

108TH CONGRESS
1ST SESSION

H. R. 2514

To freeze and repeal portions of the tax cut enacted in the Economic Growth and Tax Relief Reconciliation Act of 2001 and to apply savings therefrom to a comprehensive Medicare outpatient prescription drug benefit.

IN THE HOUSE OF REPRESENTATIVES

JUNE 18, 2003

Mr. WEXLER (for himself, Mr. STARK, Mr. WAXMAN, Mr. BROWN of Ohio, Mr. FRANK of Massachusetts, Mr. NADLER, Mr. CONYERS, and Mr. GRIJALVA) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, 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 freeze and repeal portions of the tax cut enacted in the Economic Growth and Tax Relief Reconciliation Act of 2001 and to apply savings therefrom to a comprehensive Medicare outpatient prescription drug benefit.

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.**

4 This Act may be cited as the “Honor Thy Parents
5 Act of 2003”.

TITLE I—TAX PROVISIONS**SEC. 101. FREEZE AND REPEAL OF PORTIONS OF THE TAX
CUT ENACTED IN THE ECONOMIC GROWTH
AND TAX RELIEF RECONCILIATION ACT OF
2001.**

Notwithstanding any provision of or amendment to the Internal Revenue Code of 1986 made by the Economic Growth and Tax Relief Reconciliation Act of 2001—

(1) any reduction in any rate of tax made by any amendment made by such Act which is scheduled to take effect for a year after 2003, and

(2) any increase in any deduction, limitation, or credit made by any amendment made by such Act which is scheduled to take effect for a year after 2003,

is hereby suspended. For any year for which the suspension is in effect under subsection (a), the Internal Revenue Code of 1986 and the Employee Retirement Income Security Act of 1974 shall be applied and administered as such Code and Act were in effect for years beginning in 2003.

1 **TITLE II—MEDICARE**
2 **PRESCRIPTION DRUG BENEFITS**

3 **SEC. 201. VOLUNTARY MEDICARE OUTPATIENT PRESCRIP-**
4 **TION MEDICINE PROGRAM.**

5 (a) IN GENERAL.—Title XVIII (42 U.S.C. 1395 et
6 seq.) is amended—

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

9 (2) by inserting after part C the following new
10 part:

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

13 “MEDICARE OUTPATIENT PRESCRIPTION MEDICINE
14 BENEFIT

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

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

19 “(2) DEDUCTIBLE.—The annual deductible is
20 \$100.

21 “(3) COINSURANCE.—The coinsurance is 20
22 percent.

23 “(4) OUT-OF-POCKET LIMIT.—The annual limit
24 on out-of-pocket spending on covered medicines is
25 \$2,000.

1 “NEGOTIATING FAIR PRICES WITH PHARMACEUTICAL
2 MANUFACTURERS

3 “SEC. 1859A. (a) AUTHORITY TO NEGOTIATE
4 PRICES WITH MANUFACTURERS.—The Secretary shall,
5 consistent with the requirements of this part and the goals
6 of providing quality care and containing costs under this
7 part, negotiate contracts with manufacturers of covered
8 outpatient prescription medicines that provide for the
9 maximum prices that may be charged to individuals en-
10 rolled under this part by participating pharmacies for dis-
11 pensing such medicines to such individuals.

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

17 “CONTRACT AUTHORITY

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

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

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

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

4 “(B) awards contracts to such contractors
5 to administer benefits under this part to eligible
6 beneficiaries in the region or on a national
7 basis; and

8 “(C) provides for the termination (and
9 nonrenewal) of a contract in the case of a con-
10 tractor’s failure to meet the requirements of the
11 contract and this part.

12 “(3) COMPETITIVE PROCEDURES.—Competitive
13 procedures (as defined in section 4(5) of the Office
14 of Federal Procurement Policy Act (41 U.S.C.
15 403(5))) shall be used to enter into contracts under
16 this part.

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

22 “(5) USE OF PHARMACY CONTRACTORS IN
23 PRICE NEGOTIATIONS.—Such contracts shall require
24 the contractor involved to negotiate contracts with
25 manufacturers that provide for maximum prices for

1 covered outpatient prescription medicines that are
2 lower than the maximum prices negotiated under
3 section 1859A(a), if applicable. The price reductions
4 shall be passed on to eligible beneficiaries and the
5 Secretary shall hold the contractor accountable for
6 meeting performance requirements with respect to
7 price reductions and limiting price increases.

