.—

16 Not later than 90 days after the date of
17 the enactment of this Act, the Secretary of
18 Health and Human Services shall promul-
19 gate an interim rule for implementing sec-
20 tion 804 of the Federal Food, Drug, and
21 Cosmetic Act, as added by subsection (a)
22 of this section. Such rule shall be devel-
23 oped and promulgated by the Secretary
24 without providing general notice of pro-
25 posed rulemaking. Not later than 1 year

1 after the date on which the interim rule is
2 promulgated, the Secretary shall, in accord-
3 ance with procedures under section 553 of
4 title 5, United States Code, promulgate a
5 final rule for implementing such section
6 804, which may incorporate by reference
7 provisions of the interim rule, to the extent
8 that such provisions are not modified.

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

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

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

18 (III) from Australia, a member
19 country of the European Union as of
20 January 1, 2003, Japan, New Zea-
21 land, or Switzerland by registered im-
22 porters on the date that is 1 year
23 after the date of the enactment of this
24 Act.

1 (B) CERTAIN EXPORTERS.—The interim
2 rule under subparagraph (A) shall provide that,
3 in the review of registrations submitted under
4 subsection (b) of the section 804 referred to in
5 such subparagraph, registrations submitted by
6 entities in Canada that are significant exporters
7 of prescription drugs to individuals in the
8 United States as of the date of the enactment
9 of this Act will have priority during the period
10 in which the interim rule under subparagraph
11 (A) is in effect. During such period, the ref-
12 erence in subsection (b)(2)(A) of such section
13 804 to 90 days (relating to approval or dis-
14 approval of registrations) is, as applied to such
15 entities, deemed to be 30 days.

16 (C) DRUGS FOR IMPORT FROM CANADA.—
17 The notices with respect to drugs to be im-
18 ported from Canada that are required under
19 subsection (g)(2)(C)(i)(I) of such section 804
20 and that require approval under subsection
21 (g)(2)(D) or (E) of such section 804 shall be
22 submitted to the Secretary not later than 30
23 days after the date of enactment of this Act.
24 The notices with respect to drugs to be im-
25 ported from Canada that are required under

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

6 (D) DRUGS FOR IMPORT FROM OTHER
7 COUNTRIES.—The notices with respect to drugs
8 to be imported from Australia, a member coun-
9 try of the European Union as of January 1,
10 2003, Japan, New Zealand, or Switzerland that
11 are required under subsection (g)(2)(C)(i)(I) of
12 such section 804 and that require approval
13 under subsection (g)(2)(D) or (E) of such sec-
14 tion 804 shall be submitted to the Secretary not
15 later than 180 days after the date of enactment
16 of this Act. The notices with respect to drugs
17 to be imported from such countries that are re-
18 quired under subsection (g)(2)(C)(i)(II) of such
19 section 804 and that do not require approval
20 under subsection (g)(2)(D) or (E) of such sec-
21 tion 804 shall be submitted to the Secretary not
22 later than 270 days after the date of enactment
23 of this Act.

24 (2) PERSONAL IMPORTATION FROM CANADA.—

25 Until the expiration of the 60-day period beginning

1 on the date on which the interim rule under para-
2 graph (1)(A) is promulgated, an individual may im-
3 port a prescription drug from Canada for personal
4 use or for the use of a family member of the indi-
5 vidual (rather than for resale), subject to compliance
6 with the following conditions:

7 (A) The drug is not—

8 (i) a controlled substance, as defined
9 in section 102 of the Controlled Sub-
10 stances Act (21 U.S.C. 802);

11 (ii) a biological product, as defined in
12 section 351 of the Public Health Service
13 Act (42 U.S.C. 262);

14 (iii) an infused drug, including a peri-
15 toneal dialysis solution;

16 (iv) an intravenously injected drug;

17 (v) a drug that is inhaled during sur-
18 gery; or

19 (vi) a drug approved by the Secretary
20 under subpart H of part 314 of title 21,
21 Code of Federal Regulations (relating to
22 accelerated approval) with restrictions
23 under section 520 of such part to assure
24 safe use.

1 (B) The drug is dispensed by a person li-
2 censed in Canada to dispense such drugs.

3 (C) The drug is accompanied by a copy of
4 the prescription for the drug, which prescrip-
5 tion—

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

8 (ii) was issued by a practitioner who,
9 under the law of a State of which the indi-
10 vidual is a resident, or in which the indi-
11 vidual receives care from the practitioner
12 who issues the prescription, is authorized
13 to administer prescription drugs.

14 (D) The drug is accompanied by a copy of
15 the document that was required in Canada as
16 a condition of dispensing the drug to the indi-
17 vidual.

18 (E) The copies referred to in subpara-
19 graphs (C) and (D) are marked in a manner
20 sufficient—

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

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

1 (F) The quantity of the drug does not ex-
2 ceed a 90-day supply.

3 (3) FACILITATION OF CANADIAN IMPORTS.—

4 Not less than 15 days after the enactment of this
5 Act and until the expiration of the 60-day period
6 that begins on the date on which the interim rule
7 under paragraph (1)(A) is promulgated, the Sec-
8 retary shall, through the Internet website of the
9 Food and Drug Administration, make readily avail-
10 able to the public a list of persons licensed in Can-
11 ada to dispense prescription drugs who are willing to
12 export drugs under paragraph (2) to individuals in
13 the United States.

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

18 (d) AMENDMENT OF CERTAIN PROVISION.—Section
19 801 of the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 381) is amended by striking subsection (g) and in-
21 serting the following:

22 “(g) With respect to a prescription drug that is im-
23 ported or offered for import into the United States by an
24 individual who is not in the business of such importation,
25 that is not shipped by a registered exporter under section

1 804, and that is refused admission under subsection (a),
 2 the Secretary shall notify the individual that—

3 “(1) the drug has been refused admission be-
 4 cause the drug was not a lawful import under sec-
 5 tion 804;

6 “(2) the drug is not otherwise subject to a
 7 waiver of the requirements of subsection (a);

8 “(3) the individual may under section 804 law-
 9 fully import certain prescription drugs from Cana-
 10 dian exporters registered with the Secretary; and

11 “(4) the individual can find information about
 12 such importation, including a list of registered ex-
 13 porters, on the Internet website of the Food and
 14 Drug Administration.”.

15 (e) ANTICOMPETITIVE PRACTICES RELATING TO IM-
 16 PORTING AND EXPORTING DRUGS TO THE UNITED
 17 STATES.—

18 (1) IN GENERAL.—The Clayton Act (15 U.S.C.
 19 12 et seq.) is amended by adding at the end the fol-
 20 lowing:

21 **“SEC. 27. RESTRAINT OF TRADE REGARDING PRESCRIP-**
 22 **TION DRUGS.**

23 “(a) IN GENERAL.—It shall be unlawful for any per-
 24 son engaged in commerce, directly or indirectly to—

1 “(1) charge a higher price for prescription
2 drugs sold to a registered exporter or other person
3 that exports prescription drugs to the United States
4 under section 804 of the Federal Food, Drug, and
5 Cosmetic Act than the price that is charged to an-
6 other person that is in the same country and that
7 does not export prescription drugs into the United
8 States under section 804 of such Act;

9 “(2) charge a higher price for prescription
10 drugs sold to a registered importer or other person
11 that distributes, sells, or uses prescription drugs im-
12 ported to the United States under section 804 of
13 such Act than the price that is charged to another
14 person in the United States that does not import
15 prescription drugs under section 804 of such Act, or
16 that does not distribute, sell, or use such drugs;

17 “(3) deny supplies of prescription drugs to a
18 registered exporter or other person that exports pre-
19 scription drugs to the United States under section
20 804 of such Act or to a registered importer or other
21 person that distributes, sells, or uses prescription
22 drugs imported to the United States under section
23 804 of such Act;

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

1 son that exports prescription drugs to the United
2 States under section 804 of such Act or with a reg-
3 istered importer or other person that distributes,
4 sells, or uses prescription drugs imported to the
5 United States under section 804 of such Act;

6 “(5) specifically restrict supplies of prescription
7 drugs to a registered exporter or other person that
8 exports prescription drugs to the United States
9 under section 804 of such Act or to a registered im-
10 porter or other person that distributes, sells, or uses
11 prescription drugs imported to the United States
12 under section 804 of such Act;

13 “(6) fail to submit a notice under subsection
14 (g)(2)(C)(i) of section 804 of such Act, fail to sub-
15 mit such a notice on or before the date specified in
16 subsection (g)(2)(C)(v) of section 804 of such Act,
17 submit such a notice that makes a materially false,
18 fictitious, or fraudulent statement, or fail to provide
19 promptly any information requested by the Secretary
20 of Health and Human Services to review such a no-
21 tice;

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

1 tion 804 of such Act, submit such an application
2 that makes a materially false, fictitious, or fraudu-
3 lent statement, or fail to provide promptly any infor-
4 mation requested by the Secretary of Health and
5 Human Services to review such an application;

6 “(8) cause there to be a difference (including a
7 difference in active ingredient, route of administra-
8 tion, dosage form, strength, formulation, manufac-
9 turing establishment, manufacturing process, or per-
10 son that manufactures the drug) between a prescrip-
11 tion drug for distribution in the United States and
12 a prescription drug for distribution in Australia,
13 Canada, a member country of the European Union
14 as of January 1, 2003, Japan, New Zealand, or
15 Switzerland for the purpose of restricting importa-
16 tion of the drug to the United States under section
17 804 of such Act;

18 “(9) refuse to allow an inspection authorized
19 under section 804 of such Act of an establishment
20 that manufactures a prescription drug that is of-
21 fered for import under such section;

22 “(10) fail to conform to the methods used in,
23 or the facilities used for, the manufacturing, proc-
24 essing, packing, or holding of a prescription drug of-

1 ferred for import under section 804 to good manufac-
2 turing practice under such Act; or

3 “(11) engage in any other action that the Fed-
4 eral Trade Commission determines to unfairly re-
5 strict competition under section 804 of such Act.

6 “(b) PRESUMPTION.—A difference (including a dif-
7 ference in active ingredient, route of administration, dos-
8 age form, strength, formulation, manufacturing establish-
9 ment, manufacturing process, or person that manufac-
10 tures the drug) between a prescription drug for distribu-
11 tion in the United States and a prescription drug for dis-
12 tribution in Australia, Canada, a member country of the
13 European Union as of January 1, 2003, Japan, New Zea-
14 land, or Switzerland made after January 1, 2004, shall
15 be presumed to be for the purpose of restricting importa-
16 tion of the drug to the United States under section 804
17 of the Federal Food, Drug, and Cosmetic Act unless—

18 “(1) the person manufacturing the drug for dis-
19 tribution in the United States proves that the dif-
20 ference was required by the country in which the
21 drug is distributed;

22 “(2) the Secretary of Health and Human Serv-
23 ices, acting through the Commissioner of Food and
24 Drug, determines that the difference was necessary
25 to improve the safety or efficacy of the drug; or

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

8 “(c) AFFIRMATIVE DEFENSE.—It shall be an affirm-
9 ative defense to a charge that a person has violated para-
10 graph (1), (2), (3), (4), or (5) of subsection (a) that the
11 higher prices charged for prescription drugs sold to a per-
12 son, the denial of supplies of prescription drugs to a per-
13 son, the refusal to do business with a person, or the spe-
14 cific restriction or delay of supplies to a person is not
15 based, in whole or in part, on—

16 “(1) the person exporting or importing pre-
17 scription drugs to the United States under section
18 804 of the Federal Food, Drug, and Cosmetic Act;
19 or

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

23 “(d) DEFINITIONS.—In this section:

24 “(1) PRESCRIPTION DRUG.—The term ‘pre-
25 scription drug’ means a drug that is described in

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

3 “(2) REGISTERED IMPORTER.—The term ‘reg-
4 istered importer’ has the meaning given such term
5 in section 804 of the Federal Food, Drug, and Cos-
6 metic Act.

7 “(3) REGISTERED EXPORTER.—The term ‘reg-
8 istered exporter’ has the same meaning as in section
9 804 of the Federal Food, Drug, and Cosmetic Act.”.

10 (2) APPLICABILITY OF AMENDMENTS TO IM-
11 PORTATION UNDER THE PHARMACEUTICAL MARKET
12 ACCESS AND FAIR TRADE ACT OF 2004.—

13 (A) PERSONAL IMPORTATION FROM CAN-
14 ADA.—Paragraphs (1) through (5) and (11) of
15 subsection (a) of section 27 of the Clayton Act
16 (15 U.S.C. et seq.) (as amended by paragraph
17 (1)) shall apply with respect to the importation
18 of drugs from Canada under subsection (c)(2).

19 (B) NOTICES RESPECTING DRUG FOR IM-
20 PORT.—Paragraph (6) of subsection (a) of sec-
21 tion 27 of the Clayton Act (15 U.S.C. et seq.)
22 (as amended by paragraph (1)) shall apply with
23 respect to notices required under section
24 804(g)(2)(C)(i) of the Federal Food Drug and
25 Cosmetic Act (21 U.S.C. 384(g)(2)(C)(i)) that

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

3 (f) EXHAUSTION.—

4 (1) IN GENERAL.—Section 271 of title 35,
5 United States Code, is amended—

6 (A) by redesignating subsections (h) and
7 (i) as (i) and (j), respectively; and

8 (B) by inserting after subsection (g) the
9 following:

10 “(h) It shall not be an act of infringement to use,
11 offer to sell, or sell within the United States or to import
12 into the United States any patented invention under sec-
13 tion 804 of the Federal Food, Drug, and Cosmetic Act
14 that was first sold abroad by or under authority of the
15 owner or licensee of such patent.”.

16 (2) RULE OF CONSTRUCTION.—Nothing in the
17 amendment made by paragraph (1) shall be con-
18 strued to affect the ability of a patent owner or li-
19 censee to enforce their patent, subject to such
20 amendment.

1 **SEC. 104. ADDITIONAL WAIVERS REGARDING PERSONAL**
2 **IMPORTATION; ENFORCEMENT POLICIES OF**
3 **SECRETARY.**

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

7 “(p)(1) Waivers under this subsection are in addition
8 to, and independent of, the waiver pursuant to section
9 804(a)(2)(B).

10 “(2) With respect to the standards referred to in sub-
11 section (d)(1), the Secretary shall establish by regulation
12 a waiver of such standards in the case of the importation
13 by an individual of a drug into the United States in the
14 following circumstances:

15 “(A) The drug was dispensed to the individual
16 while the individual was in the United States, the
17 drug was dispensed by a pharmacist or by a practi-
18 tioner licensed by law to administer the drug, and
19 the individual traveled from the United States with
20 the drug.

21 “(B) The individual is entering the United
22 States and the drug accompanies the individual at
23 the time of entry.

24 “(C) The drug does not appear to the Secretary
25 to be adulterated.

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

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

6 “(F) Such additional standards as the Sec-
7 retary determines to be appropriate to protect the
8 public health.

9 “(3) With respect to the standards referred to in sub-
10 sections (a) and (d)(1), the Secretary shall establish by
11 regulation a waiver of such standards in the case of the
12 importation by an individual of a drug into the United
13 States in the following circumstances:

14 “(A) The drug was dispensed to the individual
15 while the individual was in a foreign country, and
16 the drug was dispensed in accordance with the laws
17 and regulations of such country.

18 “(B) The individual is entering the United
19 States and the drug accompanies the individual at
20 the time of entry.

21 “(C) The drug is approved for commercial dis-
22 tribution in the foreign country in which the drug
23 was obtained.

24 “(D) The drug does not appear to the Secretary
25 to be adulterated.

1 “(E) The quantity of the drug does not ex-
2 ceed—

3 “(i) a 90-day supply if the drug is dis-
4 pensed in Australia, Canada, a member country
5 of the European Union as of January 1, 2003,
6 Japan, New Zealand, or Switzerland; or

7 “(ii) a 14-day supply otherwise.

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

11 “(G) Such additional standards as the Sec-
12 retary determines to be appropriate to protect the
13 public health.

14 “(q) The Secretary may not administer any enforce-
15 ment policy that has the effect of permitting the importa-
16 tion of a prescription drug into the United States in viola-
17 tion of this Act or section 351 of the Public Health Service
18 Act.”.

