

107TH CONGRESS
1ST SESSION

S. 925

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

IN THE SENATE OF THE UNITED STATES

MAY 22, 2001

Mr. WELLSTONE introduced the following bill; which was read twice and referred to the Committee on Finance

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 2001”.

7 (b) **TABLE OF CONTENTS.**—The table of contents for
8 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 medicines 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.

1 SEC. 2. FINDINGS.

2 Congress makes the following findings:

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

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

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

4 (4) Medicare beneficiaries at all income levels
5 lack prescription medicine coverage, with more than
6 $\frac{1}{2}$ of such beneficiaries having incomes greater than
7 150 percent of the poverty line.

8 (5) The number of private firms offering retiree
9 health coverage is declining.

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

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

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

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

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

1 regardless of whether the medicine is included in any
2 formulary established under this part if such medi-
3 cine is certified as medically necessary by such
4 health care professional (except that the Secretary
5 shall encourage to the maximum extent possible the
6 substitution and use of lower-cost generics), up to
7 the benefit limits specified in section 1860B; and

8 “(2) charging by pharmacies of the negotiated
9 price—

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

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

17 “(b) COVERED PRESCRIPTION MEDICINES.—

18 “(1) IN GENERAL.—Covered prescription medi-
19 cines, for purposes of this part, include all prescrip-
20 tion medicines (as defined in section 1860K(1)), in-
21 cluding smoking cessation agents, except as other-
22 wise provided in this subsection.

23 “(2) EXCLUSIONS FROM COVERAGE.—Covered
24 prescription medicines shall not include drugs or
25 classes of drugs described in subparagraphs (A)

1 through (D) and (F) through (H) of section
2 1927(d)(2) unless—

3 “(A) specifically provided otherwise by the
4 Secretary with respect to a drug in any of such
5 classes; or

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

9 “(3) EXCLUSION OF PRESCRIPTION MEDICINES
10 TO THE EXTENT COVERED UNDER PART A OR B.—
11 A medicine prescribed for an individual that would
12 otherwise be a covered prescription medicine under
13 this part shall not be so considered to the extent
14 that payment for such medicine is available under
15 part A or B, including all injectable drugs and
16 biologicals for which payment was made or should
17 have been made by a carrier under section
18 1861(s)(2) (A) or (B) as of the date of enactment
19 of the Medicare Extension of Drugs to Seniors
20 (MEDS) Act of 2001. Medicines otherwise covered
21 under part A or B shall be covered under this part
22 to the extent that benefits under part A or B are ex-
23 hausted.

24 “(4) STUDY ON INCLUSION OF HOME INFUSION
25 THERAPY SERVICES.—Not later than 1 year after

1 the date of enactment of the Medicare Extension of
2 Drugs to Seniors (MEDS) Act of 2001, the Sec-
3 retary shall submit to Congress a legislative proposal
4 for the delivery of home infusion therapy services
5 under this title and for a system of payment for
6 such a benefit that coordinates items and services
7 furnished under part B and under this part.

8 “PAYMENT OF BENEFITS; BENEFIT LIMITS

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

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

17 “(A) with respect to costs incurred for cov-
18 ered prescription medicine furnished during a
19 year, before the individual has incurred out-of-
20 pocket expenses under this subsection equal to
21 the catastrophic out-of-pocket limit specified in
22 subsection (b), an amount equal to the applica-
23 ble percentage (specified in paragraph (2)) of
24 the negotiated price for each such covered pre-
25 scription medicine or such higher percentage as
26 is proposed under section 1860G(b)(7); and

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

9 “(2) APPLICABLE PERCENTAGE.—The applica-
10 ble percentage specified in this paragraph is 80 per-
11 cent or such higher percentage as is proposed under
12 section 1860G(b)(7), if the Secretary finds that such
13 higher percentage will not increase aggregate costs
14 to the Prescription Medicine Insurance Account.

15 “(b) CATASTROPHIC LIMIT ON OUT-OF-POCKET EX-
16 PENSES.—

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

20 “(A) for each of calendar years 2003 and
21 2004, \$2,000; and

22 “(B) subject to paragraph (2), for calendar
23 year 2005 and each subsequent calendar year is
24 equal to the limit for the preceding year under
25 this paragraph adjusted by the sustainable

1 growth rate percentage (determined under sec-
2 tion 1861I(b)) for the year involved.

3 “(2) ROUNDING.—Any amount determined
4 under paragraph (1)(E) that is not a multiple of
5 \$10 shall be rounded to the nearest multiple of \$10.

6 “ELIGIBILITY AND ENROLLMENT

7 “SEC. 1860C. (a) ELIGIBILITY.—Every individual
8 who, in or after 2003, is entitled to hospital insurance ben-
9 efits under part A or enrolled in the medical insurance
10 program under part B is eligible to enroll, in accordance
11 with the provisions of this section, in the insurance pro-
12 gram under this part, during an enrollment period pre-
13 scribed in or under this section, in such manner and form
14 as may be prescribed by regulations.

15 “(b) ENROLLMENT.—

16 “(1) IN GENERAL.—Each individual who satis-
17 fies subsection (a) shall be enrolled (or eligible to en-
18 roll) in the program under this part in accordance
19 with the provisions of section 1837, as if that section
20 applied to this part, except as otherwise explicitly
21 provided in this part.

22 “(2) SINGLE ENROLLMENT PERIOD.—Except as
23 provided in section 1837(i) (as such section applies
24 to this part), 1860E, or 1860H(e), or as otherwise
25 explicitly provided, no individual shall be entitled to
26 enroll in the program under this part at any time

1 after the initial enrollment period without penalty,
2 and in the case of all other late enrollments, the Sec-
3 retary shall develop a late enrollment penalty for the
4 individual that fully recovers the additional actuarial
5 risk involved providing coverage for the individual.

6 “(3) SPECIAL ENROLLMENT PERIOD FOR
7 2003.—

8 “(A) IN GENERAL.—An individual who
9 first satisfies subsection (a) in 2003 may, at
10 any time on or before December 31, 2003—

11 “(i) enroll in the program under this
12 part; and

13 “(ii) enroll or reenroll in such pro-
14 gram after having previously declined or
15 terminated enrollment in such program.

16 “(B) EFFECTIVE DATE OF COVERAGE.—
17 An individual who enrolls under the program
18 under this part pursuant to subparagraph (A)
19 shall be entitled to benefits under this part be-
20 ginning on the first day of the month following
21 the month in which such enrollment occurs.

22 “(c) PERIOD OF COVERAGE.—

23 “(1) IN GENERAL.—Except as otherwise pro-
24 vided in this part, an individual’s coverage under the
25 program under this part shall be effective for the pe-

1 riod provided in section 1838, as if that section ap-
 2 plied to the program under this part.

