

108TH CONGRESS
1ST SESSION

H. R. 1733

To amend XVIII and XIX of the Social Security Act to provide for a voluntary Medicare prescription medicine benefit, to provide greater access to affordable pharmaceuticals, to provide for substantial reductions in the cost of prescription drugs made available to Medicare beneficiaries, to amend the Internal Revenue Code of 1986 to disallow deductions for direct-to-consumer advertisement of prescription drugs, to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals and preserving access to safe affordable Canadian medicines, to amend the Federal Election Campaign Act of 1971 to prohibit campaign contributions by chief executive officers of pharmaceutical companies, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 10, 2003

Mr. CROWLEY (for himself, Mr. ALLEN, Ms. KAPTUR, Mr. KILDEE, Mr. SANDERS, Mr. MCNULTY, and Mr. FROST) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Veterans' Affairs, and House Administration, 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 XVIII and XIX of the Social Security Act to provide for a voluntary Medicare prescription medicine benefit, to provide greater access to affordable pharmaceuticals, to provide for substantial reductions in the cost of prescription drugs made available to Medicare beneficiaries, to amend the Internal Revenue Code of 1986 to disallow deductions for direct-to-consumer adver-

tisement of prescription drugs, to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals and preserving access to safe affordable Canadian medicines, to amend the Federal Election Campaign Act of 1971 to prohibit campaign contributions by chief executive officers of pharmaceutical companies, and for other purposes.

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 “Senior Bill of Rights Act of 2003”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings.
- Sec. 3. Purposes.

TITLE I—MEDICARE PRESCRIPTION MEDICINE BENEFIT

- Sec. 101. Voluntary medicare outpatient prescription medicine program.
- Sec. 102. Provision of medicare outpatient prescription medicine coverage under the Medicare+Choice program.
- Sec. 103. Medigap revisions.
- Sec. 104. Transitional assistance for low income beneficiaries.

TITLE II—REFORM IN PRESCRIPTION DRUG PRICES FOR SENIORS

Subtitle A—Prescription Drug Fairness for Seniors

- Sec. 201. Short title.
- Sec. 202. Findings and purposes.
- Sec. 203. Participating manufacturers.
- Sec. 204. Special provision with respect to hospice programs.
- Sec. 205. Administration.
- Sec. 206. Reports to Congress regarding effectiveness of act.
- Sec. 207. Definitions.
- Sec. 208. Effective date.

Subtitle B—Sense of Congress on cost disparity between identical prescription drugs sold in the United States, Canada, and Mexico

Sec. 211. Sense of Congress on cost disparity between identical prescription drugs sold in the United States, Canada, and Mexico.

TITLE III—DISALLOWANCE OF DEDUCTION FOR DIRECT-TO-CONSUMER ADVERTISEMENT OF PRESCRIPTION DRUGS.

Sec. 301 DISALLOWANCE OF DEDUCTION FOR DIRECT-TO-CONSUMER ADVERTISEMENT OF PRESCRIPTION DRUGS.

TITLE IV—GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS

Sec. 401. Short title.
 Sec. 402. Findings; purposes.
 Sec. 403. Accelerated generic drug competition.
 Sec. 404. Bioequivalence testing methods.
 Sec. 405. Citizen petitions.
 Sec. 406. Patent certification.
 Sec. 407. Patent information.
 Sec. 408. Report.

TITLE V—NONDISCRIMINATION AGAINST IMPORTS OF PRESCRIPTION DRUGS.

Sec. 501. Short title.
 Sec. 502. Findings.
 Sec. 503. Nondiscrimination against imports of prescription drugs.

TITLE VI—REQUIREMENT FOR WRITTEN STATEMENT OF TOTAL COST OF RESEARCH FOR APPROVAL OF NEW DRUGS

Sec. 601. Requirement for written statement of total cost of research for approval of new drugs.

TITLE VII—PROHIBITION ON CERTAIN CAMPAIGN CONTRIBUTIONS

Sec. 701. Prohibition on campaign contributions by chief executive officers of pharmaceutical companies.

TITLE VIII—ADDITIONAL PROVISIONS

Sec. 801. Repeal of February 2002 increase in copayments for medications furnished to veterans by the Department of Veterans Affairs.
 Sec. 802. Social security and medicare lock box.

1 **SEC. 2. FINDINGS.**

2 The Congress makes the following findings:

3 (1) Manufacturers of prescription drugs engage
 4 in price discrimination practices that compel many
 5 Americans to pay substantially more for prescription
 6 drugs than consumers in foreign nations.

1 (2) Individual Americans who buy their own
2 prescription drugs often pay twice as much for pre-
3 scription drugs as consumers in foreign nations and
4 the drug manufacturers' most favored U.S. cus-
5 tomers. In some cases, older Americans pay 10
6 times more for prescription drugs than such cus-
7 tomers.

8 (3) The discriminatory pricing by major drug
9 manufacturers sustains multi-billion profits but
10 causes financial hardship and impairs the health and
11 well-being of millions of older Americans.

12 (4) Foreign nations and U.S. federally funded
13 health care programs use purchasing power to ob-
14 tain prescription drugs at low prices. Medicare bene-
15 ficiaries are denied this benefit and cannot obtain
16 their prescription drugs at the lower prices available
17 to such nations and programs.

18 (5) Medicare beneficiaries have high out-of-
19 pocket drug costs. Medicare beneficiaries average
20 out-of-pocket drug costs was \$860 for 2002.

21 (6) NAFTA trade laws must be interpreted and
22 enforced to protect all NAFTA constituents from
23 price gouging, barriers to entry, and unfair hurdles
24 to goods.

1 **SEC. 3. PURPOSES.**

2 The purposes of this Act are as follows:

3 (1) To protect Americans from exceptionally
4 high drug costs.

5 (2) To make prescription drugs available to
6 Americans at substantially reduced prices.

7 (3) To facilitate pharmaceutical trade amongst
8 NAFTA countries.

9 **TITLE I—MEDICARE PRESCRIP-**
10 **TION MEDICINE BENEFIT**

11 **SEC. 101. VOLUNTARY MEDICARE OUTPATIENT PRESCRIP-**
12 **TION MEDICINE PROGRAM.**

13 (a) AMENDMENTS TO SOCIAL SECURITY ACT.—Ex-
14 cept as otherwise specifically provided, whenever in this
15 title an amendment is expressed in terms of an amend-
16 ment to or repeal of a section or other provision, the ref-
17 erence shall be considered to be made to that section or
18 other provision of the Social Security Act.

19 (b) VOLUNTARY PRESCRIPTION MEDICINE BENEFIT
20 FOR THE AGED AND DISABLED.—Title XVIII (42 U.S.C.
21 1395 et seq.) is amended—

22 (1) by redesignating section 1859 and part D
23 as section 1858 and part E, respectively; and

24 (2) by inserting after part C the following new
25 part:

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

3 “MEDICARE OUTPATIENT PRESCRIPTION MEDICINE
4 BENEFIT

5 “SEC. 1859. Subject to the succeeding provisions of
6 this part, the voluntary prescription medicine benefit pro-
7 gram under this part provides the following:

8 “(1) PREMIUM.—The monthly premium is \$25.

9 “(2) DEDUCTIBLE.—The annual deductible is
10 \$100.

11 “(3) COINSURANCE.—The coinsurance is 20
12 percent.

13 “(4) OUT-OF-POCKET LIMIT.—The annual limit
14 on out-of-pocket spending on covered medicines is
15 \$2,000.

16 “NEGOTIATING FAIR PRICES WITH PHARMACEUTICAL
17 MANUFACTURERS

18 “SEC. 1859A. (a) AUTHORITY TO NEGOTIATE
19 PRICES WITH MANUFACTURERS.—The Secretary shall,
20 consistent with the requirements of this part and the goals
21 of providing quality care and containing costs under this
22 part, negotiate contracts with manufacturers of covered
23 outpatient prescription medicines that provide for the
24 maximum prices that may be charged to individuals en-
25 rolled under this part by participating pharmacies for dis-
26 pensing such medicines to such individuals.

1 “(b) PROMOTION OF BREAKTHROUGH MEDICINES.—
2 In conducting negotiations with manufacturers under this
3 part, the Secretary shall take into account the goal of pro-
4 moting the development of breakthrough medicines (as de-
5 fined in section 1859H(b)).

6 “CONTRACT AUTHORITY

7 “SEC. 1859B. (a) CONTRACT AUTHORITY.—

8 “(1) IN GENERAL.—The Secretary is respon-
9 sible for the administration of this part and shall
10 enter into contracts with appropriate pharmacy con-
11 tractors on a national or regional basis to administer
12 the benefits under this part.

13 “(2) PROCEDURES.—The Secretary shall estab-
14 lish procedures under which the Secretary—

15 “(A) accepts bids submitted by entities to
16 serve as pharmacy contractors under this part
17 in a region or on a national basis;

18 “(B) awards contracts to such contractors
19 to administer benefits under this part to eligible
20 beneficiaries in the region or on a national
21 basis; and

22 “(C) provides for the termination (and
23 nonrenewal) of a contract in the case of a con-
24 tractor’s failure to meet the requirements of the
25 contract and this part.

1 “(3) COMPETITIVE PROCEDURES.—Competitive
2 procedures (as defined in section 4(5) of the Office
3 of Federal Procurement Policy Act (41 U.S.C.
4 403(5))) shall be used to enter into contracts under
5 this part.

6 “(4) TERMS AND CONDITIONS.—Such contracts
7 shall have such terms and conditions as the Sec-
8 retary shall specify and shall be for such terms (of
9 at least 2 years, but not to exceed 5 years) as the
10 Secretary shall specify consistent with this part.

11 “(5) USE OF PHARMACY CONTRACTORS IN
12 PRICE NEGOTIATIONS.—Such contracts shall require
13 the contractor involved to negotiate contracts with
14 manufacturers that provide for maximum prices for
15 covered outpatient prescription medicines that are
16 lower than the maximum prices negotiated under
17 section 1859A(a), if applicable. The price reductions
18 shall be passed on to eligible beneficiaries and the
19 Secretary shall hold the contractor accountable for
20 meeting performance requirements with respect to
21 price reductions and limiting price increases.

22 “(6) AREA FOR CONTRACTS.—

23 “(A) REGIONAL BASIS.—

24 “(i) IN GENERAL.—Except as pro-
25 vided in clause (ii) and subject to subpara-

1 graph (B), the contract entered into be-
2 tween the Secretary and a pharmacy con-
3 tractor shall require the contractor to ad-
4 minister the benefits under this part in a
5 region determined by the Secretary under
6 subparagraph (B) or on a national basis.

7 “(ii) PARTIAL REGIONAL BASIS.—

8 “(I) IN GENERAL.—If deter-
9 mined appropriate by the Secretary,
10 the Secretary may permit the benefits
11 to be administered in a partial region
12 determined appropriate by the Sec-
13 retary.

14 “(II) REQUIREMENTS.—If the
15 Secretary permits administration pur-
16 suant to subclause (I), the Secretary
17 shall ensure that the partial region in
18 which administration is effected is no
19 smaller than a State and is at least
20 the size of the commercial service area
21 of the contractor for that area.

22 “(B) DETERMINATION.—

23 “(i) IN GENERAL.—In determining re-
24 gions for contracts under this part, the
25 Secretary shall—

1 “(I) take into account the num-
2 ber of individuals enrolled under this
3 part in an area in order to encourage
4 participation by pharmacy contrac-
5 tors; and

6 “(II) ensure that there are at
7 least 10 different regions in the
8 United States.

9 “(ii) NO ADMINISTRATIVE OR JUDI-
10 CIAL REVIEW.—The determination of ad-
11 ministrative areas under this paragraph
12 shall not be subject to administrative or ju-
13 dicial review.

14 “(7) SUBMISSION OF BIDS.—

15 “(A) SUBMISSION.—

16 “(i) IN GENERAL.—Subject to sub-
17 paragraph (B), each entity desiring to
18 serve as a pharmacy contractor under this
19 part in an area shall submit a bid with re-
20 spect to such area to the Secretary at such
21 time, in such manner, and accompanied by
22 such information as the Secretary may rea-
23 sonably require.

24 “(ii) BID THAT COVERS MULTIPLE
25 AREAS.—The Secretary shall permit an en-

1 tity to submit a single bid for multiple
2 areas if the bid is applicable to all such
3 areas.

4 “(B) REQUIRED INFORMATION.—The bids
5 described in subparagraph (A) shall include—

6 “(i) a proposal for the estimated
7 prices of covered outpatient prescription
8 medicines and the projected annual in-
9 creases in such prices, including the addi-
10 tional reduction in price negotiated below
11 the Secretary’s maximum price and dif-
12 ferentials between preferred and nonpre-
13 ferred prices, if applicable;

14 “(ii) a statement regarding the
15 amount that the entity will charge the Sec-
16 retary for administering the benefits under
17 the contract;

18 “(iii) a statement regarding whether
19 the entity will reduce the applicable coin-
20 surance percentage pursuant to section
21 1859E(a)(1)(A)(ii) and if so, the amount
22 of such reduction and how such reduction
23 is tied to the performance requirements de-
24 scribed in subsection (c)(4)(A)(ii);

1 “(iv) a detailed description of the per-
2 formance requirements for which the ad-
3 ministrative fee of the entity will be subject
4 to risk pursuant to subsection (c)(4)(A)(ii);

5 “(v) a detailed description of access to
6 pharmacy services provided by the entity,
7 including information regarding whether
8 the pharmacy contractor will use a pre-
9 ferred pharmacy network, and, if so, how
10 the pharmacy contractor will ensure access
11 to pharmacies that choose to be outside of
12 that network, and whether there will be in-
13 creased cost-sharing for beneficiaries if
14 they obtain medicines at such pharmacies;

15 “(vi) a detailed description of the pro-
16 cedures and standards the entity will use
17 for—

18 “(I) selecting preferred prescrip-
19 tion medicines; and

20 “(II) determining when and how
21 often the list of preferred prescription
22 medicines should be modified;

23 “(vii) a detailed description of any
24 ownership or shared financial interests
25 with pharmaceutical manufacturers, phar-

1 macies, and other entities involved in the
2 administration or delivery of benefits under
3 this part as proposed in the bid;

4 “(viii) a detailed description of the en-
5 tity’s estimated marketing and advertising
6 expenditures related to enrolling and re-
7 taining eligible beneficiaries; and

8 “(ix) such other information that the
9 Secretary determines is necessary in order
10 to carry out this part, including informa-
11 tion relating to the bidding process under
12 this part.

13 The procedures under clause (vi) shall include
14 the use of a pharmaceutical and therapeutics
15 committee the members of which include prac-
16 ticing pharmacists.

17 “(8) AWARDING OF CONTRACTS.—

18 “(A) NUMBER OF CONTRACTS.—The Sec-
19 retary shall, consistent with the requirements of
20 this part and the goals of providing quality care
21 and of containing costs under this part, award
22 in a competitive manner at least 2 contracts to
23 administer benefits under this part in each area
24 specified under paragraph (6), unless only 1
25 pharmacy contractor submitting a bid meets the

1 minimum standards specified under this part
2 and by the Secretary.

3 “(B) DETERMINATION.—In determining
4 which of the pharmacy contractors that sub-
5 mitted bids that meet the minimum standards
6 specified under this part and by the Secretary
7 to award a contract, the Secretary shall con-
8 sider the comparative merits of each bid, as de-
9 termined on the basis of relevant factors, with
10 respect to—

11 “(i) how well the contractor meets
12 such minimum standards;

13 “(ii) the amount that the contractor
14 will charge the Secretary for administering
15 the benefits under the contract;

16 “(iii) the performance standards es-
17 tablished under subsection (c)(2) and per-
18 formance requirements for which the ad-
19 ministrative fee of the entity will be subject
20 to risk pursuant to subsection (c)(4)(A)(ii);

21 “(iv) the proposed negotiated prices of
22 covered outpatient medicines and annual
23 increases in such prices;

1 “(v) factors relating to benefits, qual-
2 ity and performance, beneficiary cost-shar-
3 ing, and consumer satisfaction;

4 “(vi) past performance and prior ex-
5 perience of the contractor in administering
6 a prescription medicine benefit program;

7 “(vii) effectiveness of the contractor
8 in containing costs through pricing incen-
9 tives and utilization management; and

10 “(viii) such other factors as the Sec-
11 retary deems necessary to evaluate the
12 merits of each bid.