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

1 not meet such standards, provided that such waiver is no
2 more permissive than the guidance, as in effect on Janu-
3 ary 1, 2004, that is provided in the item numbered 2 (re-
4 lating to a specific situation, consisting of conditions (a)
5 through (d)) under the heading “Drugs, Biologics, and
6 Devices” in chapter 9 of the FDA/ORA Regulatory Proce-
7 dures Manual (relating to import operations/actions), in
8 the subchapter relating to coverage of personal importa-
9 tions.

10 **SEC. 105. DISPOSITION OF CERTAIN DRUGS DENIED ADMIS-**
11 **SION INTO UNITED STATES.**

12 (a) IN GENERAL.—Chapter VIII of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.),
14 as amended by section 102, is further amended by adding
15 at the end the following section:

16 **“SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED AD-**
17 **MISSION.**

18 “(a) IN GENERAL.—The Secretary of Homeland Se-
19 curity shall refuse admission to a shipment of drugs that
20 is imported or offered for import into the United States
21 if the shipment has a declared value of less than \$10,000
22 and the drugs are in violation of any standard referred
23 to in section 801(a) or 801(d)(1), including any drugs im-
24 ported or offered for import under enforcement policies
25 prohibited under section 801(q).

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

7 “(c) DESTRUCTION OF VIOLATIVE SHIPMENTS.—
8 Drugs refused admission under subsection (a) or (b) shall
9 be destroyed, subject to subsection (e). Section 801(b)
10 does not authorize the delivery of the drugs pursuant to
11 the execution of a bond, and the drugs may not be ex-
12 ported.

13 “(d) CERTAIN PROCEDURES.—

14 “(1) IN GENERAL.—The refusal of admission
15 and destruction of drugs under this section may be
16 carried out without notice to the importer, owner, or
17 consignee of the drugs except as required by section
18 801(g) or section 804(i)(2). The issuance of receipts
19 for the drugs, and recordkeeping activities regarding
20 the drugs, may be carried out on a summary basis.

21 “(2) OBJECTIVE OF PROCEDURES.—Procedures
22 promulgated under paragraph (1) shall be designed
23 toward the objective of ensuring that, with respect to
24 efficiently utilizing Federal resources available for
25 carrying out this section, a substantial majority of

1 shipments of drugs subject to subsection (a) or (b)
2 are identified and refused admission and destroyed.

3 “(e) EVIDENCE EXCEPTION.—Drugs may not be de-
4 stroyed under subsection (c) to the extent that the Attor-
5 ney General of the United States determines that the
6 drugs should be preserved as evidence or potential evi-
7 dence with respect to an offense against the United States.

8 “(f) RULE OF CONSTRUCTION.—This section may
9 not be construed as having any legal effect on applicable
10 law with respect to a shipment of drugs that is imported
11 or offered for import into the United States and has a
12 declared value equal to or greater than \$10,000.”.

13 (b) PROCEDURES.—Procedures for carrying out sec-
14 tion 805 of the Federal Food, Drug, and Cosmetic Act,
15 as added by subsection (a), shall be established not later
16 than 90 days after the date of the enactment of this Act.

17 **SEC. 106. CIVIL ACTIONS REGARDING PROPERTY.**

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

21 “(g)(1) If a person is alienating or disposing of prop-
22 erty, or intends to alienate or dispose of property, that
23 is obtained as a result of or is traceable to a drug imported
24 in violation of section 801(a) or 801(d), the Attorney Gen-
25 eral may commence a civil action in any Federal court—

1 (C) by striking subparagraph (B) and in-
2 serting the following:

3 “(B) The fact that a drug subject to subsection (b)
4 is exported from the United States does not with respect
5 to such drug exempt any person that is engaged in the
6 business of the wholesale distribution of the drug from
7 providing the statement described in subparagraph (A) to
8 the person that receives the drug pursuant to the export
9 of the drug.

10 “(C)(i) The Secretary may by regulation establish re-
11 quirements that supersede subparagraph (A) (referred to
12 in this subparagraph as ‘alternative requirements’) to
13 identify the chain of custody of a drug subject to sub-
14 section (b) from the manufacturer of the drug throughout
15 the wholesale distribution of the drug to a pharmacist who
16 intends to sell the drug at retail if the Secretary deter-
17 mines that the alternative requirements, which may in-
18 clude anti-counterfeiting or track-and-trace technologies,
19 will identify such chain of custody or the identity of the
20 drug with equal certainty to the requirements of subpara-
21 graph (A), and that the alternative requirements are eco-
22 nomically and technically feasible.

23 “(ii) If the Secretary promulgates a final rule to es-
24 tablish such alternative requirements, the final rule in ad-
25 dition shall, with respect to the registration condition es-

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

4 (2) in paragraph (2)(A), by adding at the end
5 the following: “The preceding sentence may not be
6 construed as having any applicability with respect to
7 a registered exporter under section 804.”; and

8 (3) in paragraph (3), by striking “and sub-
9 section (d)—” in the matter preceding subparagraph
10 (A) and all that follows through “the term ‘whole-
11 sale distribution’ means” in subparagraph (B) and
12 inserting the following: “and subsection (d), the
13 term ‘wholesale distribution’ means”.

14 (b) CONFORMING AMENDMENT.—Section 503(d) of
15 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 353(d)) is amended by adding at the end the following:

17 “(4) Each manufacturer of a drug subject to sub-
18 section (b) shall maintain at its corporate offices a current
19 list of the authorized distributors of record of such drug.

20 “(5) For purposes of this subsection, the term ‘au-
21 thorized distributors of record’ means those distributors
22 with whom a manufacturer has established an ongoing re-
23 lationship to distribute such manufacturer’s products.”.

1 **SEC. 108. REPEAL OF IMPORTATION EXEMPTION UNDER**
2 **CONTROLLED SUBSTANCES IMPORT AND EX-**
3 **PORT ACT.**

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

6 **SEC. 109. EFFECT ON ADMINISTRATION PRACTICES.**

7 Notwithstanding any provision of this Act (and the
8 amendments made by this Act), nothing in this Act (or
9 the amendments made by this Act) shall be construed to
10 change, limit, or restrict the practices of the Food and
11 Drug Administration or the Bureau of Customs and Bor-
12 der Protection in effect on January 1, 2004, with respect
13 to the importation of prescription drugs into the United
14 States by an individual, on the person of such individual,
15 for personal use.

16 **Subtitle B—Ensuring Drug Safety**

17 **SEC. 121. DRUG SAFETY.**

18 (a) IN GENERAL.—Chapter V of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
20 ed by inserting after section 506C the following:

21 **“SEC. 507. DRUG SAFETY.**

22 **“(a) PHASE IV STUDIES.—**

23 **“(1) IN GENERAL.—**The Secretary may require
24 that the sponsor of a drug that is approved or li-
25 censed under section 505(c) or under section 351 of
26 the Public Health Service Act conduct one or more

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

7 “(A) the MedWatch post-market surveil-
8 lance system;

9 “(B) a clinical or epidemiological study; or

10 “(C) the scientific literature.

11 “(b) SUPPLEMENTS.—The sponsor of a drug that is
12 approved or licensed under section 505(c) or under section
13 351 of the Public Health Service Act shall promptly sub-
14 mit the results of a study required under subsection (a)
15 as a supplement to the application for the drug.

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

21 “(1) a notice in the Federal Register; and

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

25 “(d) CIVIL PENALTIES.—

1 “(1) IN GENERAL.—The Secretary may order
2 the sponsor of a drug that is approved or licensed
3 under section 505(c) or under section 351 of the
4 Public Health Service Act to pay a civil penalty, sub-
5 ject to paragraph (2), if, after providing an oppor-
6 tunity for an informal hearing, the Secretary deter-
7 mines that—

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

11 “(B) there is no legitimate reason for such
12 failure.

13 “(2) AMOUNT OF PENALTIES.—The civil pen-
14 alty order under paragraph (1) may be assessed for
15 each day the completion of a required study of a
16 drug is delayed in an amount that is not more than
17 3 times the gross revenue received by the sponsor
18 for the average sales of the drug in a day.

19 “(3) RECORDS RELATING TO GROSS REV-
20 ENUE.—When provided an opportunity for an infor-
21 mal hearing under paragraph (1), a drug sponsor
22 shall provide to the Secretary all records relating to
23 the gross revenues received by the sponsor for aver-
24 age sales of the drug in a day.

1 “(4) PROCEDURE.—The provisions of para-
2 graphs (3) (other than subparagraph (A)), (4), and
3 (5) of section 303(f) shall apply to a violation under
4 subsection (a) in the same manner as such provi-
5 sions apply to a violation of a requirement of this
6 Act that relates to devices.”.

7 (b) RESOURCES.—In addition to fees that may be
8 available to the Office of Drug Safety under sections 735
9 and 736 of the Federal Food, Drug, and Cosmetic Act
10 (21 U.S.C. 379g and 379h), there is authorized to be ap-
11 propriated for the Office of Drug Safety within the Center
12 for Drug Evaluation and Research of the Food and Drug
13 Administration—

- 14 (1) \$30,000,000 for fiscal year 2006;
- 15 (2) \$40,000,0000 for fiscal year 2007;
- 16 (3) \$50,000,000 for fiscal year 2008;
- 17 (4) \$60,000,000 for fiscal year 2009; and
- 18 (5) \$70,00,000 for fiscal year 2010.

19 **SEC. 122. REPORT BY GAO ON DRUG SAFETY.**

20 (a) IN GENERAL.—The Government Accountability
21 Office shall provide for the conduct of a study concerning
22 measures to increase the safety of prescription drugs, in-
23 cluding—

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

1 associated with the Federal budgetary process ham-
2 pers planning;

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

8 (3) whether prolonged and rampant vacancies
9 within the Food and Drug Administration have con-
10 tributed to the ability of the Food and Drug Admin-
11 istration to properly examine drug safety;

12 (4) whether conflicts of interest exist that un-
13 duly bias approvals or later reviews of drug safety;

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

18 (6) whether the procedure of the Food and
19 Drug Administration for notifying the public of pos-
20 sible drug safety issues is appropriate and complied
21 with;

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

24 (8) other matters determined appropriate.

1 (b) REPORT.—Not later than 90 days after the date
 2 of enactment of this Act, the Government Accountability
 3 Office shall prepare and submit to the appropriate com-
 4 mittees of Congress a report concerning the results of the
 5 study conducted under subsection (a). Such report shall
 6 include a proposal (including legislative language) for im-
 7 proving the safety of prescription drugs.

8 **TITLE II—MODERNIZING THE**
 9 **HEALTH CARE SYSTEM**

10 **SEC. 201. AMENDMENT TO THE PUBLIC HEALTH SERVICE**
 11 **ACT.**

12 The Public Health Service Act (42 U.S.C. 201 et
 13 seq.) is amended by adding at the end thereof the fol-
 14 lowing:

15 **“TITLE XXIX—HEALTH CARE**
 16 **INFORMATION TECHNOLOGY**

17 **“SEC. 2901. DEFINITIONS.**

18 “In this title:

19 “(1) **COVERAGE AREA.**—The term ‘coverage
 20 area’ means the boundaries of a local health infor-
 21 mation infrastructure.

22 “(2) **DIRECTOR.**—The term ‘Director’ means
 23 the Director of the Office of Health Information
 24 Technology.

1 “(3) HEALTH CARE PROVIDER.—The term
2 ‘health care provider’ means a hospital, skilled nurs-
3 ing facility, home health entity, health care clinic,
4 community health center, group practice (as defined
5 in section 1877(h)(4) of the Social Security Act, in-
6 cluding practices with only 1 physician), and any
7 other facility or clinician determined appropriate by
8 the Director.

9 “(4) HEALTH INFORMATION TECHNOLOGY.—
10 The term ‘health information technology’ means a
11 computerized system that—

12 “(A) is consistent with the standards de-
13 veloped pursuant to section 2903;

14 “(B) permits the secure electronic trans-
15 mission of information to other health care pro-
16 viders and public health entities; and

17 “(C) includes—

18 “(i) an electronic health record
19 (EHR) that provides access in real-time to
20 the patient’s complete medical record;

21 “(ii) a personal health record (PHR)
22 through which an individual (and anyone
23 authorized by such individual) can main-
24 tain and manage their health information;

1 “(iii) computerized provider order
2 entry (CPOE) technology that permits the
3 electronic ordering of diagnostic and treat-
4 ment services, including prescription drugs;

5 “(iv) decision support to assist physi-
6 cians in making clinical decisions by pro-
7 viding electronic alerts and reminders to
8 improve compliance with best practices,
9 promote regular screenings and other pre-
10 ventive practices, and facilitate diagnoses
11 and treatments;

12 “(v) error notification procedures so
13 that a warning is generated if an order is
14 entered that is likely to lead to a signifi-
15 cant adverse outcome for the patient; and

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

20 “(5) LOCAL HEALTH INFORMATION INFRA-
21 STRUCTURES.—The term ‘local health information
22 infrastructure’ means an independent organization
23 of health care entities established for the purpose of
24 linking health information systems to electronically

1 shared information. A local health information infra-
2 structure may not be a single business entity.

3 “(6) OFFICE.—The term ‘Office’ means the Of-
4 fice of Health Information Technology established
5 under section 2902.

6 **“SEC. 2902. OFFICE OF HEALTH INFORMATION TECH-**
7 **NOLOGY.**

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

13 “(b) PURPOSE.—It shall be the purpose of the Office
14 to—

15 “(1) improve the quality and increase the effi-
16 ciency of health care delivery through the use of
17 health information technology;

18 “(2) provide national leadership relating to, and
19 encourage the adoption of, health information tech-
20 nology;

21 “(3) direct all health information technology ac-
22 tivities within the Federal Government; and

23 “(4) facilitate the interaction between the Fed-
24 eral Government and the private sector relating to
25 health information technology development and use.

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

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

9 “(2) FEDERAL LEADERSHIP.—The Office
10 shall—

11 “(A) serve as the principle advisor to the
12 President concerning health information tech-
13 nology;

14 “(B) direct all health information tech-
15 nology activity within the Federal Government,
16 including approving or disapproving agency
17 policies submitted under paragraph (3);

18 “(C) work with public and private health
19 information technology stakeholders to imple-
20 ment the national strategy described in para-
21 graph (1); and

22 “(D) ensure that health information tech-
23 nology is utilized as fully as practicable in car-
24 rying out health surveillance efforts.

25 “(3) AGENCY POLICIES.—

1 “(A) IN GENERAL.—The Office shall, in
2 accordance with this paragraph, approve or dis-
3 approve the policies of Federal departments or
4 agencies with respect to any policy proposed to
5 be implemented by such agency or department
6 that would significantly affect that agency or
7 department’s use of health information tech-
8 nology.

9 “(B) SUBMISSION OF PROPOSAL.—The
10 head of any Federal Government agency or de-
11 partment that desires to implement any policy
12 with respect to such agency or department that
13 would significantly affect that agency or depart-
14 ment’s use of health information technology
15 shall submit an implementation proposal to the
16 Office at least 60 days prior to the proposed
17 date of the implementation of such policy.

18 “(C) APPROVAL OR DISAPPROVAL.—Not
19 later than 60 days after the date on which a
20 proposal is received under subparagraph (B),
21 the Office shall determine whether to approve
22 the implementation of such proposal. In making
23 such determination, the Office shall consider
24 whether the proposal is consistent with the na-
25 tional strategy described in paragraph (1). If

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

4 “(D) FAILURE TO APPROVE.—Except as
5 otherwise provided for by law, a proposal sub-
6 mitted under subparagraph (B) may not be im-
7 plemented unless such proposal is approved or
8 deemed to be approved under subparagraph
9 (C).

10 “(4) COORDINATION.—The Office shall—

11 “(A) encourage the development and adop-
12 tion of clinical, messaging, and decision support
13 health information data standards, pursuant to
14 the requirements of section 2903;

15 “(B) ensure the maintenance and imple-
16 mentation of the data standards described in
17 subparagraph (A);

18 “(C) oversee and coordinate the health in-
19 formation technology efforts of the Federal
20 Government;

21 “(D) ensure the compliance of the Federal
22 Government with Federally adopted health in-
23 formation technology data standards;

24 “(E) ensure that the Federal Government
25 consults and collaborates on decision making

1 with respect to health information technology
2 with the private sector and other interested par-
3 ties; and

4 “(F) in consultation with private sector,
5 adopt certification and testing criteria to deter-
6 mine if electronic health information systems
7 interoperate.