3 “(2) PART D COVERAGE TERMINATED BY TER-
 4 MINATION OF COVERAGE UNDER PARTS A AND B.—
 5 In addition to the causes of termination specified in
 6 section 1838, an individual’s coverage under this
 7 part shall be terminated when the individual retains
 8 coverage under neither the program under part A
 9 nor the program under part B, effective on the effec-
 10 tive date of termination of coverage under part A or
 11 (if later) under part B.

12 “PREMIUMS

13 “SEC. 1860D. (a) ANNUAL ESTABLISHMENT OF
 14 MONTHLY PREMIUM RATES.—

15 “(1) IN GENERAL.—The Secretary shall, during
 16 September of 2002 and of each succeeding year, de-
 17 termine and promulgate a monthly premium rate for
 18 the succeeding year in accordance with the provi-
 19 sions of this subsection.

20 “(2) INITIAL PREMIUMS.—For months in 2003,
 21 the monthly premium rate under this subsection
 22 shall be—

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

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

4 “(3) SUBSEQUENT YEARS.—

5 “(A) IN GENERAL.—For months in a year
6 after 2003, the monthly premium under this
7 subsection shall be (subject to subparagraph
8 (B)) the monthly premium (computed under
9 this subsection without regard to subparagraph
10 (B)) for the previous year increased by the an-
11 nual percentage increase in average per capita
12 aggregate expenditures for covered outpatient
13 medicines in the United States for medicare
14 beneficiaries, as estimated and published by the
15 Secretary in September before the year and for
16 the year involved.

17 “(B) ROUNDING.—The monthly premium
18 determined under subparagraph (A) shall be
19 rounded to the nearest multiple of 10 cents if
20 it is not a multiple of 10 cents.

21 “(C) PUBLICATION OF ASSUMPTIONS.—
22 The Secretary shall publish, together with the
23 promulgation of the monthly premium rates
24 under this paragraph, a statement setting forth
25 the actuarial assumptions and bases employed

1 in arriving at the monthly premium under sub-
2 paragraph (A).

3 “(b) PAYMENT OF PREMIUMS.—

4 “(1) PAYMENTS BY DEDUCTION FROM SOCIAL
5 SECURITY, RAILROAD RETIREMENT BENEFITS, OR
6 BENEFITS ADMINISTERED BY OPM.—

7 “(A) DEDUCTION FROM BENEFITS.—In
8 the case of an individual who is entitled to or
9 receiving benefits as described in subsection (a),
10 (b), or (d) of section 1840, premiums payable
11 under this part shall be collected by deduction
12 from such benefits at the same time and in the
13 same manner as premiums payable under part
14 B are collected pursuant to section 1840.

15 “(B) TRANSFERS TO PRESCRIPTION MEDI-
16 CINE INSURANCE ACCOUNT.—The Secretary of
17 the Treasury shall, from time to time, but not
18 less often than quarterly, transfer premiums
19 collected pursuant to subparagraph (A) to the
20 Prescription Medicine Insurance Account from
21 the appropriate funds and accounts described in
22 subsections (a)(2), (b)(2), and (d)(2) of section
23 1840, on the basis of the certifications de-
24 scribed in such subsections. The amounts of
25 such transfers shall be appropriately adjusted

1 to the extent that prior transfers were too great
2 or too small.

3 “(2) DIRECT PAYMENTS TO SECRETARY.—

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

16 “(B) PAYMENTS BY OTHER ENROLLEES.—
17 An individual enrolled in the insurance program
18 under this part with respect to whom none of
19 the preceding provisions of this subsection ap-
20 plies (or to whom section 1840(c) applies) shall
21 pay premiums to the Secretary at such times
22 and in such manner as the Secretary shall by
23 regulations prescribe.

24 “(C) DEPOSIT OF PREMIUMS.—Amounts
25 paid to the Secretary under this paragraph

1 shall be deposited in the Treasury to the credit
2 of the Prescription Medicine Insurance Account
3 in the Supplementary Medical Insurance Trust
4 Fund.

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

8 “SPECIAL ELIGIBILITY, ENROLLMENT, AND COPAYMENT
9 RULES FOR LOW-INCOME INDIVIDUALS

10 “SEC. 1860E. (a) STATE AGREEMENTS FOR COV-
11 ERAGE.—

12 “(1) IN GENERAL.—The Secretary shall, at the
13 request of a State, enter into an agreement with the
14 State under which all individuals described in para-
15 graph (2) are enrolled in the program under this
16 part, without regard to whether any such individual
17 has previously declined the opportunity to enroll in
18 such program.

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

23 “(A)(i) eligible individuals within the
24 meaning of section 1843; and

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

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

6 “(3) COVERAGE PERIOD.—The period of cov-
 7 erage under this part of an individual enrolled under
 8 an agreement under this subsection shall be as fol-
 9 lows:

10 “(A) INDIVIDUALS ELIGIBLE (AT STATE
 11 OPTION) FOR PART B BUY-IN.—In the case of
 12 an individual described in subsection (a)(2)(A),
 13 the coverage period shall be the same period
 14 that applies (or would apply) pursuant to sec-
 15 tion 1843(d).

16 “(B) QUALIFIED MEDICARE MEDICINE
 17 BENEFICIARIES.—In the case of an individual
 18 described in subsection (a)(2)(B)—

19 “(i) the coverage period shall begin on
 20 the latest of—

21 “(I) January 1, 2003;

22 “(II) the first day of the third
 23 month following the month in which
 24 the State agreement is entered into;

25 or

1 “(III) the first day of the first
2 month following the month in which
3 the individual satisfies section
4 1860C(a); and

5 “(ii) the coverage period shall end on
6 the last day of the month in which the in-
7 dividual is determined by the State to have
8 become ineligible for medicare medicine
9 cost-sharing.

10 “(4) ALTERNATIVE ENROLLMENT METHODS.—

11 In the process of enrolling low-income individuals
12 under this part, the Secretary shall use the system
13 provided under section 154 of the Social Security
14 Act Amendments of 1994 for newly eligible medicare
15 beneficiaries and shall apply a similar system for
16 other medicare beneficiaries. Such system shall use
17 existing Federal Government databases to identify
18 eligibility. Such system shall not require that bene-
19 ficiaries apply for, or enroll through, State medicaid
20 systems in order to obtain low-income assistance de-
21 scribed in this section.

22 “(b) SPECIAL PART D ENROLLMENT OPPORTUNITY
23 FOR INDIVIDUALS LOSING MEDICAID ELIGIBILITY.—In
24 the case of an individual who—

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

1 “(2) loses eligibility for benefits under the State
2 plan under title XIX after having been enrolled
3 under such plan or having been determined eligible
4 for such benefits;
5 the Secretary shall provide an opportunity for enrollment
6 under the program under this part during the period that
7 begins on the date that such individual loses such eligi-
8 bility and ends on the date specified by the Secretary.