13 “(C) EXCEPTION TO CONFLICT OF INTER-
14 EST RULES.—In awarding contracts with phar-
15 macy contractors under this part, the Secretary
16 may waive conflict of interest laws generally ap-
17 plicable to Federal acquisitions (subject to such
18 safeguards as the Secretary may find necessary
19 to impose) in circumstances where the Sec-
20 retary finds that such waiver—

21 “(i) is not inconsistent with the—

22 “(I) purposes of the programs
23 under this part; or

24 “(II) best interests of bene-
25 ficiaries enrolled under this part; and

1 “(ii) permits a sufficient level of com-
2 petition for such contracts, promotes effi-
3 ciency of benefits administration, or other-
4 wise serves the objectives of the program
5 under this part.

6 “(D) NO ADMINISTRATIVE OR JUDICIAL
7 REVIEW.—The determination of the Secretary
8 to award or not award a contract to a phar-
9 macy contractor under this part shall not be
10 subject to administrative or judicial review.

11 “(9) ACCESS TO BENEFITS IN CERTAIN
12 AREAS.—

13 “(A) AREAS NOT COVERED BY CON-
14 TRACTS.—The Secretary shall develop proce-
15 dures for the provision of covered outpatient
16 prescription medicines under this part to each
17 eligible beneficiary enrolled under this part that
18 resides in an area that is not covered by any
19 contract under this part.

20 “(B) BENEFICIARIES RESIDING IN DIF-
21 FERENT LOCATIONS.—The Secretary shall de-
22 velop procedures to ensure that each eligible
23 beneficiary enrolled under this part that resides
24 in different areas in a year is provided the ben-
25 efits under this part throughout the entire year.

1 “(b) QUALITY, FINANCIAL, AND OTHER STANDARDS
2 AND PROGRAMS.—In consultation with appropriate phar-
3 macy contractors, pharmacists, and health care profes-
4 sionals with expertise in prescribing, dispensing, and the
5 appropriate use of prescription medicines, the Secretary
6 shall establish standards and programs for the administra-
7 tion of this part to ensure appropriate prescribing, dis-
8 pensing, and utilization of outpatient medicines under this
9 part, to avoid adverse medicine reactions, and to contin-
10 ually reduce errors in the delivery of medically appropriate
11 covered benefits. The Secretary shall not award a contract
12 to a pharmacy contractor under this part unless the Sec-
13 retary finds that the contractor agrees to comply with
14 such standards and programs and other terms and condi-
15 tions as the Secretary shall specify. The standards and
16 programs under this subsection shall be applied to any ad-
17 ministrative agreements described in subsection (a) the
18 Secretary enters into. Such standards and programs shall
19 include the following:

20 “(1) ACCESS.—

21 “(A) IN GENERAL.—The pharmacy con-
22 tractor shall ensure that covered outpatient pre-
23 scription medicines are accessible and conven-
24 ient to eligible beneficiaries enrolled under this
25 part for whom benefits are administered by the

1 pharmacy contractor, including by offering the
2 services 24 hours a day and 7 days a week for
3 emergencies.

4 “(B) ON-LINE REVIEW.—The pharmacy
5 contractor shall provide for on-line prospective
6 review available 24 hours a day and 7 days a
7 week in order to evaluate each prescription for
8 medicine therapy problems due to duplication,
9 interaction, or incorrect dosage or duration of
10 therapy.

11 “(C) GUARANTEED ACCESS TO MEDICINES
12 IN RURAL AND HARD-TO-SERVE AREAS.—The
13 Secretary shall ensure that all beneficiaries
14 have guaranteed access to the full range of
15 pharmaceuticals under this part, and shall give
16 special attention to access, pharmacist coun-
17 seling, and delivery in rural and hard-to-serve
18 areas, including through the use of incentives
19 such as bonus payments to retail pharmacists
20 in rural areas and extra payments to the phar-
21 macy contractor for the cost of rapid delivery of
22 pharmaceuticals and any other actions nec-
23 essary.

24 “(D) PREFERRED PHARMACY NET-
25 WORKS.—

1 “(i) IN GENERAL.—If a pharmacy
2 contractor uses a preferred pharmacy net-
3 work to deliver benefits under this part,
4 such network shall meet minimum access
5 standards established by the Secretary.

6 “(ii) STANDARDS.—In establishing
7 standards under clause (i), the Secretary
8 shall take into account reasonable dis-
9 tances to pharmacy services in both urban
10 and rural areas.

11 “(E) ADHERENCE TO NEGOTIATED
12 PRICES.—The pharmacy contractor shall have
13 in place procedures to assure compliance of
14 pharmacies with the requirements of subsection
15 (d)(3)(C) (relating to adherence to negotiated
16 prices).

17 “(F) CONTINUITY OF CARE.—

18 “(i) IN GENERAL.—The pharmacy
19 contractor shall ensure that, in the case of
20 an eligible beneficiary who loses coverage
21 under this part with such entity under cir-
22 cumstances that would permit a special
23 election period (as established by the Sec-
24 retary under section 1859C(b)(3)), the
25 contractor will continue to provide cov-

1 erage under this part to such beneficiary
2 until the beneficiary enrolls and receives
3 such coverage with another pharmacy con-
4 tractor under this part or, if eligible, with
5 a Medicare+Choice organization.

6 “(ii) LIMITED PERIOD.—In no event
7 shall a pharmacy contractor be required to
8 provide the extended coverage required
9 under clause (i) beyond the date which is
10 30 days after the coverage with such con-
11 tractor would have terminated but for this
12 subparagraph.

13 “(2) ENROLLEE GUIDELINES.—The pharmacy
14 contractor shall, consistent with State law, apply
15 guidelines for counseling enrollees regarding—

16 “(A) the proper use of covered outpatient
17 prescription medicine; and

18 “(B) interactions and contra-indications.

19 “(3) EDUCATION.—The pharmacy contractor
20 shall apply methods to identify and educate pro-
21 viders, pharmacists, and enrollees regarding—

22 “(A) instances or patterns concerning the
23 unnecessary or inappropriate prescribing or dis-
24 pensing of covered outpatient prescription medi-
25 cines;

1 “(B) instances or patterns of substandard
2 care;

3 “(C) potential adverse reactions to covered
4 outpatient prescription medicines;

5 “(D) inappropriate use of antibiotics;

6 “(E) appropriate use of generic products;

7 and

8 “(F) the importance of using covered out-
9 patient prescription medicines in accordance
10 with the instruction of prescribing providers.

11 “(4) COORDINATION.—The pharmacy con-
12 tractor shall coordinate with State prescription med-
13 icine programs, other pharmacy contractors, phar-
14 macies, and other relevant entities as necessary to
15 ensure appropriate coordination of benefits with re-
16 spect to enrolled individuals when such individual is
17 traveling outside the home service area, and under
18 such other circumstances as the Secretary may
19 specify.

20 “(5) COST DATA.—

21 “(A) The pharmacy contractor shall make
22 data on prescription medicine negotiated prices
23 (including data on discounts) available to the
24 Secretary.

1 “(B) The Secretary shall require, either di-
2 rectly or through a pharmacy contractor, that
3 participating pharmacists, physicians, and man-
4 ufacturers—

5 “(i) maintain their prescription medi-
6 cine cost data (including data on dis-
7 counts) in a form and manner specified by
8 the Secretary;

9 “(ii) make such prescription medicine
10 cost data available for review and audit by
11 the Secretary; and

12 “(iii) certify that the prescription
13 medicine cost data are current, accurate,
14 and complete, and reflect all discounts ob-
15 tained by the pharmacist or physician in
16 the purchasing of covered outpatient pre-
17 scription medicines.

18 Discounts referred to in subparagraphs (A) and (B)
19 shall include all volume discounts, manufacturer re-
20 bates, prompt payment discounts, free goods, in-kind
21 services, or any other thing of financial value pro-
22 vided explicitly or implicitly in exchange for the pur-
23 chase of a covered outpatient prescription medicine.

1 “(6) REPORTING.—The pharmacy contractor
2 shall provide the Secretary with periodic reports
3 on—

4 “(A) the contractor’s costs of admin-
5 istering this part;

6 “(B) utilization of benefits under this part;

7 “(C) marketing and advertising expendi-
8 tures related to enrolling and retaining individ-
9 uals under this part; and

10 “(D) grievances and appeals.

11 “(7) RECORDS AND AUDITS.—The pharmacy
12 contractor shall maintain adequate records related to
13 the administration of benefits under this part and
14 afford the Secretary access to such records for au-
15 diting purposes.

16 “(8) APPROVAL OF MARKETING MATERIAL AND
17 APPLICATION FORMS.—The pharmacy contractor
18 shall comply with requirements of section 1851(h)
19 (relating to marketing material and application
20 forms) with respect to this part in the same manner
21 as such requirements apply under part C, except
22 that the provisions of paragraph (4)(A) of such sec-
23 tion shall not apply with respect to discounts or re-
24 bates provided in accordance with this part.

1 “(c) INCENTIVES FOR COST AND UTILIZATION MAN-
2 AGEMENT AND QUALITY IMPROVEMENT.—

3 “(1) IN GENERAL.—The Secretary shall include
4 in a contract awarded under subsection (b) with a
5 pharmacy contractor such incentives for cost and
6 utilization management and quality improvement as
7 the Secretary may deem appropriate. The contract
8 may provide financial or other incentives to encour-
9 age greater savings to the program under this part.

10 “(2) PERFORMANCE STANDARDS.—The Sec-
11 retary shall provide for performance standards
12 (which may include monetary bonuses if the stand-
13 ards are met and penalties if the standards are not
14 met), including standards relating to the time taken
15 to answer member and pharmacy inquiries (written
16 or by telephone), the accuracy of responses, claims
17 processing accuracy, online system availability, ap-
18 peal procedure turnaround time, system availability,
19 the accuracy and timeliness of reports, and level of
20 beneficiary satisfaction.

21 “(3) OTHER INCENTIVES.—Such incentives
22 under this subsection may also include—

23 “(A) financial incentives under which sav-
24 ings derived from the substitution of generic
25 and other preferred multi-source medicines in

1 lieu of nongeneric and nonpreferred medicines
2 are made available to pharmacy contractors,
3 pharmacies, beneficiaries, and the Federal
4 Medicare Prescription Medicine Trust Fund;
5 and

6 “(B) any other incentive that the Secretary
7 deems appropriate and likely to be effective in
8 managing costs or utilization or improving qual-
9 ity that does not reduce the access of bene-
10 ficiaries to medically necessary covered out-
11 patient medicines.

12 “(4) REQUIREMENTS FOR PROCEDURES.—

13 “(A) IN GENERAL.—The Secretary shall
14 establish procedures for making payments to
15 each pharmacy contractor with a contract under
16 this part for the administration of the benefits
17 under this part. The procedures shall provide
18 for the following:

19 “(i) ADMINISTRATIVE PAYMENT.—
20 Payment of administrative fees for such
21 administration.

22 “(ii) RISK REQUIREMENT.—An ad-
23 justment of a percentage (determined
24 under subparagraph (B)) of the adminis-
25 trative fee payments made to a pharmacy

1 contractor to ensure that the contractor, in
2 administering the benefits under this part,
3 pursues performance requirements estab-
4 lished by the Secretary, including the fol-
5 lowing:

6 “(I) QUALITY SERVICE.—The
7 contractor provides eligible bene-
8 ficiaries for whom it administers bene-
9 fits with quality services, as measured
10 by such factors as sustained pharmacy
11 network access, timeliness and accu-
12 racy of service delivery in claims proc-
13 essing and card production, pharmacy
14 and member service support access,
15 and timely action with regard to ap-
16 peals and current beneficiary service
17 surveys.

18 “(II) QUALITY CLINICAL CARE.—
19 The contractor provides such bene-
20 ficiaries with quality clinical care, as
21 measured by such factors as providing
22 notification to such beneficiaries and
23 to providers in order to prevent ad-
24 verse drug reactions and reduce medi-
25 cation errors and specific clinical sug-

1 gestions to improve health and patient
2 and prescriber education as appro-
3 priate.

4 “(III) CONTROL OF MEDICARE
5 COSTS.—The contractor contains costs
6 under this part to the Federal Medi-
7 care Prescription Medicine Trust
8 Fund and enrollees, as measured by
9 generic substitution rates, price dis-
10 counts, and other factors determined
11 appropriate by the Secretary that do
12 not reduce the access of beneficiaries
13 to medically necessary covered out-
14 patient prescription medicines.

15 “(B) PERCENTAGE OF PAYMENT TIED TO
16 RISK.—

17 “(i) IN GENERAL.—Subject to clause
18 (ii), the Secretary shall determine the per-
19 centage of the administrative payments to
20 a pharmacy contractor that will be tied to
21 the performance requirements described in
22 subparagraph (A)(ii).

23 “(ii) LIMITATION ON RISK TO ENSURE
24 PROGRAM STABILITY.—In order to provide
25 for program stability, the Secretary may

1 not establish a percentage to be adjusted
2 under this paragraph at a level that jeop-
3 ardizes the ability of a pharmacy con-
4 tractor to administer the benefits under
5 this part or administer such benefits in a
6 quality manner.

7 “(C) RISK ADJUSTMENT OF PAYMENTS
8 BASED ON ENROLLEES IN PLAN.—To the extent
9 that a pharmacy contractor is at risk under this
10 paragraph, the procedures established under
11 this paragraph may include a methodology for
12 risk adjusting the payments made to such con-
13 tractor based on the differences in actuarial
14 risk of different enrollees being served if the
15 Secretary determines such adjustments to be
16 necessary and appropriate.

17 “(d) AUTHORITY RELATING TO PHARMACY PARTICI-
18 PATION.—

19 “(1) IN GENERAL.—Subject to the succeeding
20 provisions of this subsection, a pharmacy contractor
21 may establish consistent with this part conditions for
22 the participation of pharmacies, including conditions
23 relating to quality (including reduction of medical
24 errors) and technology.

1 “(2) AGREEMENTS WITH PHARMACIES.—Each
2 pharmacy contractor shall enter into a participation
3 agreement with any pharmacy that meets the re-
4 quirements of this subsection and section 1859E to
5 furnish covered outpatient prescription medicines to
6 individuals enrolled under this part.

7 “(3) TERMS OF AGREEMENT.—An agreement
8 under this subsection shall include the following
9 terms and conditions:

10 “(A) APPLICABLE REQUIREMENTS.—The
11 pharmacy shall meet (and throughout the con-
12 tract period continue to meet) all applicable
13 Federal requirements and State and local li-
14 censing requirements.

15 “(B) ACCESS AND QUALITY STANDARDS.—
16 The pharmacy shall comply with such standards
17 as the Secretary (and such a pharmacy con-
18 tractor) shall establish concerning the quality
19 of, and enrolled individuals’ access to, phar-
20 macy services under this part. Such standards
21 shall require the pharmacy—

22 “(i) not to refuse to dispense covered
23 outpatient prescription medicines to any
24 individual enrolled under this part;

1 “(ii) to keep patient records (includ-
2 ing records on expenses) for all covered
3 outpatient prescription medicines dispensed
4 to such enrolled individuals;

5 “(iii) to submit information (in a
6 manner specified by the Secretary to be
7 necessary to administer this part) on all
8 purchases of such medicines dispensed to
9 such enrolled individuals; and

10 “(iv) to comply with periodic audits to
11 assure compliance with the requirements of
12 this part and the accuracy of information
13 submitted.

14 “(C) ADHERENCE TO NEGOTIATED
15 PRICES.—(i) The total charge for each medicine
16 dispensed by the pharmacy to an enrolled indi-
17 vidual under this part, without regard to wheth-
18 er the individual is financially responsible for
19 any or all of such charge, shall not exceed the
20 price negotiated under section 1859A(a) or, if
21 lower, negotiated under subsection (a)(5) (or, if
22 less, the retail price for the medicine involved)
23 with respect to such medicine plus a reasonable
24 dispensing fee determined contractually with
25 the pharmacy contractor.

1 “(ii) The pharmacy does not charge (or
2 collect from) an enrolled individual an amount
3 that exceeds the individual’s obligation (as de-
4 termined in accordance with the provisions of
5 this part) of the applicable price described in
6 clause (i).