8 “(5) COMMUNICATION.—The Office shall—

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

12 “(B) work with the private sector to collect
13 and disseminate best health information tech-
14 nology practices.

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

19 “(A) evaluate and disseminate information
20 relating to evidence of the costs and benefits of
21 health information technology and to whom
22 those costs and benefits accrue;

23 “(B) evaluate and disseminate information
24 on the impact of health information technology

1 on the quality and efficiency of patient care;
2 and

3 “(C) review Federal payment structures
4 and differentials for health care providers that
5 utilize health information technology systems.

6 “(7) TECHNICAL ASSISTANCE.—The Office
7 shall utilize existing private sector quality improve-
8 ment organizations to—

9 “(A) promote the adoption of health infor-
10 mation technology among healthcare providers;
11 and

12 “(B) provide technical assistance con-
13 cerning the implementation of health informa-
14 tion technology to healthcare providers.

15 “(8) FEDERAL REIMBURSEMENT.—

16 “(A) IN GENERAL.—Not later than 6
17 months after the date of enactment of this title,
18 the Office shall make recommendations to the
19 President and the Secretary of Health and
20 Human Services on changes to Federal reim-
21 bursement and payment structures that would
22 encourage the adoption of information tech-
23 nology (IT) to improve health care quality and
24 safety.

1 “(B) PLAN.—Not later than 90 days after
2 receiving recommendations under subparagraph
3 (A), the Secretary shall provide to the relevant
4 Committees of Congress a report that provides,
5 with respect to each recommendation, a plan for
6 the implementation, or an explanation as to
7 why implementation is inadvisable, of such rec-
8 ommendations. The Office shall continue to
9 monitor federally funded and supported infor-
10 mation technology and quality initiatives (includ-
11 ing the initiatives authorized in this title), and
12 periodically update recommendations to the
13 President and the Secretary.

14 “(d) RESOURCES.—The President shall make avail-
15 able to the Office, the resources, both financial and other-
16 wise, necessary to enable the Director to carry out the pur-
17 poses of, and perform the duties and responsibilities of
18 the Office under, this section.

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

1 **“SEC. 2903. PROMOTING THE INTEROPERABILITY OF**
2 **HEALTH CARE INFORMATION TECHNOLOGY**
3 **SYSTEMS.**

4 “(a) DEVELOPMENT, AND FEDERAL GOVERNMENT
5 ADOPTION, OF STANDARDS.—

6 “(1) ADOPTION.—

7 “(A) IN GENERAL.—Not later than 2 years
8 after the date of the enactment of this title, the
9 Director, in collaboration with the Consolidated
10 Health Informatics Initiative (or a successor or-
11 ganization to such Initiative), shall provide for
12 the adoption by the Federal Government of na-
13 tional data and communication health informa-
14 tion technology standards that promote the effi-
15 cient exchange of data between varieties of pro-
16 vider health information technology systems. In
17 carrying out the preceding sentence, the Direc-
18 tor may adopt existing standards. Except as
19 otherwise provided for in this title, standards
20 adopted under this section shall be voluntary
21 for private sector entities.

22 “(B) GRANTS OR CONTRACTS.—The Direc-
23 tor may utilize grants or contracts to provide
24 for the private sector development of standards
25 for adoption by the Federal Government under
26 subparagraph (A).

1 “(C) DEFINITION.—In this paragraph, the
2 term ‘provide for’ means that the Director shall
3 promulgate, and each Federal agency or depart-
4 ment shall adopt, regulations to ensure that
5 each such agency or department complies with
6 the requirements of subsection (b).

7 “(2) REQUIREMENTS.—The standards devel-
8 oped and adopted under paragraph (1) shall be de-
9 signed to—

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

13 “(B) promote the interoperability of health
14 care information across health care settings;

15 “(C) facilitate clinical decision support
16 through the use of health information tech-
17 nology; and

18 “(D) ensure the privacy and confidentiality
19 of medical records.

20 “(3) PUBLIC PRIVATE PARTNERSHIP.—Con-
21 sistent with activities being carried out on the date
22 of enactment of this title, including the Consolidated
23 Health Informatics Initiative (or a successor organi-
24 zation to such Initiative), health information tech-
25 nology standards shall be adopted by the Director

1 under paragraph (1) at the conclusion of a collabo-
2 rative process that includes consultation between the
3 Federal Government and private sector health care
4 and information technology stakeholders.

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

14 “(5) PILOT TESTS.—To the extent practical,
15 the Director shall pilot test the health information
16 technology data standards developed under para-
17 graph (1) prior to their implementation under this
18 section.

19 “(6) DISSEMINATION.—

20 “(A) IN GENERAL.—The Director shall en-
21 sure that the standards adopted under para-
22 graph (1) are widely disseminated to interested
23 stakeholders.

24 “(B) LICENSING.—To facilitate the dis-
25 semination and implementation of the stand-

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

5 “(b) IMPLEMENTATION OF STANDARDS.—

6 “(1) PURCHASE OF SYSTEMS BY THE SEC-
7 RETARY.—Effective beginning on the date that is 1
8 year after the adoption of the technology standards
9 pursuant to subsection (a), the Secretary shall not
10 purchase any health care information technology
11 system unless such system is in compliance with the
12 standards adopted under subsection (a), nor shall
13 the Director approve any proposal pursuant to sec-
14 tion 2902(c)(3) unless such proposal utilizes systems
15 that are in compliance with the standards adopted
16 under subsection (a).

17 “(2) RECIPIENTS OF FEDERAL FUNDS.—Effec-
18 tive on the date described in paragraph (1), no ap-
19 propriated funds may be used to purchase a health
20 care information technology system unless such sys-
21 tem is in compliance with applicable standards
22 adopted under subsection (a).

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

1 tion technology standards developed under subsection (a)
2 to—

3 “(1) identify gaps or other shortcomings in
4 such standards; and

5 “(2) modify such standards when determined
6 appropriate or develop additional standards, in col-
7 laboration with standard setting organizations.

8 **“SEC. 2904. LOAN GUARANTEES FOR THE ADOPTION OF**
9 **HEALTH INFORMATION TECHNOLOGY.**

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

13 “(1) to implement local health information in-
14 frastructures to facilitate the development of inter-
15 operability across health care settings to improve
16 quality and efficiency; or

17 “(2) to facilitate the purchase and adoption of
18 health information technology to improve quality and
19 efficiency.

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

22 “(1) with respect to an entity desiring a loan
23 guarantee—

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

1 sortium of health care stakeholders within a
2 community that—

3 “(i) includes—

4 “(I) physicians (as defined in
5 section 1881(r)(1) of the Social Secu-
6 rity Act);

7 “(II) hospitals; and

8 “(III) group health plans or
9 other health insurance issuers (as
10 such terms are defined in section
11 2791); and

12 “(ii) may include any other health
13 care providers; or

14 “(B) under subsection (a)(2) be a health
15 care provider;

16 “(2) to the extent practicable, adopt the na-
17 tional health information technology standards
18 adopted under section 2903;

19 “(3) provide assurances that the entity shall
20 submit to the Director regular reports on the activi-
21 ties carried out under the loan guarantee, includ-
22 ing—

23 “(A) a description of the financial costs
24 and benefits of the project involved and of the
25 entities to which such costs and benefits accrue;

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

3 “(C) a description of any reduction in du-
4 plicative or unnecessary care as a result of the
5 project involved;

6 “(4) provide assurances that not later than 30
7 days after the development of the standard quality
8 measures pursuant to section 2906, the entity shall
9 submit to the Director regular reports on such meas-
10 ures, including provider level data and analysis of
11 the impact of information technology on such meas-
12 ures;

13 “(5) prepare and submit to the Director an ap-
14 plication at such time, in such manner, and con-
15 taining such information as the Director may re-
16 quire.

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

19 “(1) with respect to a loan guarantee described
20 in subsection (a)(1)—

21 “(A) to develop a plan for the implementa-
22 tion of a local health information infrastructure
23 under this section;

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

1 information technology standards developed
2 under section 2903;

3 “(C) to purchase directly related inte-
4 grated hardware and software to establish an
5 interoperable health information technology sys-
6 tem that is capable of linking to a local health
7 care information infrastructure; and

8 “(D) to train staff, maintain health infor-
9 mation technology systems, and maintain ade-
10 quate security and privacy protocols;

11 “(2) with respect to a loan guarantee described
12 in subsection (a)(2)—

13 “(A) to develop a plan for the purchase
14 and installation of health information tech-
15 nology;

16 “(B) to purchase directly related inte-
17 grated hardware and software to establish an
18 interoperable health information technology sys-
19 tem that is capable of linking to a national or
20 local health care information infrastructure;
21 and

22 “(C) to train staff, maintain health infor-
23 mation technology systems, and maintain ade-
24 quate security and privacy protocols; and

1 “(3) to carry out any other activities deter-
2 mined appropriate by the Director.

3 “(d) SPECIAL CONSIDERATIONS FOR CERTAIN ENTI-
4 TIES.—In awarding loan guarantees under this section,
5 the Director shall give special consideration to eligible en-
6 tities that—

7 “(1) provide service to low-income and under-
8 served populations; and

9 “(2) agree to electronically submit the informa-
10 tion described in paragraphs (3) and (4) of sub-
11 section (b) on a daily basis.

12 “(e) SPECIAL CONSIDERATIONS FOR LOCAL HEALTH
13 INFORMATION INFRASTRUCTURES.—In awarding loan
14 guarantees under this section to local health information
15 infrastructures, the Director shall give special consider-
16 ation to eligible entities that—

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

19 “(2) incorporate public health surveillance and
20 reporting into the overall architecture of the pro-
21 posed infrastructure; and

22 “(3) link local health information infrastruc-
23 tures.

1 “(f) AREAS OF SPECIFIC INTEREST.—In awarding
2 loan guarantees under this section, the Director shall in-
3 clude—

4 “(1) entities with a coverage area that includes
5 an entire State; and

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

7 “(g) ADMINISTRATIVE PROVISIONS.—

8 “(1) AGGREGATE AMOUNT.—

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

17 “(B) EXCEPTION.—The cumulative total
18 of the principal of the loans outstanding at any
19 time to which guarantees have been issued
20 under subsection (a) may not exceed such limi-
21 tations as may be specified in appropriation
22 Acts.

23 “(2) PROTECTION OF FEDERAL GOVERN-
24 MENT.—

1 “(A) IN GENERAL.—The Director may not
2 approve an application for a loan guarantee
3 under this section unless the Director deter-
4 mines that—

5 “(i) the terms, conditions, security (if
6 any), and schedule and amount of repay-
7 ments with respect to the loan are suffi-
8 cient to protect the financial interests of
9 the United States and are otherwise rea-
10 sonable, including a determination that the
11 rate of interest does not exceed such per-
12 cent per annum on the principal obligation
13 outstanding as the Director determines to
14 be reasonable, taking into account the
15 range of interest rates prevailing in the
16 private market for loans with similar ma-
17 turities, terms, conditions, and security
18 and the risks assumed by the United
19 States; and

20 “(ii) the loan would not be available
21 on reasonable terms and conditions with-
22 out the enactment of this section.

23 “(B) RECOVERY.—

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

1 cant for a loan guarantee under this sec-
2 tion the amount of any payment made pur-
3 suant to such loan guarantee, unless the
4 Director for good cause waives such right
5 of recovery, and, upon making any such
6 payment, the United States shall be sub-
7 rogated to all of the rights of the recipient
8 of the payments with respect to which the
9 loan was made.

10 “(ii) MODIFICATION OF TERMS.—Any
11 terms and conditions applicable to a loan
12 guarantee under this section may be modi-
13 fied by the Director to the extent the Di-
14 rector determines it to be consistent with
15 the financial interest of the United States.

16 “(3) DEFAULTS.—The Director may take such
17 action as the Director deems appropriate to protect
18 the interest of the United States in the event of a
19 default on a loan guaranteed under this section, in-
20 cluding taking possession of, holding, and using real
21 property pledged as security for such a loan guar-
22 antee.

23 “(h) AUTHORIZATION OF APPROPRIATIONS.—

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

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

3 “(2) AVAILABILITY.—Amounts appropriated
4 under subparagraph (A) shall remain available for
5 obligation until expended.

6 **“SEC. 2905. GRANTS FOR THE PURCHASE OF HEALTH IN-**
7 **FORMATION TECHNOLOGY.**

8 “(a) IN GENERAL.—The Director may award com-
9 petitive grants to eligible entities—

10 “(1) to implement local health information in-
11 frastructures to facilitate the development of inter-
12 operability across health care settings; or

13 “(2) to facilitate the purchase and adoption of
14 health information technology.

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

17 “(1) demonstrate financial need to the Director;

18 “(2) with respect to an entity desiring a
19 grant—

20 “(A) under subsection (a)(1), represent an
21 independent consortium of health care stake-
22 holders within a community that—

23 “(i) includes—

1 “(I) physicians (as defined in
2 section 1881(r)(1) of the Social Secu-
3 rity Act);

4 “(II) hospitals; and

5 “(III) group health plans or
6 other health insurance issuers (as
7 such terms are defined in section
8 2791); and

9 “(ii) may include any other health
10 care providers; or

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

14 “(3) adopt the national health information tech-
15 nology standards developed under section 2903;

16 “(4) provide assurances that the entity shall
17 submit to the Director regular reports on the activi-
18 ties carried out under the loan guarantee, includ-
19 ing—

20 “(A) a description of the financial costs
21 and benefits of the project involved and of the
22 entities to which such costs and benefits accrue;

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

1 “(C) a description of any reduction in du-
2 plicative or unnecessary care as a result of the
3 project involved;

4 “(5) provide assurances that not later than 30
5 days after the development of the standard quality
6 measures pursuant to section 2906, the entity shall
7 submit to the Director regular reports on such meas-
8 ures, including provider level data and analysis of
9 the impact of information technology on such meas-
10 ures;

11 “(6) prepare and submit to the Director an ap-
12 plication at such time, in such manner, and con-
13 taining such information as the Director may re-
14 quire; and

15 “(7) agree to provide matching funds in accord-
16 ance with subsection (g).

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

19 “(1) with respect to a grant described in sub-
20 section (a)(1)—

21 “(A) to develop a plan for the implementa-
22 tion of a local health information infrastructure
23 under this section;

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

1 information technology standards developed
2 under section 2903;

3 “(C) to implement, enhance, or upgrade a
4 comprehensive, electronic health information
5 technology system; and

6 “(D) to maintain adequate security and
7 privacy protocols;

8 “(2) with respect to a grant described in sub-
9 section (a)(2)—

10 “(A) to develop a plan for the purchase
11 and installation of health information tech-
12 nology;

13 “(B) to purchase directly related inte-
14 grated hardware and software to establish an
15 interoperable health information technology sys-
16 tem that is capable of linking to a national or
17 local health care information infrastructure;
18 and

19 “(C) to train staff, maintain health infor-
20 mation technology systems, and maintain ade-
21 quate security and privacy protocols;

22 “(3) maintain adequate security and privacy
23 protocols; and

24 “(4) carry out any other activities determined
25 appropriate by the Director.

1 “(d) SPECIAL CONSIDERATIONS FOR CERTAIN ENTI-
2 TIES.—In awarding grants under this section, the Direc-
3 tor shall give special consideration to eligible entities
4 that—

5 “(1) provide service to low-income and under-
6 served populations; and

7 “(2) agree to electronically submit the informa-
8 tion described in paragraphs (4) and (5) of sub-
9 section (b).

10 “(e) SPECIAL CONSIDERATIONS FOR LOCAL HEALTH
11 INFORMATION INFRASTRUCTURES.—In awarding grants
12 under this section to local health information infrastruc-
13 tures, the Director shall give special consideration to eligi-
14 ble entities that—

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

17 “(2) incorporate public health surveillance and
18 reporting into the overall architecture of the pro-
19 posed infrastructure; and

20 “(3) link local health information infrastruc-
21 tures;

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

24 “(1) entities with a coverage area that includes
25 an entire State; and

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

2 “(g) MATCHING REQUIREMENT.—

3 “(1) IN GENERAL.—The Director may not
4 make a grant under this section to an entity unless
5 the entity agrees that, with respect to the costs to
6 be incurred by the entity in carrying out the infra-
7 structure program for which the grant was awarded,
8 the entity will make available (directly or through
9 donations from public or private entities) non-Fed-
10 eral contributions toward such costs in an amount
11 equal to not less than 20 percent of such costs (\$1
12 for each \$5 of Federal funds provided under the
13 grant).