9 “(c) STATE OPTION TO BUY-IN DUALY ELIGIBLE
10 INDIVIDUALS.—

11 “(1) COVERAGE OF PREMIUMS AS MEDICAL AS-
12 SISTANCE.—For purposes of applying the second
13 sentence of section 1905(a), any reference to pre-
14 miums under part B shall be considered to include
15 a reference to premiums under this part.

16 “(2) STATE COMMITMENT TO CONTINUE PAR-
17 TICIPATION IN PART D AFTER BENEFIT LIMIT
18 REACHED.—As a condition of additional funding to
19 a State under subsection (d), the State, in its State
20 plan under title XIX, shall provide that in the case
21 of any individual whose eligibility for medical assist-
22 ance under title XIX is not limited to medicare cost-
23 sharing and for whom the State elects to pay pre-
24 miums under this part pursuant to this section, the
25 State will purchase all prescription medicines for

1 such individual in accordance with the provisions of
 2 this part without regard to whether the benefit limit
 3 for such individual under section 1860B(b) has been
 4 reached.

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

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

10 “(B) the difference between the amount
 11 that is paid under section 1860B and the
 12 amount that would be paid under such section
 13 if any reference to ‘80 percent’ in subsection
 14 (a)(2) of such section were deemed a reference
 15 to ‘100 percent’ (or, if the Secretary approves
 16 a higher percentage under such section, if such
 17 percentage were deemed to be 100 percent).

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

20 “(1) IN GENERAL.—The Secretary shall provide
 21 for payment under this subsection to each State that
 22 provides for—

23 “(A) medicare cost-sharing described in
 24 section 1905(p)(3)(A)(ii) for individuals who
 25 would be qualified medicare beneficiaries de-

1 scribed in section 1905(p)(1) but for the fact
2 that their income exceeds the income level es-
3 tablished by the State under section 1905(p)(2)
4 and is at least 120 percent, but less than 135
5 percent, of the official poverty line (referred to
6 in such section) for a family of the size involved
7 and who are not otherwise eligible for medical
8 assistance under the State plan; and

9 “(B) medicare medicine cost-sharing (as
10 defined in subsection (e)(2)) for qualified medi-
11 care medicine beneficiaries described in sub-
12 section (e)(1).

13 “(2) AMOUNT OF PAYMENT.—The amount of
14 payment under paragraph (1) shall equal 100 per-
15 cent of the cost-sharing described in such paragraph,
16 except that, in the case of an individual whose eligi-
17 bility for medical assistance under title XIX is not
18 limited to medicare cost-sharing or medicare medi-
19 cine cost-sharing, the amount of payment under
20 paragraph (1)(B) shall be equal to the Federal med-
21 ical assistance percentage described in section
22 1905(b)) of amounts as expended for such cost-shar-
23 ing.

24 “(3) METHOD OF PAYMENT; RELATION TO
25 OTHER PAYMENTS.—Amounts shall be paid to

1 States under this subsection in a manner similar to
2 that provided under section 1903(d). Payments
3 under this subsection shall be made in lieu of any
4 payments that otherwise may be made for medical
5 assistance provided under section
6 1902(a)(10)(E)(iv).

7 “(4) TREATMENT OF TERRITORIES.—

8 “(A) IN GENERAL.—Subject to subpara-
9 graph (B), this subsection shall not apply to
10 States other than the 50 States and the Dis-
11 trict of Columbia.

12 “(B) PAYMENTS.—In the case of a State
13 (other than the 50 States and the District of
14 Columbia) that develops and implements a plan
15 of assistance for pharmaceuticals provided to
16 low-income medicare beneficiaries, the Secretary
17 shall provide for payment to the State in an
18 amount that is reasonable in relation to the
19 payment levels provided to other States under
20 paragraph (2).

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

23 “(1) QUALIFIED MEDICARE MEDICINE BENE-
24 FICIARY.—The term ‘qualified medicare medicine
25 beneficiary’ means an individual—

1 “(A) who is entitled to hospital insurance
2 benefits under part A (including an individual
3 entitled to such benefits pursuant to an enroll-
4 ment under section 1818, but not including an
5 individual entitled to such benefits only pursu-
6 ant to an enrollment under section 1818A);

7 “(B) whose income (as determined under
8 section 1612 for purposes of the supplemental
9 security income program, except as provided in
10 section 1905(p)(2)(D)) is above 100 percent
11 but below 150 percent of the official poverty
12 line (as defined by the Office of Management
13 and Budget, and revised annually in accordance
14 with section 673(2) of the Omnibus Budget
15 Reconciliation Act of 1981) applicable to a fam-
16 ily of the size involved; and

17 “(C) whose resources (as determined under
18 section 1613 for purposes of the supplemental
19 security income program) do not exceed twice
20 the maximum amount of resources that an indi-
21 vidual may have and obtain benefits under that
22 program.

23 “(2) MEDICARE MEDICINE COST-SHARING.—
24 The term ‘medicare medicine cost-sharing’ means
25 the following costs incurred with respect to a quali-

1 fied medicare medicine beneficiary, without regard to
2 whether the costs incurred were for items and serv-
3 ices for which medical assistance is otherwise avail-
4 able under a State plan under title XIX:

5 “(A) In the case of a qualified medicare
6 medicine beneficiary whose income (as deter-
7 mined under paragraph (1)) is less than 135
8 percent of the official poverty line—

9 “(i) premiums under section 1860D;

10 and

11 “(ii) the difference between the
12 amount that is paid under section 1860B
13 and the amount that would be paid under
14 such section if any reference to ‘50 per-
15 cent’ therein were deemed a reference to
16 ‘100 percent’ (or, if the Secretary approves
17 a higher percentage under such section, if
18 such percentage were deemed to be 100
19 percent).

20 “(B) In the case of a qualified medicare
21 medicine beneficiary whose income (as deter-
22 mined under paragraph (1)) is at least 135 per-
23 cent but less than 150 percent of the official
24 poverty line, a percentage of premiums under
25 section 1860D, determined on a linear sliding

1 scale ranging from 100 percent for individuals
 2 with incomes at 135 percent of such line to 0
 3 percent for individuals with incomes at 150 per-
 4 cent of such line.

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

8 “(4) TREATMENT OF DRUGS PURCHASED.—The
 9 provisions of section 1927 shall not apply to pre-
 10 scription drugs purchased under this part pursuant
 11 to an agreement with the Secretary under this sec-
 12 tion (including any drugs so purchased after the
 13 limit under section 1860B(b) has been exceeded).