7 “(D) ADDITIONAL REQUIREMENTS.—The
8 pharmacy shall meet such additional contract
9 requirements as the applicable pharmacy con-
10 tractor specifies under this section.

11 “(4) APPLICABILITY OF FRAUD AND ABUSE
12 PROVISIONS.—The provisions of section 1128
13 through 1128C (relating to fraud and abuse) apply
14 to pharmacies participating in the program under
15 this part.

16 “ELIGIBILITY; VOLUNTARY ENROLLMENT; COVERAGE

17 “SEC. 1859C. (a) ELIGIBILITY.—Each individual
18 who is entitled to hospital insurance benefits under part
19 A or is eligible to be enrolled in the medical insurance pro-
20 gram under part B is eligible to enroll in accordance with
21 this section for outpatient prescription medicine benefits
22 under this part.

23 “(b) VOLUNTARY ENROLLMENT.—

24 “(1) IN GENERAL.—An individual may enroll
25 under this part only in such manner and form as
26 may be prescribed by regulations, and only during

1 an enrollment period prescribed in or under this sub-
2 section.

3 “(2) INITIAL ENROLLMENT PERIOD.—

4 “(A) INDIVIDUALS CURRENTLY COV-
5 ERED.—In the case of an individual who satis-
6 fies subsection (a) as of November 1, 2005, the
7 initial general enrollment period shall begin on
8 August 1, 2005, and shall end on March 1,
9 2006.

10 “(B) INDIVIDUAL COVERED IN FUTURE.—

11 In the case of an individual who first satisfies
12 subsection (a) on or after November 1, 2005,
13 the individual’s initial enrollment period shall
14 begin on the first day of the third month before
15 the month in which such individual first satis-
16 fies such paragraph and shall end seven months
17 later. The Secretary shall apply rules similar to
18 the rule described in the second sentence of sec-
19 tion 1837(d).

20 “(3) SPECIAL ENROLLMENT PERIODS (WITHOUT
21 PREMIUM PENALTY).—

22 “(A) EMPLOYER COVERAGE AT TIME OF
23 INITIAL GENERAL ENROLLMENT PERIOD.—In
24 the case of an individual who—

1 “(i) at the time the individual first
2 satisfies subsection (a) is enrolled in a
3 group health plan (including continuation
4 coverage) that provides outpatient pre-
5 scription medicine coverage by reason of
6 the individual’s (or the individual’s
7 spouse’s) current (or, in the case of con-
8 tinuation coverage, former) employment
9 status, and

10 “(ii) has elected not to enroll (or to be
11 deemed enrolled) under this subsection
12 during the individual’s initial enrollment
13 period,

14 there shall be a special enrollment period of 6
15 months beginning with the first month that in-
16 cludes the date of the individual’s (or individ-
17 ual’s spouse’s) retirement from or termination
18 of current employment status with the employer
19 that sponsors the plan, or, in the case of con-
20 tinuation coverage, that includes the date of
21 termination of such coverage, or that includes
22 the date the plan substantially terminates out-
23 patient prescription medicine coverage.

1 “(B) DROPPING OF RETIREE PRESCRIP-
2 TION MEDICINE COVERAGE.—In the case of an
3 individual who—

4 “(i) at the time the individual first
5 satisfies subsection (a) is enrolled in a
6 group health plan that provides outpatient
7 prescription medicine coverage other than
8 by reason of the individual’s (or the indi-
9 vidual’s spouse’s) current employment; and

10 “(ii) has elected not to enroll (or to be
11 deemed enrolled) under this subsection
12 during the individual’s initial enrollment
13 period,

14 there shall be a special enrollment period of 6
15 months beginning with the first month that in-
16 cludes the date that the plan substantially ter-
17 minates outpatient prescription medicine cov-
18 erage and ending 6 months later.

19 “(C) LOSS OF MEDICARE+CHOICE PRE-
20 SCRIPTION MEDICINE COVERAGE.—In the case
21 of an individual who is enrolled under part C in
22 a Medicare+Choice plan that provides prescrip-
23 tion medicine benefits, if such enrollment is ter-
24 minated because of the termination or reduction
25 in service area of the plan, there shall be a spe-

1 cial enrollment period of 6 months beginning
2 with the first month that includes the date that
3 such plan is terminated or such reduction oc-
4 curs and ending 6 months later.

5 “(D) LOSS OF MEDICAID PRESCRIPTION
6 MEDICINE COVERAGE.—In the case of an indi-
7 vidual who—

8 “(i) satisfies subsection (a);

9 “(ii) loses eligibility for benefits (that
10 include benefits for prescription medicine)
11 under a State plan after having been en-
12 rolled (or determined to be eligible) for
13 such benefits under such plan; and

14 “(iii) is not otherwise enrolled under
15 this subsection at the time of such loss of
16 eligibility,

17 there shall be a special enrollment period speci-
18 fied by the Secretary of not less than 6 months
19 beginning with the first month that includes the
20 date that the individual loses such eligibility.

21 “(4) LATE ENROLLMENT WITH PREMIUM PEN-
22 ALTY.—The Secretary shall permit an individual
23 who satisfies subsection (a) to enroll other than dur-
24 ing the initial enrollment period under paragraph (2)
25 or a special enrollment period under paragraph (3).

1 But, in the case of such an enrollment, the amount
2 of the monthly premium of the individual is subject
3 to an increase under section 1859C(e)(1).

4 “(5) INFORMATION.—

5 “(A) IN GENERAL.—The Secretary shall
6 broadly distribute information to individuals
7 who satisfy subsection (a) on the benefits pro-
8 vided under this part. The Secretary shall peri-
9 odically make available information on the cost
10 differentials to enrollees for the use of generic
11 medicines and other medicines.

12 “(B) TOLL-FREE HOTLINE.—The Sec-
13 retary shall maintain a toll-free telephone hot-
14 line (which may be a hotline already used by
15 the Secretary under this title) for purposes of
16 providing assistance to beneficiaries in the pro-
17 gram under this part, including responding to
18 questions concerning coverage, enrollment, ben-
19 efits, grievances and appeals procedures, and
20 other aspects of such program.

21 “(6) ENROLLEE DEFINED.—For purposes of
22 this part, the term ‘enrollee’ means an individual en-
23 rolled for benefits under this part.

24 “(c) COVERAGE PERIOD.—

1 “(1) IN GENERAL.—The period during which
2 an individual is entitled to benefits under this part
3 (in this subsection referred to as the individual’s
4 ‘coverage period’) shall begin on such a date as the
5 Secretary shall establish consistent with the type of
6 coverage rules described in subsections (a) and (e)
7 of section 1838, except that in no case shall a cov-
8 erage period begin before January 1, 2006. No pay-
9 ments may be made under this part with respect to
10 the expenses of an individual unless such expenses
11 were incurred by such individual during a period
12 which, with respect to the individual, is a coverage
13 period.

14 “(2) TERMINATION.—The Secretary shall pro-
15 vide for the application of provisions under this sub-
16 section similar to the provisions in section 1838(b).

17 “(d) PROVISION OF BENEFITS TO
18 MEDICARE+CHOICE ENROLLEES.—In the case of an indi-
19 vidual who is enrolled under this part and is enrolled in
20 a Medicare+Choice plan under part C, the individual shall
21 be provided the benefits under this part through such plan
22 and not through payment under this part.

23 “(e) LATE ENROLLMENT PENALTIES; PAYMENT OF
24 PREMIUMS.—

25 “(1) LATE ENROLLMENT PENALTY.—

1 “(A) IN GENERAL.—In the case of a late
2 enrollment described in subsection (b)(4), sub-
3 ject to the succeeding provisions of this para-
4 graph, the Secretary shall establish procedures
5 for increasing the amount of the monthly pre-
6 mium under this part applicable to such en-
7 rollee by an amount that the Secretary deter-
8 mines is actuarially sound for each such period.

9 “(B) PERIODS TAKEN INTO ACCOUNT.—
10 For purposes of calculating any 12-month pe-
11 riod under subparagraph (A), there shall be
12 taken into account months of lapsed coverage in
13 a manner comparable to that applicable under
14 the second sentence of section 1839(b).

15 “(C) PERIODS NOT TAKEN INTO AC-
16 COUNT.—

17 “(i) IN GENERAL.—For purposes of
18 calculating any 12-month period under
19 subparagraph (A), subject to clause (ii),
20 there shall not be taken into account
21 months for which the enrollee can dem-
22 onstrate that the enrollee was covered
23 under a group health plan that provides
24 coverage of the cost of prescription medi-
25 cines whose actuarial value (as defined by

1 the Secretary) to the enrollee equals or ex-
2 ceeds the actuarial value of the benefits
3 provided to an individual enrolled in the
4 outpatient prescription medicine benefit
5 program under this part.

6 “(ii) APPLICATION.—This subpara-
7 graph shall only apply with respect to a
8 coverage period the enrollment for which
9 occurs before the end of the 60-day period
10 that begins on the first day of the month
11 which includes the date on which the plan
12 terminates or reduces its service area (in a
13 manner that results in termination of en-
14 rollment), ceases to provide, or reduces the
15 value of the prescription medicine coverage
16 under such plan to below the value of the
17 coverage provided under the program
18 under this part.

19 “(2) INCORPORATION OF PREMIUM PAYMENT
20 AND GOVERNMENT CONTRIBUTIONS PROVISIONS.—

21 The provisions of sections 1840 and 1844(a)(1) shall
22 apply to enrollees under this part in the same man-
23 ner as they apply to individuals 65 years of age or
24 older enrolled under part B. For purposes of this
25 subsection, any reference in a section referred to in

1 a previous subsection to the Federal Supplementary
2 Medical Insurance Trust Fund is deemed a reference
3 to the Federal Medicare Prescription Medicine Trust
4 Fund.

5 “(f) ELECTION OF PHARMACY CONTRACTOR TO AD-
6 MINISTER BENEFITS.—The Secretary shall establish a
7 process whereby each individual enrolled under this part
8 and residing in a region may elect the pharmacy con-
9 tractor that will administer the benefits under this part
10 with respect to the individual. Such process shall permit
11 the individual to make an initial election and to change
12 such an election on at least an annual basis and under
13 such other circumstances as the Secretary shall specify.

14 “PROVISION OF, AND ENTITLEMENT TO, BENEFITS

15 “SEC. 1859D. (a) BENEFITS.—Subject to the suc-
16 ceeding provisions of this section, the benefits provided to
17 an enrollee by the program under this part shall consist
18 of the following:

19 “(1) COVERED OUTPATIENT PRESCRIPTION
20 MEDICINE BENEFITS.—Entitlement to have payment
21 made on the individual’s behalf for covered out-
22 patient prescription medicines.

23 “(2) LIMITATION ON COST-SHARING FOR PART
24 B OUTPATIENT PRESCRIPTION MEDICINES.—

25 “(A) IN GENERAL.—Once an enrollee has
26 incurred aggregate countable cost-sharing (as

1 defined in subparagraph (B)) equal to the stop-
2 loss limit specified in subsection (c)(4) for ex-
3 penses in a year, entitlement to the elimination
4 of cost-sharing otherwise applicable under part
5 B for additional expenses incurred in the year
6 for outpatient prescription medicines or
7 biologicals for which payment is made under
8 part B.

9 “(B) COUNTABLE COST-SHARING DE-
10 FINED.—For purposes of this part, the term
11 ‘countable cost-sharing’ means—

12 “(i) out-of-pocket expenses for out-
13 patient prescription medicines with respect
14 to which benefits are payable under part
15 B, and

16 “(ii) cost-sharing under subsections
17 (c)(3)(B) and (c)(3)(C)(i).

18 “(b) COVERED OUTPATIENT PRESCRIPTION MEDI-
19 CINE DEFINED.—

20 “(1) IN GENERAL.—Except as provided in para-
21 graph (2), for purposes of this part the term ‘cov-
22 ered outpatient prescription medicine’ means any of
23 the following products:

24 “(A) A medicine which may be dispensed
25 only upon prescription, and—

1 “(i) which is approved for safety and
2 effectiveness as a prescription medicine
3 under section 505 of the Federal Food,
4 Drug, and Cosmetic Act;

5 “(ii)(I) which was commercially used
6 or sold in the United States before the
7 date of enactment of the Drug Amend-
8 ments of 1962 or which is identical, simi-
9 lar, or related (within the meaning of sec-
10 tion 310.6(b)(1) of title 21 of the Code of
11 Federal Regulations) to such a medicine,
12 and (II) which has not been the subject of
13 a final determination by the Secretary that
14 it is a ‘new drug’ (within the meaning of
15 section 201(p) of the Federal Food, Drug,
16 and Cosmetic Act) or an action brought by
17 the Secretary under section 301, 302(a),
18 or 304(a) of such Act to enforce section
19 502(f) or 505(a) of such Act; or

20 “(iii)(I) which is described in section
21 107(e)(3) of the Drug Amendments of
22 1962 and for which the Secretary has de-
23 termined there is a compelling justification
24 for its medical need, or is identical, simi-
25 lar, or related (within the meaning of sec-

1 tion 310.6(b)(1) of title 21 of the Code of
2 Federal Regulations) to such a medicine,
3 and (II) for which the Secretary has not
4 issued a notice of an opportunity for a
5 hearing under section 505(e) of the Fed-
6 eral Food, Drug, and Cosmetic Act on a
7 proposed order of the Secretary to with-
8 draw approval of an application for such
9 medicine under such section because the
10 Secretary has determined that the medi-
11 cine is less than effective for all conditions
12 of use prescribed, recommended, or sug-
13 gested in its labeling.

14 “(B) A biological product which—

15 “(i) may only be dispensed upon pre-
16 scription;

17 “(ii) is licensed under section 351 of
18 the Public Health Service Act; and

19 “(iii) is produced at an establishment
20 licensed under such section to produce
21 such product.

22 “(C) Insulin approved under appropriate
23 Federal law, and needles, syringes, and dispos-
24 able pumps for the administration of such insu-
25 lin.

1 “(D) A prescribed medicine or biological
2 product that would meet the requirements of
3 subparagraph (A) or (B) but that is available
4 over-the-counter in addition to being available
5 upon prescription, but only if the particular
6 dosage form or strength prescribed and re-
7 quired for the individual is not available over-
8 the-counter.

9 “(E) Smoking cessation agents (as speci-
10 fied by the Secretary).

11 “(2) EXCLUSION.—The term ‘covered out-
12 patient prescription medicine’ does not include—

13 “(A) medicines or classes of medicines, or
14 their medical uses, which may be excluded from
15 coverage or otherwise restricted under section
16 1927(d)(2), other than subparagraph (E) there-
17 of (relating to smoking cessation agents), as the
18 Secretary may specify and does not include
19 such other medicines, classes, and uses as the
20 Secretary may specify consistent with the goals
21 of providing quality care and containing costs
22 under this part;

23 “(B) except as provided in paragraphs
24 (1)(D) and (1)(E), any product which may be

1 distributed to individuals without a prescrip-
2 tion;

3 “(C) any product when furnished as part
4 of, or as incident to, a diagnostic service or any
5 other item or service for which payment may be
6 made under this title; or

7 “(D) any product that is covered under
8 part B of this title.

9 “(c) PAYMENT OF BENEFITS.—

10 “(1) COVERED OUTPATIENT PRESCRIPTION
11 MEDICINES.—There shall be paid from the Federal
12 Medicare Prescription Medicine Trust Fund, in the
13 case of each enrollee who incurs expenses for medi-
14 cines with respect to which benefits are payable
15 under this part under subsection (a)(1), amounts
16 equal to the sum of—

17 “(A) the price for which the medicine is
18 made available under this part (consistent with
19 sections 1859A and 1859B), reduced by any
20 applicable cost-sharing under paragraphs (2)
21 and (3); and

22 “(B) a reasonable dispensing fee.

23 The price under subparagraph (A) shall in no case
24 exceed the retail price for the medicine involved.

1 “(2) DEDUCTIBLE.—The amount of payment
2 under paragraph (1) for expenses incurred in a year,
3 beginning with 2006, shall be reduced by an annual
4 deductible equal to the amount specified in section
5 1859(2) (subject to adjustment under paragraph
6 (8)). Only expenses for countable cost-sharing (as
7 defined in subsection (a)(2)(B)) shall be taken into
8 account in applying this paragraph.