14 “(2) DETERMINATION OF AMOUNT CONTRIB-
15 UTED.—Non-Federal contributions required under
16 paragraph (1) may be in cash or in kind, fairly eval-
17 uated, including equipment, technology, or services.
18 Amounts provided by the Federal Government, or
19 services assisted or subsidized to any significant ex-
20 tent by the Federal Government, may not be in-
21 cluded in determining the amount of such non-Fed-
22 eral contributions.

23 “(h) AUTHORIZATION OF APPROPRIATIONS.—

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

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

3 “(2) AVAILABILITY.—Amounts appropriated
4 under paragraph (1) shall remain available for obli-
5 gation until expended.”.

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

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

11 **“SEC. 2906. STANDARDIZED MEASURES OF QUALITY**
12 **HEALTH CARE.**

13 “(a) IN GENERAL.—

14 “(1) COLLABORATION.—The Secretary of
15 Health and Human Services, the Secretary of De-
16 fense, and the Secretary of Veterans Affairs (re-
17 ferred to in this section as the ‘Secretaries’), in con-
18 sultation with the Quality Interagency Coordination
19 Taskforce (as established by Executive Order on
20 March 13, 1998), the Institute of Medicine, the
21 Joint Commission on Accreditation of Healthcare
22 Organizations, the National Committee for Quality
23 Assurance, the American Health Quality Associa-
24 tion, the National Quality Forum, the Medicare Pay-
25 ment Advisory Committee, and other individuals and

1 organizations determined appropriate by the Secre-
2 taries, shall establish uniform health care quality
3 measures to assess the effectiveness, timeliness, pa-
4 tient-centeredness, efficiency, equity, and safety of
5 care delivered across all federally supported health
6 delivery programs.

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

21 “(3) PILOT TESTING.—Each federally sup-
22 ported health delivery program may conduct a pilot
23 test of the quality measures developed under para-
24 graph (2) that shall include a collection of patient-

1 level data and a public release of comparative per-
2 formance reports.

3 “(b) PUBLIC REPORTING REQUIREMENTS.—The
4 Secretaries, working collaboratively, shall establish public
5 reporting requirements for clinicians, institutional pro-
6 viders, and health plans in each of the federally supported
7 health delivery program described in subsection (a). Such
8 requirements shall provide that the entities described in
9 the preceding sentence shall report to the appropriate Sec-
10 retary on the measures developed under subsection (a).

11 “(c) FULL IMPLEMENTATION.—The Secretaries,
12 working collaboratively, shall implement all sets of quality
13 measures and reporting systems developed under sub-
14 sections (a) and (b) by not later than the date that is 1
15 year after the date on which the measures are developed
16 under subsection (a)(2).

17 “(d) REPORTS.—Not later than 1 year after the date
18 of enactment of this title, and annually thereafter, the Sec-
19 retary shall—

20 “(1) submit to Congress a report that details
21 the collaborative efforts carried out under subsection
22 (a), the progress made on standardizing quality indi-
23 cators throughout the Federal Government, and the
24 state of quality measurement for priority areas that

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

3 “(2) submit to Congress a report that details
4 areas of clinical care requiring further research nec-
5 essary to establish effective clinical treatments that
6 will serve as a basis for additional quality indicators.

7 “(e) COMPARATIVE QUALITY REPORTS.—Beginning
8 not later than 3 years after the date of enactment of this
9 title, in order to make comparative quality information
10 available to health care consumers, including members of
11 health disparity populations, health professionals, public
12 health officials, researchers, and other appropriate individ-
13 uals and entities, the Secretaries shall provide for the pool-
14 ing, analysis, and dissemination of quality measures col-
15 lected under this section. Nothing in this section shall be
16 construed as modifying the privacy standards under the
17 Health Insurance Portability and Accountability Act of
18 1996 (Public Law 104–191).

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

23 “(g) EVALUATION AND REGULATIONS.—

24 “(1) EVALUATION.—

1 “(A) IN GENERAL.—The Secretary shall,
2 directly or indirectly through a contract with
3 another entity, conduct an evaluation of the col-
4 laborative efforts of the Secretaries to establish
5 uniform health care quality measures and re-
6 porting requirements for federally supported
7 health care delivery programs as required under
8 this section.

9 “(B) REPORT.—Not later than 1 year
10 after the date of enactment of this title, the
11 Secretary of Health and Human Services shall
12 submit a report to the appropriate committees
13 of Congress concerning the results of the eval-
14 uation under subparagraph (A).

15 “(2) REGULATIONS.—

16 “(A) PROPOSED.—Not later than 6
17 months after the date on which the report is
18 submitted under paragraph (1)(B), the Sec-
19 retary shall publish proposed regulations re-
20 garding the application of the uniform health
21 care quality measures and reporting require-
22 ments described in this section to federally sup-
23 ported health delivery programs.

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

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

5 “(h) DEFINITIONS.—In this section, the term ‘feder-
 6 ally supported health delivery program’ means a program
 7 that is funded by the Federal Government under which
 8 health care items or services are delivered directly to pa-
 9 tients.”.

10 **TITLE III—MAKING HEALTH**
 11 **CARE MORE AFFORDABLE**
 12 **FOR CHILDREN AND PREG-**
 13 **NANT WOMEN**

14 **Subtitle A—Covering all Children**

15 **SEC. 300. FINDINGS.**

16 Congress makes the following findings:

17 (1) NEED FOR UNIVERSAL COVERAGE.—

18 (A) Currently, there are 9,000,000 chil-
 19 dren under the age of 19 that are uninsured.
 20 One out of every 8 children are uninsured while
 21 1 in 5 Hispanic children and 1 in 7 African
 22 American children are uninsured. Three-quar-
 23 ters, approximately 6,800,000, of these children
 24 are eligible but not enrolled in the medicaid
 25 program or the State children’s health insur-

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

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

9 (C) It is estimated that 50 percent of all
10 legal immigrant children in families with in-
11 come that is less than 200 percent of the Fed-
12 eral poverty line are uninsured. In States with-
13 out programs to cover immigrant children, 57
14 percent of non-citizen children are uninsured.

15 (D) Children in the Southern and Western
16 parts of the United States were nearly 1.7
17 times more likely to be uninsured than children
18 in the Northeast. In the Northeast, 9.4 percent
19 of children are uninsured while in the Midwest,
20 8.3 percent are uninsured. The South's rate of
21 uninsured children is 14.3 percent while the
22 West has an uninsured rate of 13 percent.

23 (E) Children's health care needs are ne-
24 glected in the United States. One-quarter of
25 young children in the United States are not

1 fully up to date on their basic immunizations.
2 One-third of children with chronic asthma do
3 not get a prescription for the necessary medica-
4 tions to manage the disease.

5 (F) According to the Centers for Disease
6 Control and Prevention, nearly $\frac{1}{2}$ of all unin-
7 sured children have not had a well-child visit in
8 the past year. One out of every 5 children has
9 problems accessing needed care, and 1 out of
10 every 4 children do not receive annual dental
11 exams. One in 6 uninsured children had a de-
12 layed or unmet medical need in the past year.
13 Minority children are less likely to receive prov-
14 en treatments such as prescription medications
15 to treat chronic disease.

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

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

24 (2) ROLE OF THE MEDICAID AND STATE CHIL-
25 DREN'S HEALTH INSURANCE PROGRAMS.—

1 (A) The medicaid program and SCHIP
2 serve as a crucial health safety net for
3 30,000,000 children. During the recent eco-
4 nomic downturn and the highest number of un-
5 insured individuals ever recorded in the United
6 States, the medicaid program and SCHIP off-
7 set losses in employer-sponsored coverage.
8 While the number of children living in low-in-
9 come families increased by 2,000,000 between
10 2000 and 2003, the number of uninsured chil-
11 dren fell due to the medicaid program and
12 SCHIP.

13 (B) In 2003, 25,000,000 children were en-
14 rolled in the medicaid program, accounting for
15 $\frac{1}{2}$ of all enrollees and only 19 percent of total
16 program costs.

17 (C) The medicaid program and SCHIP do
18 more than just fill in the gaps. Gains in public
19 coverage have reduced the percentage of low-in-
20 come uninsured by a $\frac{1}{3}$ from 1997 to 2003. In
21 addition, a recent study found that publicly-in-
22 sured children are more likely to obtain medical
23 care, preventive care and dental care than simi-
24 lar low-income privately-insured children.

1 (D) Publicly funded programs such as the
2 medicaid program and SCHIP actually improve
3 children's health. Children who are currently in-
4 sured by public programs are in better health
5 than they were a year ago. Expansion of cov-
6 erage for children and pregnant women under
7 the medicaid program and SCHIP reduces
8 rates of avoidable hospitalizations by 22 per-
9 cent.

10 (E) Studies have found that children en-
11 rolled in public insurance programs experienced
12 a 68 percent improvement in measures of
13 school performance.

14 (F) Despite the success of expansions in
15 general under the medicaid program and
16 SCHIP, due to current budget constraints,
17 many States have stopped doing aggressive out-
18 reach and have raised premiums and cost-shar-
19 ing requirements on families under these pro-
20 grams. In addition, 8 States stopped enrollment
21 in SCHIP for a period of time between April
22 2003 and July 2004. As a result, SCHIP en-
23 rollment fell by 200,000 children for the first
24 time in the program's history.

1 (G) It is estimated that nearly 50 percent
2 of children covered through SCHIP do not re-
3 main in the program due to reenrollment bar-
4 riers. A recent study found that between 10 and
5 40 percent of these children are “lost” in the
6 system. Difficult renewal policies and reenroll-
7 ment barriers make seamless coverage in
8 SCHIP unattainable. Studies indicate that as
9 many as 67 percent of children who were eligi-
10 ble but not enrolled for SCHIP had applied for
11 coverage but were denied due to procedural
12 issues.

13 (H) While the medicaid program and
14 SCHIP expansions to date have done much to
15 offset what otherwise would have been a signifi-
16 cant loss of coverage among children because of
17 declining access to employer coverage, the
18 shortcomings of previous expansions, such as
19 the failure to enroll all eligible children and
20 caps on enrollment in SCHIP because of under-
21 funding, also are clear.

1 **CHAPTER 1—EXPANDED COVERAGE OF**
2 **CHILDREN UNDER MEDICAID AND SCHIP**
3 **SEC. 301. STATE OPTION TO RECEIVE 100 PERCENT FMAP**
4 **FOR MEDICAL ASSISTANCE FOR CHILDREN**
5 **IN POVERTY IN EXCHANGE FOR EXPANDED**
6 **COVERAGE OF CHILDREN IN WORKING POOR**
7 **FAMILIES UNDER TITLE XXI.**

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

12 “STATE OPTION FOR INCREASED FMAP FOR MEDICAL AS-
13 SISTANCE FOR CHILDREN IN POVERTY IN EXCHANGE
14 FOR EXPANDED COVERAGE OF CHILDREN IN WORK-
15 ING POOR FAMILIES UNDER TITLE XXI

16 “SEC. 1936. (a) 100 PERCENT FMAP.—

17 “(1) IN GENERAL.—Notwithstanding any other
18 provision of this title, in the case of a State that,
19 through an amendment to each of its State plans
20 under this title and title XXI (or to a waiver of ei-
21 ther such plan), agrees to satisfy the conditions de-
22 scribed in subsections (b), (c), and (d) the Federal
23 medical assistance percentage shall be 100 percent
24 with respect to the total amount expended by the
25 State for providing medical assistance under this
26 title for each fiscal year quarter beginning on or

1 after the date described in subsection (e) for chil-
 2 dren whose family income does not exceed 100 per-
 3 cent of the poverty line.

4 “(2) LIMITATION ON SCOPE OF APPLICATION
 5 OF INCREASE.—The increase in the Federal medical
 6 assistance percentage for a State under this section
 7 shall apply only with respect to the total amount ex-
 8 pended for providing medical assistance under this
 9 title for a fiscal year quarter for children described
 10 in paragraph (1) and shall not apply with respect
 11 to—

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

15 “(B) payments under title IV or XXI; or

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

19 “(b) ELIGIBILITY EXPANSIONS.—The condition de-
 20 scribed in this subsection is that the State agrees to do
 21 the following:

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

1 “(A) IN GENERAL.—The State agrees to
2 provide medical assistance under this title or
3 child health assistance under title XXI to chil-
4 dren whose family income exceeds the medicaid
5 applicable income level (as defined in section
6 2110(b)(4) but by substituting ‘January 1,
7 2005’ for ‘March 31, 1997’), but does not ex-
8 ceed 300 percent of the poverty line.

9 “(B) STATE OPTION TO EXPAND COV-
10 ERAGE THROUGH SUBSIDIZED PURCHASE OF
11 FAMILY COVERAGE.—A State may elect to carry
12 out subparagraph (A) through the provision of
13 assistance for the purchase of dependent cov-
14 erage under a group health plan or health in-
15 surance coverage if—

16 “(i) the dependent coverage is con-
17 sistent with the benefit standards under
18 this title or title XXI, as approved by the
19 Secretary; and

20 “(ii) the State provides ‘wrap-around’
21 coverage under this title or title XXI.

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

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

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

8 “(3) OPPORTUNITY FOR HIGHER INCOME CHIL-
9 DREN TO PURCHASE SCHIP COVERAGE.—The State
10 agrees to permit any child whose family income ex-
11 ceeds 300 percent of the poverty line to purchase
12 full or ‘wrap-around’ coverage under title XXI at the
13 full cost of providing such coverage, as determined
14 by the State.

15 “(4) COVERAGE FOR LEGAL IMMIGRANT CHIL-
16 DREN.—The State agrees to—

17 “(A) provide medical assistance under this
18 title and child health assistance under title XXI
19 for alien children who are lawfully residing in
20 the United States (including battered aliens de-
21 scribed in section 431(c) of the Personal Re-
22 sponsibility and Work Opportunity Reconcili-
23 ation Act of 1996) and who are otherwise eligi-
24 ble for such assistance in accordance with sec-
25 tion 1903(v)(4) and 2107(e)(1)(E); and

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

5 “(c) REMOVAL OF ENROLLMENT AND ACCESS BAR-
6 RIERS.—The condition described in this subsection is that
7 the State agrees to do the following:

8 “(1) PRESUMPTIVE ELIGIBILITY FOR CHIL-
9 DREN.—The State agrees to—

10 “(A) provide presumptive eligibility for
11 children under this title and title XXI in ac-
12 cordance with section 1920A;

13 “(B) treat any items or services that are
14 provided to an uncovered child (as defined in
15 section 2110(c)(8)) who is determined ineligible
16 for medical assistance under this title as child
17 health assistance for purposes of paying a pro-
18 vider of such items or services, so long as such
19 items or services would be considered child
20 health assistance for a targeted low-income
21 child under title XXI.

22 “(2) ADOPTION OF 12-MONTH CONTINUOUS EN-
23 ROLLMENT.—The State agrees to provide that eligi-
24 bility for assistance under this title and title XXI

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

3 “(3) ACCEPTANCE OF SELF-DECLARATION OF
4 INCOME.—The State agrees to permit the family of
5 a child applying for medical assistance under this
6 title or child health assistance under title XXI to de-
7 clare and certify by signature under penalty of per-
8 jury family income for purposes of collecting finan-
9 cial eligibility information.

10 “(4) ADOPTION OF ACCEPTANCE OF ELIGI-
11 BILITY DETERMINATIONS FOR OTHER ASSISTANCE
12 PROGRAMS.—The State agrees to accept determina-
13 tions (made within a reasonable period, as found by
14 the State, before its use for this purpose) of an indi-
15 vidual’s family or household income made by a Fed-
16 eral or State agency (or a public or private entity
17 making such determination on behalf of such agen-
18 cy), including the agencies administering the Food
19 Stamp Act of 1977, the Richard B. Russell National
20 School Lunch Act, and the Child Nutrition Act of
21 1966, notwithstanding any differences in budget
22 unit, disregard, deeming, or other methodology, but
23 only if—

1 “(A) such agency has fiscal liabilities or
2 responsibilities affected or potentially affected
3 by such determinations; and

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

9 “(5) NO ASSETS TEST.—The State agrees to
10 not (or demonstrates that it does not) apply any as-
11 sets or resources test for eligibility under this title
12 or title XXI with respect to children.