14 “PRESCRIPTION MEDICINE INSURANCE ACCOUNT

15 “SEC. 1860F. (a) ESTABLISHMENT.—There is cre-
 16 ated within the Federal Supplemental Medical Insurance
 17 Trust Fund established by section 1841 an account to be
 18 known as the ‘Prescription Medicine Insurance Account’
 19 (in this section referred to as the ‘Account’).

20 “(b) AMOUNTS IN ACCOUNT.—

21 “(1) IN GENERAL.—The Account shall consist
 22 of—

23 “(A) such amounts as may be deposited in,
 24 or appropriated to, such fund as provided in
 25 this part; and

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

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

7 “(c) PAYMENTS FROM ACCOUNT.—The Managing
8 Trustee shall pay from time to time from the Account such
9 amounts as the Secretary certifies are necessary to make
10 the payments provided for by this part, and the payments
11 with respect to administrative expenses in accordance with
12 section 201(g).

13 “ADMINISTRATION OF BENEFITS

14 “SEC. 1860G. (a) THROUGH HCFA.—The Secretary
15 shall provide for administration of the benefits under this
16 part through the Health Care Financing Administration
17 in accordance with the provisions of this section. The Ad-
18 ministrator of such Administration may enter into con-
19 tracts with carriers to administer this part in the same
20 manner as the Administrator enters into such contracts
21 to administer part B. Any such contract shall be separate
22 from any contract under section 1842.

23 “(b) ADMINISTRATION FUNCTIONS.—In carrying out
24 this part, the Administrator (or a carrier under a contract
25 with the Administrator) shall (or in the case of the func-

1 tion described in paragraph (9), may) perform the fol-
2 lowing functions:

3 “(1) PARTICIPATION AGREEMENTS, PRICES,
4 AND FEES.—

5 “(A) NEGOTIATED PRICES.—Establish,
6 through negotiations with medicine manufactur-
7 ers and wholesalers and pharmacies, a schedule
8 of prices for covered prescription medicines.

9 “(B) AGREEMENTS WITH PHARMACIES.—
10 Enter into participation agreements under sub-
11 section (c) with pharmacies, that include terms
12 that—

13 “(i) secure the participation of suffi-
14 cient numbers of pharmacies to ensure
15 convenient access (including adequate
16 emergency access);

17 “(ii) permit the participation of any
18 pharmacy in the service area that meets
19 the participation requirements described in
20 subsection (c); and

21 “(iii) allow for reasonable dispensing
22 and consultation fees for pharmacies.

23 “(C) LISTS OF PRICES AND PARTICIPATING
24 PHARMACIES.—Ensure that the negotiated
25 prices established under subparagraph (A) and

1 the list of pharmacies with agreements under
2 subsection (c) are regularly updated and readily
3 available to health care professionals authorized
4 to prescribe medicines, participating phar-
5 macies, and enrolled individuals.

6 “(2) TRACKING OF COVERED ENROLLED INDI-
7 VIDUALS.—Maintain accurate, updated records of all
8 enrolled individuals (other than individuals enrolled
9 in a plan under part C).

10 “(3) PAYMENT AND COORDINATION OF BENE-
11 FITS.—

12 “(A) PAYMENT.—

13 “(i) Administer claims for payment of
14 benefits under this part and encourage, to
15 the maximum extent possible, use of elec-
16 tronic means for the submissions of claims.

17 “(ii) Determine amounts of benefit
18 payments to be made.

19 “(iii) Receive, disburse, and account
20 for funds used in making such payments,
21 including through the activities specified in
22 the provisions of this paragraph.

23 “(B) COORDINATION.—Coordinate with
24 other private benefit providers, pharmacies, and
25 other relevant entities as necessary to ensure

1 appropriate coordination of benefits with re-
2 spect to enrolled individuals, including coordina-
3 tion of access to and payment for covered pre-
4 scription medicines according to an individual's
5 in-service area plan provisions, when such indi-
6 vidual is traveling outside the home service
7 area, and under such other circumstances as
8 the Secretary may specify.

9 “(C) EXPLANATION OF BENEFITS.—Fur-
10 nish to enrolled individuals an explanation of
11 benefits in accordance with section 1806(a),
12 and a notice of the balance of benefits remain-
13 ing for the current year, whenever prescription
14 medicine benefits are provided under this part
15 (except that such notice need not be provided
16 more often than monthly).

17 “(4) RULES RELATING TO PROVISION OF BENE-
18 FITS.—

19 “(A) IN GENERAL.—In providing benefits
20 under this part, the Secretary (directly or
21 through contracts) shall employ mechanisms to
22 provide benefits economically, including the use
23 of—

24 “(i) formularies (consistent with sub-
25 paragraph (B));

1 “(ii) automatic generic medicine sub-
2 stitution (unless the physician specifies
3 otherwise, in which case a 30-day prescrip-
4 tion may be dispensed pending a consulta-
5 tion with the physician on whether a ge-
6 neric substitute can be dispensed in the fu-
7 ture);

8 “(iii) tiered copayments (which may
9 include copayments at a rate lower than 20
10 percent) to encourage the use of the lowest
11 cost, on-formulary product in cases where
12 there is no restrictive prescription (de-
13 scribed in subparagraph (D)(i)); and

14 “(iv) therapeutic interchange.

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

18 “(i) use an advisory committee (or a
19 therapeutics committee) comprised of li-
20 censed practicing physicians, pharmacists,
21 and other health care practitioners to de-
22 velop and manage the formulary;

23 “(ii) include in the formulary at least
24 1 medicine from each therapeutic class

1 and, if available, a generic equivalent
2 thereof; and

3 “(iii) disclose to current and prospec-
4 tive enrollees and to participating providers
5 and pharmacies, the nature of the for-
6 mulary restrictions, including information
7 regarding the medicines included in the
8 formulary and any difference in cost-shar-
9 ing amounts.

10 “(C) CONSTRUCTION.—Nothing in this
11 subsection shall be construed to prevent the
12 Secretary (directly or through contracts) from
13 using incentives (including a lower beneficiary
14 coinsurance) to encourage enrollees to select ge-
15 neric or other cost-effective medicines, so long
16 as—

17 “(i) such incentives are designed not
18 to result in any increase in the aggregate
19 expenditures under the Federal Medicare
20 Prescription Medicine Trust Fund;

21 “(ii) the average coinsurance charged
22 to all beneficiaries by the Secretary (di-
23 rectly or through contractors) shall seek to
24 approximate (but in no case exceed) 20
25 percent for on-formulary medicines;

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

4 “(iv) the reimbursement for a pre-
5 scribed nonformulary medicine without a
6 restrictive prescription in no case shall be
7 more than the lowest reimbursement for a
8 formulary medicine in the therapeutic class
9 of the prescribed medicine.