9 “(3) COINSURANCE.—

10 “(A) IN GENERAL.—The amount of pay-
11 ment under paragraph (1) for expenses in-
12 curred in a year shall be further reduced (sub-
13 ject to the stop-loss limit under paragraph (4))
14 by coinsurance as provided under this para-
15 graph.

16 “(B) PREFERRED MEDICINES.—The coin-
17 surance under this paragraph in the case of a
18 preferred medicine (including a medicine treat-
19 ed as a preferred medicine under paragraph
20 (5)), is equal to 20 percent of the price applica-
21 ble under paragraph (1)(A) (or such lower per-
22 centage as may be provided for under section
23 1859E(a)(1)(A)(ii)). In this part, the term ‘pre-
24 ferred medicine’ means, with respect to medi-
25 cines classified within a therapeutic class, those

1 medicines which have been designated as a pre-
2 ferred medicine by the Secretary or the phar-
3 macy contractor involved with respect to that
4 class and (in the case of a nongeneric medicine)
5 with respect to which a contract has been nego-
6 tiated under this part.

7 “(C) NONPREFERRED MEDICINES.—The
8 coinsurance under this paragraph in the case of
9 a nonpreferred medicine that is not treated as
10 a preferred medicine under paragraph (5) is
11 equal to the sum of—

12 “(i) 20 percent of the price for lowest
13 price preferred medicine that is within the
14 same therapeutic class; and

15 “(ii) the amount by which—

16 “(I) the price at which the non-
17 preferred medicine is made available
18 to the enrollee; exceeds

19 “(II) the price of such lowest
20 price preferred medicine.

21 “(4) NO COINSURANCE ONCE OUT-OF-POCKET
22 EXPENDITURES EQUAL STOP-LOSS LIMIT.—Once an
23 enrollee has incurred aggregate countable cost-shar-
24 ing under paragraph (3) (including cost-sharing
25 under part B attributable to outpatient prescription

1 drugs or biologicals) equal to the amount specified
2 in section 1859(4) (subject to adjustment under
3 paragraph (8)) for expenses in a year—

4 “(A) there shall be no coinsurance under
5 paragraph (3) for additional expenses incurred
6 in the year involved; and

7 “(B) there shall be no coinsurance under
8 part B for additional expenses incurred in the
9 year involved for outpatient prescription drugs
10 and biologicals.

11 “(5) APPEALS RIGHTS RELATING TO COVERAGE
12 OF NONPREFERRED MEDICINES.—

13 “(A) PROCEDURES REGARDING THE DE-
14 TERMINATION OF MEDICINES THAT ARE MEDI-
15 CALLY NECESSARY.—Each pharmacy contractor
16 shall have in place procedures on a case-by-case
17 basis to treat a nonpreferred medicine as a pre-
18 ferred medicine under this part if the preferred
19 medicine is determined to be not as effective for
20 the enrollee or to have significant adverse effect
21 on the enrollee. Such procedures shall require
22 that such determinations are based on profes-
23 sional medical judgment, the medical condition
24 of the enrollee, and other medical evidence.

1 “(B) PROCEDURES REGARDING DENIALS
2 OF CARE.—Such contractor shall have in place
3 procedures to ensure—

4 “(i) a timely internal review for reso-
5 lution of denials of coverage (in whole or
6 in part and including those regarding the
7 coverage of nonpreferred medicines) in ac-
8 cordance with the medical exigencies of the
9 case and a timely resolution of complaints,
10 by enrollees in the plan, or by providers,
11 pharmacists, and other individuals acting
12 on behalf of each such enrollee (with the
13 enrollee’s consent) in accordance with re-
14 quirements (as established by the Sec-
15 retary) that are comparable to such re-
16 quirements for Medicare+Choice organiza-
17 tions under part C;

18 “(ii) that the entity complies in a
19 timely manner with requirements estab-
20 lished by the Secretary that (I) provide for
21 an external review by an independent enti-
22 ty selected by the Secretary of denials of
23 coverage described in clause (i) not re-
24 solved in the favor of the beneficiary (or
25 other complainant) under the process de-

1 scribed in such clause and (II) are com-
2 parable to the external review requirements
3 established for Medicare+Choice organiza-
4 tions under part C; and

5 “(iii) that enrollees are provided with
6 information regarding the appeals proce-
7 dures under this part at the time of enroll-
8 ment with a pharmacy contractor under
9 this part and upon request thereafter.

10 “(6) TRANSFER OF FUNDS TO COVER COSTS OF
11 PART B PRESCRIPTION MEDICINE CATASTROPHIC
12 BENEFIT.—With respect to benefits described in
13 subsection (a)(2), there shall transferred from the
14 Federal Medicare Prescription Medicine Trust Fund
15 to the Federal Supplementary Medical Insurance
16 Trust Fund amounts equivalent to the elimination of
17 cost-sharing described in such subsection.

18 “(7) PERMITTING APPLICATION UNDER PART B
19 OF NEGOTIATED PRICES.—For purposes of making
20 payment under part B for medicines that would be
21 covered outpatient prescription medicines but for the
22 exclusion under subparagraph (B) or (C) of sub-
23 section (b)(2), the Secretary may elect to apply the
24 payment basis used for payment of covered out-
25 patient prescription medicines under this part in-

1 stead of the payment basis otherwise used under
2 such part, if it results in a lower cost to the pro-
3 gram.

4 “(8) INFLATION ADJUSTMENT.—

5 “(A) IN GENERAL.—With respect to ex-
6 penses incurred in a year after 2006—

7 “(i) the deductible under paragraph
8 (2) is equal to the deductible determined
9 under such paragraph (or this subpara-
10 graph) for the previous year increased by
11 the percentage increase in per capita pro-
12 gram expenditures (as estimated in ad-
13 vance for the year involved under subpara-
14 graph (B)); and

15 “(ii) the stop-loss limit under para-
16 graph (3) is equal to the stop-loss limit de-
17 termined under such paragraph (or this
18 subparagraph) for the previous year in-
19 creased by such percentage increase.

20 The Secretary shall adjust such percentage in-
21 crease in subsequent years to take into account
22 misestimations made of the per capita program
23 expenditures under clauses (i) and (ii) in pre-
24 vious years. Any increase under this subpara-

1 graph that is not a multiple of \$10 shall be
2 rounded to the nearest multiple of \$10.

3 “(B) ESTIMATION OF INCREASE IN PER
4 CAPITA PROGRAM EXPENDITURES.—The Sec-
5 retary shall before the beginning of each year
6 (beginning with 2007) estimate the percentage
7 increase in average per capita aggregate ex-
8 penditures from the Federal Medicare Prescrip-
9 tion Medicine Trust Fund for the year involved
10 compared to the previous year.

11 “(C) RECONCILIATION.—The Secretary
12 shall also compute (beginning with 2008) the
13 actual percentage increase in such aggregate
14 expenditures in order to provide for reconcili-
15 ation of deductibles, stop-loss limits, and pre-
16 miums under the second sentence of subpara-
17 graph (A) and under section 1859D(d)(2).

18 “(d) AMOUNT OF PREMIUMS.—

19 “(1) MONTHLY PREMIUM RATE IN 2006.—The
20 monthly premium rate in 2006 for prescription med-
21 icine benefits under this part is the amount specified
22 in section 1859(1).

23 “(2) INFLATION ADJUSTMENT FOR SUBSE-
24 QUENT YEARS.—The monthly premium rate for a
25 year after 2006 for prescription medicine benefits

1 under this part is equal to the monthly premium
 2 rate for the previous year under this subsection in-
 3 creased by the percentage increase in per capita pro-
 4 gram expenditures (as estimated in advance for the
 5 year involved under subsection (c)(8)(B)). The Sec-
 6 retary shall adjust such percentage in subsequent
 7 years to take into account misestimations made of
 8 the per capita program expenditures under the pre-
 9 vious sentence in previous years. Any increase under
 10 this paragraph that is not a multiple of \$1 shall be
 11 rounded to the nearest multiple of \$1.

12 “ADMINISTRATION; QUALITY ASSURANCE

13 “SEC. 1859E. (a) RULES RELATING TO PROVISION
 14 OF BENEFITS.—

15 “(1) PROVISION OF BENEFITS.—

16 “(A) IN GENERAL.—In providing benefits
 17 under this part, the Secretary (directly or
 18 through the contracts with pharmacy contrac-
 19 tors) shall employ mechanisms to provide bene-
 20 fits appropriately and efficiently, and those
 21 mechanisms may include—

22 “(i) the use of—

23 “(I) price negotiations (con-
 24 sistent with subsection (b));

25 “(II) reduced coinsurance (below
 26 20 percent) to encourage the utiliza-

1 tion of appropriate preferred medi-
2 cines; and

3 “(III) methods to reduce medica-
4 tion errors and encourage appropriate
5 use of medications; and

6 “(ii) permitting pharmacy contractors,
7 as approved by the Secretary, to make ex-
8 ceptions to section 1859D(c)(3)(C) (relat-
9 ing to cost-sharing for non-preferred medi-
10 cines) to secure best prices for enrollees so
11 long as the payment amount under section
12 1859D(c)(1) does not equal zero.

13 “(B) CONSTRUCTION.—Nothing in this
14 subsection shall be construed to prevent the
15 Secretary (directly or through the contracts
16 with pharmacy contractors) from using incen-
17 tives to encourage enrollees to select generic or
18 other cost-effective medicines, so long as—

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

23 “(ii) a beneficiary’s coinsurance shall
24 be no greater than 20 percent in the case
25 of a preferred medicine (including a non-

1 preferred medicine treated as a preferred
2 medicine under section 1859D(c)(5)).

3 “(2) CONSTRUCTION.—Nothing in this part
4 shall preclude the Secretary or a pharmacy con-
5 tractor from—

6 “(A) educating prescribing providers, phar-
7 macists, and enrollees about medical and cost
8 benefits of preferred medicines;

9 “(B) requesting prescribing providers to
10 consider a preferred medicine prior to dis-
11 pensing of a nonpreferred medicine, as long as
12 such request does not unduly delay the provi-
13 sion of the medicine;

14 “(C) using mechanisms to encourage en-
15 rollees under this part to select cost-effective
16 medicines or less costly means of receiving or
17 administering medicines, including the use of
18 therapeutic interchange programs, disease man-
19 agement programs, and notification to the bene-
20 ficiary that a more affordable generic medicine
21 equivalent was not selected by the prescribing
22 provider and a statement of the lost cost sav-
23 ings to the beneficiary;

24 “(D) using price negotiations to achieve re-
25 duced prices on covered outpatient prescription

1 medicines, including new medicines, medicines
2 for which there are few therapeutic alternatives,
3 and medicines of particular clinical importance
4 to individuals enrolled under this part; and

5 “(E) utilizing information on medicine
6 prices of OECD countries and of other payors
7 in the United States in the negotiation of prices
8 under this part.

9 “(b) PRICE NEGOTIATIONS PROCESS.—

10 “(1) REQUIREMENTS WITH RESPECT TO PRE-
11 FERRED MEDICINES.—Negotiations of contracts with
12 manufacturers with respect to covered outpatient
13 prescription medicines under this part shall be con-
14 ducted in a manner so that—

15 “(A) there is at least a contract for a med-
16 icine within each therapeutic class (as defined
17 by the Secretary in consultation with such
18 Medicare Prescription Medicine Advisory Com-
19 mittee);

20 “(B) if there is more than 1 medicine
21 available in a therapeutic class, there are con-
22 tracts for at least 2 medicines within such class
23 unless determined clinically inappropriate in ac-
24 cordance with standards established by the Sec-
25 retary; and

1 “(C) if there are more than 2 medicines
2 available in a therapeutic class, there is a con-
3 tract for at least 2 medicines within such class
4 and a contract for generic medicine substitute
5 if available unless determined clinically inappro-
6 priate in accordance with standards established
7 by the Secretary.

8 “(2) ESTABLISHMENT OF THERAPEUTIC CLASS-
9 ES.—The Secretary, in consultation with the Medi-
10 care Prescription Medicine Advisory Committee (es-
11 tablished under section 1859H), shall establish for
12 purposes of this part therapeutic classes and assign
13 to such classes covered outpatient prescription medi-
14 cines.

15 “(3) DISCLOSURE CONCERNING PREFERRED
16 MEDICINES.—The Secretary shall provide, through
17 pharmacy contractors or otherwise, for—

18 “(A) disclosure to current and prospective
19 enrollees and to participating providers and
20 pharmacies in each service area a list of the
21 preferred medicines and differences in applica-
22 ble cost-sharing between such medicines and
23 nonpreferred medicines; and

24 “(B) advance disclosure to current enroll-
25 ees and to participating providers and phar-

1 macies in each service area of changes to any
2 such list of preferred medicines and differences
3 in applicable cost-sharing.

4 “(4) NO REVIEW.—The Secretary’s establish-
5 ment of therapeutic classes and the assignment of
6 medicines to such classes and the Secretary’s deter-
7 mination of what is a breakthrough medicine are not
8 subject to administrative or judicial review.

9 “(c) CONFIDENTIALITY.—The Secretary shall ensure
10 that the confidentiality of individually identifiable health
11 information relating to the provision of benefits under this
12 part is protected, consistent with the standards for the
13 privacy of such information promulgated by the Secretary
14 under the Health Insurance Portability and Accountability
15 Act of 1996, or any subsequent comprehensive and more
16 protective set of confidentiality standards enacted into law
17 or promulgated by the Secretary. Nothing in this sub-
18 section shall be construed as preventing the coordination
19 of data with a State prescription medicine program so long
20 as such program has in place confidentiality standards
21 that are equal to or exceed the standards used by the Sec-
22 retary.

23 “(d) FRAUD AND ABUSE SAFEGUARDS.—The Sec-
24 retary, through the Office of the Inspector General, is au-
25 thorized and directed to issue regulations establishing ap-

1 appropriate safeguards to prevent fraud and abuse under
2 this part. Such safeguards, at a minimum, should include
3 compliance programs, certification data, audits, and rec-
4 ordkeeping practices. In developing such regulations, the
5 Secretary shall consult with the Attorney General and
6 other law enforcement and regulatory agencies.

7 “FEDERAL MEDICARE PRESCRIPTION MEDICINE TRUST
8 FUND

9 “SEC. 1859F. (a) ESTABLISHMENT.—There is here-
10 by created on the books of the Treasury of the United
11 States a trust fund to be known as the ‘Federal Medicare
12 Prescription Medicine Trust Fund’ (in this section re-
13 ferred to as the ‘Trust Fund’). The Trust Fund shall con-
14 sist of such gifts and bequests as may be made as provided
15 in section 201(i)(1), and such amounts as may be depos-
16 ited in, or appropriated to, such fund as provided in this
17 part.

18 “(b) APPLICATION OF SMI TRUST FUND PROVI-
19 SIONS.—The provisions of subsections (b) through (i) of
20 section 1841 shall apply to this part and the Trust Fund
21 in the same manner as they apply to part B and the Fed-
22 eral Supplementary Medical Insurance Trust Fund, re-
23 spectively.

1 “(2) ANNUAL ASSURANCES AND NOTICE BE-
2 FORE TERMINATION.—The sponsor of the plan
3 shall—

4 “(A) annually attest, and provide such as-
5 surances as the Secretary may require, that the
6 coverage offered under the group health plan
7 meets the requirements of this section and will
8 continue to meet such requirements for the du-
9 ration of the sponsor’s participation in the pro-
10 gram under this section; and

11 “(B) guarantee that it will give notice to
12 the Secretary and covered enrollees—

13 “(i) at least 120 days before termi-
14 nating its plan, and

15 “(ii) immediately upon determining
16 that the actuarial value of the prescription
17 medicine benefit under the plan falls below
18 the actuarial value required under sub-
19 section (a).

20 “(3) BENEFICIARY INFORMATION.—The spon-
21 sor of the plan shall report to the Secretary, for
22 each calendar quarter for which it seeks a payment
23 under this section, the names and social security
24 numbers of all enrollees described in subsection (a)
25 covered under such plan during such quarter and

1 the dates (if less than the full quarter) during which
2 each such individual was covered.