8 “(6) AREA FOR CONTRACTS.—

9 “(A) REGIONAL BASIS.—

10 “(i) IN GENERAL.—Except as pro-
11 vided in clause (ii) and subject to subpara-
12 graph (B), the contract entered into be-
13 tween the Secretary and a pharmacy con-
14 tractor shall require the contractor to ad-
15 minister the benefits under this part in a
16 region determined by the Secretary under
17 subparagraph (B) or on a national basis.

18 “(ii) PARTIAL REGIONAL BASIS.—

19 “(I) IN GENERAL.—If deter-
20 mined appropriate by the Secretary,
21 the Secretary may permit the benefits
22 to be administered in a partial region
23 determined appropriate by the Sec-
24 retary.

1 “(II) REQUIREMENTS.—If the
2 Secretary permits administration pur-
3 suant to subclause (I), the Secretary
4 shall ensure that the partial region in
5 which administration is effected is no
6 smaller than a State and is at least
7 the size of the commercial service area
8 of the contractor for that area.

9 “(B) DETERMINATION.—

10 “(i) IN GENERAL.—In determining re-
11 gions for contracts under this part, the
12 Secretary shall—

13 “(I) take into account the num-
14 ber of individuals enrolled under this
15 part in an area in order to encourage
16 participation by pharmacy contrac-
17 tors; and

18 “(II) ensure that there are at
19 least 10 different regions in the
20 United States.

21 “(ii) NO ADMINISTRATIVE OR JUDI-
22 CIAL REVIEW.—The determination of ad-
23 ministrative areas under this paragraph
24 shall not be subject to administrative or ju-
25 dicial review.

1 “(7) SUBMISSION OF BIDS.—

2 “(A) SUBMISSION.—

3 “(i) IN GENERAL.—Subject to sub-
4 paragraph (B), each entity desiring to
5 serve as a pharmacy contractor under this
6 part in an area shall submit a bid with re-
7 spect to such area to the Secretary at such
8 time, in such manner, and accompanied by
9 such information as the Secretary may rea-
10 sonably require.

11 “(ii) BID THAT COVERS MULTIPLE
12 AREAS.—The Secretary shall permit an en-
13 tity to submit a single bid for multiple
14 areas if the bid is applicable to all such
15 areas.

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

18 “(i) a proposal for the estimated
19 prices of covered outpatient prescription
20 medicines and the projected annual in-
21 creases in such prices, including the addi-
22 tional reduction in price negotiated below
23 the Secretary’s maximum price and dif-
24 ferentials between preferred and nonpre-
25 ferred prices, if applicable;

1 “(ii) a statement regarding the
2 amount that the entity will charge the Sec-
3 retary for administering the benefits under
4 the contract;

5 “(iii) a statement regarding whether
6 the entity will reduce the applicable coin-
7 surance percentage pursuant to section
8 1859E(a)(1)(A)(ii) and if so, the amount
9 of such reduction and how such reduction
10 is tied to the performance requirements de-
11 scribed in subsection (c)(4)(A)(ii);

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

16 “(v) a detailed description of access to
17 pharmacy services provided by the entity,
18 including information regarding whether
19 the pharmacy contractor will use a pre-
20 ferred pharmacy network, and, if so, how
21 the pharmacy contractor will ensure access
22 to pharmacies that choose to be outside of
23 that network, and whether there will be in-
24 creased cost-sharing for beneficiaries if
25 they obtain medicines at such pharmacies;

1 “(vi) a detailed description of the pro-
2 cedures and standards the entity will use
3 for—

4 “(I) selecting preferred prescrip-
5 tion medicines; and

6 “(II) determining when and how
7 often the list of preferred prescription
8 medicines should be modified;

9 “(vii) a detailed description of any
10 ownership or shared financial interests
11 with pharmaceutical manufacturers, phar-
12 macies, and other entities involved in the
13 administration or delivery of benefits under
14 this part as proposed in the bid;

15 “(viii) a detailed description of the en-
16 tity’s estimated marketing and advertising
17 expenditures related to enrolling and re-
18 taining eligible beneficiaries; and

19 “(ix) such other information that the
20 Secretary determines is necessary in order
21 to carry out this part, including informa-
22 tion relating to the bidding process under
23 this part.

24 The procedures under clause (vi) shall include
25 the use of a pharmaceutical and therapeutics

1 committee the members of which include prac-
2 ticing pharmacists.

3 “(8) AWARDING OF CONTRACTS.—

4 “(A) NUMBER OF CONTRACTS.—The Sec-
5 retary shall, consistent with the requirements of
6 this part and the goals of providing quality care
7 and of containing costs under this part, award
8 in a competitive manner at least 2 contracts to
9 administer benefits under this part in each area
10 specified under paragraph (6), unless only 1
11 pharmacy contractor submitting a bid meets the
12 minimum standards specified under this part
13 and by the Secretary.