10 “(D) RESTRICTIVE PRESCRIPTION.—For
11 purposes of this section:

12 “(i) WRITTEN PRESCRIPTIONS.—In
13 the case of a written prescription for a
14 medicine, it is a restrictive prescription
15 only if the prescription indicates, in the
16 writing of the physician or other qualified
17 person prescribing the medicine and with
18 an appropriate phrase (such as ‘brand
19 medically necessary’) recognized by the
20 Secretary, that a particular medicine prod-
21 uct must be dispensed based upon a belief
22 by the physician or person prescribing the
23 medicine that the particular medicine will
24 provide even marginally superior thera-
25 peutic benefits to the individual for whom

1 the medicine is prescribed or would have
2 marginally fewer adverse reactions with re-
3 spect to such individual.

4 “(ii) TELEPHONE PRESCRIPTIONS.—
5 In the case of a prescription issued by tele-
6 phone for a medicine, it is a restrictive
7 prescription only if the prescription cannot
8 be longer than 30 days and the physician
9 or other qualified person prescribing the
10 medicine (through use of such an appro-
11 priate phrase) states that a particular
12 medicine product must be dispensed, and
13 the physician or other qualified person sub-
14 mits to the pharmacy involved, within 30
15 days after the date of the telephone pre-
16 scription, a written confirmation from the
17 physician or other qualified person pre-
18 scribing the medicine and which indicates
19 with such appropriate phrase that the par-
20 ticular medicine product was required to
21 have been dispensed based upon a belief by
22 the physician or person prescribing the
23 medicine that the particular medicine will
24 provide even marginally superior thera-
25 peutic benefits to the individual for whom

1 the medicine is prescribed or would have
2 marginally fewer adverse reactions with re-
3 spect to such individual. Such written con-
4 firmation is required to refill the prescrip-
5 tion.

6 “(iii) REVIEW OF RESTRICTIVE PRE-
7 SCRIPTIONS.—The advisory committee (es-
8 tablished under subparagraph (B)(i)) may
9 decide to review a restrictive prescription
10 and, if so, it may approve or disapprove
11 such restrictive prescription. It may not
12 disapprove such restrictive prescription un-
13 less it finds that there is no clinical evi-
14 dence or peer reviewed medical literature
15 that supports a determination that the
16 particular medicine provides even margin-
17 ally superior therapeutic benefits to the in-
18 dividual for whom the medicine is pre-
19 scribed or would have marginally fewer ad-
20 verse reactions with respect to such indi-
21 vidual. If it disapproves, upon request of
22 the prescribing physician or the enrollee,
23 the committee must provide for a review by
24 an independent contractor of such decision
25 within 48 hours of the time of submission

1 of the prescription, to determine whether
2 the prescription is an eligible benefit under
3 this part. The Secretary shall ensure that
4 independent contractors so used are com-
5 pletely independent of the contractor or its
6 advisory committee.

7 “(5) COST AND UTILIZATION MANAGEMENT;
8 QUALITY ASSURANCE.—Have in place effective cost
9 and utilization management, drug utilization review,
10 quality assurance measures, and systems to reduce
11 medical errors, including at least the following, to-
12 gether with such additional measures as the Admin-
13 istrator may specify:

14 “(A) DRUG UTILIZATION REVIEW.—A drug
15 utilization review program conforming to the
16 standards provided in section 1927(g)(2) (with
17 such modifications as the Administrator finds
18 appropriate).

19 “(B) FRAUD AND ABUSE CONTROL.—Ac-
20 tivities to control fraud, abuse, and waste, in-
21 cluding prevention of diversion of pharma-
22 ceuticals to the illegal market.

23 “(C) MEDICATION THERAPY MANAGE-
24 MENT.—

1 “(i) IN GENERAL.—A program of
2 medicine therapy management and medica-
3 tion administration that is designed to as-
4 sure that covered outpatient medicines are
5 appropriately used to achieve therapeutic
6 goals and reduce the risk of adverse
7 events, including adverse drug interactions.

8 “(ii) ELEMENTS.—Such program may
9 include—

10 “(I) enhanced beneficiary under-
11 standing of such appropriate use
12 through beneficiary education, coun-
13 seling, and other appropriate means;
14 and

15 “(II) increased beneficiary adher-
16 ence with prescription medication
17 regimens through medication refill re-
18 minders, special packaging, and other
19 appropriate means.

20 “(iii) DEVELOPMENT OF PROGRAM IN
21 COOPERATION WITH LICENSED PHAR-
22 MACISTS.—The program shall be developed
23 in cooperation with licensed pharmacists
24 and physicians.

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

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

16 “(7) BENEFICIARY PROTECTIONS.—

17 “(A) CONFIDENTIALITY OF HEALTH IN-
18 FORMATION.—Have in effect systems to safe-
19 guard the confidentiality of health care infor-
20 mation on enrolled individuals, which comply
21 with section 1106 and with section 552a of title
22 5, United States Code, and meet such addi-
23 tional standards as the Administrator may pre-
24 scribe.

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

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

11 “(A) RECORDS AND AUDITS.—Maintain
12 adequate records, and afford the Administrator
13 access to such records (including for audit pur-
14 poses).

15 “(B) REPORTS.—Make such reports and
16 submissions of financial and utilization data as
17 the Administrator may require taking into ac-
18 count standard commercial practices.

19 “(9) PROPOSAL FOR ALTERNATIVE COINSUR-
20 ANCE AMOUNT.—

21 “(A) SUBMISSION.—The Administrator
22 may provide for increased Government cost-
23 sharing for generic prescription medicines, pre-
24 scription medicines on a formulary, or prescrip-

1 tion medicines obtained through mail order
2 pharmacies.

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

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

14 The Administrator shall negotiate a schedule of prices
15 under paragraph (1)(A), except that nothing in this sen-
16 tence shall prevent a carrier under a contract with the Ad-
17 ministrators from negotiating a lower schedule of prices for
18 covered prescription medicines.

19 “(c) PHARMACY PARTICIPATION AGREEMENTS.—

20 “(1) IN GENERAL.—A pharmacy that meets the
21 requirements of this subsection shall be eligible to
22 enter an agreement with the Administrator to fur-
23 nish covered prescription medicines and pharmacists’
24 services to enrolled individuals.