3 “(4) AUDITS.—The sponsor or plan seeking
4 payment under this section shall agree to maintain,
5 and to afford the Secretary access to, such records
6 as the Secretary may require for purposes of audits
7 and other oversight activities necessary to ensure the
8 adequacy of prescription medicine coverage, the ac-
9 curacy of payments made, and such other matters as
10 may be appropriate.

11 “(c) PAYMENT.—

12 “(1) IN GENERAL.—The sponsor of a group
13 health plan that meets the requirements of sub-
14 section (b) with respect to a quarter in a calendar
15 year shall be entitled to have payment made on a
16 quarterly basis of the amount specified in paragraph
17 (2) for each individual described in subsection (a)
18 who during the quarter is covered under the plan
19 and was not enrolled in the insurance program
20 under this part.

21 “(2) AMOUNT OF PAYMENT.—

22 “(A) IN GENERAL.—The amount of the
23 payment for a quarter shall approximate, for
24 each such covered individual, $\frac{2}{3}$ of the sum of
25 the monthly Government contribution amounts

1 (computed under subparagraph (B)) for each of
2 the 3 months in the quarter.

3 “(B) COMPUTATION OF MONTHLY GOV-
4 ERNMENT CONTRIBUTION AMOUNT.—For pur-
5 poses of subparagraph (A), the monthly Gov-
6 ernment contribution amount for a month in a
7 year is equal to the amount by which—

8 “(i) $\frac{1}{12}$ of the average per capita ag-
9 gregate expenditures, as estimated under
10 section 1859D(c)(8) for the year involved;
11 exceeds

12 “(ii) the monthly premium rate under
13 section 1859D(d) for the month involved.

14 “MEDICARE PRESCRIPTION MEDICINE ADVISORY
15 COMMITTEE

16 “SEC. 1859H. (a) ESTABLISHMENT OF COM-
17 MITTEE.—There is established a Medicare Prescription
18 Medicine Advisory Committee (in this section referred to
19 as the ‘Committee’).

20 “(b) FUNCTIONS OF COMMITTEE.—The Committee
21 shall advise the Secretary on policies related to—

22 “(1) the development of guidelines for the im-
23 plementation and administration of the outpatient
24 prescription medicine benefit program under this
25 part; and

26 “(2) the development of—

1 “(A) standards required of pharmacy con-
2 tractors under section 1859D(e)(5) for deter-
3 mining if a medicine is as effective for an en-
4 rollee or has a significant adverse effect on an
5 enrollee under this part;

6 “(B) standards for—

7 “(i) defining therapeutic classes;

8 “(ii) adding new therapeutic classes;

9 “(iii) assigning to such classes covered
10 outpatient prescription medicines; and

11 “(iv) identifying breakthrough medi-
12 cines;

13 “(C) procedures to evaluate the bids sub-
14 mitted by pharmacy contractors under this
15 part;

16 “(D) procedures for negotiations, and
17 standards for entering into contracts, with
18 manufacturers, including identifying medicines
19 or classes of medicines where Secretarial nego-
20 tiation is most likely to yield savings under this
21 part significantly above those that which could
22 be achieved by a pharmacy contractor; and

23 “(E) procedures to ensure that pharmacy
24 contractors with a contract under this part are

1 in compliance with the requirements under this
2 part.

3 For purposes of this part, a medicine is a ‘breakthrough
4 medicine’ if the Secretary, in consultation with the Com-
5 mittee, determines it is a new product that will make a
6 significant and major improvement by reducing physical
7 or mental illness, reducing mortality, or reducing dis-
8 ability, and that no other product is available to bene-
9 ficiaries that achieves similar results for the same condi-
10 tion. The Committee may consider cost-effectiveness in es-
11 tablishing standards for defining therapeutic classes and
12 assigning drugs to such classes under subparagraph (B).

13 “(c) STRUCTURE AND MEMBERSHIP OF THE COM-
14 MITTEE.—

15 “(1) STRUCTURE.—The Committee shall be
16 composed of 19 members who shall be appointed by
17 the Secretary.

18 “(2) MEMBERSHIP.—

19 “(A) IN GENERAL.—The members of the
20 Committee shall be chosen on the basis of their
21 integrity, impartiality, and good judgment, and
22 shall be individuals who are, by reason of their
23 education, experience, and attainments, excep-
24 tionally qualified to perform the duties of mem-
25 bers of the Committee.

1 “(B) SPECIFIC MEMBERS.—Of the mem-
2 bers appointed under paragraph (1)—

3 “(i) 5 shall be chosen to represent
4 practicing physicians, 2 of whom shall be
5 gerontologists;

6 “(ii) 2 shall be chosen to represent
7 practicing nurse practitioners;

8 “(iii) 4 shall be chosen to represent
9 practicing pharmacists;

10 “(iv) 1 shall be chosen to represent
11 the Centers for Medicare & Medicaid Serv-
12 ices;

13 “(v) 4 shall be chosen to represent ac-
14 tuaries, pharmacoeconomists, researchers,
15 and other appropriate experts;

16 “(vi) 1 shall be chosen to represent
17 emerging medicine technologies;

18 “(vii) 1 shall be chosen to represent
19 the Food and Drug Administration; and

20 “(viii) 1 shall be chosen to represent
21 individuals enrolled under this part.

22 “(d) TERMS OF APPOINTMENT.—Each member of
23 the Committee shall serve for a term determined appro-
24 priate by the Secretary. The terms of service of the mem-
25 bers initially appointed shall begin on January 1, 2005.

1 “(e) CHAIRPERSON.—The Secretary shall designate
2 a member of the Committee as Chairperson. The term as
3 Chairperson shall be for a 1-year period.

4 “(f) COMMITTEE PERSONNEL MATTERS.—

5 “(1) MEMBERS.—

6 “(A) COMPENSATION.—Each member of
7 the Committee who is not an officer or em-
8 ployee of the Federal Government shall be com-
9 pensated at a rate equal to the daily equivalent
10 of the annual rate of basic pay prescribed for
11 level IV of the Executive Schedule under section
12 5315 of title 5, United States Code, for each
13 day (including travel time) during which such
14 member is engaged in the performance of the
15 duties of the Committee. All members of the
16 Committee who are officers or employees of the
17 United States shall serve without compensation
18 in addition to that received for their services as
19 officers or employees of the United States.

20 “(B) TRAVEL EXPENSES.—The members
21 of the Committee shall be allowed travel ex-
22 penses, including per diem in lieu of subsist-
23 ence, at rates authorized for employees of agen-
24 cies under subchapter I of chapter 57 of title 5,
25 United States Code, while away from their

1 homes or regular places of business in the per-
2 formance of services for the Committee.

3 “(2) STAFF.—The Committee may appoint
4 such personnel as the Committee considers appro-
5 priate.

6 “(g) OPERATION OF THE COMMITTEE.—

7 “(1) MEETINGS.—The Committee shall meet at
8 the call of the Chairperson (after consultation with
9 the other members of the Committee) not less often
10 than quarterly to consider a specific agenda of
11 issues, as determined by the Chairperson after such
12 consultation.

13 “(2) QUORUM.—Ten members of the Com-
14 mittee shall constitute a quorum for purposes of
15 conducting business.

16 “(h) FEDERAL ADVISORY COMMITTEE ACT.—Section
17 14 of the Federal Advisory Committee Act (5 U.S.C.
18 App.) shall not apply to the Committee.

19 “(i) TRANSFER OF PERSONNEL, RESOURCES, AND
20 ASSETS.—For purposes of carrying out its duties, the Sec-
21 retary and the Committee may provide for the transfer
22 to the Committee of such civil service personnel in the em-
23 ploy of the Department of Health and Human Services
24 (including the Centers for Medicare & Medicaid Services),

1 and such resources and assets of the Department used in
2 carrying out this title, as the Committee requires.

3 “(j) AUTHORIZATION OF APPROPRIATIONS.—There
4 are authorized to be appropriated such sums as may be
5 necessary to carry out the purposes of this section.”.

6 (c) APPLICATION OF GENERAL EXCLUSIONS FROM
7 COVERAGE.—

8 (1) APPLICATION TO PART D.—Section 1862(a)
9 (42 U.S.C. 1395y(a)) is amended in the matter pre-
10 ceding paragraph (1) by striking “part A or part B”
11 and inserting “part A, B, or D”.

12 (2) PRESCRIPTION MEDICINES NOT EXCLUDED
13 FROM COVERAGE IF APPROPRIATELY PRESCRIBED.—
14 Section 1862(a)(1) (42 U.S.C. 1395y(a)(1)) is
15 amended—

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

18 (B) in subparagraph (I), by striking the
19 semicolon at the end and inserting “, and”; and

20 (C) by adding at the end the following new
21 subparagraph:

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

1 (d) CONFORMING AMENDMENTS.—(1) Part C of title
2 XVIII is amended—

3 (A) in section 1851(a)(2)(B) (42 U.S.C.
4 1395w-21(a)(2)(B)), by striking “1859(b)(3)” and
5 inserting “1858(b)(3)”;

6 (B) in section 1851(a)(2)(C) (42 U.S.C.
7 1395w-21(a)(2)(C)), by striking “1859(b)(2)” and
8 inserting “1858(b)(2)”;

9 (C) in section 1852(a)(1) (42 U.S.C. 1395w-
10 22(a)(1)), by striking “1859(b)(3)” and inserting
11 “1858(b)(3)”;

12 (D) in section 1852(a)(3)(B)(ii) (42 U.S.C.
13 1395w-22(a)(3)(B)(ii)), by striking
14 “1859(b)(2)(B)” and inserting “1858(b)(2)(B)”;

15 (E) in section 1853(a)(1)(A) (42 U.S.C.
16 1395w-23(a)(1)(A)), by striking “1859(e)(4)” and
17 inserting “1858(e)(4)”;

18 (F) in section 1853(a)(3)(D) (42 U.S.C.
19 1395w-23(a)(3)(D)), by striking “1859(e)(4)” and
20 inserting “1858(e)(4)”.

21 (2) Section 1171(a)(5)(D) (42 U.S.C.
22 1320d(a)(5)(D)) is amended by striking “or (C)” and in-
23 serting “(C), or (D)”.

1 **SEC. 102. PROVISION OF MEDICARE OUTPATIENT PRE-**
2 **SCRIPTION MEDICINE COVERAGE UNDER**
3 **THE MEDICARE+CHOICE PROGRAM.**

4 (a) REQUIRING AVAILABILITY OF AN ACTUARIALLY
5 EQUIVALENT PRESCRIPTION MEDICINE BENEFIT.—Sec-
6 tion 1851 (42 U.S.C. 1395w–21) is amended by adding
7 at the end the following new subsection:

8 “(j) AVAILABILITY OF PRESCRIPTION MEDICINE
9 BENEFITS.—

10 “(1) IN GENERAL.—Notwithstanding any other
11 provision of this part, each Medicare+Choice organi-
12 zation that makes available a Medicare+Choice plan
13 described in section 1851(a)(2)(A) shall make avail-
14 able such a plan that offers coverage of covered out-
15 patient prescription medicines that is at least actu-
16 arially equivalent to the benefits provided under part
17 D. Information respecting such benefits shall be
18 made available in the same manner as information
19 on other benefits provided under this part is made
20 available. Nothing in this paragraph shall be con-
21 strued as requiring the offering of such coverage
22 separate from coverage that includes benefits under
23 parts A and B.

24 “(2) TREATMENT OF PRESCRIPTION MEDICINE
25 ENROLLEES.—In the case of a Medicare+Choice eli-
26 gible individual who is enrolled under part D, the

1 benefits described in paragraph (1) shall be treated
2 in the same manner as benefits described in part B
3 for purposes of coverage and payment and any ref-
4 erence in this part to the Federal Supplementary
5 Medical Insurance Trust Fund shall be deemed, with
6 respect to such benefits, to be a reference to the
7 Federal Medicare Prescription Medicine Trust
8 Fund.”.

9 (b) APPLICATION OF QUALITY STANDARDS.—Section
10 1852(e)(2)(A) (42 U.S.C. 1395w–22(e)(2)(A)) is amend-
11 ed—

12 (1) by striking “and” at the end of clause (xi);

13 (2) by striking the period at the end of clause
14 (xii) and inserting “, and”; and

15 (3) by adding at the end the following new
16 clause:

17 “(xiii) comply with the standards, and
18 apply the programs, under section
19 1859B(b) for covered outpatient prescrip-
20 tion medicines under the plan.”.

21 (c) PAYMENT SEPARATE FROM PAYMENT FOR PART
22 A AND B BENEFITS.—Section 1853 (42 U.S.C. 1395w–
23 23) is amended—

24 (1) in subsection (a)(1)(A), by striking “and
25 (i)” and inserting “(i), and (j)”; and

1 (2) by adding at the end the following new sub-
2 section:

3 “(j) PAYMENT FOR PRESCRIPTION MEDICINE COV-
4 ERAGE OPTION.—

5 “(1) IN GENERAL.—In the case of a
6 Medicare+Choice plan that provides prescription
7 medicine benefits described in section 1851(j)(1),
8 the amount of payment otherwise made to the
9 Medicare+Choice organization offering the plan
10 shall be increased by the amount described in para-
11 graph (2). Such payments shall be made in the same
12 manner and time as the amount otherwise paid, but
13 such amount shall be payable from the Federal
14 Medicare Prescription Medicine Trust Fund.

15 “(2) AMOUNT.—The amount described in this
16 paragraph is the monthly Government contribution
17 amount computed under section 1859G(e)(2)(B),
18 but subject to adjustment under paragraph (3).
19 Such amount shall be uniform geographically and
20 shall not vary based on the Medicare+Choice pay-
21 ment area involved.

22 “(3) RISK ADJUSTMENT.—The Secretary shall
23 establish a methodology for the adjustment of the
24 payment amount under this subsection in a manner
25 that takes into account the relative risks for use of

1 outpatient prescription medicines by
2 Medicare+Choice enrollees. Such methodology shall
3 be designed in a manner so that the total payments
4 under this title (including part D) are not changed
5 as a result of the application of such methodology.”.

6 (d) SEPARATE APPLICATION OF ADJUSTED COMMU-
7 NITY RATE (ACR).—Section 1854 (42 U.S.C. 1395w–24)
8 is amended by adding at the end the following:

9 “(i) APPLICATION TO PRESCRIPTION MEDICINE COV-
10 ERAGE.—The Secretary shall apply the previous provisions
11 of this section (including the computation of the adjusted
12 community rate) separately with respect to prescription
13 medicine benefits described in section 1851(j)(1).”.

14 (f) CONFORMING AMENDMENTS.—

15 (1) Section 1851 (42 U.S.C. 1395w–21) is
16 amended—

17 (A) in subsection (a)(1)(A), by striking
18 “parts A and B” and inserting “parts A, B,
19 and D”; and

20 (B) in subsection (i) by inserting “(and, if
21 applicable, part D)” after “parts A and B”.

22 (2) Section 1852(a)(1)(A) (42 U.S.C. 1395w–
23 22(a)(1)(A)) is amended by inserting “(and under
24 part D to individuals also enrolled under such part)”
25 after “parts A and B”.

1 (3) Section 1852(d)(1) (42 U.S.C. 1395w-
2 22(d)(1)) is amended—

3 (A) by striking “and” at the end of sub-
4 paragraph (D);

5 (B) by striking the period at the end of
6 subparagraph (E) and inserting “; and”; and

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

8 “(F) the plan for part D benefits guaran-
9 tees coverage of any specifically named pre-
10 scription medicine for an enrollee to the extent
11 that it would be required to be covered under
12 part D.

13 In carrying out subparagraph (F), a
14 Medicare+Choice organization has the same author-
15 ity to enter into contracts with respect to coverage
16 of preferred medicines as the Secretary has under
17 part D, but subject to an independent contractor ap-
18 peal or other appeal process that would be applicable
19 to determinations by such a pharmacy contractor
20 consistent with section 1859D(e)(5).”.

21 (e) LIMITATION ON COST-SHARING.—Section
22 1854(e) (42 U.S.C. 1395w-24(e)) is amended by adding
23 at the end the following new paragraph:

24 “(5) LIMITATION ON COST-SHARING.—In no
25 event may a Medicare+Choice organization include

1 a requirement that an enrollee pay cost-sharing in
2 excess of the cost-sharing otherwise permitted under
3 part D.”.