14 “(B) DETERMINATION.—In determining
15 which of the pharmacy contractors that sub-
16 mitted bids that meet the minimum standards
17 specified under this part and by the Secretary
18 to award a contract, the Secretary shall con-
19 sider the comparative merits of each bid, as de-
20 termined on the basis of relevant factors, with
21 respect to—

22 “(i) how well the contractor meets
23 such minimum standards;

1 “(ii) the amount that the contractor
2 will charge the Secretary for administering
3 the benefits under the contract;

4 “(iii) the performance standards es-
5 tablished under subsection (c)(2) and per-
6 formance requirements for which the ad-
7 ministrative fee of the entity will be subject
8 to risk pursuant to subsection (c)(4)(A)(ii);

9 “(iv) the proposed negotiated prices of
10 covered outpatient medicines and annual
11 increases in such prices;

12 “(v) factors relating to benefits, qual-
13 ity and performance, beneficiary cost-shar-
14 ing, and consumer satisfaction;

15 “(vi) past performance and prior ex-
16 perience of the contractor in administering
17 a prescription medicine benefit program;

18 “(vii) effectiveness of the contractor
19 in containing costs through pricing incen-
20 tives and utilization management; and

21 “(viii) such other factors as the Sec-
22 retary deems necessary to evaluate the
23 merits of each bid.

24 “(C) EXCEPTION TO CONFLICT OF INTER-
25 EST RULES.—In awarding contracts with phar-

1 macy contractors under this part, the Secretary
2 may waive conflict of interest laws generally ap-
3 plicable to Federal acquisitions (subject to such
4 safeguards as the Secretary may find necessary
5 to impose) in circumstances where the Sec-
6 retary finds that such waiver—

7 “(i) is not inconsistent with the—

8 “(I) purposes of the programs
9 under this part; or

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

12 “(ii) permits a sufficient level of com-
13 petition for such contracts, promotes effi-
14 ciency of benefits administration, or other-
15 wise serves the objectives of the program
16 under this part.

17 “(D) NO ADMINISTRATIVE OR JUDICIAL
18 REVIEW.—The determination of the Secretary
19 to award or not award a contract to a phar-
20 macy contractor under this part shall not be
21 subject to administrative or judicial review.

22 “(9) ACCESS TO BENEFITS IN CERTAIN
23 AREAS.—

24 “(A) AREAS NOT COVERED BY CON-
25 TRACTS.—The Secretary shall develop proce-

1 dures for the provision of covered outpatient
2 prescription medicines under this part to each
3 eligible beneficiary enrolled under this part that
4 resides in an area that is not covered by any
5 contract under this part.

6 “(B) BENEFICIARIES RESIDING IN DIF-
7 FERENT LOCATIONS.—The Secretary shall de-
8 velop procedures to ensure that each eligible
9 beneficiary enrolled under this part that resides
10 in different areas in a year is provided the ben-
11 efits under this part throughout the entire year.

12 “(b) QUALITY, FINANCIAL, AND OTHER STANDARDS
13 AND PROGRAMS.—In consultation with appropriate phar-
14 macy contractors, pharmacists, and health care profes-
15 sionals with expertise in prescribing, dispensing, and the
16 appropriate use of prescription medicines, the Secretary
17 shall establish standards and programs for the administra-
18 tion of this part to ensure appropriate prescribing, dis-
19 pensing, and utilization of outpatient medicines under this
20 part, to avoid adverse medicine reactions, and to contin-
21 ually reduce errors in the delivery of medically appropriate
22 covered benefits. The Secretary shall not award a contract
23 to a pharmacy contractor under this part unless the Sec-
24 retary finds that the contractor agrees to comply with
25 such standards and programs and other terms and condi-

1 tions as the Secretary shall specify. The standards and
2 programs under this subsection shall be applied to any ad-
3 ministrative agreements described in subsection (a) the
4 Secretary enters into. Such standards and programs shall
5 include the following:

6 “(1) ACCESS.—

7 “(A) IN GENERAL.—The pharmacy con-
8 tractor shall ensure that covered outpatient pre-
9 scription medicines are accessible and conven-
10 ient to eligible beneficiaries enrolled under this
11 part for whom benefits are administered by the
12 pharmacy contractor, including by offering the
13 services 24 hours a day and 7 days a week for
14 emergencies.

15 “(B) ON-LINE REVIEW.—The pharmacy
16 contractor shall provide for on-line prospective
17 review available 24 hours a day and 7 days a
18 week in order to evaluate each prescription for
19 medicine therapy problems due to duplication,
20 interaction, or incorrect dosage or duration of
21 therapy.

