

108TH CONGRESS
1ST SESSION

H. R. 2498

To amend title XVIII of the Social Security Act to provide a prescription benefit program for all Medicare beneficiaries.

IN THE HOUSE OF REPRESENTATIVES

JUNE 17, 2003

Mr. SANDERS (for himself, Mr. KUCINICH, Ms. LEE, Mr. HINCHEY, Mr. FRANK of Massachusetts, Mr. DEFazio, Mr. PAYNE, Mr. SERRANO, Mr. WEINER, Mr. OLVER, Mr. FILNER, Mr. CONYERS, Mr. NADLER, Ms. CORRINE BROWN of Florida, Ms. WATSON, Ms. BALDWIN, Ms. WOOLSEY, and Mr. DAVIS of Illinois) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XVIII of the Social Security Act to provide a prescription benefit program for all Medicare beneficiaries.

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 “Medicare Extension of Drugs to Seniors (MEDS) Act of
6 2003”.

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

- Sec. 1. Short title; table of contents.
 Sec. 2. Findings.
 Sec. 3. Prescription medicine benefit program.

“PART D—PRESCRIPTION MEDICINE BENEFIT FOR THE AGED AND
 DISABLED

- “Sec. 1860. Establishment of prescription medicine benefit program for
 the aged and disabled.
 “Sec. 1860A. Scope of benefits.
 “Sec. 1860B. Payment of benefits; benefit limits.
 “Sec. 1860C. Eligibility and enrollment.
 “Sec. 1860D. Premiums.
 “Sec. 1860E. Special eligibility, enrollment, and copayment rules for low-
 income individuals.
 “Sec. 1860F. Prescription Medicine Insurance Account.
 “Sec. 1860G. Administration of benefits.
 “Sec. 1860H. Employer Incentive Program for employment-based retiree
 medicine coverage.
 “Sec. 1860I. Promotion of pharmaceutical research on break-through medi-
 cines while providing program cost containment.
 “Sec. 1860J. Appropriations to cover Government contributions.
 “Sec. 1860K. Prescription medicine defined.
 Sec. 4. Substantial reductions in the price of prescription drugs for medicare
 beneficiaries.
 Sec. 5. Amendments to program for importation of certain prescription drugs
 by pharmacists and wholesalers.
 Sec. 6. Reasonable price agreement for federally funded research.
 Sec. 7. GAO ongoing studies and reports on program; miscellaneous reports.
 Sec. 8. Medigap transition provisions.

3 **SEC. 2. FINDINGS.**

4 Congress makes the following findings:

- 5 (1) Prescription medicine coverage was not a
 6 standard part of health insurance when the medicare
 7 program under title XVIII of the Social Security Act
 8 was enacted in 1965. Since 1965, however, medicine
 9 coverage has become a key component of most pri-
 10 vate and public health insurance coverage, except for
 11 the medicare program.

1 (2) At least $\frac{2}{3}$ of medicare beneficiaries have
2 unreliable, inadequate, or no medicine coverage at
3 all.

4 (3) Seniors who do not have medicine coverage
5 typically pay, at a minimum, 15 percent more than
6 people with coverage.

7 (4) Medicare beneficiaries at all income levels
8 lack prescription medicine coverage, with more than
9 $\frac{1}{2}$ of such beneficiaries having incomes greater than
10 150 percent of the poverty line.

11 (5) The number of private firms offering retiree
12 health coverage is declining.

13 (6) Medigap premiums for medicines are too ex-
14 pensive for most beneficiaries and are highest for
15 older senior citizens, who need prescription medicine
16 coverage the most and typically have the lowest in-
17 comes.

18 (7) All medicare beneficiaries should have ac-
19 cess to a voluntary, reliable, affordable, and defined
20 outpatient medicine benefit as part of the medicare
21 program that assists with the high cost of prescrip-
22 tion medicines and protects them against excessive
23 out-of-pocket costs.

1 **SEC. 3. PRESCRIPTION MEDICINE BENEFIT PROGRAM.**

2 (a) IN GENERAL.—Title XVIII of the Social Security
3 Act (42 U.S.C. 1395 et seq.) is amended—

4 (1) by redesignating part D as part E; and

5 (2) by inserting after part C the following new
6 part:

7 “PART D—PRESCRIPTION MEDICINE BENEFIT
8 FOR THE AGED AND DISABLED

9 “ESTABLISHMENT OF PRESCRIPTION MEDICINE BENEFIT
10 PROGRAM FOR THE AGED AND DISABLED

11 “SEC. 1860. There is established a voluntary insur-
12 ance program to provide prescription medicine benefits,
13 including pharmacy services, in accordance with the provi-
14 sions of this part for individuals who are aged or disabled
15 or have end-stage renal disease and who elect to enroll
16 under such program, to be financed from premium pay-
17 ments by enrollees together with contributions from funds
18 appropriated by the Federal Government.

19 “SCOPE OF BENEFITS

20 “SEC. 1860A. (a) IN GENERAL.—The benefits pro-
21 vided to an individual enrolled in the insurance program
22 under this part shall consist of—

23 “(1) payments made, in accordance with the
24 provisions of this part, for covered prescription
25 medicines (as specified in subsection (b)) dispensed
26 by any pharmacy participating in the program under

1 this part (and, in circumstances designated by the
2 Secretary, by a nonparticipating pharmacy), includ-
3 ing any specifically named medicine prescribed for
4 the individual by a qualified health care professional
5 regardless of whether the medicine is included in any
6 formulary established under this part if such medi-
7 cine is certified as medically necessary by such
8 health care professional (except that the Secretary
9 shall encourage to the maximum extent possible the
10 substitution and use of lower-cost generics), up to
11 the benefit limits specified in section 1860B; and

12 “(2) charging by pharmacies of the negotiated
13 price—

14 “(A) for all covered prescription medicines,
15 without regard to such benefit limit; and

16 “(B) established with respect to any drugs
17 or classes of drugs described in subparagraphs
18 (A), (B), (D), (E), or (F) of section 1927(d)(2)
19 that are available to individuals receiving bene-
20 fits under this title.

21 “(b) COVERED PRESCRIPTION MEDICINES.—

22 “(1) IN GENERAL.—Covered prescription medi-
23 cines, for purposes of this part, include all prescrip-
24 tion medicines (as defined in section 1860K(1)), in-

1 including smoking cessation agents, except as other-
2 wise provided in this subsection.

3 “(2) EXCLUSIONS FROM COVERAGE.—Covered
4 prescription medicines shall not include drugs or
5 classes of drugs described in subparagraphs (A)
6 through (D) and (F) through (H) of section
7 1927(d)(2) unless—

8 “(A) specifically provided otherwise by the
9 Secretary with respect to a drug in any of such
10 classes; or

11 “(B) a drug in any of such classes is cer-
12 tified to be medically necessary by a health care
13 professional.

14 “(3) EXCLUSION OF PRESCRIPTION MEDICINES
15 TO THE EXTENT COVERED UNDER PART A OR B.—
16 A medicine prescribed for an individual that would
17 otherwise be a covered prescription medicine under
18 this part shall not be so considered to the extent
19 that payment for such medicine is available under
20 part A or B, including all injectable drugs and
21 biologicals for which payment was made or should
22 have been made by a carrier under section
23 1861(s)(2) (A) or (B) as of the date of enactment
24 of the Medicare Extension of Drugs to Seniors
25 (MEDS) Act of 2003. Medicines otherwise covered

1 under part A or B shall be covered under this part
 2 to the extent that benefits under part A or B are ex-
 3 hausted.

4 “(4) STUDY ON INCLUSION OF HOME INFUSION
 5 THERAPY SERVICES.—Not later than one year after
 6 the date of the enactment of the Medicare Extension
 7 of Drugs to Seniors (MEDS) Act of 2003, the Sec-
 8 retary shall submit to Congress a legislative proposal
 9 for the delivery of home infusion therapy services
 10 under this title and for a system of payment for
 11 such a benefit that coordinates items and services
 12 furnished under part B and under this part.

13 “PAYMENT OF BENEFITS; BENEFIT LIMITS

14 “SEC. 1860B. (a) PAYMENT OF BENEFITS.—

15 “(1) IN GENERAL.—There shall be paid from
 16 the Prescription Medicine Insurance Account within
 17 the Supplementary Medical Insurance Trust Fund,
 18 in the case of each individual who is enrolled in the
 19 insurance program under this part and who pur-
 20 chases covered prescription medicines in a calendar
 21 year—

22 “(A) with respect to costs incurred for cov-
 23 ered prescription medicine furnished during a
 24 year, before the individual has incurred out-of-
 25 pocket expenses under this subsection equal to
 26 the catastrophic out-of-pocket limit specified in

subsection (b), an amount equal to the applicable percentage (specified in paragraph (2)) of the negotiated price for each such covered prescription medicine or such higher percentage as is proposed under section 1860G(b)(7); and

“(B) with respect to costs incurred for covered prescription medicine furnished during a year, after the individual has incurred out-of-pocket expenses under this subsection equal to the catastrophic out-of-pocket limit specified in subsection (b), an amount equal to 100 percent of the negotiated price for each such covered prescription medicine.

“(2) APPLICABLE PERCENTAGE.—The applicable percentage specified in this paragraph is 80 percent or such higher percentage as is proposed under section 1860G(b)(7), if the Secretary finds that such higher percentage will not increase aggregate costs to the Prescription Medicine Insurance Account.

“(b) CATASTROPHIC LIMIT ON OUT-OF-POCKET EXPENSES.—

“(1) IN GENERAL.—The catastrophic limit on out-of-pocket expenses specified in this subsection for—

1 “(A) for each of calendar years 2005 and
2 2006, \$2,000; and

3 “(B) subject to paragraph (2), for calendar
4 year 2007 and each subsequent calendar year is
5 equal the limit for the preceding year under this
6 paragraph adjusted by the sustainable growth
7 rate percentage (determined under section
8 1861I(b)) for the year involved.

9 “(2) ROUNDING.—Any amount determined
10 under paragraph (1)(E) that is not a multiple of
11 \$10 shall be rounded to the nearest multiple of \$10.

12 “ELIGIBILITY AND ENROLLMENT

13 “SEC. 1860C. (a) ELIGIBILITY.—Every individual
14 who, in or after 2005, is entitled to hospital insurance ben-
15 efits under part A or enrolled in the medical insurance
16 program under part B is eligible to enroll, in accordance
17 with the provisions of this section, in the insurance pro-
18 gram under this part, during an enrollment period pre-
19 scribed in or under this section, in such manner and form
20 as may be prescribed by regulations.