4 **SEC. 103. MEDIGAP REVISIONS.**

5 (a) **REQUIRED COVERAGE OF COVERED OUTPATIENT**
6 **PRESCRIPTION MEDICINES.**—Section 1882(p)(2)(B) (42
7 U.S.C. 1395ss(p)(2)(B)) is amended by inserting before
8 “and” at the end the following: “including a requirement
9 that an appropriate number of policies provide coverage
10 of medicines which complements but does not duplicate
11 the medicine benefits that beneficiaries are otherwise eligi-
12 ble for benefits under part D of this title (with the Sec-
13 retary and the National Association of Insurance Commis-
14 sioners determining the appropriate level of medicine ben-
15 efits that each benefit package must provide and ensuring
16 that policies providing such coverage are affordable for
17 beneficiaries;”.

18 (b) **EFFECTIVE DATE.**—The amendment made by
19 subsection (a) shall take effect on January 1, 2006.

20 (c) **TRANSITION PROVISIONS.**—

21 (1) **IN GENERAL.**—If the Secretary of Health
22 and Human Services identifies a State as requiring
23 a change to its statutes or regulations to conform its
24 regulatory program to the amendments made by this
25 section, the State regulatory program shall not be

1 considered to be out of compliance with the require-
2 ments of section 1882 of the Social Security Act due
3 solely to failure to make such change until the date
4 specified in paragraph (4).

5 (2) NAIC STANDARDS.—If, within 9 months
6 after the date of enactment of this Act, the National
7 Association of Insurance Commissioners (in this
8 subsection referred to as the “NAIC”) modifies its
9 NAIC Model Regulation relating to section 1882 of
10 the Social Security Act (referred to in such section
11 as the 1991 NAIC Model Regulation, as subse-
12 quently modified) to conform to the amendments
13 made by this section, such revised regulation incor-
14 porating the modifications shall be considered to be
15 the applicable NAIC model regulation (including the
16 revised NAIC model regulation and the 1991 NAIC
17 Model Regulation) for the purposes of such section.

18 (3) SECRETARY STANDARDS.—If the NAIC
19 does not make the modifications described in para-
20 graph (2) within the period specified in such para-
21 graph, the Secretary of Health and Human Services
22 shall make the modifications described in such para-
23 graph and such revised regulation incorporating the
24 modifications shall be considered to be the appro-
25 priate regulation for the purposes of such section.

1 (4) DATE SPECIFIED.—

2 (A) IN GENERAL.—Subject to subpara-
3 graph (B), the date specified in this paragraph
4 for a State is the earlier of—

5 (i) the date the State changes its stat-
6 utes or regulations to conform its regu-
7 latory program to the changes made by
8 this section; or

9 (ii) 1 year after the date the NAIC or
10 the Secretary first makes the modifications
11 under paragraph (2) or (3), respectively.

12 (B) ADDITIONAL LEGISLATIVE ACTION RE-
13 QUIRED.—In the case of a State which the Sec-
14 retary identifies as—

15 (i) requiring State legislation (other
16 than legislation appropriating funds) to
17 conform its regulatory program to the
18 changes made in this section; but

19 (ii) having a legislature which is not
20 scheduled to meet in 2004 in a legislative
21 session in which such legislation may be
22 considered;

23 the date specified in this paragraph is the first
24 day of the first calendar quarter beginning after
25 the close of the first legislative session of the

1 State legislature that begins on or after Janu-
2 ary 1, 2004. For purposes of the previous sen-
3 tence, in the case of a State that has a 2-year
4 legislative session, each year of such session
5 shall be deemed to be a separate regular session
6 of the State legislature.

7 **SEC. 104. TRANSITIONAL ASSISTANCE FOR LOW INCOME**
8 **BENEFICIARIES.**

9 (a) QMB COVERAGE OF PREMIUMS AND COST-SHAR-
10 ING.—Section 1905(p)(3) (42 U.S.C. 1396d(p)(3)) is
11 amended—

12 (1) in subparagraph (A)—

13 (A) by striking “and” at the end of clause

14 (i),

15 (B) by adding “and” at the end of clause

16 (ii), and

17 (C) by adding at the end the following new
18 clause:

19 “(iii) premiums under section 1859D(d).”;

20 (2) in subparagraph (B), by inserting “and sec-
21 tion 1859D(c)(3)(B) and 1859D(c)(3)(C)(i)” after
22 “1813”; and

23 (3) in subparagraph (C), by striking “and sec-
24 tion 1833(b)” and inserting “, section 1833(b), and
25 section 1859D(c)(2)”.

1 (b) EXPANDED SLMB ELIGIBILITY.—Section
2 1902(a)(10)(E) (42 U.S.C. 1396a(a)(10)(E)) is amend-
3 ed—

4 (1) by striking “and” at the end of clause (iii);

5 (2) by adding “and” at the end of clause (iv);

6 and

7 (3) by adding at the end the following new
8 clause:

9 “(v)(I) for making medical assistance
10 available for medicare cost-sharing described in
11 section 1905(p)(3)(A)(iii) and medicare cost-
12 sharing described in section 1905(p)(3)(B) and
13 section 1905(p)(3)(C) but only insofar as it re-
14 lates to benefits provided under part D of title
15 XVIII, subject to section 1905(p)(4), for indi-
16 viduals (other than qualified medicare bene-
17 ficiaries) who are enrolled under part D of title
18 XVIII and are described in section
19 1905(p)(1)(B) or would be so described but for
20 the fact that their income exceeds 100 percent,
21 but is less than 150 percent, of the official pov-
22 erty line (referred to in such section) for a fam-
23 ily of the size involved;

24 “(II) subject to section 1905(p)(4), for in-
25 dividuals (other than qualified medicare bene-

1 ficiaries and individuals described in subclause
2 (I) who are enrolled under part D of title
3 XVIII and would be described in section
4 1905(p)(1)(B) but for the fact that their in-
5 come exceeds 150 percent, but is less than 175
6 percent, of the official poverty line (referred to
7 in such section) for a family of the size in-
8 volved, for making medical assistance available
9 for medicare cost-sharing described in section
10 1905(p)(3)(A)(iii) and medicare cost-sharing
11 described in section 1905(p)(3)(B) and section
12 1905(p)(3)(C) but only insofar as it relates to
13 benefits provided under part D of title XVIII,
14 and the assistance for medicare cost-sharing de-
15 scribed in section 1905(p)(3)(A)(iii) is reduced
16 (on a sliding scale based on income) from 100
17 percent to 0 percent as the income increases
18 from 150 percent to 175 percent of such pov-
19 erty line;”.

20 (c) FEDERAL FINANCING.—The third sentence of
21 section 1905(b) (42 U.S.C. 1396d(b)) is amended by in-
22 serting before the period at the end the following: “and
23 with respect to amounts expended that are attributable to
24 section 1902(a)(10)(E)(v) (other than for individuals de-
25 scribed in section 1905(p)(1)(B))”.

1 (d) TREATMENT OF TERRITORIES.—

2 (1) IN GENERAL.—Section 1905(p) (42 U.S.C.
3 1396d(p)) is amended—

4 (A) by redesignating paragraphs (5) and
5 (6) as paragraphs (6) and (7), respectively; and

6 (B) by inserting after paragraph (4) the
7 following new paragraph:

8 “(5)(A) In the case of a State, other than the 50
9 States and the District of Columbia—

10 “(i) the provisions of paragraph (3) insofar as
11 they relate to section 1859D and the provisions of
12 section 1902(a)(10)(E)(v) shall not apply to resi-
13 dents of such State; and

14 “(ii) if the State establishes a plan described in
15 subparagraph (B) (for providing medical assistance
16 with respect to the provision of prescription medi-
17 cines to medicare beneficiaries), the amount other-
18 wise determined under section 1108(f) (as increased
19 under section 1108(g)) for the State shall be in-
20 creased by the amount specified in subparagraph
21 (C).

22 “(B) The plan described in this subparagraph is a
23 plan that—

24 “(i) provides medical assistance with respect to
25 the provision of covered outpatient medicines (as de-

1 fined in section 1859D(b)) to low-income medicare
2 beneficiaries; and

3 “(ii) assures that additional amounts received
4 by the State that are attributable to the operation
5 of this paragraph are used only for such assistance.

6 “(C)(i) The amount specified in this subparagraph
7 for a State for a year is equal to the product of—

8 “(I) the aggregate amount specified in clause
9 (ii); and

10 “(II) the amount specified in section 1108(g)(1)
11 for that State, divided by the sum of the amounts
12 specified in such section for all such States.

13 “(ii) The aggregate amount specified in this clause
14 for—

15 “(I) 2006, is equal to \$25,000,000; or

16 “(II) a subsequent year, is equal to the aggre-
17 gate amount specified in this clause for the previous
18 year increased by annual percentage increase speci-
19 fied in section 1859D(c)(8)(B) for the year involved.

20 “(D) The Secretary shall submit to Congress a report
21 on the application of this paragraph and may include in
22 the report such recommendations as the Secretary deems
23 appropriate.”.

24 (2) CONFORMING AMENDMENT.—Section
25 1108(f) (42 U.S.C. 1308(f)) is amended by inserting

1 “and section 1905(p)(5)(A)(ii)” after “Subject to
2 subsection (g)”.

3 (e) APPLICATION OF COST-SHARING.—Section
4 1902(n)(2) (42 U.S.C. 1396a(n)(2)) is amended by add-
5 ing at the end the following: “The previous sentence shall
6 not apply to medicare cost-sharing relating to benefits
7 under part D of title XVIII.”.

8 (f) EFFECTIVE DATE.—The amendments made by
9 this section apply to medical assistance for premiums and
10 cost-sharing incurred on or after January 1, 2006, with
11 regard to whether regulations to implement such amend-
12 ments are promulgated by such date.

13 **TITLE II—REFORM IN PRESCRIP-**
14 **TION DRUG PRICES FOR SEN-**
15 **IORS**

16 **Subtitle A—Prescription Drug**
17 **Fairness for Seniors**

18 **SEC. 201. SHORT TITLE.**

19 This subtitle may be cited as the “Prescription Drug
20 Fairness for Seniors Act of 2003”.

21 **SEC. 202. FINDINGS AND PURPOSES.**

22 (a) FINDINGS.—The Congress makes the following
23 findings:

24 (1) Manufacturers of prescription drugs engage
25 in price discrimination practices that compel many

1 older Americans to pay substantially more for pre-
2 scription drugs than consumers in foreign nations
3 and the drug manufacturers' most favored U.S. cus-
4 tomers, such as health insurers, health maintenance
5 organizations, and the Federal Government.

6 (2) Older Americans who buy their own pre-
7 scription drugs often pay twice as much for prescrip-
8 tion drugs as consumers in foreign nations and the
9 drug manufacturers' most favored U.S. customers.
10 In some cases, older Americans pay 10 times more
11 for prescription drugs than such customers.

12 (3) The discriminatory pricing by major drug
13 manufacturers sustains their high profits (for exam-
14 ple, \$27,300,000,000 in 1999), but causes financial
15 hardship and impairs the health and well-being of
16 millions of older Americans. Many older Americans
17 are forced to choose between buying their food and
18 buying their medicines.

19 (4) Foreign nations and U.S. federally funded
20 health care programs use purchasing power to ob-
21 tain prescription drugs at low prices. Medicare bene-
22 ficiaries are denied this benefit and cannot obtain
23 their prescription drugs at the lower prices available
24 to such nations and programs.

1 (5) Implementation of the policy set forth in
2 this Act will reduce prices for brand name prescrip-
3 tion drugs for many Medicare beneficiaries by an av-
4 erage of 40 percent.

5 (6) In addition to substantially lowering the
6 costs of prescription drugs for older Americans, im-
7 plementation of the policy set forth in this Act will
8 significantly improve the health and well-being of
9 older Americans and lower the costs to the Federal
10 taxpayer of the Medicare program.

11 (7) Older Americans who are terminally ill and
12 receiving hospice care services represent some of the
13 most vulnerable individuals in our nation. Making
14 prescription drugs available to Medicare beneficiaries
15 under the care of Medicare-certified hospices will as-
16 sist in extending the benefits of lower prescription
17 drug prices to those most vulnerable and in need.

18 (b) PURPOSE.—The purpose of this Act is to protect
19 Medicare beneficiaries from discriminatory pricing by drug
20 manufacturers and to make prescription drugs available
21 to Medicare beneficiaries at substantially reduced prices.

22 **SEC. 203. PARTICIPATING MANUFACTURERS.**

23 (a) IN GENERAL.—Each participating manufacturer
24 of a covered outpatient drug shall make available for pur-
25 chase by each pharmacy such covered outpatient drug in

1 the amount described in subsection (b) at the price de-
2 scribed in subsection (c).

3 (b) DESCRIPTION OF AMOUNT OF DRUGS.—The
4 amount of a covered outpatient drug that a participating
5 manufacturer shall make available for purchase by a phar-
6 macy is an amount equal to the aggregate amount of the
7 covered outpatient drug sold or distributed by the phar-
8 macy to Medicare beneficiaries.

9 (c) DESCRIPTION OF PRICE.—The price at which a
10 participating manufacturer shall make a covered out-
11 patient drug available for purchase by a pharmacy is a
12 price no greater than the manufacturer's average foreign
13 price.

14 (d) ENFORCEMENT.—The United States shall debar
15 a manufacturer of drugs or biologicals that does not com-
16 ply with the provisions of this Act.

17 **SEC. 204. SPECIAL PROVISION WITH RESPECT TO HOSPICE**
18 **PROGRAMS.**

19 For purposes of determining the amount of a covered
20 outpatient drug that a participating manufacturer shall
21 make available for purchase by a pharmacy under section
22 203, there shall be included in the calculation of such
23 amount the amount of the covered outpatient drug sold
24 or distributed by a pharmacy to a hospice program. In
25 calculating such amount, only amounts of the covered out-

1 patient drug furnished to a Medicare beneficiary enrolled
2 in the hospice program shall be included.

3 **SEC. 205. ADMINISTRATION.**

4 The Secretary shall issue such regulations as may be
5 necessary to implement this subtitle.

6 **SEC. 206. REPORTS TO CONGRESS REGARDING EFFECTIVE-**
7 **NESS OF ACT.**

8 (a) IN GENERAL.—Not later than 2 years after the
9 date of the enactment of this Act, and annually thereafter,
10 the Secretary shall report to the Congress regarding the
11 effectiveness of this Act in—

12 (1) protecting Medicare beneficiaries from dis-
13 criminatory pricing by drug manufacturers, and

14 (2) making prescription drugs available to
15 Medicare beneficiaries at substantially reduced
16 prices.

17 (b) CONSULTATION.—In preparing such reports, the
18 Secretary shall consult with public health experts, affected
19 industries, organizations representing consumers and
20 older Americans, and other interested persons.

21 (c) RECOMMENDATIONS.—The Secretary shall in-
22 clude in such reports any recommendations the Secretary
23 considers appropriate for changes in this Act to further
24 reduce the cost of covered outpatient drugs to Medicare
25 beneficiaries.

1 **SEC. 207. DEFINITIONS.**

2 In this subtitle:

3 (1) AVERAGE FOREIGN PRICE.—

4 (A) IN GENERAL.—The term “average for-
5 eign price” means, with respect to a covered
6 outpatient drug, the average price that the
7 manufacturer of the drug realizes on the sale of
8 drugs with the same active ingredient or ingre-
9 dients that are consumed in covered foreign na-
10 tions, taking into account—

11 (i) any rebate, contract term or condi-
12 tion, or other arrangement (whether with
13 the purchaser or other persons) that has
14 the effect of reducing the amount realized
15 by the manufacturer on the sale of the
16 drugs; and

17 (ii) adjustments for any differences in
18 dosage, formulation, or other relevant
19 characteristics of the drugs.

20 (B) EXEMPT TRANSACTIONS.—The Sec-
21 retary may, by regulation, exempt from the cal-
22 culation of the average foreign price of a drug
23 those prices realized by a manufacturer in
24 transactions that are entered into for charitable
25 purposes, for research purposes, or under other
26 unusual circumstances, if the Secretary deter-

1 mines that the exemption is in the public inter-
2 est and is consistent with the purposes of this
3 Act.

4 (2) COVERED FOREIGN NATION.—The term
5 “covered foreign nation” means Canada, France,
6 Germany, Italy, Japan, and the United Kingdom.