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

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

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

18 “(C) PERFORMANCE STANDARDS.—The
19 pharmacy and the pharmacist shall comply with
20 performance standards relating to—

21 “(i) measures for quality assurance,
22 reduction of medical errors, and participa-
23 tion in the drug utilization review program
24 described in subsection (b)(3)(A);

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

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

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

12 “(d) SPECIAL ATTENTION TO RURAL AND HARD-TO-
13 SERVE AREAS.—

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

20 “(2) SPECIAL ATTENTION DEFINED.—For pur-
21 poses of paragraph (1), the term ‘special attention’
22 may include bonus payments to retail pharmacists in
23 rural areas and any other actions the Secretary de-
24 termines are necessary to ensure full access to rural
25 and hard-to-serve beneficiaries.

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

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

18 “(1) bonus and penalty incentives to encourage
19 administrative efficiency;

20 “(2) incentives under which carriers share in
21 any benefit savings achieved;

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

24 “(4) financial incentives under which savings
25 derived from the substitution of generic medicines in

1 lieu of nongeneric medicines are made available to
2 carriers, pharmacies, and the Prescription Medicine
3 Insurance Account; and

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

7 “EMPLOYER INCENTIVE PROGRAM FOR EMPLOYMENT-
8 BASED RETIREE MEDICINE COVERAGE

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

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

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

24 “(A) annually attest, and provide such as-
25 surances as the Secretary may require, that the
26 coverage offered by the sponsor is a qualified

1 retiree prescription medicine plan, and will re-
2 main such a plan for the duration of the spon-
3 sor's participation in the program under this
4 section; and

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

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

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

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

20 “(c) INCENTIVE PAYMENT.—

21 “(1) IN GENERAL.—A sponsor that meets the
22 requirements of subsection (b) with respect to a
23 quarter in a calendar year shall have payment made
24 by the Secretary on a quarterly basis (to the sponsor
25 or, at the sponsor's direction, to the appropriate em-

1 ployment-based health plan) of an incentive pay-
2 ment, in the amount determined as described in
3 paragraph (2), for each retired individual (or
4 spouse) who—

5 “(A) was covered under the sponsor’s
6 qualified retiree prescription medicine plan dur-
7 ing such quarter; and

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

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

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

21 “(d) CIVIL MONEY PENALTIES.—A sponsor, health
22 plan, or other entity that the Secretary determines has,
23 directly or through its agent, provided information in con-
24 nection with a request for an incentive payment under this
25 section that the entity knew or should have known to be

1 false shall be subject to a civil monetary penalty in an
2 amount equal to \$2,000 for each false representation plus
3 an amount not to exceed 3 times the total incentive
4 amounts under subsection (c) that were paid (or would
5 have been payable) on the basis of such information.

6 “(e) PART D ENROLLMENT FOR CERTAIN INDIVID-
7 UALS COVERED BY EMPLOYMENT-BASED RETIREE
8 HEALTH COVERAGE PLANS.—

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

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

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

20 “(C)(i) the sponsor subsequently ceased to
21 offer such plan; or

22 “(ii) the value of prescription medicine cov-
23 erage under such plan is reduced below the
24 value of the coverage provided at the time the

1 individual first became eligible to participate in
2 the program under this part.

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

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

13 “(B) the individual received notice of the
14 change in benefits (in the circumstance de-
15 scribed in paragraph (1)(C)(ii)).

16 “(f) DEFINITIONS.—In this section:

17 “(1) EMPLOYMENT-BASED RETIREE HEALTH
18 COVERAGE.—The term ‘employment-based retiree
19 health coverage’ means health insurance or other
20 coverage of health care costs for retired individuals
21 (or for such individuals and their spouses and de-
22 pendants) based on their status as former employees
23 or labor union members.

24 “(2) EMPLOYER.—The term ‘employer’ has the
25 meaning given to such term by section 3(5) of the

1 Employee Retirement Income Security Act of 1974
2 (except that such term shall include only employers
3 of 2 or more employees).

4 “(3) QUALIFIED RETIREE PRESCRIPTION MEDI-
5 CINE PLAN.—The term ‘qualified retiree prescription
6 medicine plan’ means health insurance coverage in-
7 cluded in employment-based retiree health coverage
8 that—

9 “(A) provides coverage of the cost of pre-
10 scription medicines whose actuarial value to
11 each retired beneficiary equals or exceeds the
12 actuarial value of the benefits provided to an in-
13 dividual enrolled in the program under this
14 part; and

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

21 “(4) SPONSOR.—The term ‘sponsor’ has the
22 meaning given the term ‘plan sponsor’ by section
23 3(16)(B) of the Employee Retirement Income Secu-
24 rity Act of 1974.

1 “PROMOTION OF PHARMACEUTICAL RESEARCH ON
2 BREAK-THROUGH MEDICINES WHILE PROVIDING
3 PROGRAM COST CONTAINMENT

4 “SEC. 1860I. (a) MONITORING EXPENDITURES.—
5 The Secretary shall monitor expenditures under this part.
6 On October 1, 2003, the Secretary shall estimate total ex-
7 penditures under this part for 2003.

8 “(b) ESTABLISHMENT OF SUSTAINABLE GROWTH
9 RATE.—

10 “(1) IN GENERAL.—The Secretary shall estab-
11 lish a sustainable growth rate prescription medicine
12 target system for expenditures under this part for
13 each year after 2003.

14 “(2) INITIAL COMPUTATION.—Such target shall
15 equal the amount of total expenditures estimated for
16 2003 adjusted by the Secretary’s estimate of a sus-
17 tainable growth rate (in this section referred to as
18 an ‘SGR’) percentage between 2003 and 2004. Such
19 SGR shall be estimated based on the following:

20 “(A) Reasonable changes in the cost of
21 production or price of covered pharmaceuticals,
22 but in no event more than the rate of increase
23 in the Consumer Price Index for all urban con-
24 sumers for the period involved.

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

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

10 “(D) Productivity index of manufacturers
11 and distributors.

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

16 “(F) Such other factors as the Secretary
17 may determine are appropriate.

18 In no event may the sustainable growth rate exceed
19 120 percent of the estimated per capita growth in
20 total spending under this title.

21 “(3) COMPUTATION FOR SUBSEQUENT
22 YEARS.—In October of 2004 and each year there-
23 after, for purposes of setting the SGRs for the suc-
24 ceeding year, the Secretary shall adjust each current
25 year’s estimated expenditures by the estimated SGR

1 for the succeeding year, further adjusted for correc-
2 tions in earlier estimates and the receipt of addi-
3 tional data on previous years spending as follows:

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

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

12 “(C) TARGET.—An adjustment for any
13 amount (over or under) that expenditures in the
14 current year under this part are estimated to
15 differ from the target amount set for the year.
16 If expenditures in the current year are esti-
17 mated to be—

18 “(i) less than the target amount, fu-
19 ture target amounts will be adjusted down-
20 ward; or

21 “(ii) more than the target amount,
22 the Secretary shall notify all pharma-
23 ceutical manufacturers with sales of phar-
24 maceutical prescription medicine products
25 to medicare beneficiaries under this part,

1 of a rebate requirement (except as pro-
2 vided in this subparagraph) to be deposited
3 in the Federal Medicare Prescription Medi-
4 cine Trust Fund.