21 “(b) ENROLLMENT.—

22 “(1) IN GENERAL.—Each individual who satis-
23 fies subsection (a) shall be enrolled (or eligible to en-
24 roll) in the program under this part in accordance
25 with the provisions of section 1837, as if that section

1 applied to this part, except as otherwise explicitly
2 provided in this part.

3 “(2) SINGLE ENROLLMENT PERIOD.—Except as
4 provided in section 1837(i) (as such section applies
5 to this part), 1860E, or 1860H(e), or as otherwise
6 explicitly provided, no individual shall be entitled to
7 enroll in the program under this part at any time
8 after the initial enrollment period without penalty,
9 and in the case of all other late enrollments, the Sec-
10 retary shall develop a late enrollment penalty for the
11 individual that fully recovers the additional actuarial
12 risk involved providing coverage for the individual.

13 “(3) SPECIAL ENROLLMENT PERIOD FOR
14 2005.—

15 “(A) IN GENERAL.—An individual who
16 first satisfies subsection (a) in 2005 may, at
17 any time on or before December 31, 2005—

18 “(i) enroll in the program under this
19 part; and

20 “(ii) enroll or reenroll in such pro-
21 gram after having previously declined or
22 terminated enrollment in such program.

23 “(B) EFFECTIVE DATE OF COVERAGE.—

24 An individual who enrolls under the program
25 under this part pursuant to subparagraph (A)

“(1) IN GENERAL.—Except as otherwise provided in this part, an individual’s coverage under the program under this part shall be effective for the period provided in section 1838, as if that section applied to the program under this part.

In addition to the causes of termination specified in section 1838, an individual's coverage under this part shall be terminated when the individual retains coverage under neither the program under part A nor the program under part B, effective on the effective date of termination of coverage under part A or (if later) under part B.

20 “SEC. 1860D. (a) ANNUAL ESTABLISHMENT OF
21 MONTHLY PREMIUM RATES.—

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1 “(2) INITIAL PREMIUMS.—For months in 2005,
2 the monthly premium rate under this subsection
3 shall be—

4 “(A) \$24, in the case of premiums paid by
5 an individual enrolled in the program under this
6 part; and

7 “(B) \$32, in the case of premiums paid for
8 such an individual by a former employer (as de-
9 fined in section 1860H(f)(2)).

10 “(3) SUBSEQUENT YEARS.—

11 “(A) IN GENERAL.—For months in a year
12 after 2005, the monthly premium under this
13 subsection shall be (subject to subparagraph
14 (B)) the monthly premium (computed under
15 this subsection without regard to subparagraph
16 (B)) for the previous year increased by the an-
17 nual percentage increase in average per capita
18 aggregate expenditures for covered outpatient
19 medicines in the United States for medicare
20 beneficiaries, as estimated and published by the
21 Secretary in September before the year and for
22 the year involved.

23 “(B) ROUNDING.—The monthly premium
24 determined under subparagraph (A) shall be

1 rounded to the nearest multiple of 10 cents if
2 it is not a multiple of 10 cents.

3 “(C) PUBLICATION OF ASSUMPTIONS.—
4 The Secretary shall publish, together with the
5 promulgation of the monthly premium rates
6 under this paragraph, a statement setting forth
7 the actuarial assumptions and bases employed
8 in arriving at the monthly premium under sub-
9 paragraph (A).

10 “(b) PAYMENT OF PREMIUMS.—

11 “(1) PAYMENTS BY DEDUCTION FROM SOCIAL
12 SECURITY, RAILROAD RETIREMENT BENEFITS, OR
13 BENEFITS ADMINISTERED BY OPM.—

14 “(A) DEDUCTION FROM BENEFITS.—In
15 the case of an individual who is entitled to or
16 receiving benefits as described in subsection (a),
17 (b), or (d) of section 1840, premiums payable
18 under this part shall be collected by deduction
19 from such benefits at the same time and in the
20 same manner as premiums payable under part
21 B are collected pursuant to section 1840.

22 “(B) TRANSFERS TO PRESCRIPTION MEDI-
23 CINE INSURANCE ACCOUNT.—The Secretary of
24 the Treasury shall, from time to time, but not
25 less often than quarterly, transfer premiums

1 collected pursuant to subparagraph (A) to the
2 Prescription Medicine Insurance Account from
3 the appropriate funds and accounts described in
4 subsections (a)(2), (b)(2), and (d)(2) of section
5 1840, on the basis of the certifications de-
6 scribed in such subsections. The amounts of
7 such transfers shall be appropriately adjusted
8 to the extent that prior transfers were too great
9 or too small.

10 “(2) DIRECT PAYMENTS TO SECRETARY.—

11 “(A) ADDITIONAL PAYMENT BY EN-
12 ROLLEE.—An individual to whom paragraph
13 (1) applies (other than an individual receiving
14 benefits as described in section 1840(d)) and
15 who estimates that the amount that will be
16 available for deduction under such paragraph
17 for any premium payment period will be less
18 than the amount of the monthly premiums for
19 such period may (under regulations) pay to the
20 Secretary the estimated balance, or such great-
21 er portion of the monthly premium as the indi-
22 vidual chooses.

23 “(B) PAYMENTS BY OTHER ENROLLEES.—

24 An individual enrolled in the insurance program
25 under this part with respect to whom none of

1 the preceding provisions of this subsection ap-
 2 plies (or to whom section 1840(c) applies) shall
 3 pay premiums to the Secretary at such times
 4 and in such manner as the Secretary shall by
 5 regulations prescribe.

6 “(C) DEPOSIT OF PREMIUMS.—Amounts
 7 paid to the Secretary under this paragraph
 8 shall be deposited in the Treasury to the credit
 9 of the Prescription Medicine Insurance Account
 10 in the Supplementary Medical Insurance Trust
 11 Fund.

12 “(c) CERTAIN LOW-INCOME INDIVIDUALS.—For
 13 rules concerning premiums for certain low-income individ-
 14 uals, see section 1860E.

15 “SPECIAL ELIGIBILITY, ENROLLMENT, AND COPAYMENT
 16 RULES FOR LOW-INCOME INDIVIDUALS

17 “SEC. 1860E. (a) STATE AGREEMENTS FOR COV-
 18 ERAGE.—

19 “(1) IN GENERAL.—The Secretary shall, at the
 20 request of a State, enter into an agreement with the
 21 State under which all individuals described in para-
 22 graph (2) are enrolled in the program under this
 23 part, without regard to whether any such individual
 24 has previously declined the opportunity to enroll in
 25 such program.

1 “(2) ELIGIBILITY GROUPS.—The individuals de-
2 scribed in this paragraph, for purposes of paragraph
3 (1), are individuals who satisfy section 1860C(a)
4 and who are—

5 “(A)(i) eligible individuals within the
6 meaning of section 1843; and

7 “(ii) in a coverage group or groups per-
8 mitted under section 1843 (as selected by the
9 State and specified in the agreement); or

10 “(B) qualified medicare medicine bene-
11 ficiaries (as defined in subsection (e)(1)).

12 “(3) COVERAGE PERIOD.—The period of cov-
13 erage under this part of an individual enrolled under
14 an agreement under this subsection shall be as fol-
15 lows:

16 “(A) INDIVIDUALS ELIGIBLE (AT STATE
17 OPTION) FOR PART B BUY-IN.—In the case of
18 an individual described in subsection (a)(2)(A),
19 the coverage period shall be the same period
20 that applies (or would apply) pursuant to sec-
21 tion 1843(d).

22 “(B) QUALIFIED MEDICARE MEDICINE
23 BENEFICIARIES.—In the case of an individual
24 described in subsection (a)(2)(B)—

1 “(i) the coverage period shall begin on
2 the latest of—

3 “(I) January 1, 2005;

4 “(II) the first day of the third
5 month following the month in which
6 the State agreement is entered into;
7 or

8 “(III) the first day of the first
9 month following the month in which
10 the individual satisfies section
11 1860C(a); and

12 “(ii) the coverage period shall end on
13 the last day of the month in which the in-
14 dividual is determined by the State to have
15 become ineligible for medicare medicine
16 cost-sharing.

17 “(4) ALTERNATIVE ENROLLMENT METHODS.—

18 In the process of enrolling low-income individuals
19 under this part, the Secretary shall use the system
20 provided under section 154 of the Social Security
21 Act Amendments of 1994 for newly eligible medicare
22 beneficiaries and shall apply a similar system for
23 other medicare beneficiaries. Such system shall use
24 existing Federal government databases to identify
25 eligibility. Such system shall not require that bene-

1 ficiaries apply for, or enroll through, State medicaid
 2 systems in order to obtain low-income assistance de-
 3 scribed in this section.

4 “(b) SPECIAL PART D ENROLLMENT OPPORTUNITY
 5 FOR INDIVIDUALS LOSING MEDICAID ELIGIBILITY.—In
 6 the case of an individual who—

7 “(1) satisfies section 1860C(a); and

8 “(2) loses eligibility for benefits under the State
 9 plan under title XIX after having been enrolled
 10 under such plan or having been determined eligible
 11 for such benefits;

12 the Secretary shall provide an opportunity for enrollment
 13 under the program under this part during the period that
 14 begins on the date that such individual loses such eligi-
 15 bility and ends on the date specified by the Secretary.

16 “(c) STATE OPTION TO BUY-IN DUALY ELIGIBLE
 17 INDIVIDUALS.—

18 “(1) COVERAGE OF PREMIUMS AS MEDICAL AS-
 19 SISTANCE.—For purposes of applying the second
 20 sentence of section 1905(a), any reference to pre-
 21 miums under part B shall be considered to include
 22 a reference to premiums under this part.

23 “(2) STATE COMMITMENT TO CONTINUE PAR-
 24 TICIPATION IN PART D AFTER BENEFIT LIMIT
 25 REACHED.—As a condition of additional funding to

1 a State under subsection (d), the State, in its State
2 plan under title XIX, shall provide that in the case
3 of any individual whose eligibility for medical assist-
4 ance under title XIX is not limited to medicare cost-
5 sharing and for whom the State elects to pay pre-
6 miums under this part pursuant to this section, the
7 State will purchase all prescription medicines for
8 such individual in accordance with the provisions of
9 this part without regard to whether the benefit limit
10 for such individual under section 1860B(b) has been
11 reached.

12 “(3) MEDICARE COST-SHARING REQUIRED FOR
13 QUALIFIED MEDICARE BENEFICIARIES.—In applying
14 title XIX, the term ‘medicare cost-sharing’ (as de-
15 fined in section 1905(p)(3)) is deemed to include—

16 “(A) premiums under section 1860D; and

17 “(B) the difference between the amount
18 that is paid under section 1860B and the
19 amount that would be paid under such section
20 if any reference to ‘80 percent’ in subsection
21 (a)(2) of such section were deemed a reference
22 to ‘100 percent’ (or, if the Secretary approves
23 a higher percentage under such section, if such
24 percentage were deemed to be 100 percent).