13 “(6) ELIGIBILITY DETERMINATIONS AND RE-
14 DETERMINATIONS.—

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

21 “(B) NONDUPLICATION OF INFORMA-
22 TION.—

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

1 title and title XXI, the State agrees to use
2 all information in its possession (including
3 information available to the State under
4 other Federal or State programs) to deter-
5 mine eligibility or redetermine continued
6 eligibility before seeking similar informa-
7 tion from parents.

8 “(ii) RULE OF CONSTRUCTION.—

9 Nothing in clause (i) shall be construed as
10 limiting any obligation of a State to pro-
11 vide notice and a fair hearing before deny-
12 ing, terminating, or reducing a child’s cov-
13 erage based on such information in the
14 possession of the State.

15 “(7) NO WAITING LIST FOR CHILDREN UNDER

16 SCHIP.—The State agrees to not impose any numer-
17 ical limitation, waiting list, waiting period, or similar
18 limitation on the eligibility of children for child
19 health assistance under title XXI or to establish or
20 enforce other barriers to the enrollment of eligible
21 children based on the date of their application for
22 coverage.

23 “(8) ADEQUATE PROVIDER PAYMENT RATES.—

24 The State agrees to—

1 “(A) establish payment rates for children’s
2 health care providers under this title that are
3 no less than the average of payment rates for
4 similar services for such providers provided
5 under the benchmark benefit packages de-
6 scribed in section 2103(b);

7 “(B) establish such rates in amounts that
8 are sufficient to ensure that children enrolled
9 under this title or title XXI have adequate ac-
10 cess to comprehensive care, in accordance with
11 the requirements of section 1902(a)(30)(A);
12 and

13 “(C) include provisions in its contracts
14 with providers under this title guaranteeing
15 compliance with these requirements.

16 “(d) MAINTENANCE OF MEDICAID ELIGIBILITY LEV-
17 ELS FOR CHILDREN.—

18 “(1) IN GENERAL.—The condition described in
19 this subsection is that the State agrees to maintain
20 eligibility income, resources, and methodologies ap-
21 plied under this title (including under a waiver of
22 such title or under section 1115) with respect to
23 children that are no more restrictive than the eligi-
24 bility income, resources, and methodologies applied

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

3 “(2) RULE OF CONSTRUCTION.—Nothing in
4 this section shall be construed as implying that a
5 State does not have to comply with the minimum in-
6 come levels required for children under section
7 1902(l)(2).

8 “(e) DATE DESCRIBED.—The date described in this
9 subsection is the date on which, with respect to a State,
10 a plan amendment that satisfies the requirements of sub-
11 sections (b), (c), and (d) is approved by the Secretary.

12 “(f) DEFINITION OF POVERTY LINE.—In this sec-
13 tion, the term ‘poverty line’ has the meaning given that
14 term in section 2110(e)(5).”.

15 (b) CONFORMING AMENDMENTS.—

16 (1) The third sentence of section 1905(b) of the
17 Social Security Act (42 U.S.C. 1396d(b)) is amend-
18 ed by inserting before the period the following: “,
19 and with respect to amounts expended for medical
20 assistance for children on or after the date described
21 in subsection (d) of section 1936, in the case of a
22 State that has, in accordance with such section, an
23 approved plan amendment under this title and title
24 XXI”.

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

3 (A) in subparagraph (C), by adding “or”
4 after “section 1611(b)(1),”; and

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

7 “(D) who would not receive such medical assist-
8 ance but for State electing the option under section
9 1936 and satisfying the conditions described in sub-
10 sections (b), (c), and (d) of such section,”.

11 **SEC. 302. ELIMINATION OF CAP ON SCHIP FUNDING FOR**
12 **STATES THAT EXPAND ELIGIBILITY FOR**
13 **CHILDREN.**

14 (a) IN GENERAL.—Section 2105 of the Social Secu-
15 rity Act (42 U.S.C. 1397dd) is amended by adding at the
16 end the following:

17 “(h) **GUARANTEED FUNDING FOR CHILD HEALTH**
18 **ASSISTANCE FOR COVERAGE EXPANSION STATES.**—

19 “(1) IN GENERAL.—Only in the case of a State
20 that has, in accordance with section 1936, an ap-
21 proved plan amendment under this title and title
22 XIX, any payment cap that would otherwise apply to
23 the State under this title as a result of having ex-
24 pended all allotments available for expenditure by
25 the State with respect to a fiscal year shall not apply

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

3 “(2) APPROPRIATION.—There is appropriated,
 4 out of any money in the Treasury not otherwise ap-
 5 propriated, such sums as may be necessary for the
 6 purpose of paying a State described in paragraph
 7 (1) for each quarter beginning on or after the date
 8 described in section 1936(d), an amount equal to the
 9 enhanced FMAP of expenditures described in para-
 10 graph (1) and incurred during such quarter.”.

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

13 (1) in subsection (a), by inserting “subject to
 14 section 2105(h),” after “under this section,”;

15 (2) in subsection (b)(1), by inserting “and sec-
 16 tion 2105(h)” after “Subject to paragraph (4)”;

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

19 **CHAPTER 2—STATE OPTIONS FOR INCRE-**
 20 **MENTAL CHILD COVERAGE EXPAN-**
 21 **SIONS**

22 **SEC. 311. STATE OPTION TO ENROLL LOW-INCOME CHIL-**
 23 **DREN OF STATE EMPLOYEES IN SCHIP.**

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

1 (1) by redesignating subparagraphs (A) and
2 (B) as clauses (i) and (ii), respectively and realign-
3 ing the left margins of such clauses appropriately;

4 (2) by striking “Such term” and inserting the
5 following:

6 “(A) IN GENERAL.—Such term”; and

7 (3) by adding at the end the following:

8 “(B) STATE OPTION TO ENROLL LOW-IN-
9 COME CHILDREN OF STATE EMPLOYEES.—At
10 the option of a State, subparagraph (A)(ii) shall
11 not apply to any low-income child who would
12 otherwise be eligible for child health assistance
13 under this title but for such subparagraph.”.

14 **SEC. 312. STATE OPTION FOR PASSIVE RENEWAL OF ELIGI-**
15 **BILITY FOR CHILDREN UNDER MEDICAID**
16 **AND SCHIP.**

17 (a) IN GENERAL.—Section 1902(l) of the Social Se-
18 curity Act (42 U.S.C. 1396a(l)) is amended by adding at
19 the end the following:

20 “(5) Notwithstanding any other provision of this title,
21 a State may provide that an individual who has not at-
22 tained 21 years of age who has been determined eligible
23 for medical assistance under this title shall remain eligible
24 for medical assistance until such time as the State has

1 information demonstrating that the individual is no longer
2 so eligible.”.

3 (b) APPLICATION UNDER TITLE XXI.—Section
4 2107(e)(1) of the Social Security Act (42 U.S.C.
5 1397gg(e)) is amended—

6 (1) by redesignating subparagraphs (B)
7 through (D) as subparagraphs (C) through (E), re-
8 spectively; and

9 (2) by inserting after subparagraph (A), the fol-
10 lowing:

11 “(B) Section 1902(l)(5) (relating to pas-
12 sive renewal of eligibility for children).”.

13 **CHAPTER 3—TAX INCENTIVES FOR**
14 **HEALTH INSURANCE COVERAGE OF**
15 **CHILDREN**

16 **SEC. 321. REFUNDABLE CREDIT FOR HEALTH INSURANCE**
17 **COVERAGE OF CHILDREN.**

18 (a) IN GENERAL.—Subpart C of part IV of sub-
19 chapter A of chapter 1 of the Internal Revenue Code of
20 1986 (relating to refundable credits) is amended by redес-
21 ignating section 36 as section 37 and by inserting after
22 section 35 the following new section:

23 **“SEC. 36. HEALTH INSURANCE COVERAGE OF CHILDREN.**

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

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

7 “(b) DEPENDENT CHILD.—For purposes of this sec-
8 tion, the term ‘dependent child’ means any child (as de-
9 fined in section 152(f)(1)) who has not attained the age
10 of 19 as of the close of the calendar year in which the
11 taxable year of the taxpayer begins and with respect to
12 whom a deduction under section 151 is allowable to the
13 taxpayer.

14 “(c) QUALIFIED HEALTH INSURANCE.—For pur-
15 poses of this section—

16 “(1) IN GENERAL.—The term ‘qualified health
17 insurance’ means insurance, either employer-pro-
18 vided or made available under title XIX or XXI of
19 the Social Security Act, which constitutes medical
20 care as defined in section 213(d) without regard
21 to—

22 “(A) paragraph (1)(C) thereof, and

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

1 “(2) EXCLUSION OF CERTAIN OTHER CON-
2 TRACTS.—Such term shall not include insurance if a
3 substantial portion of its benefits are excepted bene-
4 fits (as defined in section 9832(c)).

5 “(d) MEDICAL SAVINGS ACCOUNT AND HEALTH SAV-
6 INGS ACCOUNT CONTRIBUTIONS.—

7 “(1) IN GENERAL.—If a deduction would (but
8 for paragraph (2)) be allowed under section 220 or
9 223 to the taxpayer for a payment for the taxable
10 year to the medical savings account or health sav-
11 ings account of an individual, subsection (a) shall be
12 applied by treating such payment as a payment for
13 qualified health insurance for such individual.

14 “(2) DENIAL OF DOUBLE BENEFIT.—No deduc-
15 tion shall be allowed under section 220 or 223 for
16 that portion of the payments otherwise allowable as
17 a deduction under section 220 or 223 for the taxable
18 year which is equal to the amount of credit allowed
19 for such taxable year by reason of this subsection.

20 “(e) SPECIAL RULES.—

21 “(1) DETERMINATION OF INSURANCE COSTS.—
22 The Secretary shall provide rules for the allocation
23 of the cost of any qualified health insurance for fam-
24 ily coverage to the coverage of any dependent child
25 under such insurance.

1 “(2) COORDINATION WITH DEDUCTION FOR
2 HEALTH INSURANCE COSTS OF SELF-EMPLOYED IN-
3 DIVIDUALS.—In the case of a taxpayer who is eligi-
4 ble to deduct any amount under section 162(l) for
5 the taxable year, this section shall apply only if the
6 taxpayer elects not to claim any amount as a deduc-
7 tion under such section for such year.

8 “(3) COORDINATION WITH MEDICAL EXPENSE
9 AND HIGH DEDUCTIBLE HEALTH PLAN DEDUC-
10 TIONS.—The amount which would (but for this
11 paragraph) be taken into account by the taxpayer
12 under section 213 or 224 for the taxable year shall
13 be reduced by the credit (if any) allowed by this sec-
14 tion to the taxpayer for such year.

15 “(4) DENIAL OF CREDIT TO DEPENDENTS.—No
16 credit shall be allowed under this section to any indi-
17 vidual with respect to whom a deduction under sec-
18 tion 151 is allowable to another taxpayer for a tax-
19 able year beginning in the calendar year in which
20 such individual’s taxable year begins.

21 “(5) DENIAL OF DOUBLE BENEFIT.—No credit
22 shall be allowed under subsection (a) if the credit
23 under section 35 is allowed and no credit shall be al-
24 lowed under 35 if a credit is allowed under this sec-
25 tion.

1 “(6) ELECTION NOT TO CLAIM CREDIT.—This
2 section shall not apply to a taxpayer for any taxable
3 year if such taxpayer elects to have this section not
4 apply for such taxable year.”.

5 (b) INFORMATION REPORTING.—

6 (1) IN GENERAL.—Subpart B of part III of
7 subchapter A of chapter 61 of the Internal Revenue
8 Code of 1986 (relating to information concerning
9 transactions with other persons) is amended by in-
10 serting after section 6050T the following new sec-
11 tion:

12 **“SEC. 6050U. RETURNS RELATING TO PAYMENTS FOR**
13 **QUALIFIED HEALTH INSURANCE.**

14 “(a) IN GENERAL.—Any governmental unit or any
15 person who, in connection with a trade or business con-
16 ducted by such person, receives payments during any cal-
17 endar year from any individual for coverage of a depend-
18 ent child (as defined in section 36(b)) of such individual
19 under creditable health insurance, shall make the return
20 described in subsection (b) (at such time as the Secretary
21 may by regulations prescribe) with respect to each indi-
22 vidual from whom such payments were received.

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

1 “(1) is in such form as the Secretary may pre-
2 scribe, and

3 “(2) contains—

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

7 “(B) the name, address, and TIN of each
8 dependent child (as so defined) who was pro-
9 vided by such person with coverage under cred-
10 itable health insurance by reason of such pay-
11 ments and the period of such coverage, and

12 “(C) such other information as the Sec-
13 retary may reasonably prescribe.

14 “(c) CREDITABLE HEALTH INSURANCE.—For pur-
15 poses of this section, the term ‘creditable health insurance’
16 means qualified health insurance (as defined in section
17 36(c)).

18 “(d) STATEMENTS TO BE FURNISHED TO INDIVID-
19 UALS WITH RESPECT TO WHOM INFORMATION IS RE-
20 QUIRED.—Every person required to make a return under
21 subsection (a) shall furnish to each individual whose name
22 is required under subsection (b)(2)(A) to be set forth in
23 such return a written statement showing—

1 “(1) the name and address of the person re-
2 quired to make such return and the phone number
3 of the information contact for such person,

4 “(2) the aggregate amount of payments de-
5 scribed in subsection (a) received by the person re-
6 quired to make such return from the individual to
7 whom the statement is required to be furnished, and

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

10 The written statement required under the preceding sen-
11 tence shall be furnished on or before January 31 of the
12 year following the calendar year for which the return
13 under subsection (a) is required to be made.

14 “(e) RETURNS WHICH WOULD BE REQUIRED TO BE
15 MADE BY 2 OR MORE PERSONS.—Except to the extent
16 provided in regulations prescribed by the Secretary, in the
17 case of any amount received by any person on behalf of
18 another person, only the person first receiving such
19 amount shall be required to make the return under sub-
20 section (a).”.

21 (2) ASSESSABLE PENALTIES.—

22 (A) Subparagraph (B) of section
23 6724(d)(1) of such Code (relating to defini-
24 tions) is amended by redesignating clauses (xiii)
25 through (xviii) as clauses (xiv) through (xix),

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

3 “(xiii) section 6050U (relating to re-
4 turns relating to payments for qualified
5 health insurance),”.

6 (B) Paragraph (2) of section 6724(d) of
7 such Code is amended by striking “or” at the
8 end of the next to last subparagraph, by strik-
9 ing the period at the end of the last subpara-
10 graph and inserting “, or”, and by adding at
11 the end the following new subparagraph:

12 “(CC) section 6050U(d) (relating to re-
13 turns relating to payments for qualified health
14 insurance).”.

15 (3) CLERICAL AMENDMENT.—The table of sec-
16 tions for subpart B of part III of subchapter A of
17 chapter 61 of such Code is amended by inserting
18 after the item relating to section 6050T the fol-
19 lowing new item:

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

20 (c) CONFORMING AMENDMENTS.—

21 (1) Paragraph (2) of section 1324(b) of title
22 31, United States Code, is amended by inserting be-
23 fore the period “, or from section 36 of such Code”.

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

 “Sec. 36. Health insurance coverage of children.
 “Sec. 37. Overpayments of tax.”.

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

8 **SEC. 322. FORFEITURE OF PERSONAL EXEMPTION FOR ANY**
 9 **CHILD NOT COVERED BY HEALTH INSUR-**
 10 **ANCE.**

11 (a) **IN GENERAL.**—Section 151(d) of the Internal
 12 Revenue Code of 1986 (relating to exemption amount) is
 13 amended by adding at the end the following new para-
 14 graph:

15 “(5) **REDUCTION OF EXEMPTION AMOUNT FOR**
 16 **ANY CHILD NOT COVERED BY HEALTH INSUR-**
 17 **ANCE.**—

18 “(A) **IN GENERAL.**—Except as otherwise
 19 provided in this paragraph, the exemption
 20 amount otherwise determined under this sub-
 21 section for any dependent child (as defined in
 22 section 36(b)) for any taxable year shall be re-
 23 duced by the same percentage as the percentage
 24 of such taxable year during which such depend-

1 ent child was not covered by qualified health in-
 2 surance (as defined in section 36(c)).