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

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

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

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

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

24 “(v) such other actions by the manu-
25 facturer that the Secretary may determine

1 has contributed to the failure to meet the
2 SGR target.

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

14 “(c) BREAKTHROUGH MEDICINES.—

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

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

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

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

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

20 “(d) NO REVIEW.—The Secretary’s determination of
21 the rebate amounts under this section, and the Drug Re-
22 view Board’s determination of what is a breakthrough
23 drug, are not subject to administrative or judicial review.

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

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

9 (b) CONFORMING AMENDMENTS.—

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

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

15 (i) by striking “and” after “section
16 201(i)(1)”;

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

22 (B) in subsection (g), by inserting after
23 “by this part,” the following: “the payments
24 provided for under part D (in which case the
25 payments shall come from the Prescription

1 Medicine Insurance Account in the Supple-
 2 mentary Medical Insurance Trust Fund),”;

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

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

11 (i) by striking “and” after “section
 12 1840(b)(1)”;

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

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

21 (A) ELIGIBILITY, ELECTION, AND ENROLL-
 22 MENT.—Section 1851 of the Social Security Act
 23 (42 U.S.C. 1395w-21) is amended—

1 (i) in subsection (a)(1)(A), by striking
2 “parts A and B” and inserting “parts A,
3 B, and D”; and

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

7 (B) VOLUNTARY BENEFICIARY ENROLL-
8 MENT FOR MEDICINE COVERAGE.—Section
9 1852(a)(1)(A) of such Act (42 U.S.C. 1395w-
10 22(a)(1)(A)) is amended by inserting “(and
11 under part D to individuals also enrolled under
12 that part)” after “parts A and B”.

13 (C) ACCESS TO SERVICES.—Section
14 1852(d)(1) of such Act (42 U.S.C. 1395w-
15 22(d)(1)) is amended—

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

18 (ii) in subparagraph (E), by striking
19 the period at the end and inserting “;
20 and”; and

21 (iii) by adding at the end the fol-
22 lowing new subparagraph:

23 “(F) the plan for prescription medicine
24 benefits under part D guarantees coverage of
25 any specifically named covered prescription

1 medicine for an enrollee, when prescribed by a
2 physician in accordance with the provisions of
3 such part, regardless of whether such medicine
4 would otherwise be covered under an applicable
5 formulary or discount arrangement.”.

6 (D) PAYMENTS TO ORGANIZATIONS.—Sec-
7 tion 1853(a)(1)(A) of such Act (42 U.S.C.
8 1395w-23(a)(1)(A)) is amended—

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

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

19 (iii) by inserting before the last sen-
20 tence the following: “In the case of the
21 payments for benefits under part D, such
22 payment shall initially be adjusted for the
23 risk factors of each enrollee as the Sec-
24 retary determines to be feasible and appro-
25 priate. By 2006, the adjustments would be

1 for the same risk factors applicable for
2 benefits under parts A and B.”.

3 (E) CALCULATION OF ANNUAL MEDICARE
4 +CHOICE CAPITATION RATES.—Section 1853(c)
5 of such Act (42 U.S.C. 1395w-23(c)) is
6 amended—

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

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

16 (iii) by adding at the end the fol-
17 lowing new paragraph:

18 “(8) PAYMENT FOR PRESCRIPTION MEDI-
19 CINES.—The Secretary shall determine a capitation
20 rate for prescription medicines—

21 “(A) dispensed in 2003, which is based on
22 the projected national per capita costs for pre-
23 scription medicine benefits under part D and
24 associated claims processing costs for bene-

1 ficiaries under the original medicare fee-for-
2 service program; and

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

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

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

19 (G) REQUIREMENT FOR ADDITIONAL BEN-
20 EFITS.—Section 1854(f)(1) of such Act (42
21 U.S.C. 1395w–24(f)(1)) is amended by adding
22 at the end the following new sentence: “Such
23 determination shall be made separately for ben-
24 efits under parts A and B and for prescription
25 medicine benefits under part D.”.

1 (3) EXCLUSIONS FROM COVERAGE.—

2 (A) APPLICATION TO PART D.—Section
3 1862(a) of the Social Security Act (42 U.S.C.
4 1395y(a)) is amended in the matter preceding
5 paragraph (1) by striking “part A or part B”
6 and inserting “part A, B, or D”.

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

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

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

16 (iii) by adding at the end the fol-
17 lowing new subparagraph:

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

21 **SEC. 4. SUBSTANTIAL REDUCTIONS IN THE PRICE OF PRE-**
22 **SCRIPTION DRUGS FOR MEDICARE BENE-**
23 **FICIARIES.**

24 (a) PARTICIPATING MANUFACTURERS.—

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

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

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

18 (A) The lowest price paid for the covered
19 outpatient drug by any agency or department of
20 the United States.

21 (B) The manufacturer's best price for the
22 covered outpatient drug, as defined in section
23 1927(c)(1)(C) of the Social Security Act (42
24 U.S.C. 1396r-8(c)(1)(C)).

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

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

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

20 (d) REPORTS TO CONGRESS REGARDING EFFECTIVE-
21 NESS OF SECTION.—

22 (1) IN GENERAL.—Not later than 2 years after
23 the date of enactment of this Act, and annually
24 thereafter, the Secretary shall report to Congress re-
25 garding the effectiveness of this section in—

1 (A) protecting medicare beneficiaries from
2 discriminatory pricing by drug manufacturers;
3 and

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

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

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

17 (e) DEFINITIONS.—For purposes of this section:

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

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

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

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

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

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

20 **SEC. 5. AMENDMENTS TO PROGRAM FOR IMPORTATION OF**
21 **CERTAIN PRESCRIPTION DRUGS BY PHAR-**
22 **MACISTS AND WHOLESALERS.**

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

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

3 “(e) TESTING; APPROVED LABELING.—

4 “(1) TESTING.—Regulations under subsection
5 (a)—

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

11 “(B) shall require that, if such tests are
12 conducted by the importer, information needed
13 to authenticate the product being tested be sup-
14 plied by the manufacturer of such product to
15 the importer; and

16 “(C) shall provide for the protection of any
17 information supplied by the manufacturer
18 under subparagraph (B) that is a trade secret
19 or commercial or financial information that is
20 privileged or confidential.