1 “(d) PAYMENT TO STATES FOR COVERAGE OF CER-
2 TAIN MEDICARE COST-SHARING.—

3 “(1) IN GENERAL.—The Secretary shall provide
4 for payment under this subsection to each State that
5 provides for—

6 “(A) medicare cost-sharing described in
7 section 1905(p)(3)(A)(ii) for individuals who
8 would be qualified medicare beneficiaries de-
9 scribed in section 1905(p)(1) but for the fact
10 that their income exceeds the income level es-
11 tablished by the State under section 1905(p)(2)
12 and is at least 120 percent, but less than 135
13 percent, of the official poverty line (referred to
14 in such section) for a family of the size involved
15 and who are not otherwise eligible for medical
16 assistance under the State plan; and

17 “(B) medicare medicine cost-sharing (as
18 defined in subsection (e)(2)) for qualified medi-
19 care medicine beneficiaries described in sub-
20 section (e)(1).

21 “(2) AMOUNT OF PAYMENT.—The amount of
22 payment under paragraph (1) shall equal 100 per-
23 cent of the cost-sharing described in such paragraph,
24 except that, in the case of an individual whose eligi-
25 bility for medical assistance under title XIX is not

1 limited to medicare cost-sharing or medicare medi-
2 cine cost-sharing, the amount of payment under
3 paragraph (1)(B) shall be equal to the Federal med-
4 ical assistance percentage described in section
5 1905(b)) of amounts as expended for such cost-shar-
6 ing.

7 “(3) METHOD OF PAYMENT; RELATION TO
8 OTHER PAYMENTS.—Amounts shall be paid to
9 States under this subsection in a manner similar to
10 that provided under section 1903(d). Payments
11 under this subsection shall be made in lieu of any
12 payments that otherwise may be made for medical
13 assistance provided under section
14 1902(a)(10)(E)(iv).

15 “(4) TREATMENT OF TERRITORIES.—

16 “(A) IN GENERAL.—Subject to subpara-
17 graph (B), this subsection shall not apply to
18 States other than the 50 States and the Dis-
19 trict of Columbia.

20 “(B) PAYMENTS.—In the case of a State
21 (other than the 50 States and the District of
22 Columbia) that develops and implements a plan
23 of assistance for pharmaceuticals provided to
24 low-income medicare beneficiaries, the Secretary
25 shall provide for payment to the State in an

1 amount that is reasonable in relation to the
2 payment levels provided to other States under
3 paragraph (2).

4 “(e) DEFINITIONS; SPECIAL RULES.—For purposes
5 of this section:

6 “(1) QUALIFIED MEDICARE MEDICINE BENE-
7 FICIARY.—The term ‘qualified medicare medicine
8 beneficiary’ means an individual—

9 “(A) who is entitled to hospital insurance
10 benefits under part A (including an individual
11 entitled to such benefits pursuant to an enroll-
12 ment under section 1818, but not including an
13 individual entitled to such benefits only pursu-
14 ant to an enrollment under section 1818A);

15 “(B) whose income (as determined under
16 section 1612 for purposes of the supplemental
17 security income program, except as provided in
18 section 1905(p)(2)(D)) is above 100 percent
19 but below 150 percent of the official poverty
20 line (as defined by the Office of Management
21 and Budget, and revised annually in accordance
22 with section 673(2) of the Omnibus Budget
23 Reconciliation Act of 1981) applicable to a fam-
24 ily of the size involved; and

1 “(C) whose resources (as determined under
 2 section 1613 for purposes of the supplemental
 3 security income program) do not exceed twice
 4 the maximum amount of resources that an indi-
 5 vidual may have and obtain benefits under that
 6 program.

7 “(2) MEDICARE MEDICINE COST-SHARING.—
 8 The term ‘medicare medicine cost-sharing’ means
 9 the following costs incurred with respect to a quali-
 10 fied medicare medicine beneficiary, without regard to
 11 whether the costs incurred were for items and serv-
 12 ices for which medical assistance is otherwise avail-
 13 able under a State plan under title XIX:

14 “(A) In the case of a qualified medicare
 15 medicine beneficiary whose income (as deter-
 16 mined under paragraph (1)) is less than 135
 17 percent of the official poverty line—

18 “(i) premiums under section 1860D;
 19 and

20 “(ii) the difference between the
 21 amount that is paid under section 1860B
 22 and the amount that would be paid under
 23 such section if any reference to ‘50 per-
 24 cent’ therein were deemed a reference to
 25 ‘100 percent’ (or, if the Secretary approves

1 a higher percentage under such section, if
 2 such percentage were deemed to be 100
 3 percent).

4 “(B) In the case of a qualified medicare
 5 medicine beneficiary whose income (as deter-
 6 mined under paragraph (1)) is at least 135 per-
 7 cent but less than 150 percent of the official
 8 poverty line, a percentage of premiums under
 9 section 1860D, determined on a linear sliding
 10 scale ranging from 100 percent for individuals
 11 with incomes at 135 percent of such line to 0
 12 percent for individuals with incomes at 150 per-
 13 cent of such line.

14 “(3) STATE.—The term ‘State’ has the mean-
 15 ing given such term under section 1101(a) for pur-
 16 poses of title XIX.

17 “(4) TREATMENT OF DRUGS PURCHASED.—The
 18 provisions of section 1927 shall not apply to pre-
 19 scription drugs purchased under this part pursuant
 20 to an agreement with the Secretary under this sec-
 21 tion (including any drugs so purchased after the
 22 limit under section 1860B(b) has been exceeded).

23 “PRESCRIPTION MEDICINE INSURANCE ACCOUNT

24 “SEC. 1860F. (a) ESTABLISHMENT.—There is cre-
 25 ated within the Federal Supplemental Medical Insurance
 26 Trust Fund established by section 1841 an account to be

1 known as the ‘Prescription Medicine Insurance Account’
2 (in this section referred to as the ‘Account’).

3 “(b) AMOUNTS IN ACCOUNT.—

4 “(1) IN GENERAL.—The Account shall consist
5 of—

6 “(A) such amounts as may be deposited in,
7 or appropriated to, such fund as provided in
8 this part; and

9 “(B) such gifts and bequests as may be
10 made as provided in section 201(i)(1).

11 “(2) SEPARATION OF FUNDS.—Funds provided
12 under this part to the Account shall be kept sepa-
13 rate from all other funds within the Federal Supple-
14 mental Medical Insurance Trust Fund.

15 “(c) PAYMENTS FROM ACCOUNT.—The Managing
16 Trustee shall pay from time to time from the Account such
17 amounts as the Secretary certifies are necessary to make
18 the payments provided for by this part, and the payments
19 with respect to administrative expenses in accordance with
20 section 201(g).

21 “ADMINISTRATION OF BENEFITS

22 “SEC. 1860G. (a) THROUGH CMS.—The Secretary
23 shall provide for administration of the benefits under this
24 part through the Centers for Medicare & Medicaid Serv-
25 ices in accordance with the provisions of this section. The
26 Administrator of such Centers may enter into contracts

1 with carriers to administer this part in the same manner
 2 as the Administrator enters into such contracts to admin-
 3 ister part B. Any such contract shall be separate from any
 4 contract under section 1842.

5 “(b) ADMINISTRATION FUNCTIONS.—In carrying out
 6 this part, the Administrator (or a carrier under a contract
 7 with the Administrator) shall (or in the case of the func-
 8 tion described in paragraph (9), may) perform the fol-
 9 lowing functions:

10 “(1) PARTICIPATION AGREEMENTS, PRICES,
 11 AND FEES.—

12 “(A) NEGOTIATED PRICES.—Establish,
 13 through negotiations with medicine manufactur-
 14 ers and wholesalers and pharmacies, a schedule
 15 of prices for covered prescription medicines.

16 “(B) AGREEMENTS WITH PHARMACIES.—
 17 Enter into participation agreements under sub-
 18 section (c) with pharmacies, that include terms
 19 that—

20 “(i) secure the participation of suffi-
 21 cient numbers of pharmacies to ensure
 22 convenient access (including adequate
 23 emergency access);

24 “(ii) permit the participation of any
 25 pharmacy in the service area that meets

1 the participation requirements described in
2 subsection (c); and

3 “(iii) allow for reasonable dispensing
4 and consultation fees for pharmacies.

5 “(C) LISTS OF PRICES AND PARTICIPATING
6 PHARMACIES.—Ensure that the negotiated
7 prices established under subparagraph (A) and
8 the list of pharmacies with agreements under
9 subsection (c) are regularly updated and readily
10 available to health care professionals authorized
11 to prescribe medicines, participating phar-
12 macies, and enrolled individuals.

13 “(2) TRACKING OF COVERED ENROLLED INDIVIDUALS.—Maintain accurate, updated records of all
14 enrolled individuals (other than individuals enrolled
15 in a plan under part C).

17 “(3) PAYMENT AND COORDINATION OF BENEFITS.—
18

19 “(A) PAYMENT.—

20 “(i) Administer claims for payment of
21 benefits under this part and encourage, to
22 the maximum extent possible, use of elec-
23 tronic means for the submissions of claims.

24 “(ii) Determine amounts of benefit
25 payments to be made.

1 “(iii) Receive, disburse, and account
2 for funds used in making such payments,
3 including through the activities specified in
4 the provisions of this paragraph.

5 “(B) COORDINATION.—Coordinate with
6 other private benefit providers, pharmacies, and
7 other relevant entities as necessary to ensure
8 appropriate coordination of benefits with re-
9 spect to enrolled individuals, including coordina-
10 tion of access to and payment for covered pre-
11 scription medicines according to an individual’s
12 in-service area plan provisions, when such indi-
13 vidual is traveling outside the home service
14 area, and under such other circumstances as
15 the Secretary may specify.

16 “(C) EXPLANATION OF BENEFITS.—Fur-
17 nish to enrolled individuals an explanation of
18 benefits in accordance with section 1806(a),
19 and a notice of the balance of benefits remain-
20 ing for the current year, whenever prescription
21 medicine benefits are provided under this part
22 (except that such notice need not be provided
23 more often than monthly).