3 “(B) FULL REDUCTION IF NO PROOF OF
 4 COVERAGE IS PROVIDED.—For purposes of sub-
 5 paragraph (A), in the case of any taxpayer who
 6 fails to attach to the return of tax for any tax-
 7 able year a copy of the statement furnished to
 8 such taxpayer under section 6050U, the per-
 9 centage reduction under such subparagraph
 10 shall be deemed to be 100 percent.

11 “(C) NONAPPLICATION OF PARAGRAPH TO
 12 TAXPAYERS IN LOWEST TAX BRACKET.—This
 13 paragraph shall not apply to any taxpayer
 14 whose taxable income for the taxable year does
 15 not exceed the initial bracket amount deter-
 16 mined under section 1(i)(1)(B).”.

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

20 **CHAPTER 4—MISCELLANEOUS**

21 **SEC. 331. REQUIREMENT FOR GROUP MARKET HEALTH IN-** 22 **SURERS TO OFFER DEPENDENT COVERAGE** 23 **OPTION FOR WORKERS WITH CHILDREN.**

24 (a) ERISA.—

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

5 **“SEC. 714. REQUIREMENT TO OFFER OPTION TO PURCHASE**
 6 **DEPENDENT COVERAGE FOR CHILDREN.**

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

13 “(b) NO EMPLOYER CONTRIBUTION REQUIRED.—An
 14 employer shall not be required to contribute to the cost
 15 of purchasing dependent coverage for a child by an indi-
 16 vidual who is an employee of such employer.

17 “(c) DEFINITION OF CHILD.—In this section, the
 18 term ‘child’ means an individual who has not attained 21
 19 years of age.”.

20 (2) CLERICAL AMENDMENT.—The table of con-
 21 tents in section 1 of the Employee Retirement In-
 22 come Security Act of 1974 (29 U.S.C. 1001) is
 23 amended by inserting after the item relating to sec-
 24 tion 713 the following:

 “Sec. 714. Requirement to offer option to purchase dependent coverage for chil-
 dren.”.

1 (b) PUBLIC HEALTH SERVICE ACT.—Subpart 2 of
2 part A of title XXVII of the Public Health Service Act
3 (42 U.S.C. 300gg–4 et seq.) is amended by adding at the
4 end the following:

5 **“SEC. 2707. REQUIREMENT TO OFFER OPTION TO PUR-**
6 **CHASE DEPENDENT COVERAGE FOR CHIL-**
7 **DREN.**

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

14 “(b) NO EMPLOYER CONTRIBUTION REQUIRED.—An
15 employer shall not be required to contribute to the cost
16 of purchasing dependent coverage for a child by an indi-
17 vidual who is an employee of such employer.

18 “(c) DEFINITION OF CHILD.—In this section, the
19 term ‘child’ means an individual who has not attained 21
20 years of age.”.

21 (c) EFFECTIVE DATE.—The amendments made by
22 this section shall apply with respect to plan years begin-
23 ning on or after January 1, 2006.

1 **SEC. 332. EFFECTIVE DATE.**

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

8 **Subtitle B—Covering Pregnant**
 9 **Women**

10 **SEC. 351. STATE OPTION TO EXPAND OR ADD COVERAGE**
 11 **OF PREGNANT WOMEN UNDER THE MED-**
 12 **ICAID PROGRAM AND STATE CHILDREN'S**
 13 **HEALTH INSURANCE PROGRAM.**

14 (a) MEDICAID.—

15 (1) AUTHORITY TO EXPAND COVERAGE.—Sec-
 16 tion 1902(l)(2)(A)(i) of the Social Security Act (42
 17 U.S.C. 1396a(l)(2)(A)(i)) is amended by inserting
 18 “(or such higher percentage as the State may elect
 19 for purposes of expenditures for medical assistance
 20 for pregnant women described in section
 21 1905(u)(4)(A))” after “185 percent”.

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

1 (A) in the fourth sentence of subsection
2 (b), by striking “or (u)(4)” and inserting “,
3 (u)(4), or (u)(5)”; and

4 (B) in subsection (u)—

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

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

9 “(5) For purposes of the fourth sentence of sub-
10 section (b) and section 2105(a), the expenditures de-
11 scribed in this paragraph are the following:

12 “(A) CERTAIN PREGNANT WOMEN.—If the con-
13 ditions described in subparagraph (B) are met, ex-
14 penditures for medical assistance for pregnant
15 women described in subsection (n) or under section
16 1902(l)(1)(A) in a family the income of which ex-
17 ceeds 185 percent of the poverty line, but does not
18 exceed the income eligibility level established under
19 title XXI for a targeted low-income child.

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

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

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

3 “(ii) The State does not apply an effective
4 income level for pregnant women that is lower
5 than the effective income level (expressed as a
6 percent of the poverty line and considering ap-
7 plicable income disregards) that has been speci-
8 fied under the State plan under subsection
9 (a)(10)(A)(i)(III) or (l)(2)(A) of section 1902,
10 as of January 1, 2005, to be eligible for medical
11 assistance as a pregnant woman.

12 “(C) DEFINITION OF POVERTY LINE.—In this
13 subsection, the term ‘poverty line’ has the meaning
14 given such term in section 2110(e)(5).”.

15 (3) PAYMENT FROM TITLE XXI ALLOTMENT
16 FOR MEDICAID EXPANSION COSTS; ELIMINATION OF
17 COUNTING MEDICAID CHILD PRESUMPTIVE ELIGI-
18 BILITY COSTS AGAINST TITLE XXI ALLOTMENT.—
19 Section 2105(a)(1) of the Social Security Act (42
20 U.S.C. 1397ee(a)(1)) is amended—

21 (A) in the matter preceding subparagraph
22 (A), by striking “(or, in the case of expendi-
23 tures described in subparagraph (B), the Fed-
24 eral medical assistance percentage (as defined
25 in the first sentence of section 1905(b)))”; and

1 (B) by striking subparagraph (B) and in-
 2 serting the following new subparagraph:

3 “(B) for the provision of medical assist-
 4 ance that is attributable to expenditures de-
 5 scribed in section 1905(u)(5)(A);”.

6 (b) SCHIP.—

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

10 **“SEC. 2111. OPTIONAL COVERAGE OF TARGETED LOW-IN-**
 11 **COME PREGNANT WOMEN.**

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

18 “(1) the State has established an income eligi-
 19 bility level for pregnant women under subsection
 20 (a)(10)(A)(i)(III) or (1)(2)(A) of section 1902 that is
 21 at least 185 percent of the income official poverty
 22 line; and

23 “(2) the State meets the conditions described in
 24 section 1905(u)(5)(B).

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

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

11 “(2) TARGETED LOW-INCOME PREGNANT
12 WOMAN.—The term ‘targeted low-income pregnant
13 woman’ means a woman—

14 “(A) during pregnancy and through the
15 end of the month in which the 60-day period
16 (beginning on the last day of her pregnancy)
17 ends;

18 “(B) whose family income exceeds the ef-
19 fective income level (expressed as a percent of
20 the poverty line and considering applicable in-
21 come disregards) that has been specified under
22 subsection (a)(10)(A)(i)(III) or (l)(2)(A) of sec-
23 tion 1902, as of January 1, 2005, to be eligible
24 for medical assistance as a pregnant woman
25 under title XIX but does not exceed the income

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

4 “(C) who satisfies the requirements of
5 paragraphs (1)(A), (1)(C), (2), and (3) of sec-
6 tion 2110(b).

7 “(c) REFERENCES TO TERMS AND SPECIAL
8 RULES.—In the case of, and with respect to, a State pro-
9 viding for coverage of pregnancy-related assistance to tar-
10 geted low-income pregnant women under subsection (a),
11 the following special rules apply:

12 “(1) Any reference in this title (other than in
13 subsection (b)) to a targeted low-income child is
14 deemed to include a reference to a targeted low-in-
15 come pregnant woman.

16 “(2) Any such reference to child health assist-
17 ance with respect to such women is deemed a ref-
18 erence to pregnancy-related assistance.

19 “(3) Any such reference to a child is deemed a
20 reference to a woman during pregnancy and the pe-
21 riod described in subsection (b)(2)(A).

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

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

3 “(5) There shall be no exclusion of benefits for
4 services described in subsection (b)(1) based on any
5 preexisting condition and no waiting period (includ-
6 ing any waiting period imposed to carry out section
7 2102(b)(3)(C)) shall apply.

8 “(6) Subsection (a) of section 2103 (relating to
9 required scope of health insurance coverage) shall
10 not apply insofar as a State limits coverage to serv-
11 ices described in subsection (b)(1) and the reference
12 to such section in section 2105(a)(1)(C) is deemed
13 not to require, in such case, compliance with the re-
14 quirements of section 2103(a).

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

20 “(8) The reference in section 2107(e)(1)(D) to
21 section 1920A (relating to presumptive eligibility for
22 children) is deemed a reference to section 1920 (re-
23 lating to presumptive eligibility for pregnant
24 women).

1 “(d) AUTOMATIC ENROLLMENT FOR CHILDREN
2 BORN TO WOMEN RECEIVING PREGNANCY-RELATED AS-
3 SISTANCE.—If a child is born to a targeted low-income
4 pregnant woman who was receiving pregnancy-related as-
5 sistance under this section on the date of the child’s birth,
6 the child shall be deemed to have applied for child health
7 assistance under the State child health plan and to have
8 been found eligible for such assistance under such plan
9 or to have applied for medical assistance under title XIX
10 and to have been found eligible for such assistance under
11 such title, as appropriate, on the date of such birth and
12 to remain eligible for such assistance until the child at-
13 tains 1 year of age. During the period in which a child
14 is deemed under the preceding sentence to be eligible for
15 child health or medical assistance, the child health or med-
16 ical assistance eligibility identification number of the
17 mother shall also serve as the identification number of the
18 child, and all claims shall be submitted and paid under
19 such number (unless the State issues a separate identifica-
20 tion number for the child before such period expires).”.

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

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

1 ed by inserting after subsection (c) the fol-
2 lowing new subsection:

3 “(d) ADDITIONAL ALLOTMENTS FOR PROVIDING
4 COVERAGE OF PREGNANT WOMEN.—

5 “(1) APPROPRIATION; TOTAL ALLOTMENT.—

6 For the purpose of providing additional allotments
7 to States under this title, there is appropriated, out
8 of any money in the Treasury not otherwise appro-
9 priated, for each of fiscal years 2006 through 2009,
10 \$200,000,000.

11 “(2) STATE AND TERRITORIAL ALLOTMENTS.—

12 In addition to the allotments provided under sub-
13 sections (b) and (c), subject to paragraphs (3) and
14 (4), of the amount available for the additional allot-
15 ments under paragraph (1) for a fiscal year, the
16 Secretary shall allot to each State with a State child
17 health plan approved under this title—

18 “(A) in the case of such a State other than
19 a commonwealth or territory described in sub-
20 paragraph (B), the same proportion as the pro-
21 portion of the State’s allotment under sub-
22 section (b) (determined without regard to sub-
23 section (f)) to the total amount of the allot-
24 ments under subsection (b) for such States eli-

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

3 “(B) in the case of a commonwealth or ter-
4 ritory described in subsection (c)(3), the same
5 proportion as the proportion of the common-
6 wealth’s or territory’s allotment under sub-
7 section (c) (determined without regard to sub-
8 section (f)) to the total amount of the allot-
9 ments under subsection (c) for commonwealths
10 and territories eligible for an allotment under
11 this paragraph for such fiscal year.

12 “(3) USE OF ADDITIONAL ALLOTMENT.—Addi-
13 tional allotments provided under this subsection are
14 not available for amounts expended before October
15 1, 2005. Such amounts are available for amounts ex-
16 pended on or after such date for child health assist-
17 ance for targeted low-income children, as well as for
18 pregnancy-related assistance for targeted low-income
19 pregnant women.

20 “(4) NO PAYMENTS UNLESS ELECTION TO EX-
21 PAND COVERAGE OF PREGNANT WOMEN.—No pay-
22 ments may be made to a State under this title from
23 an allotment provided under this subsection unless
24 the State provides pregnancy-related assistance for
25 targeted low-income pregnant women under this

1 title, or provides medical assistance for pregnant
2 women under title XIX, whose family income ex-
3 ceeds the effective income level applicable under sub-
4 section (a)(10)(A)(i)(III) or (l)(2)(A) of section
5 1902 to a family of the size involved as of January
6 1, 2005.”.

7 (B) CONFORMING AMENDMENTS.—Section
8 2104 of the Social Security Act (42 U.S.C.
9 1397dd), as amended by section 302(b), is
10 amended—

11 (i) in subsection (a), in the matter
12 preceding paragraph (1), by inserting
13 “subsection (d) and” before “section
14 2105(h)”;

15 (ii) in subsection (b)(1), by inserting
16 “, subsection (d),” after “Subject to para-
17 graph (4)”;

18 (iii) in subsection (c)(1), by inserting
19 “subsection (d) and” after “section
20 2105(h)”.

21 (3) ADDITIONAL CONFORMING AMENDMENTS.—

22 (A) NO COST-SHARING FOR PREGNANCY-
23 RELATED BENEFITS.—Section 2103(e)(2) of
24 the Social Security Act (42 U.S.C.
25 1397cc(e)(2)) is amended—

1 (i) in the heading, by inserting “OR
 2 PREGNANCY-RELATED SERVICES” after
 3 “PREVENTIVE SERVICES”; and

4 (ii) by inserting before the period at
 5 the end the following: “or for pregnancy-
 6 related services”.

7 (B) NO WAITING PERIOD.—Section
 8 2102(b)(1)(B) (42 U.S.C. 1397bb(b)(1)(B)) is
 9 amended—

10 (i) in clause (i), by striking “, and” at
 11 the end and inserting a semicolon;

12 (ii) in clause (ii), by striking the pe-
 13 riod at the end and inserting “; and”; and

14 (iii) by adding at the end the fol-
 15 lowing new clause:

16 “(iii) may not apply a waiting period
 17 (including a waiting period to carry out
 18 paragraph (3)(C)) in the case of a targeted
 19 low-income pregnant woman.”.

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

1 (1) in the subsection heading, by inserting
2 “AND CERTAIN PREGNANCY COVERAGE EXPANSION
3 STATES” after “QUALIFYING STATES”;

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

5 “(4) SPECIAL AUTHORITY FOR CERTAIN PREG-
6 NANCY COVERAGE EXPANSION STATES.—

7 “(A) IN GENERAL.—In the case of a State
8 that, as of the date of enactment of the Afford-
9 able Health Care Act of 2005, has an income
10 eligibility standard under title XIX or this title
11 (under section 1902(a)(10)(A) or under a state-
12 wide waiver in effect under section 1115 with
13 respect to title XIX or this title) that is at least
14 185 percent of the poverty line with respect to
15 pregnant women, the State may elect to use not
16 more than 20 percent of any allotment under
17 section 2104 for any fiscal year (insofar as it
18 is available under subsections (e) and (g) of
19 such section) for payments under title XIX in
20 accordance with subparagraph (B), instead of
21 for expenditures under this title.

22 “(B) PAYMENTS TO STATES.—

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

1 subparagraph, subject to the availability of
2 funds under such subparagraph and, if ap-
3 plicable, paragraph (1)(A), with respect to
4 the State, the Secretary shall pay the State
5 an amount each quarter equal to the addi-
6 tional amount that would have been paid
7 to the State under title XIX with respect
8 to expenditures described in clause (ii) if
9 the enhanced FMAP (as determined under
10 subsection (b)) had been substituted for
11 the Federal medical assistance percentage
12 (as defined in section 1905(b)).

13 “(ii) EXPENDITURES DESCRIBED.—
14 For purposes of this subparagraph, the ex-
15 penditures described in this clause are ex-
16 penditures, made after the date of the en-
17 actment of this paragraph and during the
18 period in which funds are available to the
19 State for use under subparagraph (A), for
20 medical assistance under title XIX for
21 pregnant women whose family income is at
22 least 185 percent of the poverty line.

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

1 paragraph (A) that uses amounts paid
2 under this paragraph for expenditures de-
3 scribed in clause (ii) that are incurred
4 under a waiver approved for the State, any
5 budget neutrality determinations with re-
6 spect to such waiver shall be determined
7 without regard to such amounts paid.”;
8 and

9 (3) in paragraph (3), by striking “and (2)” and
10 inserting “(2), and (4)”.