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

11 (4) DEBAR.—The term “debar” means to ex-
12 clude, pursuant to established administrative proce-
13 dures, from Government contracting and subcon-
14 tracting for a specified period of time commensurate
15 with the seriousness of the failure or offense or the
16 inadequacy of performance.

17 (5) HOSPICE PROGRAM.—The term “hospice
18 program” has the meaning given that term under
19 section 1861(dd)(2) of the Social Security Act (42
20 U.S.C. 1395x(dd)(2)).

21 (6) MEDICARE BENEFICIARY.—The term
22 “Medicare beneficiary” means an individual entitled
23 to benefits under part A of title XVIII of the Social
24 Security Act or enrolled under part B of such title,
25 or both.

1 (7) PARTICIPATING MANUFACTURER.—The
2 term “participating manufacturer” means any man-
3 ufacturer of drugs or biologicals that, on or after the
4 date of the enactment of this Act, enters into a con-
5 tract or agreement with the United States for the
6 sale or distribution of covered outpatient drugs to
7 the United States.

8 (8) SECRETARY.—The term “Secretary” means
9 the Secretary of Health and Human Services.

10 **SEC. 208. EFFECTIVE DATE.**

11 The Secretary shall implement this Act as expedi-
12 tiously as practicable and in a manner consistent with the
13 obligations of the United States.

14 **Subtitle B—Sense of Congress on**
15 **cost disparity between identical**
16 **prescription drugs sold in the**
17 **United States, Canada, and Mex-**
18 **ico**

19 **SEC. 211. SENSE OF CONGRESS ON COST DISPARITY BE-**
20 **TWEEN IDENTICAL PRESCRIPTION DRUGS**
21 **SOLD IN THE UNITED STATES, CANADA, AND**
22 **MEXICO.**

23 (a) FINDINGS.—The Congress makes the following
24 findings:

1 (1) The Comptroller General of the United
2 States has found that a consumer in the United
3 States pays on average one-third more for a pre-
4 scription drug than a consumer pays for the same
5 drug in another country.

6 (2) According to the Comptroller General, costs
7 for prescription drugs between 1993 and 1998 in-
8 creased an average of 12.4 percent per year as com-
9 pared to an increase of 5 percent per year for health
10 care expenditures in general.

11 (3) Currently one-third of senior citizens in the
12 United States are without prescription drug insur-
13 ance, and these individuals pay on average 15 per-
14 cent more for a prescription than do citizens with
15 prescription drug insurance coverage.

16 (4) It is difficult for many Americans, including
17 senior citizens, to afford the prescription drugs that
18 they need to stay healthy.

19 (5) Many senior citizens in the United States
20 leave the country and go to Canada or Mexico to
21 buy prescription drugs that are developed, manufac-
22 tured, and approved in the United States in order to
23 buy such drugs at lower prices than such drugs are
24 sold for in the United States.

1 (6) The United States has made a strong com-
2 mitment to supporting the research and development
3 of new drugs through taxpayer-supported funding of
4 the National Institutes of Health, through the re-
5 search and development tax credit, and through
6 other means.

7 (7) The development of new drugs is important
8 because the use of such drugs enables people to live
9 longer and lead healthier, more productive lives.

10 (8) Citizens of other countries should pay a
11 portion of the research and development costs for
12 new drugs, or their fair share of such costs, rather
13 than just reap the benefits of such drugs.

14 (9) Many State governments are undertaking a
15 variety of plans to address the needs of citizens who
16 lack affordable drug coverage.

17 (b) SENSE OF CONGRESS.—It is the sense of the
18 Congress that the cost disparity between identical pre-
19 scription drugs sold in the United States, Canada, and
20 Mexico should be reduced or eliminated.

1 **TITLE III—DISALLOWANCE OF**
2 **DEDUCTION FOR DIRECT-TO-**
3 **CONSUMER ADVERTISEMENT**
4 **OF PRESCRIPTION DRUGS.**

5 **SEC. 301 DISALLOWANCE OF DEDUCTION FOR DIRECT-TO-**
6 **CONSUMER ADVERTISEMENT OF PRESCRIP-**
7 **TION DRUGS.**

8 (a) IN GENERAL.—Part IX of subchapter B of chap-
9 ter 1 of the Internal Revenue Code of 1986 (relating to
10 items not deductible) is amended by adding at the end
11 the following new section:

12 **“SEC. 280I. DIRECT-TO-CONSUMER ADVERTISEMENT OF**
13 **PRESCRIPTION DRUGS.**

14 “No deduction shall be allowed under this chapter for
15 any amount paid or incurred for a direct-to-consumer ad-
16 vertisement of a prescription drug.”.

17 (b) CLERICAL AMENDMENT.—The table of sections
18 for part IX of subchapter B of chapter 1 of such Code
19 is amended by adding at the end thereof the following new
20 item:

“Sec. 280I. Direct-to-consumer advertisement of prescription
drugs.”.

21 (c) EFFECTIVE DATE.—The amendments made by
22 this section shall apply to amounts paid or incurred after
23 December 31, 2002.

1 **TITLE IV—GREATER ACCESS TO**
2 **AFFORDABLE PHARMA-**
3 **CEUTICALS**

4 **SEC. 401. SHORT TITLE.**

5 This title may be cited as the “Greater Access to Af-
6 fordable Pharmaceuticals Act of 2003”.

7 **SEC. 402. FINDINGS; PURPOSES.**

8 (a) FINDINGS.—Congress finds that—

9 (1) prescription drug costs are increasing at an
10 alarming rate and are a major worry of American
11 families and senior citizens;

12 (2) enhancing competition between generic drug
13 manufacturers and brand-name manufacturers can
14 significantly reduce prescription drug costs for
15 American families;

16 (3) the pharmaceutical market has become in-
17 creasingly competitive during the last decade be-
18 cause of the increasing availability and accessibility
19 of generic pharmaceuticals, but competition must be
20 further stimulated and strengthened;

21 (4) the Federal Trade Commission has discov-
22 ered that there are increasing opportunities for drug
23 companies owning patents on brand-name drugs and
24 generic drug companies to enter into private finan-
25 cial deals in a manner that could restrain trade and

1 greatly reduce competition and increase prescription
2 drug costs for consumers;

3 (5) generic pharmaceuticals are approved by the
4 Food and Drug Administration on the basis of sci-
5 entific testing and other information establishing
6 that pharmaceuticals are therapeutically equivalent
7 to brand-name pharmaceuticals, ensuring consumers
8 a safe, efficacious, and cost-effective alternative to
9 brand-name innovator pharmaceuticals;

10 (6) the Congressional Budget Office estimates
11 that—

12 (A) the use of generic pharmaceuticals for
13 brand-name pharmaceuticals could save pur-
14 chasers of pharmaceuticals between
15 \$8,000,000,000 and \$10,000,000,000 each
16 year; and

17 (B) generic pharmaceuticals cost between
18 25 percent and 60 percent less than brand-
19 name pharmaceuticals, resulting in an esti-
20 mated average savings of \$15 to \$30 on each
21 prescription;

22 (7) generic pharmaceuticals are widely accepted
23 by consumers and the medical profession, as the
24 market share held by generic pharmaceuticals com-
25 pared to brand-name pharmaceuticals has more than

1 doubled during the last decade, from approximately
2 19 percent to 43 percent, according to the Congres-
3 sional Budget Office;

4 (8) expanding access to generic pharmaceuticals
5 can help consumers, especially senior citizens and
6 the uninsured, have access to more affordable pre-
7 scription drugs;

8 (9) Congress should ensure that measures are
9 taken to effectuate the amendments made by the
10 Drug Price Competition and Patent Term Restora-
11 tion Act of 1984 (98 Stat. 1585) (referred to in this
12 section as the “Hatch-Waxman Act”) to make ge-
13 neric drugs more accessible, and thus reduce health
14 care costs; and

15 (10) it would be in the public interest if patents
16 on drugs for which applications are approved under
17 section 505(c) of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 355(c)) were extended only
19 through the patent extension procedure provided
20 under the Hatch-Waxman Act rather than through
21 the attachment of riders to bills in Congress.

22 (b) PURPOSES.—The purposes of this title are—

23 (1) to increase competition, thereby helping all
24 Americans, especially seniors and the uninsured, to
25 have access to more affordable medication; and

1 (2) to ensure fair marketplace practices and
2 deter pharmaceutical companies (including generic
3 companies) from engaging in anticompetitive action
4 or actions that tend to unfairly restrain trade.

5 **SEC. 403. ACCELERATED GENERIC DRUG COMPETITION.**

6 (a) IN GENERAL.—Section 505(j)(5) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is
8 amended—

9 (1) in subparagraph (B)(iv), by striking sub-
10 clause (II) and inserting the following:

11 “(II) the earlier of—

12 “(aa) the date of a final decision of a
13 court in an action described in clause (iii)
14 (from which no appeal can or has been
15 taken); or

16 “(bb) the date of a settlement order
17 or consent decree signed by a Federal
18 judge that enters a final judgment and in-
19 cludes a finding that the patents that are
20 the subject of the certification are invalid
21 or not infringed;”;

22 (2) by redesignating subparagraphs (C) and
23 (D) as subparagraphs (E) and (F), respectively; and

24 (3) by inserting after subparagraph (B) the fol-
25 lowing:

1 “(C) FORFEITURE OF 180-DAY PERIOD.—

2 “(i) IN GENERAL.—The 180-day pe-
3 riod described in subparagraph (B)(iv)
4 shall be forfeited by the previous applicant
5 and become available to the next applicant
6 submitting an application containing a cer-
7 tification described in paragraph
8 (2)(A)(vii)(IV) if—

9 “(I) the previous applicant fails
10 to market the drug within 90 days
11 after the date on which the approval
12 of the application for the drug is
13 made effective under subparagraph
14 (B)(iii);

15 “(II) the previous applicant with-
16 draws the application;

17 “(III) the previous applicant
18 amends the certification from a cer-
19 tification under subclause (IV) to a
20 certification under paragraph
21 (2)(A)(vii)(III), either voluntarily or
22 as a result of a settlement or defeat in
23 patent litigation;

24 “(IV) the previous applicant fails
25 to get tentative approval of the appli-

1 cation within 30 months after the
2 date on which the application is filed,
3 unless the failure is caused by—

4 “(aa) a change in the re-
5 quirements for tentative approval
6 of the application imposed after
7 the date on which the application
8 was filed; or

9 “(bb) other extraordinary or
10 unusual circumstances, as deter-
11 mined by the Secretary;

12 “(V) in a case in which, after the
13 date on which the previous application
14 was submitted under this subsection,
15 new patent information is submitted
16 for the drug under subsection (c)(2)
17 for a patent for which certification is
18 required under paragraph
19 (2)(A)(vii)(IV), the previous applicant
20 fails to challenge the patent that is
21 the subject of the information within
22 60 days after the date on which the
23 patent information is submitted; or

24 “(VI) the previous applicant is
25 determined by the Secretary, after a

1 fair and sufficient hearing and in con-
2 sultation with the Federal Trade
3 Commission, to have engaged in anti-
4 competitive or collusive conduct, or
5 any other conduct intended to unfairly
6 monopolize the commercial manufac-
7 turing of the drug of the application.

8 “(ii) AVAILABILITY.—The 180-day pe-
9 riod described in subparagraph (B)(iv)
10 shall be available only to—

11 “(I) the previous applicant sub-
12 mitting an application for a drug
13 under this subsection containing a
14 certification described in paragraph
15 (2)(A)(vii)(IV) with respect to any
16 patent; or

17 “(II) under clause (i), the next
18 applicant submitting an application
19 for a drug under this subsection con-
20 taining such a certification with re-
21 spect to any patent;

22 even if an application has been submitted
23 for the drug under this subsection con-
24 taining such a certification with respect to
25 a different patent.

1 “(iii) APPLICABILITY.—The 180-day
2 period described in subparagraph (B)(iv)
3 shall apply only if—

4 “(I) the application contains a
5 certification described in paragraph
6 (2)(A)(vii)(IV); and

7 “(II) an action is brought for in-
8 fringement of a patent that is the
9 subject of the certification or the ap-
10 plicant brings an action (not later
11 than 50 days after the date on which
12 the notice provided under paragraph
13 (2)(B)(ii) was received), against the
14 holder of the approved application for
15 the listed drug.”.

16 (b) EFFECTIVE DATE.—The amendment made by
17 this section shall be effective only with respect to an appli-
18 cation filed under section 505(j) of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 355(j)) for a listed
20 drug for which no certification under section
21 505(j)(2)(A)(vii)(IV) of that Act was made before the date
22 of the enactment of this Act.

23 **SEC. 404. BIOEQUIVALENCE TESTING METHODS.**

24 Section 505(j)(8)(B) of the Federal Food, Drug, and
25 Cosmetic Act (21 U.S.C. 355(j)(8)(B)) is amended—

1 (1) in clause (i), by striking “or” at the end;

2 (2) in clause (ii), by striking the period at the

3 end and inserting “; or”; and

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

5 “(iii)(I) clauses (i) and (ii) are not applica-
6 ble, as determined by the Secretary;

7 “(II) the effects of the drug and the listed
8 drug do not show a significant difference based
9 on tests (other than tests that assess rate and
10 extent of absorption), including—

11 “(aa) a bioequivalence study with a
12 pharmacodynamic endpoint;

13 “(bb) a bioequivalence study with a
14 clinical endpoint;

15 “(cc) in vitro methods; or

16 “(dd) any other methodology that
17 demonstrates that no significant dif-
18 ferences in therapeutic effects of active in-
19 gredients are expected; and

20 “(III) limited confirmatory studies to sup-
21 plement the bioequivalence testing are consid-
22 ered necessary by the Secretary.”.

23 **SEC. 405. CITIZEN PETITIONS.**

24 Section 505(j)(5) of the Federal Food, Drug, and
25 Cosmetic Act (21 U.S.C. 355(j)(5)) (as amended by sec-

1 tion 403(a)) is amended by inserting after subparagraph
2 (C) the following:

3 “(D) CITIZEN PETITIONS.—

4 “(i) IN GENERAL.—Notwithstanding
5 any other provision of law, any petition
6 submitted under section 10.30 of title 21,
7 Code of Federal Regulations (or any suc-
8 cessor regulation), shall include a state-
9 ment that to the best knowledge and belief
10 of the petitioner, the petition—

11 “(I) includes all information and
12 views on which the petitioner relies;

13 “(II) is well grounded in fact and
14 is warranted by law (including regula-
15 tions);

16 “(III) is not submitted for any
17 improper purpose, such as to harass
18 or cause unnecessary delay;

19 “(IV) does not contain a materi-
20 ally false, misleading, or fraudulent
21 statement that the petitioner has
22 knowingly and willingly included; and

23 “(V) includes all representative
24 data and information known to the

1 petitioner that is favorable or unfavor-
2 able to the petition.

3 “(ii) APPLICABILITY OF CRIMINAL
4 PROVISION.—Section 1001 of title 18,
5 United States Code, shall apply to a per-
6 son that submits a petition under section
7 10.30 of title 21, Code of Federal Regula-
8 tions (or any successor regulation).

9 “(iii) INVESTIGATIONS.—

10 “(I) IN GENERAL.—The Federal
11 Trade Commission shall investigate,
12 on receipt of a complaint or upon its
13 own initiative, any petition submitted
14 under section 10.30 of title 21, Code
15 of Federal Regulations (or any suc-
16 cessor regulation), that may have been
17 submitted for an improper purpose,
18 such as to delay competition or agen-
19 cy action.

20 “(II) REFERRAL.—If the Com-
21 mission finds that a petitioner has en-
22 gaged in conduct that may be illegal,
23 the Commission shall refer the peti-
24 tion to the Antitrust Division of the

1 Department of Justice for further ac-
2 tion.

3 “(iv) NOTICE OF RECEIPT OF CONSID-
4 ERATION.—

5 “(I) IN GENERAL.—A person
6 that submits a petition under section
7 10.30 of title 21, Code of Federal
8 Regulations (or any successor regula-
9 tion), shall provide a written notice to
10 the Federal Trade Commission if the
11 person receives any consideration for
12 submitting the petition.