24 “(4) RULES RELATING TO PROVISION OF BENE-
25 FITS.—

1 “(A) IN GENERAL.—In providing benefits
2 under this part, the Secretary (directly or
3 through contracts) shall employ mechanisms to
4 provide benefits economically, including the use
5 of—

6 “(i) formularies (consistent with sub-
7 paragraph (B));

8 “(ii) automatic generic medicine sub-
9 stitution (unless the physician specifies
10 otherwise, in which case a 30-day prescrip-
11 tion may be dispensed pending a consulta-
12 tion with the physician on whether a ge-
13 neric substitute can be dispensed in the fu-
14 ture);

15 “(iii) tiered copayments (which may
16 include copayments at a rate lower than 20
17 percent) to encourage the use of the lowest
18 cost, on-formulary product in cases where
19 there is no restrictive prescription (de-
20 scribed in subparagraph (D)(i)); and

21 “(iv) therapeutic interchange.

22 “(B) REQUIREMENTS WITH RESPECT TO
23 FORMULARIES.—If a formulary is used to con-
24 tain costs under this part—

1 “(i) use an advisory committee (or a
2 therapeutics committee) comprised of li-
3 censed practicing physicians, pharmacists,
4 and other health care practitioners to de-
5 velop and manage the formulary;

6 “(ii) include in the formulary at least
7 1 medicine from each therapeutic class
8 and, if available, a generic equivalent
9 thereof; and

10 “(iii) disclose to current and prospec-
11 tive enrollees and to participating providers
12 and pharmacies, the nature of the for-
13 mulary restrictions, including information
14 regarding the medicines included in the
15 formulary and any difference in cost-shar-
16 ing amounts.

17 “(C) CONSTRUCTION.—Nothing in this
18 subsection shall be construed to prevent the
19 Secretary (directly or through contracts) from
20 using incentives (including a lower beneficiary
21 coinsurance) to encourage enrollees to select ge-
22 neric or other cost-effective medicines, so long
23 as—

24 “(i) such incentives are designed not
25 to result in any increase in the aggregate

1 expenditures under the Federal Medicare
2 Prescription Medicine Trust Fund;

3 “(ii) the average coinsurance charged
4 to all beneficiaries by the Secretary (di-
5 rectly or through contractors) shall seek to
6 approximate (but in no case exceed) 20
7 percent for on-formulary medicines;

8 “(iii) a beneficiary’s coinsurance shall
9 be no greater than 20 percent if the pre-
10 scription is a restrictive prescription; and

11 “(iv) the reimbursement for a pre-
12 scribed nonformulary medicine without a
13 restrictive prescription in no case shall be
14 more than the lowest reimbursement for a
15 formulary medicine in the therapeutic class
16 of the prescribed medicine.

17 “(D) RESTRICTIVE PRESCRIPTION.—For
18 purposes of this section:

19 “(i) WRITTEN PRESCRIPTIONS.—In
20 the case of a written prescription for a
21 medicine, it is a restrictive prescription
22 only if the prescription indicates, in the
23 writing of the physician or other qualified
24 person prescribing the medicine and with
25 an appropriate phrase (such as ‘brand

1 medically necessary') recognized by the
2 Secretary, that a particular medicine prod-
3 uct must be dispensed based upon a belief
4 by the physician or person prescribing the
5 medicine that the particular medicine will
6 provide even marginally superior thera-
7 peutic benefits to the individual for whom
8 the medicine is prescribed or would have
9 marginally fewer adverse reactions with re-
10 spect to such individual.

11 “(ii) TELEPHONE PRESCRIPTIONS.—

12 In the case of a prescription issued by tele-
13 phone for a medicine, it is a restrictive
14 prescription only if the prescription cannot
15 be longer than 30 days and the physician
16 or other qualified person prescribing the
17 medicine (through use of such an appro-
18 priate phrase) states that a particular
19 medicine product must be dispensed, and
20 the physician or other qualified person sub-
21 mits to the pharmacy involved, within 30
22 days after the date of the telephone pre-
23 scription, a written confirmation from the
24 physician or other qualified person pre-
25 scribing the medicine and which indicates

1 with such appropriate phrase that the par-
2 ticular medicine product was required to
3 have been dispensed based upon a belief by
4 the physician or person prescribing the
5 medicine that the particular medicine will
6 provide even marginally superior thera-
7 peutic benefits to the individual for whom
8 the medicine is prescribed or would have
9 marginally fewer adverse reactions with re-
10 spect to such individual. Such written con-
11 firmation is required to refill the prescrip-
12 tion.

13 “(iii) REVIEW OF RESTRICTIVE PRE-
14 SCRIPTIONS.—The advisory committee (es-
15 tablished under subparagraph (B)(i)) may
16 decide to review a restrictive prescription
17 and, if so, it may approve or disapprove
18 such restrictive prescription. It may not
19 disapprove such restrictive prescription un-
20 less it finds that there is no literature ap-
21 proved by the Food and Drug Administra-
22 tion that supports a determination that the
23 particular medicine provides even margin-
24 ally superior therapeutic benefits to the in-
25 dividual for whom the medicine is pre-

1 scribed or would have marginally fewer ad-
2 verse reactions with respect to such indi-
3 vidual. If it disapproves, upon request of
4 the prescribing physician or the enrollee,
5 the committee must provide for a review by
6 an independent contractor of such decision
7 within 48 hours of the time of submission
8 of the prescription, to determine whether
9 the prescription is an eligible benefit under
10 this part. The Secretary shall ensure that
11 independent contractors so used are com-
12 pletely independent of the contractor or its
13 advisory committee.

14 “(5) COST AND UTILIZATION MANAGEMENT;
15 QUALITY ASSURANCE.—Have in place effective cost
16 and utilization management, drug utilization review,
17 quality assurance measures, and systems to reduce
18 medical errors, including at least the following, to-
19 gether with such additional measures as the Admin-
20 istrator may specify:

21 “(A) DRUG UTILIZATION REVIEW.—A drug
22 utilization review program conforming to the
23 standards provided in section 1927(g)(2) (with
24 such modifications as the Administrator finds
25 appropriate).

1 “(B) FRAUD AND ABUSE CONTROL.—Ac-
2 tivities to control fraud, abuse, and waste, in-
3 cluding prevention of diversion of pharma-
4 ceuticals to the illegal market.

5 “(C) MEDICATION THERAPY MANAGE-
6 MENT.—

7 “(i) IN GENERAL.—A program of
8 medicine therapy management and medica-
9 tion administration that is designed to as-
10 sure that covered outpatient medicines are
11 appropriately used to achieve therapeutic
12 goals and reduce the risk of adverse
13 events, including adverse drug interactions.

14 “(ii) ELEMENTS.—Such program may
15 include—

16 “(I) enhanced beneficiary under-
17 standing of such appropriate use
18 through beneficiary education, coun-
19 seling, and other appropriate means;
20 and

21 “(II) increased beneficiary adher-
22 ence with prescription medication
23 regimens through medication refill re-
24 minders, special packaging, and other
25 appropriate means.

1 “(iii) DEVELOPMENT OF PROGRAM IN
2 COOPERATION WITH LICENSED PHAR-
3 MACISTS.—The program shall be developed
4 in cooperation with licensed pharmacists
5 and physicians.

6 “(iv) CONSIDERATIONS IN PHARMACY
7 FEES.—There shall be taken into account,
8 in establishing fees for pharmacists and
9 others providing services under the medica-
10 tion therapy management program, the re-
11 sources and time used in implementing the
12 program.

13 “(6) EDUCATION AND INFORMATION ACTIVI-
14 TIES.—Have in place mechanisms for disseminating
15 educational and informational materials to enrolled
16 individuals and health care providers designed to en-
17 courage effective and cost-effective use of prescrip-
18 tion medicine benefits and to ensure that enrolled in-
19 dividuals understand their rights and obligations
20 under the program.

21 “(7) BENEFICIARY PROTECTIONS.—

22 “(A) CONFIDENTIALITY OF HEALTH IN-
23 FORMATION.—Have in effect systems to safe-
24 guard the confidentiality of health care infor-
25 mation on enrolled individuals, which comply

1 with section 1106 and with section 552a of title
2 5, United States Code, and meet such addi-
3 tional standards as the Administrator may pre-
4 scribe.

5 “(B) GRIEVANCE AND APPEAL PROCE-
6 DURES.—Have in place such procedures as the
7 Administrator may specify for hearing and re-
8 solving grievances and appeals, including expe-
9 dited appeals, brought by enrolled individuals
10 against the Administrator or a pharmacy con-
11 cerning benefits under this part, which shall in-
12 clude procedures equivalent to those specified in
13 subsections (f) and (g) of section 1852.

14 “(8) RECORDS, REPORTS, AND AUDITS.—

15 “(A) RECORDS AND AUDITS.—Maintain
16 adequate records, and afford the Administrator
17 access to such records (including for audit pur-
18 poses).

19 “(B) REPORTS.—Make such reports and
20 submissions of financial and utilization data as
21 the Administrator may require taking into ac-
22 count standard commercial practices.

23 “(9) PROPOSAL FOR ALTERNATIVE COINSUR-
24 ANCE AMOUNT.—

1 “(A) SUBMISSION.—The Administrator
2 may provide for increased Government cost-
3 sharing for generic prescription medicines, pre-
4 scription medicines on a formulary, or prescrip-
5 tion medicines obtained through mail order
6 pharmacies.

7 “(B) CONTENTS.—The proposal submitted
8 under subparagraph (A) shall contain evidence
9 that such increased cost-sharing would not re-
10 sult in an increase in aggregate costs to the Ac-
11 count, including an analysis of differences in
12 projected drug utilization patterns by bene-
13 ficiaries whose cost-sharing would be reduced
14 under the proposal and those making the cost-
15 sharing payments that would otherwise apply.

16 “(10) OTHER REQUIREMENTS.—Meet such
17 other requirements as the Secretary may specify.

18 The Administrator shall negotiate a schedule of prices
19 under paragraph (1)(A), except that nothing in this sen-
20 tence shall prevent a carrier under a contract with the Ad-
21 ministrator from negotiating a lower schedule of prices for
22 covered prescription medicines.

23 “(c) PHARMACY PARTICIPATION AGREEMENTS.—

24 “(1) IN GENERAL.—A pharmacy that meets the
25 requirements of this subsection shall be eligible to

1 enter an agreement with the Administrator to fur-
2 nish covered prescription medicines and pharmacists’
3 services to enrolled individuals.

4 “(2) TERMS OF AGREEMENT.—An agreement
5 under this subsection shall include the following
6 terms and requirements:

7 “(A) LICENSING.—The pharmacy and
8 pharmacists shall meet (and throughout the
9 contract period will continue to meet) all appli-
10 cable State and local licensing requirements.

11 “(B) LIMITATION ON CHARGES.—Phar-
12 macies participating under this part shall not
13 charge an enrolled individual more than the ne-
14 gotiated price for an individual medicine as es-
15 tablished under subsection (b)(1), regardless of
16 whether such individual has attained the benefit
17 limit under section 1860B(b), and shall not
18 charge an enrolled individual more than the in-
19 dividual’s share of the negotiated price as deter-
20 mined under the provisions of this part.