11 (d) OTHER AMENDMENTS TO MEDICAID.—

12 (1) ELIGIBILITY OF A NEWBORN.—Section
13 1902(e)(4) of the Social Security Act (42 U.S.C.
14 1396a(e)(4)) is amended in the first sentence by
15 striking “so long as the child is a member of the
16 woman’s household and the woman remains (or
17 would remain if pregnant) eligible for such assist-
18 ance”.

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

1 “The term ‘qualified provider’ includes a qualified entity
2 as defined in section 1920A(b)(3).”.

3 (e) EFFECTIVE DATE.—The amendments made by
4 this section apply to items and services furnished on or
5 after October 1, 2005, without regard to whether regula-
6 tions implementing such amendments have been promul-
7 gated.

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

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

12 (1) in paragraph (1), by striking “paragraph
13 (2)” and inserting “paragraphs (2) and (4)”; and

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

16 “(4)(A) A State may elect (in a plan amendment
17 under this title) to provide medical assistance under this
18 title for aliens who are lawfully residing in the United
19 States (including battered aliens described in section
20 431(e) of the Personal Responsibility and Work Oppor-
21 tunity Reconciliation Act of 1996) and who are otherwise
22 eligible for such assistance, within any of the following eli-
23 gibility categories:

1 “(i) PREGNANT WOMEN.—Women during preg-
2 nancy (and during the 60-day period beginning on
3 the last day of the pregnancy).

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

7 “(B)(i) In the case of a State that has elected to pro-
8 vide medical assistance to a category of aliens under sub-
9 paragraph (A), no debt shall accrue under an affidavit of
10 support against any sponsor of such an alien on the basis
11 of provision of assistance to such category and the cost
12 of such assistance shall not be considered as an unreim-
13 bursed cost.

14 “(ii) The provisions of sections 401(a), 402(b), 403,
15 and 421 of the Personal Responsibility and Work Oppor-
16 tunity Reconciliation Act of 1996 shall not apply to a
17 State that makes an election under subparagraph (A).”.

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

21 “(E) Section 1903(v)(4) (relating to op-
22 tional coverage of permanent resident alien
23 pregnant women and children), but only with
24 respect to an eligibility category under this title,

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

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

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

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

13 (1) by striking subparagraph (E);

14 (2) by redesignating subparagraphs (F)
 15 through (J) as subparagraphs (E) through (I), re-
 16 spectively; and

17 (3) in subparagraph (F) (as redesignated by
 18 paragraph (2)), by inserting before the period at the
 19 end the following: “, except agents approved by the
 20 Food and Drug Administration for purposes of pro-
 21 moting, and when used to promote, tobacco ces-
 22 sation”.

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

1 tion 1905 of the Social Security Act (42 U.S.C.
2 1396d(a)(4)) is amended—

3 (1) in subsection (a)(4)—

4 (A) by striking “and” before “(C)”; and

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

7 (D) counseling for cessation of tobacco use (as
8 defined in subsection (x)) for pregnant women”;

9 and

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

11 “(y)(1) For purposes of this title, the term ‘coun-
12 seling for cessation of tobacco use’ means therapy and
13 counseling for cessation of tobacco use for pregnant
14 women who use tobacco products or who are being treated
15 for tobacco use that is furnished—

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

17 or

18 “(B) by any other health care professional
19 who—

20 “(i) is legally authorized to furnish such
21 services under State law (or the State regu-
22 latory mechanism provided by State law) of the
23 State in which the services are furnished; and

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

4 “(2) Subject to paragraph (3), such term is limited
5 to—

6 “(A) therapy and counseling services rec-
7 ommended in ‘Treating Tobacco Use and Depend-
8 ence: A Clinical Practice Guideline’, published by the
9 Public Health Service in June 2000, or any subse-
10 quent modification of such Guideline; and

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

13 “(3) Such term shall not include coverage for drugs
14 or biologicals that are not otherwise covered under this
15 title.”.

16 (c) REMOVAL OF COST-SHARING FOR TOBACCO CES-
17 SATION COUNSELING SERVICES FOR PREGNANT
18 WOMEN.—Section 1916 of the Social Security Act (42
19 U.S.C. 1396o) is amended in each of subsections (a)(2)(B)
20 and (b)(2)(B) by inserting “, and counseling for cessation
21 of tobacco use (as defined in section 1905(x))” after “com-
22 plicate the pregnancy”.

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

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

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

6 (a) QUALITY MATERNAL AND CHILD HEALTH SERV-
7 ICES INCLUDES TOBACCO CESSATION COUNSELING AND
8 MEDICATIONS.—

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

12 “(c) For purposes of this title, counseling for ces-
13 sation of tobacco use (as defined in section 1905(y)),
14 drugs and biologicals used to promote smoking cessation,
15 and the inclusion of antitobacco messages in health pro-
16 motion counseling shall be considered to be part of quality
17 maternal and child health services.”.

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

21 (b) EVALUATION OF NATIONAL CORE PERFORMANCE
22 MEASURES.—

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

1 ures and national core outcome measures utilized
2 under the Maternal and Child Health Block Grant
3 under title V of the Social Security Act (42 U.S.C.
4 701 et seq.) for purposes of expanding such meas-
5 ures to include some of the known causes of low
6 birthweight and prematurity, including the percent-
7 age of infants born to pregnant women who smoked
8 during pregnancy.

9 (2) REPORT.—Not later than 1 year after the
10 date of enactment of this Act, the Administrator of
11 the Health Resources and Services Administration
12 shall submit to the appropriate committees of Con-
13 gress a report concerning the results of the evalua-
14 tion conducted under paragraph (1).

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

20 (a) IN GENERAL.—Title XIX of the Social Security
21 Act (42 U.S.C. 1396 et seq.), as amended by section
22 301(a), is amended—

23 (1) by redesignating section 1937 as section
24 1938; and

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

3 “(2) be provided in accordance with the restric-
4 tions on deductions, cost sharing, or similar charges
5 imposed under section 1916(a)(2)(D).

6 “(c) OPTION TO EXTEND COVERAGE DURING A
7 POST-ELIGIBILITY PERIOD.—

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

18 “(2) ADDITIONAL EXTENSION.—A State plan
19 amendment made under subsection (a) may provide
20 that any individual who has received medical assist-
21 ance described in section 1905(a)(4)(C) during the
22 entire 6-month period described in paragraph (1)
23 may be extended coverage for such assistance for a
24 succeeding 6-month period.”.

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

4 **SEC. 356. STATE OPTION TO EXTEND THE POSTPARTUM PE-**
5 **RIOD FOR PROVISION OF FAMILY PLANNING**
6 **SERVICES AND SUPPLIES.**

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

9 (1) by striking “eligible under the plan, as
10 though” and inserting “eligible under the plan—

11 “(A) as though”;

12 (2) by striking the period and inserting “;
13 and”; and

14 (3) by adding at the end the following new sub-
15 paragraph:

16 “(B) for medical assistance described in section
17 1905(a)(4)(C) for so long as the family income of
18 such woman does not exceed the maximum income
19 level established by the State for the woman to be
20 eligible for medical assistance under the State plan
21 (as a result of pregnancy or otherwise).”.

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

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

4 (a) IN GENERAL.—

5 (1) SCHIP.—

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

10 (i) in paragraph (1)(C), by inserting
 11 “, subject to paragraph (5),” after “under
 12 title XIX or”; and

13 (ii) by adding at the end the fol-
 14 lowing:

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

23 “(A) services for a child with special health
 24 care needs; or

25 “(B) all services.

1 In waiving such requirement, a State may limit the
2 application of the waiver to children whose family in-
3 come does not exceed a level specified by the State,
4 so long as the level so specified does not exceed the
5 maximum income level otherwise established for
6 other children under the State child health plan.”.

7 (B) CONDITIONS DESCRIBED.—Section
8 2105(c) of the Social Security Act (42 U.S.C.
9 1397ee(c)) is amended by adding at the end the
10 following:

11 “(8) CONDITIONS FOR PROVISION OF WRAP-
12 AROUND COVERAGE.—For purposes of section
13 2110(b)(5), the conditions described in this para-
14 graph are the following:

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

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

21 “(ii) subject to subparagraph (B),
22 does not limit the acceptance of applica-
23 tions for children; and

1 “(iii) provides benefits to all children
2 in the State who apply for and meet eligi-
3 bility standards.

4 “(B) NO WAITING LIST IMPOSED.—With
5 respect to children whose family income is at or
6 below 200 percent of the poverty line, the State
7 does not impose any numerical limitation, wait-
8 ing list, or similar limitation on the eligibility of
9 such children for child health assistance under
10 such State plan.

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

17 (C) STATE OPTION TO WAIVE WAITING PE-
18 RIOD.—Section 2102(b)(1)(B) of the Social Se-
19 curity Act (42 U.S.C. 1397bb(b)(1)(B)), as
20 amended by section 2(b)(3)(B), is amended—

21 (i) in clause (ii), by striking “, and”
22 at the end and inserting a semicolon;

23 (ii) in clause (iii), by striking the pe-
24 riod at the end and inserting “; and”; and

1 (iii) by adding at the end the fol-
2 lowing new clause:

3 “(iv) at State option, may not apply a
4 waiting period in the case of a child de-
5 scribed in section 2110(b)(5), if the State
6 satisfies the requirements of section
7 2105(c)(8).”.

8 (2) APPLICATION OF ENHANCED MATCH UNDER
9 MEDICAID.—Section 1905 of the Social Security Act
10 (42 U.S.C. 1396d), as amended by section 2(a)(2),
11 is amended—

12 (A) in subsection (b), in the fourth sen-
13 tence, by striking “or (u)(4)” and inserting
14 “(u)(4), or (u)(5)”; and

15 (B) in subsection (u)—

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

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

20 “(5) For purposes of subsection (b), the ex-
21 penditures described in this paragraph are expendi-
22 tures for items and services for children described in
23 section 2110(b)(5), but only in the case of a State
24 that satisfies the requirements of section
25 2105(c)(8).”.

1 (3) APPLICATION OF SECONDARY PAYOR PROVI-
2 SIONS.—Section 2107(e)(1) of the Social Security
3 Act (42 U.S.C. 1397gg(e)(1)), as amended by sec-
4 tion 3(b), is amended by adding at the end the fol-
5 lowing:

6 “(F) Section 1902(a)(25) (relating to co-
7 ordination of benefits and secondary payor pro-
8 visions) with respect to children covered under
9 a waiver described in section 2110(b)(5).”.

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

14 **SEC. 358. INNOVATIVE OUTREACH PROGRAMS.**

15 Title XXI of the Social Security Act (42 U.S.C.
16 1397aa et seq.), as amended by section 351(b), is amend-
17 ed by adding at the end the following:

18 **“SEC. 2112. EXPANDED OUTREACH ACTIVITIES.**

19 “(a) IN GENERAL.—Funds made available under
20 subsection (f) for expenditure under this section for a fis-
21 cal year shall be used by the Secretary to award grants
22 to eligible entities to conduct innovative outreach and en-
23 rollment efforts that are designed to increase the enroll-
24 ment and participation of eligible children under this title
25 and title XIX.

1 “(b) PRIORITY FOR GRANTS IN CERTAIN AREAS.—

2 In making grants under subsection (a), the Secretary shall
3 give priority to eligible entities that propose to target geo-
4 graphic areas with high rates of—

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

7 “(2) families for whom English is not their pri-
8 mary language; or

9 “(3) racial and ethnic minorities and health dis-
10 parity populations

11 “(c) APPLICATION.—An eligible entity that desires to
12 receive a grant under this section shall submit an applica-
13 tion to the Secretary in such form and manner, and con-
14 taining such information, as the Secretary may decide.
15 Such application shall include—

16 “(1) quality and outcomes performance meas-
17 ures to evaluate the effectiveness of activities funded
18 by a grant under this paragraph to ensure that the
19 activities are meeting their goals; and

20 “(2) an assurance that the entity will—

21 “(A) collect and report enrollment data;
22 and

23 “(B) disseminate findings from evaluations
24 of the activities funded under the grant.

1 “(d) REPORT.—The Secretary shall report to Con-
2 gress on an annual basis the results of the outreach efforts
3 under grants awarded under this section.

4 “(e) DEFINITION OF ELIGIBLE ENTITY.—In this sec-
5 tion, the term ‘eligible entity’ means any of the following:

6 “(1) A State.

7 “(2) A national, local, or community-based pub-
8 lic or nonprofit private organization.

9 “(f) APPROPRIATION.—For the purpose of awarding
10 grants to eligible entities under this section, there is ap-
11 propriated, out of any money in the Treasury not other-
12 wise appropriated, \$50,000,000 for each of fiscal years
13 2006 and 2007.”.

14 **Subtitle C—Affirming the**
15 **Importance of Medicaid**

16 **SEC. 361. SENSE OF THE SENATE.**

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

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

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

3 (2) Medicaid provides health insurance for more
4 than $\frac{1}{4}$ of America's children and is the largest pur-
5 chaser of maternity care, paying for more than $\frac{1}{3}$
6 of all the births in the United States each year.

7 (3) Medicaid provides critical help for the elder-
8 ly and individuals living with disabilities. Medicaid is
9 America's single largest purchaser of nursing home
10 services and other long-term care, covering the ma-
11 jority of nursing home residents.

12 (4) Medicaid pays for personal care and other
13 supportive services, which are typically not provided
14 by private health insurance, even if individuals could
15 obtain it. These services are necessary to enable in-
16 dividuals with spinal cord injuries, developmental
17 disabilities, neurological degenerative diseases, seri-
18 ous and persistent mental illnesses, HIV/AIDS, and
19 other chronic conditions to remain in the commu-
20 nity, to work, and to maintain independence.

21 (5) Medicaid is an essential supplement to the
22 Medicare program under title XVIII of the Social
23 Security Act (42 U.S.C. 1395 et seq.) for more than
24 6,000,000 Medicare beneficiaries who are low-income
25 elderly or disabled, assisting them with their Medi-

1 care premiums and co-insurance, wrap-around bene-
2 fits, and, in most States, the costs of nursing home
3 care that Medicare does not cover.

4 (6) About 42 percent of all Medicaid spending
5 is for those who are elderly or are living with disabil-
6 ities and are dually eligible for Medicare and Med-
7 icaid.

8 (7) Medicaid faces an ever growing burden as
9 a result of Medicare's gaps. The Medicaid program
10 spent nearly \$40,000,000,000 on uncovered Medi-
11 care services in 2002. Medicaid payments for low-in-
12 come Medicare beneficiary cost-sharing are the larg-
13 est and fastest growing share of Medicaid spending.

14 (8) The Medicare drug benefit imposes addi-
15 tional costs on States, which will add to the already
16 significant long-term care cost burden. Medicaid
17 spending on Medicare beneficiaries' long-term care
18 costs is expected to double from \$25,000,000,000 in
19 2002 to \$51,000,000,000 in 2012.

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

1 (10) Medicaid serves a major role in ensuring
2 that the number of Americans without health insur-
3 ance, approximately 45,000,000 in 2003, is not sub-
4 stantially higher. Medicaid helps buffer the drop in
5 private coverage during recessions. More than
6 4,800,000 Americans lost employer sponsored cov-
7 erage between 2000 and 2003. Medicaid covered an
8 additional 5,800,000 Americans during this period,
9 preventing even greater numbers of uninsured.

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

19 (12) Medicaid is critical for children with dis-
20 abilities. Medicaid covers 78 percent of poor children
21 with disabilities who are under 5 years of age and
22 70 percent of poor children with disabilities who are
23 between the ages of 5 and 17. Similarly, Medicaid
24 covers a substantial portion of children with disabil-
25 ities who are near poor, covering 40 percent of chil-

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

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

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

16 (15) The system of Federal matching for State
17 Medicaid expenditures ensures that Federal funds
18 will grow as State spending increases in response to
19 unmet needs.

20 (16) Despite the varied population served by
21 the Medicaid program, including those with signifi-
22 cant health care needs, Medicaid per capita growth
23 has been consistently about half the rate of growth
24 in private insurance premiums and Medicaid has far
25 lower administrative costs. Medicaid costs less per

1 person than private coverage for people who have
2 similar health status.

