

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.

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## 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

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## 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           “(A) to enjoin such alienation or disposition of  
2 property; or

3           “(B) for a restraining order to—

4                 “(i) prohibit any person from withdrawing,  
5 transferring, removing, dissipating, or disposing  
6 of any such property or property of equivalent  
7 value; and

8                 “(ii) appoint a temporary receiver to ad-  
9 minister such restraining order.

10          “(2) Proceedings under paragraph (1) shall be car-  
11 ried out in the same manner as applies under section 1345  
12 of title 18, United States Code.”.

13 **SEC. 107. WHOLESALE DISTRIBUTION OF DRUGS; STATE-**  
14 **MENTS REGARDING PRIOR SALE, PURCHASE,**  
15 **OR TRADE.**

16          (a) STRIKING OF EXEMPTIONS; APPLICABILITY TO  
17 REGISTERED EXPORTERS.—Section 503(e) of the Federal  
18 Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is  
19 amended—

20                 (1) in paragraph (1)—

21                         (A) by striking “and who is not the manu-  
22 facturer or an authorized distributor of record  
23 of such drug”;

24                         (B) by striking “to an authorized dis-  
25 tributor of record or”; and



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

3           “STATE OPTION TO PROVIDE FAMILY PLANNING

4                                 SERVICES AND SUPPLIES

5           “SEC. 1937. (a) IN GENERAL.—Subject to sub-  
6           sections (b) and (c), a State may elect (through a State  
7           plan amendment) to make medical assistance described in  
8           section 1905(a)(4)(C) available to any individual whose  
9           family income does not exceed the greater of—

10                 “(1) 185 percent of the income official poverty  
11           line (as defined by the Office of Management and  
12           Budget, and revised annually in accordance with sec-  
13           tion 673(2) of the Omnibus Budget Reconciliation  
14           Act of 1981) applicable to a family of the size in-  
15           volved; or

16                 “(2) the eligibility income level (expressed as a  
17           percentage of such poverty line) that has been speci-  
18           fied under a waiver authorized by the Secretary or  
19           under section 1902(r)(2)), as of January 1, 2005,  
20           for an individual to be eligible for medical assistance  
21           under the State plan.

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

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

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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