21 “(C) PERFORMANCE STANDARDS.—The
22 pharmacy and the pharmacist shall comply with
23 performance standards relating to—

24 “(i) measures for quality assurance,
25 reduction of medical errors, and participa-

1 tion in the drug utilization review program
2 described in subsection (b)(3)(A);

3 “(ii) systems to ensure compliance
4 with the confidentiality standards applica-
5 ble under subsection (b)(5)(A); and

6 “(iii) other requirements as the Sec-
7 retary may impose to ensure integrity, effi-
8 ciency, and the quality of the program.

9 “(D) DISCLOSURE OF PRICE OF GENERIC
10 MEDICINE.—A pharmacy participating under
11 this part shall inform an enrollee of the dif-
12 ference in price between generic and non-ge-
13 neric equivalents.

14 “(d) SPECIAL ATTENTION TO RURAL AND HARD-TO-
15 SERVE AREAS.—

16 “(1) IN GENERAL.—The Secretary shall ensure
17 that all beneficiaries have access to the full range of
18 pharmaceuticals under this part, and shall give spe-
19 cial attention to access, pharmacist counseling, and
20 delivery in rural and hard-to-serve areas (as the Sec-
21 retary may define by regulation).

22 “(2) SPECIAL ATTENTION DEFINED.—For pur-
23 poses of paragraph (1), the term ‘special attention’
24 may include bonus payments to retail pharmacists in
25 rural areas and any other actions the Secretary de-

1 termines are necessary to ensure full access to rural
2 and hard-to-serve beneficiaries.

3 “(3) GAO REPORT.—Not later than 2 years
4 after the implementation of this part the Comp-
5 troller General of the United States shall submit to
6 Congress a report on the access of medicare bene-
7 ficiaries to pharmaceuticals and pharmacists’ serv-
8 ices in rural and hard-to-serve areas under this part
9 together with any recommendations of the Comp-
10 troller General regarding any additional steps the
11 Secretary may need to take to ensure the access of
12 medicare beneficiaries to pharmaceuticals and phar-
13 macists’ services in such areas under this part.

14 “(e) INCENTIVES FOR COST AND UTILIZATION MAN-
15 AGEMENT AND QUALITY IMPROVEMENT.—The Secretary
16 is authorized to include in a contract awarded under sub-
17 section (b) with a carrier such incentives for cost and utili-
18 zation management and quality improvement as the Sec-
19 retary may deem appropriate, including—

20 “(1) bonus and penalty incentives to encourage
21 administrative efficiency;

22 “(2) incentives under which carriers share in
23 any benefit savings achieved;

24 “(3) risk-sharing arrangements related to ini-
25 tiatives to encourage savings in benefit payments;

1 “(4) financial incentives under which savings
 2 derived from the substitution of generic medicines in
 3 lieu of non-generic medicines are made available to
 4 carriers, pharmacies, and the Prescription Medicine
 5 Insurance Account; and

6 “(5) any other incentive that the Secretary
 7 deems appropriate and likely to be effective in man-
 8 aging costs or utilization.

9 “EMPLOYER INCENTIVE PROGRAM FOR EMPLOYMENT-
 10 BASED RETIREE MEDICINE COVERAGE

11 “SEC. 1860H. (a) PROGRAM AUTHORITY.—The Sec-
 12 retary shall develop and implement a program under this
 13 section called the ‘Employer Incentive Program’ that en-
 14 courages employers and other sponsors of employment-
 15 based health care coverage to provide adequate prescrip-
 16 tion medicine benefits to retired individuals and to main-
 17 tain such existing benefit programs, by subsidizing, in
 18 part, the sponsor’s cost of providing coverage under quali-
 19 fying plans.

20 “(b) SPONSOR REQUIREMENTS.—In order to be eligi-
 21 ble to receive an incentive payment under this section with
 22 respect to coverage of an individual under a qualified re-
 23 tiree prescription medicine plan (as defined in subsection
 24 (f)(3)), a sponsor shall meet the following requirements:

25 “(1) ASSURANCES.—The sponsor shall—

1 “(A) annually attest, and provide such as-
2 surances as the Secretary may require, that the
3 coverage offered by the sponsor is a qualified
4 retiree prescription medicine plan, and will re-
5 main such a plan for the duration of the spon-
6 sor’s participation in the program under this
7 section; and

8 “(B) guarantee that it will give notice to
9 the Secretary and covered retirees—

10 “(i) at least 120 days before termi-
11 nating its plan; and

12 “(ii) immediately upon determining
13 that the actuarial value of the prescription
14 medicine benefit under the plan falls below
15 the actuarial value of the insurance benefit
16 under this part.

17 “(2) OTHER REQUIREMENTS.—The sponsor
18 shall provide such information, and comply with
19 such requirements, including information require-
20 ments to ensure the integrity of the program, as the
21 Secretary may find necessary to administer the pro-
22 gram under this section.

23 “(c) INCENTIVE PAYMENT.—

24 “(1) IN GENERAL.—A sponsor that meets the
25 requirements of subsection (b) with respect to a

1 quarter in a calendar year shall have payment made
2 by the Secretary on a quarterly basis (to the sponsor
3 or, at the sponsor's direction, to the appropriate em-
4 ployment-based health plan) of an incentive pay-
5 ment, in the amount determined as described in
6 paragraph (2), for each retired individual (or
7 spouse) who—

8 “(A) was covered under the sponsor's
9 qualified retiree prescription medicine plan dur-
10 ing such quarter; and

11 “(B) was eligible for but was not enrolled
12 in the insurance program under this part.

13 “(2) AMOUNT OF INCENTIVE.—The payment
14 under this section with respect to each individual de-
15 scribed in paragraph (1) for a month shall be equal
16 to $\frac{2}{3}$ of the monthly premium amount payable from
17 the Prescription Medicine Insurance Account for an
18 enrolled individual, as set for the calendar year pur-
19 suant to section 1860D(a)(2).

20 “(3) PAYMENT DATE.—The incentive under
21 this section with respect to a calendar quarter shall
22 be payable as of the end of the next succeeding cal-
23 endar quarter.

24 “(d) CIVIL MONEY PENALTIES.—A sponsor, health
25 plan, or other entity that the Secretary determines has,

1 directly or through its agent, provided information in con-
 2 nection with a request for an incentive payment under this
 3 section that the entity knew or should have known to be
 4 false shall be subject to a civil monetary penalty in an
 5 amount equal to \$2,000 for each false representation plus
 6 an amount not to exceed 3 times the total incentive
 7 amounts under subsection (c) that were paid (or would
 8 have been payable) on the basis of such information.

9 “(e) PART D ENROLLMENT FOR CERTAIN INDIVID-
 10 UALS COVERED BY EMPLOYMENT-BASED RETIREE
 11 HEALTH COVERAGE PLANS.—

12 “(1) ELIGIBLE INDIVIDUALS.—An individual
 13 shall be given the opportunity to enroll in the pro-
 14 gram under this part during the period specified in
 15 paragraph (2) if—

16 “(A) the individual declined enrollment in
 17 the program under this part at the time the in-
 18 dividual first satisfied section 1860C(a);

19 “(B) at that time, the individual was cov-
 20 ered under a qualified retiree prescription medi-
 21 cine plan for which an incentive payment was
 22 paid under this section; and

23 “(C)(i) the sponsor subsequently ceased to
 24 offer such plan; or

1 “(ii) the value of prescription medicine cov-
 2 erage under such plan is reduced below the
 3 value of the coverage provided at the time the
 4 individual first became eligible to participate in
 5 the program under this part.

6 “(2) SPECIAL ENROLLMENT PERIOD.—An indi-
 7 vidual described in paragraph (1) shall be eligible to
 8 enroll in the program under this part during the 6-
 9 month period beginning on the first day of the
 10 month in which—

11 “(A) the individual receives a notice that
 12 coverage under such plan has terminated (in
 13 the circumstance described in paragraph
 14 (1)(C)(i)) or notice that a claim has been de-
 15 nied because of such a termination; or

16 “(B) the individual received notice of the
 17 change in benefits (in the circumstance de-
 18 scribed in paragraph (1)(C)(ii)).

19 “(f) DEFINITIONS.—In this section:

20 “(1) EMPLOYMENT-BASED RETIREE HEALTH
 21 COVERAGE.—The term ‘employment-based retiree
 22 health coverage’ means health insurance or other
 23 coverage of health care costs for retired individuals
 24 (or for such individuals and their spouses and de-

pendents) based on their status as former employees or labor union members.

“(2) EMPLOYER.—The term ‘employer’ has the meaning given to such term by section 3(5) of the Employee Retirement Income Security Act of 1974 (except that such term shall include only employers of 2 or more employees).

“(3) QUALIFIED RETIREE PRESCRIPTION MEDICINE PLAN.—The term ‘qualified retiree prescription medicine plan’ means health insurance coverage included in employment-based retiree health coverage that—

“(A) provides coverage of the cost of prescription medicines whose actuarial value to each retired beneficiary equals or exceeds the actuarial value of the benefits provided to an individual enrolled in the program under this part; and

“(B) does not deny, limit, or condition the coverage or provision of prescription medicine benefits for retired individuals based on age or any health status-related factor described in section 2702(a)(1) of the Public Health Service Act.

1 “(4) SPONSOR.—The term ‘sponsor’ has the
2 meaning given the term ‘plan sponsor’ by section
3 3(16)(B) of the Employee Retirement Income Secu-
4 rity Act of 1974.

5 “PROMOTION OF PHARMACEUTICAL RESEARCH ON
6 BREAK-THROUGH MEDICINES WHILE PROVIDING
7 PROGRAM COST CONTAINMENT

8 “SEC. 1860I. (a) MONITORING EXPENDITURES.—
9 The Secretary shall monitor expenditures under this part.
10 On October 1, 2005, Secretary shall estimate total expend-
11 itures under this part for 2005.

12 “(b) ESTABLISHMENT OF SUSTAINABLE GROWTH
13 RATE.—

14 “(1) IN GENERAL.—The Secretary shall estab-
15 lish a sustainable growth rate prescription medicine
16 target system for expenditures under this part for
17 each year after 2005.

18 “(2) INITIAL COMPUTATION.—Such target shall
19 equal the amount of total expenditures estimated for
20 2005 adjusted by the Secretary’s estimate of a sus-
21 tainable growth rate (in this section referred to as
22 an ‘SGR’) percentage between 2005 and 2006. Such
23 SGR shall be estimated based on the following:

24 “(A) Reasonable changes in the cost of
25 production or price of covered pharmaceuticals,
26 but in no event more than the rate of increase

1 in the consumer price index for all urban con-
2 sumers for the period involved.