3 (b) SENSE OF THE SENATE.—It is the sense of the
4 Senate that—

5 (1) the Medicaid program under title XIX of
6 the Social Security Act (42 U.S.C. 1396 et seq.) is
7 a critical component of the health care system of the
8 United States;

9 (2) Federal support for the Medicaid program
10 must be adequate to support State spending meeting
11 the essential health needs of the low-income elderly,
12 low-income individuals with disabilities, and low-in-
13 come children and families, and should not be cut or
14 capped; and

15 (3) any retreat from the Federal commitment
16 to Medicaid would threaten not only the health care
17 safety net of the United States but the entire health
18 care system

1 **TITLE IV—REDUCING HEALTH**
2 **CARE COSTS FOR SMALL EM-**
3 **PLOYERS**

4 **Subtitle A—Tax Relief**

5 **SEC. 401. REFUNDABLE CREDIT FOR SMALL BUSINESS EM-**
6 **PLOYEE HEALTH INSURANCE EXPENSES.**

7 (a) IN GENERAL.—Subpart C of part IV of sub-
8 chapter A of chapter 1 of the Internal Revenue Code of
9 1986 (relating to refundable credits) is amended by redес-
10 ignating section 36 as section 37 and inserting after sec-
11 tion 35 the following new section:

12 **“SEC. 36. SMALL BUSINESS EMPLOYEE HEALTH INSURANCE**
13 **EXPENSES.**

14 “(a) DETERMINATION OF AMOUNT.—In the case of
15 a qualified small employer, there shall be allowed as a
16 credit against the tax imposed by this subtitle for the tax-
17 able year an amount equal to the expense amount de-
18 scribed in subsection (b) paid by the taxpayer during the
19 taxable year.

20 “(b) EXPENSE AMOUNT.—For purposes of this sec-
21 tion—

22 “(1) IN GENERAL.—The expense amount de-
23 scribed in this subsection is the applicable percent-
24 age of the amount of qualified employee health in-
25 surance expenses of each qualified employee.

1 “(2) APPLICABLE PERCENTAGE.—For purposes
2 of paragraph (1), the applicable percentage is equal
3 to—

4 “(A) for any qualified small employer de-
5 scribed in subparagraph (A) of paragraph (4),
6 50 percent,

7 “(B) for any qualified small employer de-
8 scribed in subparagraph (B) of paragraph (4),
9 35 percent, and

10 “(C) for any qualified small employer de-
11 scribed in subparagraph (C) of paragraph (4),
12 25 percent.

13 “(3) PER EMPLOYEE DOLLAR LIMITATION.—
14 The amount of qualified employee health insurance
15 expenses taken into account under paragraph (1)
16 with respect to any qualified employee for any tax-
17 able year shall not exceed—

18 “(A) \$1,500 in the case of self-only cov-
19 erage; and

20 “(B) \$3,500 in the case of family coverage.

21 “(4) QUALIFIED SMALL EMPLOYERS DE-
22 SCRIBED.—A qualified small employer is described
23 in—

1 “(A) this subparagraph if such employer
2 employed an average of 9 or fewer employees
3 (as determined under subsection (c)(1)(A)(ii)),

4 “(B) this subparagraph if such employer
5 employed an average of more than 9 but less
6 than 25 employees (as so determined), and

7 “(C) this subparagraph if such employer
8 employed an average of more than 24 but not
9 more than 50 employees (as so determined).

10 “(c) DEFINITIONS.—For purposes of this section—

11 “(1) QUALIFIED SMALL EMPLOYER.—

12 “(A) IN GENERAL.—The term ‘qualified
13 small employer’ means, with respect to any cal-
14 endar year, any employer if—

15 “(i) such employer pays or incurs at
16 least 75 percent of the qualified employee
17 health insurance expenses of each qualified
18 employee (determined without regard to
19 subsection (b)(3)), and

20 “(ii) such employer employed an aver-
21 age of 50 or fewer employees on business
22 days during either of the 2 preceding cal-
23 endar years.

24 For purposes of clause (ii), a preceding cal-
25 endar year may be taken into account only if

1 the employer was in existence throughout such
2 year.

3 “(B) EMPLOYERS NOT IN EXISTENCE IN
4 PRECEDING YEAR.—In the case of an employer
5 which was not in existence throughout the 1st
6 preceding calendar year, the determination
7 under subparagraph (A)(ii) shall be based on
8 the average number of employees that it is rea-
9 sonably expected such employer will employ on
10 business days in the current calendar year.

11 “(2) QUALIFIED EMPLOYEE HEALTH INSUR-
12 ANCE EXPENSES.—

13 “(A) IN GENERAL.—The term ‘qualified
14 employee health insurance expenses’ means any
15 amount paid by an employer for health insur-
16 ance coverage (as defined in section 9832(b)(1))
17 to the extent such amount is attributable to
18 coverage provided to any employee while such
19 employee is a qualified employee.

20 “(B) EXCEPTION FOR AMOUNTS PAID
21 UNDER SALARY REDUCTION ARRANGEMENTS.—
22 No amount paid or incurred for health insur-
23 ance coverage pursuant to a salary reduction
24 arrangement shall be taken into account under
25 subparagraph (A).

1 “(3) QUALIFIED EMPLOYEE.—

2 “(A) IN GENERAL.—The term ‘qualified
3 employee’ means, with respect to any period, an
4 employee of an employer if—

5 “(i) the annual amount of hours in
6 the employ of such employer by such em-
7 ployee is at least 400 hours,

8 “(ii) the total amount of wages paid
9 or incurred by such employer to such em-
10 ployee at an annual rate during the taxable
11 year is at least \$5,000, and

12 “(iii) such employee is not eligible
13 for—

14 “(I) any benefits under title
15 XVIII, XIX, or XXI of the Social Se-
16 curity Act, or

17 “(II) any other publicly-spon-
18 sored health insurance program.

19 “(B) TREATMENT OF CERTAIN EMPLOY-
20 EES.—For purposes of subparagraph (A), the
21 term ‘employee’—

22 “(i) shall not include an employee
23 within the meaning of section 401(c)(1),
24 and

1 “(ii) shall include a leased employee
2 within the meaning of section 414(n).

3 “(C) WAGES.—The term ‘wages’ has the
4 meaning given such term by section 3121(a)
5 (determined without regard to any dollar limita-
6 tion contained in such section).

7 “(d) CERTAIN RULES MADE APPLICABLE.—For pur-
8 poses of this section, rules similar to the rules of section
9 52 shall apply.

10 “(e) COORDINATION WITH DEDUCTION FOR HEALTH
11 INSURANCE COSTS OF SELF-EMPLOYED INDIVIDUALS.—
12 In the case of a taxpayer who is eligible to deduct any
13 amount under section 162(l) for the taxable year, this sec-
14 tion shall apply only if the taxpayer elects not to claim
15 any amount as a deduction under such section for such
16 year.”.

17 (b) CONFORMING AMENDMENTS.—

18 (1) Paragraph (2) of section 1324(b) of title
19 31, United States Code, is amended by inserting be-
20 fore the period “, or from section 36 of such Code”.

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

 “Sec. 36. Small business employee health insurance expenses.
 “Sec. 37. Overpayments of tax.”.

1 (e) EFFECTIVE DATE.—The amendments made by
 2 this section shall apply to amounts paid or incurred in tax-
 3 able years beginning after December 31, 2005.

4 **Subtitle B—Three-Share Program**

5 **SEC. 421. THREE-SHARE PROGRAMS.**

6 The Social Security Act (42 U.S.C. 301 et seq.) is
 7 amended by adding at the end the following:

8 **“TITLE XXII—PROVIDING FOR** 9 **THE UNINSURED**

10 **“SEC. 2201. THREE-SHARE PROGRAMS.**

11 “(a) PILOT PROGRAMS.—The Secretary, acting
 12 through the Administrator, shall award grants under this
 13 section for the startup and operation of 25 eligible three-
 14 share pilot programs for a 5-year period.

15 “(b) GRANTS FOR THREE-SHARE PROGRAMS.—

16 “(1) ESTABLISHMENT.—The Administrator
 17 may award grants to eligible entities—

18 “(A) to establish three-share programs;

19 “(B) to provide for contributions to the
 20 premiums assessed for coverage under a three-
 21 share program as provided for in subsection
 22 (c)(2)(B)(iii); and

23 “(C) to establish risk pools.

24 “(2) THREE-SHARE PROGRAM PLAN.—Each en-
 25 tity desiring a grant under this subsection shall de-

1 velop a plan for the establishment and operation of
2 a three-share program that meets the requirements
3 of paragraphs (2) and (3) of subsection (c).

4 “(3) APPLICATION.—Each entity desiring a
5 grant under this subsection shall submit an applica-
6 tion to the Administrator at such time, in such man-
7 ner and containing such information as the Adminis-
8 trator may require, including—

9 “(A) the three-share program plan de-
10 scribed in paragraph (2); and

11 “(B) an assurance that the eligible entity
12 will—

13 “(i) determine a benefit package;

14 “(ii) recruit businesses and employees
15 for the three-share program;

16 “(iii) build and manage a network of
17 health providers or contract with an exist-
18 ing network or licensed insurance provider;

19 “(iv) manage all administrative needs;
20 and

21 “(v) establish relationships among
22 community, business, and provider inter-
23 ests.

1 “(4) PRIORITY.—In awarding grants under this
2 section the Secretary shall give priority to an appli-
3 cant—

4 “(A) that is an existing three-share pro-
5 gram;

6 “(B) that is an eligible three-share pro-
7 gram that has demonstrated community sup-
8 port; or

9 “(C) that is located in a State with insur-
10 ance laws and regulations that permit three-
11 share program expansion.

12 “(c) GRANT ELIGIBILITY.—

13 “(1) IN GENERAL.—The Secretary, acting
14 through the Administrator, shall promulgate regula-
15 tions providing for the eligibility of three-share pro-
16 grams for participation in the pilot program under
17 this section.

18 “(2) THREE-SHARE PROGRAM REQUIRE-
19 MENTS.—

20 “(A) IN GENERAL.—To be determined to
21 be an eligible three-share program for purposes
22 of participation in the pilot program under this
23 section a three-share program shall—

24 “(i) be either a non-profit or local
25 governmental entity;

1 “(ii) define the region in which such
2 program will provide services;

3 “(iii) have the capacity to carry out
4 administrative functions of managing
5 health plans, including monthly billings,
6 verification/enrollment of eligible employers
7 and employees, maintenance of member-
8 ship rosters, development of member mate-
9 rials (such as handbooks and identification
10 cards), customer service, and claims proc-
11 essing; and

12 “(iv) have demonstrated community
13 involvement.

14 “(B) PAYMENT.—To be eligible under
15 paragraph (1), a three-share program shall pay
16 the costs of services provided under subpara-
17 graph (A)(ii) by charging a monthly premium
18 for each covered individual to be divided as fol-
19 lows:

20 “(i) Not more than 30 percent of such
21 premium shall be paid by a qualified em-
22 ployee desiring coverage under the three-
23 share program.

1 “(ii) Not more than 30 percent of
2 such premium shall be paid by the quali-
3 fied employer of such a qualified employee.

4 “(iii) At least 40 percent of such pre-
5 mium shall be paid from amounts provided
6 under a grant under this section.

7 “(iv) Any remaining amount shall be
8 paid by the three-share program from
9 other public, private, or charitable sources.

10 “(C) PROGRAM FLEXIBILITY.—A three-
11 share program may set an income eligibility
12 guideline for enrollment purposes.

13 “(3) COVERAGE.—

14 “(A) IN GENERAL.—To be an eligible
15 three-share program under this section, the
16 three-share program shall provide at least the
17 following benefits:

18 “(i) Physicians services.

19 “(ii) In-patient hospital services.

20 “(iii) Out-patient services.

21 “(iv) Emergency room visits.

22 “(v) Emergency ambulance services.

23 “(vi) Diagnostic lab fees and x-rays.

24 “(vii) Prescription drug benefits.

1 “(B) LIMITATION.—Nothing in subpara-
2 graph (A) shall be construed to require that a
3 three-share program provide coverage for serv-
4 ices performed outside the region described in
5 paragraph (2)(A)(i).

6 “(C) PREEXISTING CONDITIONS.—A pro-
7 gram described in subparagraph (A) shall not
8 be an eligible three-share program under para-
9 graph (1) if any individual can be excluded
10 from coverage under such program because of
11 a preexisting health condition.

12 “(d) GRANTS FOR EXISTING THREE-SHARE PRO-
13 GRAMS TO MEET CERTIFICATION REQUIREMENTS.—

14 “(1) IN GENERAL.—The Administrator may
15 award grants to three-share programs that are oper-
16 ating on the date of enactment of this section.

17 “(2) APPLICATION.—Each eligible entity desir-
18 ing a grant under this subsection shall submit an
19 application to the Administrator at such time, in
20 such manner, and containing such information as
21 the Administrator may require.

22 “(e) APPLICATION OF STATE LAWS.—Nothing in this
23 section shall be construed to preempt State law.

24 “(f) DISTRESSED BUSINESS FORMULA.—

1 “(1) IN GENERAL.—Not later than 60 days
2 after the date of enactment of this section, the Ad-
3 ministrator of the Health Resources and Services
4 Administration shall develop a formula to determine
5 which businesses qualify as distressed businesses for
6 purposes of this section.

7 “(2) EFFECT ON INSURANCE MARKET.—Grant-
8 ing eligibility to a distressed business using the for-
9 mula under paragraph (1) shall not interfere with
10 the insurance market. Any business found to have
11 reduced benefits to qualify as a distressed business
12 under the formula under paragraph (1) shall not be
13 eligible to be a three-share program for purposes of
14 this section.

15 “(g) DEFINITIONS.—In this section:

16 “(1) ADMINISTRATOR.—The term ‘Adminis-
17 trator’ means the Administrator of the Health Re-
18 sources and Services Administration.

19 “(2) COVERED INDIVIDUAL.—The term ‘cov-
20 ered individual’ means—

21 “(A) a qualified employee; or

22 “(B) a child under the age of 23 or a
23 spouse of such qualified employee who—

1 “(i) lacks access to health care cov-
2 erage through their employment or em-
3 ployer;

4 “(ii) lacks access to health coverage
5 through a family member;

6 “(iii) is not eligible for coverage under
7 the medicare program under title XVIII or
8 the medicaid program under title XIX; and

9 “(iv) does not qualify for benefits
10 under the State Children’s Health Insur-
11 ance Program under title XXI.

12 “(3) DISTRESSED BUSINESS.—The term ‘dis-
13 tressed business’ means a business that—

14 “(A) in light of economic hardship and ris-
15 ing health care premiums may be forced to dis-
16 continue or scale back its health care coverage;
17 and

18 “(B) qualifies as a distressed business ac-
19 cording to the formula under subsection (g).

20 “(4) ELIGIBLE ENTITY.—The term ‘eligible en-
21 tity’ means an entity that meets the requirements of
22 subsection (a)(2)(A).

23 “(5) QUALIFIED EMPLOYEE.—The term ‘quali-
24 fied employee’ means any individual employed by a

1 qualified employer who meets certain criteria includ-
2 ing—

3 “(A) lacking access to health coverage
4 through a family member or common law part-
5 ner;

6 “(B) not being eligible for coverage under
7 the medicare program under title XVIII or the
8 medicaid program under title XIX; and

9 “(C) agreeing that the share of fees de-
10 scribed in subsection (a)(2)(B)(i) shall be paid
11 in the form of payroll deductions from the
12 wages of such individual.

13 “(6) QUALIFIED EMPLOYER.—The term ‘quali-
14 fied employer’ means an employer as defined in sec-
15 tion 3(d) of the Fair Labor Standards Act of 1938
16 (29 U.S.C. 203(d)) who—

17 “(A) is a small business concern as defined
18 in section 3(a) of the Small Business Act (15
19 U.S.C. 632);

20 “(B) is located in the region described in
21 subsection (a)(2)(A)(i); and

22 “(C) has not contributed to the health care
23 benefits of its employees for at least 12 months
24 consecutively or currently provides insurance
25 but is classified as a distressed business.

1 “(h) EVALUATION.—Not later than 90 days after the
2 end of the 5-year period during which grants are available
3 under this section, the Government Accountability Office
4 shall submit to the Secretary and the appropriate commit-
5 tees of Congress a report concerning—

6 “(1) the effectiveness of the programs estab-
7 lished under this section;

8 “(2) the number of individuals covered under
9 such programs;

10 “(3) any resulting best practices; and

11 “(4) the level of community involvement.

12 “(i) AUTHORIZATION OF APPROPRIATIONS.—There
13 are authorized to be appropriated to carry out this section,
14 such sums as may be necessary for each of fiscal years
15 2006 through 2011.”.

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