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

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

9 (2) by striking subsections (h) and (i) and in-
10 serting the following subsections:

11 “(h) PROHIBITED AGREEMENTS; NONDISCRIMINA-
12 TION.—

13 “(1) PROHIBITED AGREEMENTS.—No manufac-
14 turer of a covered product may enter into a contract
15 or agreement that includes a provision to prevent
16 the sale or distribution of covered products imported
17 pursuant to subsection (a).

18 “(2) NONDISCRIMINATION.—No manufacturer
19 of a covered product may take actions that discrimi-
20 nate against, or cause other persons to discriminate
21 against, United States pharmacists, wholesalers, or
22 consumers regarding the sale or distribution of cov-
23 ered products.

24 “(i) STUDY AND REPORT.—

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

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

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

17 “(2) REPORT.—Not later than 5 years after the
18 effective date of final regulations issued pursuant to
19 this section, the Comptroller General of the United
20 States shall prepare and submit to Congress a re-
21 port containing the study described in paragraph
22 (1).”;

23 (3) in subsection (k)(2)—

1 (A) by redesignating subparagraphs (A)
2 through (E) as subparagraphs (B) through (F),
3 respectively; and

4 (B) by inserting before subparagraph (B)
5 (as so redesignated) the following subpara-
6 graph:

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

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

16 (5) by inserting after subsection (l) the fol-
17 lowing subsection:

18 “(m) FUNDING.—For the purpose of carrying out
19 this section, there are authorized to be appropriated such
20 sums as may be necessary for fiscal year 2002 and each
21 subsequent fiscal year.”.

22 **SEC. 6. REASONABLE PRICE AGREEMENT FOR FEDERALLY**
23 **FUNDED RESEARCH.**

24 (a) IN GENERAL.—If any Federal agency or any non-
25 profit entity undertakes federally funded health care re-

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

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

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

21 (2) qualified bidders compete on the basis of
22 the least sales revenues before prices are adjusted in
23 accordance with a cost-based reasonable pricing for-
24 mula;

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

5 (4) qualified bidders compete on the basis of
6 the shortest period of exclusivity; or

7 (5) qualified bidders compete under other com-
8 petitive bidding systems.

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

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

18 **SEC. 7. GAO ONGOING STUDIES AND REPORTS ON PRO-**
19 **GRAM; MISCELLANEOUS REPORTS.**

20 (a) ONGOING STUDY.—The Comptroller General of
21 the United States shall conduct an ongoing study and
22 analysis of the prescription medicine benefit program
23 under part D of the medicare program under title XVIII
24 of the Social Security Act (as added by section 3 of this
25 Act), including an analysis of each of the following:

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

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

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

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

16 (5) Such other issues as the Comptroller Gen-
17 eral may consider.

18 (b) REPORTS.—The Comptroller General shall issue
19 such reports on the results of the ongoing study described
20 in subsection (a) as the Comptroller General shall deem
21 appropriate and shall notify Congress on a timely basis
22 of significant problems in the operation of the part D pre-
23 scription medicine program and the need for legislative ad-
24 justments and improvements.

25 (c) MISCELLANEOUS STUDIES AND REPORTS.—

1 (1) STUDY ON METHODS TO ENCOURAGE ADDI-
2 TIONAL RESEARCH ON BREAKTHROUGH PHARMA-
3 CEUTICALS.—

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

11 (B) REPORT.—Not later than January 1,
12 2003, the Secretary shall submit to Congress a
13 report on such study. The report shall include
14 recommended methods to encourage the phar-
15 maceutical industry to devote more resources to
16 research and development of new covered prod-
17 ucts than it devotes to overhead expenses.

18 (2) STUDY ON PHARMACEUTICAL SALES PRAC-
19 TICES AND IMPACT ON COSTS AND QUALITY OF
20 CARE.—

21 (A) IN GENERAL.—The Secretary of
22 Health and Human Services shall conduct a
23 study on the methods used by the pharma-
24 ceutical industry to advertise and sell to con-
25 sumers and educate and sell to providers.

1 (B) REPORT.—Not later than January 1,
2 2003, the Secretary shall submit to Congress a
3 report on such study. The report shall include
4 the estimated direct and indirect costs of the
5 sales methods used, the quality of the informa-
6 tion conveyed, and whether such sales efforts
7 leads (or could lead) to inappropriate pre-
8 scribing. Such report may include legislative
9 and regulatory recommendations to encourage
10 more appropriate education and prescribing
11 practices.

12 (3) STUDY ON COST OF PHARMACEUTICAL RE-
13 SEARCH.—

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

19 (B) REPORT.—Not later than January 1,
20 2003, the Secretary shall submit to Congress a
21 report on such study. The report shall include
22 a description of the full-range of taxpayer-as-
23 sisted programs impacting pharmaceutical re-
24 search, including tax, trade, government re-
25 search, and regulatory assistance. The report

1 may also include legislative and regulatory rec-
2 ommendations that are designed to ensure that
3 the taxpayer's investment in pharmaceutical re-
4 search results in the availability of pharma-
5 ceuticals at reasonable prices.

6 (4) REPORT ON PHARMACEUTICAL PRICES IN
7 MAJOR FOREIGN NATIONS.—Not later than January
8 1, 2003, the Secretary of Health and Human Serv-
9 ices shall submit to Congress a report on the retail
10 price of major pharmaceutical products in various
11 developed nations, compared to prices for the same
12 or similar products in the United States. The report
13 shall include a description of the principal reasons
14 for any price differences that may exist.

15 **SEC. 8. MEDIGAP TRANSITION PROVISIONS.**

16 (a) IN GENERAL.—Notwithstanding any other provi-
17 sion of law, no new medicare supplemental policy that pro-
18 vides coverage of expenses for prescription drugs may be
19 issued under section 1882 of the Social Security Act on
20 or after January 1, 2003, to an individual unless it re-
21 places a medicare supplemental policy that was issued to
22 that individual and that provided some coverage of ex-
23 penses for prescription drugs.

1 (b) ISSUANCE OF SUBSTITUTE POLICIES IF PRE-
2 SCRIPTON DRUG COVERAGE IS OBTAINED THROUGH
3 MEDICARE.—

4 (1) IN GENERAL.—The issuer of a medicare
5 supplemental policy—

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

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

19 (C) may not impose an exclusion of bene-
20 fits based on a preexisting condition under such
21 policy,

22 in the case of an individual described in paragraph
23 (2) who seeks to enroll under the policy not later
24 than 63 days after the date of the termination of en-
25 rollment described in such paragraph and who sub-

1 mits evidence of the date of termination or
2 disenrollment along with the application for such
3 medicare supplemental policy.

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

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

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

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

21 (4) DEFINITIONS.—For purposes of this sub-
22 section, the term “medicare supplemental policy”
23 has the meaning given such term in section 1882(g)
24 of the Social Security Act (42 U.S.C. 1395ss(g)).

○