3 “(B) Population enrolled in this part, both
4 in numbers and in average age and severity of
5 chronic and acute illnesses.

6 “(C) Appropriate changes in utilization of
7 pharmaceuticals, as determined by the Drug
8 Review Board (established under subsection
9 (c)(3)) and based on best estimates of utiliza-
10 tion change if there were no direct-to-consumer
11 advertising or promotions to providers.

12 “(D) Productivity index of manufacturers
13 and distributors.

14 “(E) Percentage of products with patent
15 and market exclusivity protection versus prod-
16 ucts without patent protection and changes in
17 the availability of generic substitutes.

18 “(F) Such other factors as the Secretary
19 may determine are appropriate.

20 In no event may the sustainable growth rate exceed
21 120 percent of the estimated per capita growth in
22 total spending under this title.

23 “(3) COMPUTATION FOR SUBSEQUENT
24 YEARS.—In October of 2006 and each year there-
25 after, for purposes of setting the SGRs for the suc-

ceeding year, the Secretary shall adjust each current year's estimated expenditures by the estimated SGR for the succeeding year, further adjusted for corrections in earlier estimates and the receipt of additional data on previous years spending as follows:

“(A) ERROR ESTIMATES.—An adjustment (up or down) for errors in the estimate of total expenditures under this part for the previous year.

“(B) COSTS.—An adjustment (up or down) for corrections in the cost of production of prescriptions covered under this part between the current calendar year and the previous year.

“(C) TARGET.—An adjustment for any amount (over or under) that expenditures in the current year under this part are estimated to differ from the target amount set for the year. If expenditures in the current year are estimated to be—

“(i) less than the target amount, future target amounts will be adjusted downward; or

“(ii) more than the target amount, the Secretary shall notify all pharmaceutical manufacturers with sales of phar-

1 maceutical prescription medicine products
2 to medicare beneficiaries under this part,
3 of a rebate requirement (except as pro-
4 vided in this subparagraph) to be deposited
5 in the Federal Medicare Prescription Medi-
6 cine Trust Fund.

7 “(D) REBATE DETERMINATION.—The
8 amount of the rebate described in subparagraph
9 (C)(ii) may vary among manufacturers and
10 shall be based on the manufacturer’s estimated
11 contribution to the expenditure above the target
12 amount, taking into consideration such factors
13 as—

14 “(i) above average increases in the
15 cost of the manufacturer’s product;

16 “(ii) increases in utilization due to
17 promotion activities of the manufacturer,
18 wholesaler, or retailer;

19 “(iii) launch prices of new drugs at
20 the same or higher prices as similar drugs
21 already in the marketplace (so-called ‘me
22 too’ or ‘copy-cat’ drugs);

23 “(iv) the role of the manufacturer in
24 delaying the entry of generic products into
25 the market; and

1 “(v) such other actions by the manu-
2 facturer that the Secretary may determine
3 has contributed to the failure to meet the
4 SGR target.

5 The rebates shall be established under such
6 subparagraph so that the total amount of the
7 rebates is estimated to ensure that the amount
8 the target for the current year is estimated to
9 be exceeded is recovered in lower spending in
10 the subsequent year; except that, no rebate
11 shall be made in any manufacturer’s product
12 which the Food and Drug Administration has
13 determined is a breakthrough medicine (as de-
14 termined under subsection (c)) or an orphan
15 medicine.

16 “(c) BREAKTHROUGH MEDICINES.—

17 “(1) DETERMINATION.—For purposes of this
18 section, a medicine is a ‘breakthrough medicine’ if
19 the Drug Review Board (established under para-
20 graph (3)) determines—

21 “(A) it is a new product that will make a
22 significant and major improvement by reducing
23 physical or mental illness, reducing mortality,
24 or reducing disability; and

1 “(B) that no other product is available to
2 beneficiaries that achieves similar results for
3 the same condition at a lower cost.

4 “(2) CONDITION.—An exemption from rebates
5 under subsection (b)(3) for a breakthrough medicine
6 shall continue as long as the medicine is certified as
7 a breakthrough medicine but shall be limited to 7
8 calendar years from 2003 or 7 calendar years from
9 the date of the initial determination under para-
10 graph (1), whichever is later.

11 “(3) DRUG REVIEW BOARD.—The Drug Review
12 Board under this paragraph shall consist of the
13 Commissioner of Food and Drugs, the Directors of
14 the National Institutes of Health, the Director of
15 the National Science Foundation, and 10 experts in
16 pharmaceuticals, medical research, and clinical care,
17 selected by the Commissioner of Food and Drugs
18 from the faculty of academic medical centers, except
19 that no person who has (or who has an immediate
20 family member that has) any conflict of interest with
21 any pharmaceutical manufacturer shall serve on the
22 Board.

23 “(d) NO REVIEW.—The Secretary’s determination of
24 the rebate amounts under this section, and the Drug Re-

1 view Board’s determination of what is a breakthrough
 2 drug, are not subject to administrative or judicial review.

3 “APPROPRIATIONS TO COVER GOVERNMENT

4 CONTRIBUTIONS

5 “SEC. 1860J. (a) IN GENERAL.—There are author-
 6 ized to be appropriated from time to time, out of any mon-
 7 eys in the Treasury not otherwise appropriated, to the
 8 Prescription Medicine Insurance Account, a Government
 9 contribution equal to—

10 “(1) the aggregate premiums payable for a
 11 month pursuant to section 1860D(a)(2) by individ-
 12 uals enrolled in the program under this part; plus

13 “(2) one-half the aggregate premiums payable
 14 for a month pursuant to such section for such indi-
 15 viduals by former employers; plus

16 “(3) the benefits payable by reason of the appli-
 17 cation of paragraph (2) of section 1860B(a) (relat-
 18 ing to catastrophic benefits).

19 “(b) APPROPRIATIONS TO COVER INCENTIVES FOR
 20 EMPLOYMENT-BASED RETIREE MEDICINE COVERAGE.—

21 There are authorized to be appropriated to the Prescrip-
 22 tion Medicine Insurance Account from time to time, out
 23 of any moneys in the Treasury not otherwise appropriated
 24 such sums as may be necessary for payment of incentive
 25 payments under section 1860H(c).

1 “PRESCRIPTION MEDICINE DEFINED

2 “SEC. 1860K. As used in this part, the term ‘pre-
3 scription medicine’ means—

4 “(1) a drug that may be dispensed only upon
5 a prescription, and that is described in subpara-
6 graph (A)(i), (A)(ii), or (B) of section 1927(k)(2);
7 and

8 “(2) insulin certified under section 506 of the
9 Federal Food, Drug, and Cosmetic Act, and needles,
10 syringes, and disposable pumps for the administra-
11 tion of such insulin.”.

12 (b) CONFORMING AMENDMENTS.—

13 (1) AMENDMENTS TO FEDERAL SUPPLE-
14 MENTARY HEALTH INSURANCE TRUST FUND.—Sec-
15 tion 1841 of the Social Security Act (42 U.S.C.
16 1395t) is amended—

17 (A) in the last sentence of subsection (a)—

18 (i) by striking “and” after “section
19 201(i)(1)”;

20 (ii) by inserting before the period the
21 following: “, and such amounts as may be
22 deposited in, or appropriated to, the Pre-
23 scription Medicine Insurance Account es-
24 tablished by section 1860F”;

(B) in subsection (g), by inserting after “by this part,” the following: “the payments provided for under part D (in which case the payments shall come from the Prescription Medicine Insurance Account in the Supplementary Medical Insurance Trust Fund),”;

(C) in the first sentence of subsection (h), by inserting before the period the following: “and section 1860D(b)(4) (in which case the payments shall come from the Prescription Medicine Insurance Account in the Supplementary Medical Insurance Trust Fund)”;

(D) in the first sentence of subsection (i)—

(i) by striking “and” after “section 1840(b)(1)”;

(ii) by inserting before the period the following: “, section 1860D(b)(2) (in which case the payments shall come from the Prescription Medicine Insurance Account in the Supplementary Medical Insurance Trust Fund)”.

(2) PRESCRIPTION MEDICINE OPTION UNDER
MEDICARE+CHOICE PLANS.—

1 (A) ELIGIBILITY, ELECTION, AND ENROLL-
 2 MENT.—Section 1851 of the Social Security Act
 3 (42 U.S.C. 1395w–21) is amended—

4 (i) in subsection (a)(1)(A), by striking
 5 “parts A and B” inserting “parts A, B,
 6 and D”; and

7 (ii) in subsection (i)(1), by striking
 8 “parts A and B” and inserting “parts A,
 9 B, and D”.

10 (B) VOLUNTARY BENEFICIARY ENROLL-
 11 MENT FOR MEDICINE COVERAGE.—Section
 12 1852(a)(1)(A) of such Act (42 U.S.C. 1395w–
 13 22(a)(1)(A)) is amended by inserting “(and
 14 under part D to individuals also enrolled under
 15 that part)” after “parts A and B”.

16 (C) ACCESS TO SERVICES.—Section
 17 1852(d)(1) of such Act (42 U.S.C. 1395w–
 18 22(d)(1)) is amended—

19 (i) in subparagraph (D), by striking
 20 “and” at the end;

21 (ii) in subparagraph (E), by striking
 22 the period at the end and inserting “;
 23 and”; and

24 (iii) by adding at the end the fol-
 25 lowing new subparagraph:

1 “(F) the plan for prescription medicine
2 benefits under part D guarantees coverage of
3 any specifically named covered prescription
4 medicine for an enrollee, when prescribed by a
5 physician in accordance with the provisions of
6 such part, regardless of whether such medicine
7 would otherwise be covered under an applicable
8 formulary or discount arrangement.”.

9 (D) PAYMENTS TO ORGANIZATIONS.—Sec-
10 tion 1853(a)(1)(A) of such Act (42 U.S.C.
11 1395w-23(a)(1)(A)) is amended—

12 (i) by inserting “determined sepa-
13 rately for benefits under parts A and B
14 and under part D (for individuals enrolled
15 under that part)” after “as calculated
16 under subsection (c)”;

17 (ii) by striking “that area, adjusted
18 for such risk factors” and inserting “that
19 area. In the case of payment for benefits
20 under parts A and B, such payment shall
21 be adjusted for such risk factors as”; and

22 (iii) by inserting before the last sen-
23 tence the following: “In the case of the
24 payments for benefits under part D, such
25 payment shall initially be adjusted for the

1 risk factors of each enrollee as the Sec-
 2 retary determines to be feasible and appro-
 3 priate. By 2008, the adjustments would be
 4 for the same risk factors applicable for
 5 benefits under parts A and B.”.