13 “(II) A notice under subclause
14 (I) shall include—

15 “(aa) the name of the per-
16 son or entity that provided the
17 consideration;

18 “(bb) the dollar value of the
19 consideration, if provided in cash,
20 or a description of such consider-
21 ation;

22 “(cc) the date on which the
23 consideration was provided; and

1 “(dd) any other information
2 that the Commission requires to
3 be disclosed.”.

4 **SEC. 406. PATENT CERTIFICATION.**

5 (a) ABBREVIATED NEW DRUG APPLICATIONS.—Sec-
6 tion 505(j)(5) of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 355(j)(5)) (as amended by section
8 403(a)(2)) is amended—

9 (1) in subparagraph (B), by striking clause (iii)
10 and inserting the following:

11 “(iii) CERTIFICATION THAT PATENT
12 IS INVALID OR WILL NOT BE INFRINGED.—

13 “(I) IN GENERAL.—Except as
14 provided in subclauses (II) and (III),
15 if the applicant made a certification
16 described in paragraph
17 (2)(A)(vii)(IV), the approval shall be
18 made effective on the expiration of 45
19 days after the date on which the no-
20 tice provided under paragraph
21 (2)(B)(ii) was received.

22 “(II) ACTION FOR PATENT IN-
23 FRINGEMENT.—If an action is
24 brought for infringement of a patent
25 that is the subject of the certification

1 before the expiration of the 45-day pe-
2 riod beginning on the date on which
3 the notice provided under paragraph
4 (2)(B)(ii) was received, the approval
5 shall be made effective on the expira-
6 tion of the 45-day period unless the
7 court grants a preliminary injunction
8 prohibiting the applicant from engag-
9 ing in the commercial manufacture or
10 sale of the drug until the court de-
11 cides the issues of patent validity and
12 infringement.

13 “(III) PATENT INVALID OR NOT
14 INFRINGED.—If the court decides that
15 the patent is invalid or was not in-
16 fringed, the approval shall be made ef-
17 fective on the date of the court deci-
18 sion.

19 “(IV) PATENT INFRINGED.—If
20 the court decides that the patent was
21 infringed, the approval shall be made
22 effective on such date as the court or-
23 ders under section 271(e)(4)(A) of
24 title 35, United States Code.

1 “(V) PROCEDURE.—In an action
2 described in subclause (II)—

3 “(aa) each of the parties
4 shall reasonably cooperate in ex-
5 pediting the action;

6 “(bb) until the expiration of
7 45 days after the date the notice
8 provided under paragraph
9 (2)(B)(i) was received, no civil
10 action may be brought under sec-
11 tion 2201 of title 28, United
12 States Code, for a declaratory
13 judgment with respect to the pat-
14 ent, except as provided in sub-
15 paragraph (H); and

16 “(cc) any such civil action
17 shall be brought in the judicial
18 district in which the defendant
19 has its principal place of business
20 or a regular and established place
21 of business.”; and

22 (2) by adding at the end the following:

23 “(G) CIVIL ACTION FOR DECLARATORY
24 JUDGMENT.—A person that files an abbreviated
25 application for a new drug under this para-

1 graph may bring a civil action against the hold-
2 er of an approved application for a listed drug
3 for a declaratory judgment to determine wheth-
4 er the patent that claims the listed drug or a
5 method of using the drug is invalid or will not
6 be infringed.

7 “(H) CIVIL ACTION TO DETERMINE LEGAL
8 STATUS.—Notwithstanding any other provision
9 of law, if information on a patent for a listed
10 drug has been published under subsection (c)(2)
11 for at least 1 year after the date on which an
12 abbreviated application for approval of a new
13 drug was filed under this subsection in relation
14 to the listed drug, the person that filed the ab-
15 breviated application or the holder of the ap-
16 proved application for the listed drug may im-
17 mediately bring a civil action to determine the
18 legal status of the patent for the listed drug.”.

19 (b) NEW DRUG APPLICATIONS.—Section 505(c)(3)
20 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
21 355(c)(3)) is amended by striking subparagraph (C) and
22 inserting the following:

23 “(C) CERTIFICATION THAT PATENT IS IN-
24 VALID OR WILL NOT BE INFRINGED.—

1 “(i) IN GENERAL.—Except as pro-
2 vided in clauses (ii) and (iii), if the appli-
3 cant made a certification described in sub-
4 section (b)(2)(A)(iv), the approval shall be
5 made effective on the expiration of 45 days
6 after the date on which the notice provided
7 under subsection (b)(3)(B) was received.

8 “(ii) ACTION BROUGHT BEFORE EXPI-
9 RATION OF 45 DAYS.—If an action is
10 brought for infringement of a patent that
11 is the subject of the certification before the
12 expiration of the 45-day period beginning
13 on the date the notice provided under sub-
14 section (b)(3)(B) was received, the ap-
15 proval shall be made effective on the expi-
16 ration of the 45-day period unless the
17 court grants a preliminary injunction pro-
18 hibiting the applicant from engaging in the
19 commercial manufacture or sale of the
20 drug until the court decides the issues of
21 patent validity and infringement.

22 “(iii) PATENT INVALID OR NOT IN-
23 FRINGED.—If the court decides that the
24 patent is invalid or not infringed, the ap-

1 proval shall be made effective on the date
2 of the court decision.

3 “(iv) PATENT INFRINGED.—If the
4 court decides that the patent has been in-
5 fringed, the approval may be made effec-
6 tive on such date as the court orders under
7 section 271(e)(4)(A) of title 35, United
8 States Code.

9 “(v) PROCEDURE.—In an action de-
10 scribed in clause (ii)—

11 “(I) each of the parties shall rea-
12 sonably cooperate in expediting the
13 action;

14 “(II) until the expiration of 45
15 days after the date the notice provided
16 under subsection (b)(3)(B) was re-
17 ceived, no civil action may be brought
18 under section 2201 of title 28, United
19 States Code, for a declaratory judg-
20 ment with respect to the patent, ex-
21 cept as provided in subsection
22 (j)(5)(H); and

23 “(III) any such civil action shall
24 be brought in the judicial district
25 where the defendant has its principal

1 place of business or a regular and es-
2 tablished place of business.”.

3 (c) EFFECTIVE DATE.—The amendments made by
4 this section shall not apply to an application submitted
5 under section 505 of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 355) before the date of the enact-
7 ment of this Act.

8 **SEC. 407. PATENT INFORMATION.**

9 Section 505 of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 355) is amended—

11 (1) in subsection (b), by striking “(b)(1) Any
12 person” and all that follows through paragraph (1)
13 and inserting the following:

14 “(b) APPLICATIONS.—

15 “(1) IN GENERAL.—

16 “(A) FILING.—Any person may file with
17 the Secretary an application with respect to any
18 drug subject to subsection (a).

19 “(B) CONTENTS.—A person that files an
20 application shall submit to the Secretary as a
21 part of the application with respect to a drug—

22 “(i) full reports of investigations that
23 have been made to show whether or not
24 such drug is safe for use and whether the
25 drug is effective in use;

1 “(ii) a full list of the articles used as
2 components of the drug;

3 “(iii) a full statement of the composi-
4 tion of the drug;

5 “(iv) a full description of the methods
6 used in, and the facilities and controls
7 used for, the manufacture, processing, and
8 packing of the drug;

9 “(v) such samples of the drug and of
10 the articles used as components of the
11 drug as the Secretary may require; and

12 “(vi) specimens of the labeling pro-
13 posed to be used for the drug.

14 “(C) PATENT INFORMATION.—

15 “(i) IN GENERAL.—The applicant
16 shall file with the application the patent
17 number and expiration date of any patent
18 that claims a drug or method of using a
19 drug and with respect to which a claim of
20 patent infringement could reasonably be
21 asserted if a person not licensed by the
22 owner engaged in the manufacture, use, or
23 sale of the drug for which the applicant
24 submitted the application.

1 “(ii) AMENDMENT OF APPLICATION.—

2 If an application is filed with respect to a
3 drug and a patent as described in clause
4 (i) is issued after the filing date but before
5 approval of the application, the applicant
6 shall amend the application to include the
7 information required by clause (i).

8 “(iii) PUBLICATION OF INFORMA-
9 TION.—On approval of the application, the
10 Secretary shall publish information sub-
11 mitted under clauses (i) and (ii).

12 “(D) GUIDANCE.—The Secretary shall, in
13 consultation with the Director of the National
14 Institutes of Health and with representatives of
15 the drug manufacturing industry, review and
16 develop guidance, as appropriate, on the inclu-
17 sion of women and minorities in clinical trials
18 required by subparagraph (B)(i).”; and

19 (2) in paragraph (2)(A)—

20 (A) by striking “which claims” the first
21 place it appears and all that follows through
22 “subsection and”; and

23 (B) by striking “subsection (c)—” and in-
24 serting “and with respect to which a claim of
25 patent infringement could reasonably be as-

1 serted if a person not licensed by the owner en-
2 gaged in the manufacture, use, or sale of the
3 drug for which the investigations were con-
4 ducted—”;

5 (3) in the first sentence of subsection (c)(2)—

6 (A) by inserting “such patent information”
7 after “shall file”; and

8 (B) by striking “Secretary,” and all that
9 follows and inserting “Secretary.”;

10 (4) in subsection (j)(2)(vii), by striking “which
11 claims the listed drug” and all that follows through
12 “under this subsection and” and inserting “for the
13 listed drug referred to in clause (i)”; and

14 (5) by adding at the end the following:

15 “(o) PATENT INFORMATION.—

16 “(1) APPLICABILITY.—This subsection applies
17 to a holder of an approved application under sub-
18 section (c) that files a patent—

19 “(A) that claims, with regard to a drug of
20 the application, a drug or method of using a
21 drug; and

22 “(B) for which a claim of patent infringe-
23 ment could reasonably be asserted if a person
24 not licensed by the owner engaged in the manu-

1 facture, use, or sale of the drug, after the date
2 of approval of the application.

3 “(2) CERTIFICATION.—A holder of a patent de-
4 scribed in paragraph (1) shall—

5 “(A) inform the Secretary of the filing of
6 the patent; and

7 “(B) certify that the information is a com-
8 plete and accurate listing of all such patents.

9 “(3) SECRETARY.—The Secretary shall list the
10 information provided under paragraph (2) in accord-
11 ance with subsection (j)(7).”.

12 **SEC. 408. REPORT.**

13 (a) IN GENERAL.—Not later than the date that is
14 5 years after the date of the enactment of this Act, the
15 Federal Trade Commission shall submit to Congress a re-
16 port describing the extent to which implementation of the
17 amendments made by this title—

18 (1) has enabled products to come to market in
19 a fair and expeditious manner, consistent with the
20 rights of patent owners under intellectual property
21 law; and

22 (2) has promoted lower prices of drugs and
23 greater access to drugs through price competition.

1 (b) AUTHORIZATION OF APPROPRIATIONS.—There is
2 authorized to be appropriated to carry out this section
3 \$5,000,000.

4 **TITLE V—NONDISCRIMINATION**
5 **AGAINST IMPORTS OF PRE-**
6 **SCRIPTION DRUGS.**

7 **SEC. 501. SHORT TITLE.**

8 This title may be cited as the “Preserving Access to
9 Safe Affordable Canadian Medicines Act of 2003”.

10 **SEC. 502. FINDINGS.**

11 The Congress makes the following findings:

12 (1) Prescription drug manufacturers charge
13 substantially more for their products in the United
14 States than in Canada.

15 (2) Many Americans cannot afford the higher
16 U.S. prices and are forced to either go without their
17 needed medications or sacrifice other necessities of
18 life in order to afford them.

19 (3) Increasingly, Americans have turned to the
20 Canadian market to purchase their needed medica-
21 tions at substantially lower prices and the Food and
22 Drug Administration now estimates that two million
23 parcels containing prescription drugs enter the U.S.
24 for personal use each year.

1 “(b) NONDISCRIMINATION.—No manufacturer of a
2 prescription medication may take actions that discrimi-
3 nate against, or cause other persons to discriminate
4 against, United States consumers regarding the purchase
5 of a prescription medication from Canadian pharmacies.

6 “(c) DEFINITION.—For purposes of this section, the
7 term ‘discrimination’ means a contract provision, a limita-
8 tion on supply, or other measure which has the effect of
9 providing U.S. consumers access to prescription medica-
10 tions on terms or conditions that are less favorable than
11 the terms or conditions provided to any foreign purchaser
12 of such products, or otherwise has the effect of restricting
13 or reducing access by United States consumers to a pre-
14 scription medication from Canadian pharmacies.”.

15 (b) PROHIBITED ACT.—Section 301 of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
17 ed by adding at the end the following:

18 “(hh) Discrimination by a manufacturer in violation
19 of section 805.”.

20 (c) CIVIL PENALTIES.—Section 303 of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amend-
22 ed by adding at the end the following subsection:

23 “(h)(1) Any manufacturer of a prescription medica-
24 tion that knowingly violates section 805(b) shall be liable

1 to the United States for a civil penalty in an amount not
2 to exceed \$1,000,000.

3 “(2) Paragraphs (3) through (5) of subsection (g)
4 apply with respect to a civil penalty under paragraph (1)
5 of this subsection to the same extent and in the same man-
6 ner as such paragraphs (3) through (5) apply with respect
7 to a civil penalty under paragraph (1) or (2) of subsection
8 (g).”.

9 **TITLE VI—REQUIREMENT FOR**
10 **WRITTEN STATEMENT OF**
11 **TOTAL COST OF RESEARCH**
12 **FOR APPROVAL OF NEW**
13 **DRUGS**

14 **SEC. 601. REQUIREMENT FOR WRITTEN STATEMENT OF**
15 **TOTAL COST OF RESEARCH FOR APPROVAL**
16 **OF NEW DRUGS.**

17 Notwithstanding any other provision of law, the Com-
18 missioner of Food and Drugs may not approve any appli-
19 cation for a new drug submitted on or after the date of
20 the enactment of this Act by an entity that does not, be-
21 fore completion of the approval process, provide to the
22 Secretary of Health and Human Services a written state-
23 ment specifying the total cost of research and development
24 with respect to such drug, by stage of drug development,

1 including a separate statement specifying the portion paid
2 with Federal funds and the portion paid with State funds.

3 **TITLE VII—PROHIBITION ON**
4 **CERTAIN CAMPAIGN CON-**
5 **TRIBUTIONS**

6 **SEC. 701. PROHIBITION ON CAMPAIGN CONTRIBUTIONS BY**
7 **CHIEF EXECUTIVE OFFICERS OF PHARMA-**
8 **CEUTICAL COMPANIES.**

9 Section 315 of Federal Election Campaign Act of
10 1971 (2 U.S.C. 441a) is amended by adding at the end
11 the following new subsection:

12 “(k) PROHIBITION ON CAMPAIGN CONTRIBUTIONS
13 BY CHIEF EXECUTIVE OFFICERS OF PHARMACEUTICAL
14 COMPANIES.—No individual who is a chief executive offi-
15 cer of a pharmaceutical company may make a contribution
16 to a political party or candidate.”.

17 **TITLE VIII—ADDITIONAL**
18 **PROVISIONS**

19 **SEC. 801. REPEAL OF FEBRUARY 2002 INCREASE IN COPAY-**
20 **MENTS FOR MEDICATIONS FURNISHED TO**
21 **VETERANS BY THE DEPARTMENT OF VET-**
22 **ERANS AFFAIRS.**

23 (a) RESCISSION OF INCREASE IN VETERANS MEDICA-
24 TION COPAYMENT.—The February 2002 veterans medica-
25 tion copayment increase is hereby rescinded. The copay-

1 ment amount for purposes of section 1722A(a) of title 38,
2 United States Code, is reinstated as \$2, effective as of
3 the date of the enactment of this Act.

4 (b) FEBRUARY 2002 VETERANS MEDICATION CO-
5 PAYMENT INCREASE DEFINED.—For purposes of sub-
6 section (a), the term “February 2002 veterans medication
7 copayment increase” means the increase in the copayment
8 amount in effect under section 1722A(a) of title 38,
9 United States Code, that was effective on February 4,
10 2002, in accordance with an announcement by the Sec-
11 retary of Veterans Affairs of December 6, 2001, pursuant
12 to a direction from the President.

13 **SEC. 802. SOCIAL SECURITY AND MEDICARE LOCK BOX.**

14 All Social Security and Medicare funds shall be
15 walled off into a lock box that may not be raided for new
16 programs or tax cuts for the rich.

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