6 (E) CALCULATION OF ANNUAL MEDICARE
 7 +CHOICE CAPITATION RATES.—Section 1853(c)
 8 of such Act (42 U.S.C. 1395w–23(c)) is amend-
 9 ed—

10 (i) in paragraph (1), in the matter
 11 preceding subparagraph (A), by inserting
 12 “for benefits under parts A and B” after
 13 “capitation rate”;

14 (ii) in paragraph (6)(A), by striking
 15 “rate of growth in expenditures under this
 16 title” and inserting “rate of growth in ex-
 17 penditures for benefits available under
 18 parts A and B”; and

19 (iii) by adding at the end the fol-
 20 lowing new paragraph:

21 “(8) PAYMENT FOR PRESCRIPTION MEDI-
 22 CINES.—The Secretary shall determine a capitation
 23 rate for prescription medicines—

24 “(A) dispensed in 2005, which is based on
 25 the projected national per capita costs for pre-

1 scripted medicine benefits under part D and
2 associated claims processing costs for bene-
3 ficiaries under the original medicare fee-for-
4 service program; and

5 “(B) dispensed in each subsequent year,
6 which shall be equal to the rate for the previous
7 year updated by the Secretary’s estimate of the
8 projected per capita rate of growth in expendi-
9 tures under this title for an individual enrolled
10 under part D.”.

11 (F) LIMITATION ON ENROLLEE LIABIL-
12 ITY.—Section 1854(e) of such Act (42 U.S.C.
13 1395w-24(e)) is amended by adding at the end
14 the following new paragraph:

15 “(5) SPECIAL RULE FOR PROVISION OF PART D
16 BENEFITS.—In no event may a Medicare+Choice or-
17 ganization include as part of a plan for prescription
18 medicine benefits under part D a requirement that
19 an enrollee pay a deductible, or a coinsurance per-
20 centage that exceeds 20 percent.”.

21 (G) REQUIREMENT FOR ADDITIONAL BEN-
22 EFITS.—Section 1854(f)(1) of such Act (42
23 U.S.C. 1395w-24(f)(1)) is amended by adding
24 at the end the following new sentence: “Such
25 determination shall be made separately for ben-

1 efits under parts A and B and for prescription
2 medicine benefits under part D.”.

3 (3) EXCLUSIONS FROM COVERAGE.—

4 (A) APPLICATION TO PART D.—Section
5 1862(a) of the Social Security Act (42 U.S.C.
6 1395y(a)) is amended in the matter preceding
7 paragraph (1) by striking “part A or part B”
8 and inserting “part A, B, or D”.

9 (B) PRESCRIPTION MEDICINES NOT EX-
10 CLUDED FROM COVERAGE IF APPROPRIATELY
11 PRESCRIBED.—Section 1862(a)(1) of such Act
12 (42 U.S.C. 1395y(a)(1)) is amended—

13 (i) in subparagraph (H), by striking
14 “and” at the end;

15 (ii) in subparagraph (I), by striking
16 the semicolon at the end and inserting “,
17 and”; and

18 (iii) by adding at the end the fol-
19 lowing new subparagraph:

20 “(J) in the case of prescription medicines
21 covered under part D, which are not prescribed
22 in accordance with such part;”.

1 **SEC. 4. SUBSTANTIAL REDUCTIONS IN THE PRICE OF PRE-**
2 **SCRIPTION DRUGS FOR MEDICARE BENE-**
3 **FICIARIES.**

4 (a) PARTICIPATING MANUFACTURERS.—

5 (1) IN GENERAL.—Each participating manufac-
6 turer of a covered outpatient drug shall make avail-
7 able for purchase by each pharmacy such covered
8 outpatient drug in the amount described in para-
9 graph (2) at the price described in paragraph (3).

10 (2) DESCRIPTION OF AMOUNT OF DRUGS.—The
11 amount of a covered outpatient drug that a partici-
12 pating manufacturer shall make available for pur-
13 chase by a pharmacy is an amount equal to the ag-
14 gregate amount of the covered outpatient drug sold
15 or distributed by the pharmacy to medicare bene-
16 ficiaries.

17 (3) DESCRIPTION OF PRICE.—The price at
18 which a participating manufacturer shall make a
19 covered outpatient drug available for purchase by a
20 pharmacy is the price equal to the lowest of the fol-
21 lowing:

22 (A) The lowest price paid for the covered
23 outpatient drug by any agency or department of
24 the United States.

25 (B) The manufacturer's best price for the
26 covered outpatient drug, as defined in section

1 1927(c)(1)(C) of the Social Security Act (42
2 U.S.C. 1396r-8(c)(1)(C)).

3 (C) The lowest price at which the drug is
4 available (as determined by the Secretary)
5 through importation consistent with the provi-
6 sions of section 804 of the Federal Food, Drug,
7 and Cosmetic Act.

8 (b) SPECIAL PROVISION WITH RESPECT TO HOSPICE
9 PROGRAMS.—For purposes of determining the amount of
10 a covered outpatient drug that a participating manufac-
11 turer shall make available for purchase by a pharmacy
12 under subsection (a), there shall be included in the cal-
13 culation of such amount the amount of the covered out-
14 patient drug sold or distributed by a pharmacy to a hos-
15 pice program. In calculating such amount, only amounts
16 of the covered outpatient drug furnished to a medicare
17 beneficiary enrolled in the hospice program shall be in-
18 cluded.

19 (c) ADMINISTRATION.—The Secretary shall issue
20 such regulations as may be necessary to implement this
21 section.

22 (d) REPORTS TO CONGRESS REGARDING EFFECTIVE-
23 NESS OF SECTION.—

24 (1) IN GENERAL.—Not later than 2 years after
25 the date of the enactment of this Act, and annually

1 thereafter, the Secretary shall report to the Con-
2 gress regarding the effectiveness of this section in—

3 (A) protecting medicare beneficiaries from
4 discriminatory pricing by drug manufacturers;
5 and

6 (B) making prescription drugs available to
7 medicare beneficiaries at substantially reduced
8 prices.

9 (2) CONSULTATION.—In preparing such re-
10 ports, the Secretary shall consult with public health
11 experts, affected industries, organizations rep-
12 resenting consumers and older Americans, and other
13 interested persons.

14 (3) RECOMMENDATIONS.—The Secretary shall
15 include in such reports any recommendations they
16 consider appropriate for changes in this section to
17 further reduce the cost of covered outpatient drugs
18 to medicare beneficiaries.

19 (f) DEFINITIONS.—For purposes of this section:

20 (1) PARTICIPATING MANUFACTURER.—The
21 term “participating manufacturer” means any man-
22 ufacturer of drugs or biologicals that, on or after the
23 date of the enactment of this Act, enters into a con-
24 tract or agreement with the United States for the

1 sale or distribution of covered outpatient drugs to
2 the United States.

3 (2) COVERED OUTPATIENT DRUG.—The term
4 “covered outpatient drug” has the meaning given
5 that term in section 1927(k)(2) of the Social Secu-
6 rity Act (42 U.S.C. 1396r–8(k)(2)).

7 (3) MEDICARE BENEFICIARY.—The term
8 “medicare beneficiary” means an individual entitled
9 to benefits under part A of title XVIII of the Social
10 Security Act or enrolled under part B of such title,
11 or both.

12 (4) HOSPICE PROGRAM.—The term “hospice
13 program” has the meaning given that term under
14 section 1861(dd)(2) of the Social Security Act (42
15 U.S.C. 1395x(dd)(2)).

16 (5) SECRETARY.—The term “Secretary” means
17 the Secretary of Health and Human Services.

18 (f) EFFECTIVE DATE.—The Secretary shall imple-
19 ment this section as expeditiously as practicable and in
20 a manner consistent with the obligations of the United
21 States.

1 **SEC. 5. AMENDMENTS TO PROGRAM FOR IMPORTATION OF**
2 **CERTAIN PRESCRIPTION DRUGS BY PHAR-**
3 **MACISTS AND WHOLESALEERS.**

4 Section 804 of the Federal Food, Drug, and Cosmetic
5 Act (as added by section 745(c)(2) of Public Law 106–
6 387) is amended—

7 (1) by striking subsections (e) and (f) and in-
8 serting the following subsections:

9 “(e) TESTING; APPROVED LABELING.—

10 “(1) TESTING.—Regulations under subsection
11 (a)—

12 “(A) shall require that testing referred to
13 in paragraphs (6) through (8) of subsection (d)
14 be conducted by the importer of the covered
15 product pursuant to subsection (a), or the man-
16 ufacturer of the product;

17 “(B) shall require that, if such tests are
18 conducted by the importer, information needed
19 to authenticate the product being tested be sup-
20 plied by the manufacturer of such product to
21 the importer; and

22 “(C) shall provide for the protection of any
23 information supplied by the manufacturer
24 under subparagraph (B) that is a trade secret
25 or commercial or financial information that is
26 privileged or confidential.

1 “(2) APPROVED LABELING.—For purposes of
2 importing a covered product pursuant to subsection
3 (a), the importer involved may use the labeling ap-
4 proved for the product under section 505, notwith-
5 standing any other provision of law.

6 “(f) DISCRETION OF SECRETARY REGARDING TEST-
7 ING.—The Secretary may waive or modify testing require-
8 ments described in subsection (d) if, with respect to spe-
9 cific countries or specific distribution chains, the Secretary
10 has entered into agreements or otherwise approved ar-
11 rangements that the Secretary determines ensure that the
12 covered products involved are not adulterated or in viola-
13 tion of section 505.”;

14 (2) by striking subsections (h) and (i) and in-
15 serting the following subsections:

16 “(h) PROHIBITED AGREEMENTS; NONDISCRIMINA-
17 TION.—

18 “(1) PROHIBITED AGREEMENTS.—No manufac-
19 turer of a covered product may enter into a contract
20 or agreement that includes a provision to prevent
21 the sale or distribution of covered products imported
22 pursuant to subsection (a).

23 “(2) NONDISCRIMINATION.—No manufacturer
24 of a covered product may take actions that discrimi-
25 nate against, or cause other persons to discriminate

1 against, United States pharmacists, wholesalers, or
2 consumers regarding the sale or distribution of cov-
3 ered products.

4 “(i) STUDY AND REPORT.—

5 “(1) STUDY.—The Comptroller General of the
6 United States shall conduct a study on the imports
7 permitted under this section, taking into consider-
8 ation the information received under subsection (a).
9 In conducting such study, the Comptroller General
10 shall—

11 “(A) evaluate importers’ compliance with
12 regulations, determine the number of ship-
13 ments, if any, permitted under this section that
14 have been determined to be counterfeit, mis-
15 branded, or adulterated; and

16 “(B) consult with the United States Trade
17 Representative and United States Patent and
18 Trademark Office to evaluate the effect of im-
19 portations permitted under this section on trade
20 and patent rights under Federal law.

21 “(2) REPORT.—Not later than 5 years after the
22 effective date of final regulations issued pursuant to
23 this section, the Comptroller General of the United
24 States shall prepare and submit to Congress a re-

1 port containing the study described in paragraph
2 (1).”;

3 (3) in subsection (k)(2)—

4 (A) by redesignating subparagraphs (A)
5 through (E) as subparagraphs (B) through (F),
6 respectively; and

7 (B) by inserting before subparagraph (B)
8 (as so redesignated) the following subpara-
9 graph:

10 “(A) The term ‘discrimination’ includes a
11 contract provision, a limitation on supply, or
12 other measure which has the effect of providing
13 United States pharmacists, wholesalers, or con-
14 sumers access to covered products on terms or
15 conditions that are less favorable than the
16 terms or conditions provided to any foreign pur-
17 chaser of such products.”;

18 (4) by striking subsection (m); and

19 (5) by inserting after subsection (l) the fol-
20 lowing subsection:

21 “(m) FUNDING.—For the purpose of carrying out
22 this section, there are authorized to be appropriated such
23 sums as may be necessary for fiscal year 2004 and each
24 subsequent fiscal year.”.

1 **SEC. 6. REASONABLE PRICE AGREEMENT FOR FEDERALLY**
2 **FUNDED RESEARCH.**

3 (a) IN GENERAL.—If any Federal agency or any non-
4 profit entity undertakes federally funded health care re-
5 search and development and is to convey or provide a pat-
6 ent or other exclusive right to use such research and devel-
7 opment for a drug or other health care technology, such
8 agency or entity shall not make such conveyance or pro-
9 vide such patent or other right until the person who will
10 receive such conveyance or patent or other right first
11 agrees to a reasonable pricing agreement with the Sec-
12 retary of Health and Human Services or the Secretary
13 makes a determination that the public interest is served
14 by a waiver of the reasonable pricing agreement provided
15 in accordance with subsection (c).

16 (b) CONSIDERATION OF COMPETITIVE BIDDING.—In
17 cases where the Federal Government conveys or licenses
18 exclusive rights to federally funded research under sub-
19 section (a), consideration shall be given to mechanisms for
20 determining reasonable prices which are based upon a
21 competitive bidding process. When appropriate, the mech-
22 anisms should be considered where—

23 (1) qualified bidders compete on the basis of
24 the lowest prices that will be charged to consumers;

25 (2) qualified bidders compete on the basis of
26 the least sales revenues before prices are adjusted in

1 accordance with a cost based reasonable pricing for-
2 mula;

3 (3) qualified bidders compete on the basis of
4 the least period of time before prices are adjusted in
5 accordance with a cost based reasonable pricing for-
6 mula;

7 (4) qualified bidders compete on the basis of
8 the shortest period of exclusivity; or

9 (5) qualified bidders compete under other com-
10 petitive bidding systems.

11 Such competitive bidding process may incorporate require-
12 ments for minimum levels of expenditures on research,
13 marketing, maximum price, or other factors.

14 (c) WAIVER.—No waiver shall take effect under sub-
15 section (a) before the public is given notice of the proposed
16 waiver and provided a reasonable opportunity to comment
17 on the proposed waiver. A decision to grant a waiver shall
18 set out the Secretary's finding that such a waiver is in
19 the public interest.

20 **SEC. 7. GAO ONGOING STUDIES AND REPORTS ON PRO-**
21 **GRAM; MISCELLANEOUS REPORTS.**

22 (a) ONGOING STUDY.—The Comptroller General of
23 the United States shall conduct an ongoing study and
24 analysis of the prescription medicine benefit program
25 under part D of the medicare program under title XVIII

1 of the Social Security Act (as added by section 3 of this
2 Act), including an analysis of each of the following:

3 (1) The extent to which the administering enti-
4 ties have achieved volume-based discounts similar to
5 the favored price paid by other large purchasers.

6 (2) Whether access to the benefits under such
7 program are in fact available to all beneficiaries,
8 with special attention given to access for bene-
9 ficiaries living in rural and hard-to-serve areas.

10 (3) The success of such program in reducing
11 medication error and adverse medicine reactions and
12 improving quality of care, and whether it is probable
13 that the program has resulted in savings through re-
14 duced hospitalizations and morbidity due to medica-
15 tion errors and adverse medicine reactions.

16 (4) Whether patient medical record confiden-
17 tiality is being maintained and safe-guarded.

18 (5) Such other issues as the Comptroller Gen-
19 eral may consider.

20 (b) REPORTS.—The Comptroller General shall issue
21 such reports on the results of the ongoing study described
22 in (a) as the Comptroller General shall deem appropriate
23 and shall notify Congress on a timely basis of significant
24 problems in the operation of the part D prescription medi-

1 cine program and the need for legislative adjustments and
2 improvements.

3 (c) MISCELLANEOUS STUDIES AND REPORTS.—

4 (1) STUDY ON METHODS TO ENCOURAGE ADDI-
5 TIONAL RESEARCH ON BREAKTHROUGH PHARMA-
6 CEUTICALS.—

7 (A) IN GENERAL.—The Secretary of
8 Health and Human Services shall seek the ad-
9 vice of the Secretary of the Treasury on pos-
10 sible tax and trade law changes to encourage
11 increased original research on new pharma-
12 ceutical breakthrough products designed to ad-
13 dress disease and illness.

14 (B) REPORT.—Not later than January 1,
15 2005, the Secretary shall submit to Congress a
16 report on such study. The report shall include
17 recommended methods to encourage the phar-
18 maceutical industry to devote more resources to
19 research and development of new covered prod-
20 ucts than it devotes to overhead expenses.

21 (2) STUDY ON PHARMACEUTICAL SALES PRAC-
22 TICES AND IMPACT ON COSTS AND QUALITY OF
23 CARE.—

24 (A) IN GENERAL.—The Secretary of
25 Health and Human Services shall conduct a

1 study on the methods used by the pharma-
2 ceutical industry to advertise and sell to con-
3 sumers and educate and sell to providers.

4 (B) REPORT.—Not later than January 1,
5 2005, the Secretary shall submit to Congress a
6 report on such study. The report shall include
7 the estimated direct and indirect costs of the
8 sales methods used, the quality of the informa-
9 tion conveyed, and whether such sales efforts
10 leads (or could lead) to inappropriate pre-
11 scribing. Such report may include legislative
12 and regulatory recommendations to encourage
13 more appropriate education and prescribing
14 practices.

15 (3) STUDY ON COST OF PHARMACEUTICAL RE-
16 SEARCH.—

17 (A) IN GENERAL.—The Secretary of
18 Health and Human Services shall conduct a
19 study on the costs of, and needs for, the phar-
20 maceutical research and the role that the tax-
21 payer provides in encouraging such research.

22 (B) REPORT.—Not later than January 1,
23 2005, the Secretary shall submit to Congress a
24 report on such study. The report shall include
25 a description of the full-range of taxpayer-as-

1 sisted programs impacting pharmaceutical re-
2 search, including tax, trade, government re-
3 search, and regulatory assistance. The report
4 may also include legislative and regulatory rec-
5 ommendations that are designed to ensure that
6 the taxpayer's investment in pharmaceutical re-
7 search results in the availability of pharma-
8 ceuticals at reasonable prices.

9 (4) REPORT ON PHARMACEUTICAL PRICES IN
10 MAJOR FOREIGN NATIONS.—Not later than January
11 1, 2005, the Secretary of Health and Human Serv-
12 ices shall submit to Congress a report on the retail
13 price of major pharmaceutical products in various
14 developed nations, compared to prices for the same
15 or similar products in the United States. The report
16 shall include a description of the principal reasons
17 for any price differences that may exist.

18 **SEC. 8. MEDIGAP TRANSITION PROVISIONS.**

19 (a) IN GENERAL.—Notwithstanding any other provi-
20 sion of law, no new medicare supplemental policy that pro-
21 vides coverage of expenses for prescription drugs may be
22 issued under section 1882 of the Social Security Act on
23 or after January 1, 2005, to an individual unless it re-
24 places a medicare supplemental policy that was issued to

1 that individual and that provided some coverage of ex-
2 penses for prescription drugs.

3 (b) ISSUANCE OF SUBSTITUTE POLICIES IF OBTAIN-
4 ING PRESCRIPTION DRUG COVERAGE THROUGH MEDI-
5 CARE.—

6 (1) IN GENERAL.—The issuer of a medicare
7 supplemental policy—

8 (A) may not deny or condition the issuance
9 or effectiveness of a medicare supplemental pol-
10 icy that has a benefit package classified as “A”,
11 “B”, “C”, “D”, “E”, “F”, or “G” (under the
12 standards established under subsection (p)(2) of
13 section 1882 of the Social Security Act, 42
14 U.S.C. 1395ss) and that is offered and is avail-
15 able for issuance to new enrollees by such
16 issuer;

17 (B) may not discriminate in the pricing of
18 such policy, because of health status, claims ex-
19 perience, receipt of health care, or medical con-
20 dition; and

21 (C) may not impose an exclusion of bene-
22 fits based on a pre-existing condition under
23 such policy,

24 in the case of an individual described in paragraph

25 (2) who seeks to enroll under the policy not later

1 than 63 days after the date of the termination of en-
2 rollment described in such paragraph and who sub-
3 mits evidence of the date of termination or
4 disenrollment along with the application for such
5 medicare supplemental policy.

6 (2) INDIVIDUAL COVERED.—An individual de-
7 scribed in this paragraph is an individual who—

8 (A) enrolls in a prescription drug plan
9 under part D of title XVIII of the Social Secu-
10 rity Act; and

11 (B) at the time of such enrollment was en-
12 rolled and terminates enrollment in a medicare
13 supplemental policy which has a benefit pack-
14 age classified as “H”, “I”, or “J” under the
15 standards referred to in paragraph (1)(A) or
16 terminates enrollment in a policy to which such
17 standards do not apply but which provides ben-
18 efits for prescription drugs.

19 (3) ENFORCEMENT.—The provisions of para-
20 graph (1) shall be enforced as though they were in-
21 cluded in section 1882(s) of the Social Security Act
22 (42 U.S.C. 1395ss(s)).

23 (4) DEFINITIONS.—For purposes of this sub-
24 section, the term “medicare supplemental policy”

- 1 has the meaning given such term in section 1882(g)
- 2 of the Social Security Act (42 U.S.C. 1395ss(g)).