22 “(C) GUARANTEED ACCESS TO MEDICINES
23 IN RURAL AND HARD-TO-SERVE AREAS.—The
24 Secretary shall ensure that all beneficiaries
25 have guaranteed access to the full range of

1 pharmaceuticals under this part, and shall give
2 special attention to access, pharmacist coun-
3 seling, and delivery in rural and hard-to-serve
4 areas, including through the use of incentives
5 such as bonus payments to retail pharmacists
6 in rural areas and extra payments to the phar-
7 macy contractor for the cost of rapid delivery of
8 pharmaceuticals and any other actions nec-
9 essary.

10 “(D) PREFERRED PHARMACY NET-
11 WORKS.—

12 “(i) IN GENERAL.—If a pharmacy
13 contractor uses a preferred pharmacy net-
14 work to deliver benefits under this part,
15 such network shall meet minimum access
16 standards established by the Secretary.

17 “(ii) STANDARDS.—In establishing
18 standards under clause (i), the Secretary
19 shall take into account reasonable dis-
20 tances to pharmacy services in both urban
21 and rural areas.

22 “(E) ADHERENCE TO NEGOTIATED
23 PRICES.—The pharmacy contractor shall have
24 in place procedures to assure compliance of
25 pharmacies with the requirements of subsection

1 (d)(3)(C) (relating to adherence to negotiated
2 prices).

3 “(F) CONTINUITY OF CARE.—

4 “(i) IN GENERAL.—The pharmacy
5 contractor shall ensure that, in the case of
6 an eligible beneficiary who loses coverage
7 under this part with such entity under cir-
8 cumstances that would permit a special
9 election period (as established by the Sec-
10 retary under section 1859C(b)(3)), the
11 contractor will continue to provide cov-
12 erage under this part to such beneficiary
13 until the beneficiary enrolls and receives
14 such coverage with another pharmacy con-
15 tractor under this part or, if eligible, with
16 a Medicare+Choice organization.

17 “(ii) LIMITED PERIOD.—In no event
18 shall a pharmacy contractor be required to
19 provide the extended coverage required
20 under clause (i) beyond the date which is
21 30 days after the coverage with such con-
22 tractor would have terminated but for this
23 subparagraph.

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

4 “(A) the proper use of covered outpatient
5 prescription medicine: and

6 “(B) interactions and contra-indications.

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

10 “(A) instances or patterns concerning the
11 unnecessary or inappropriate prescribing or dis-
12 pensing of covered outpatient prescription medi-
13 cines;

14 “(B) instances or patterns of substandard
15 care;

16 “(C) potential adverse reactions to covered
17 outpatient prescription medicines;

18 “(D) inappropriate use of antibiotics;

19 “(E) appropriate use of generic products;
20 and

21 “(F) the importance of using covered out-
22 patient prescription medicines in accordance
23 with the instruction of prescribing providers.

24 “(4) COORDINATION.—The pharmacy con-
25 tractor shall coordinate with State prescription med-

1 icine programs, other pharmacy contractors, phar-
2 macies, and other relevant entities as necessary to
3 ensure appropriate coordination of benefits with re-
4 spect to enrolled individuals when such individual is
5 traveling outside the home service area, and under
6 such other circumstances as the Secretary may
7 specify.

8 “(5) COST DATA.—

9 “(A) The pharmacy contractor shall make
10 data on prescription medicine negotiated prices
11 (including data on discounts) available to the
12 Secretary.

13 “(B) The Secretary shall require, either di-
14 rectly or through a pharmacy contractor, that
15 participating pharmacists, physicians, and man-
16 ufacturers—

17 “(i) maintain their prescription medi-
18 cine cost data (including data on dis-
19 counts) in a form and manner specified by
20 the Secretary;

21 “(ii) make such prescription medicine
22 cost data available for review and audit by
23 the Secretary; and

24 “(iii) certify that the prescription
25 medicine cost data are current, accurate,

1 and complete, and reflect all discounts ob-
2 tained by the pharmacist or physician in
3 the purchasing of covered outpatient pre-
4 scription medicines.

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

11 “(6) REPORTING.—The pharmacy contractor
12 shall provide the Secretary with periodic reports
13 on—

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

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

17 “(C) marketing and advertising expendi-
18 tures related to enrolling and retaining individ-
19 uals under this part; and

20 “(D) grievances and appeals.

21 “(7) RECORDS AND AUDITS.—The pharmacy
22 contractor shall maintain adequate records related to
23 the administration of benefits under this part and
24 afford the Secretary access to such records for au-
25 diting purposes.

1 “(8) APPROVAL OF MARKETING MATERIAL AND
2 APPLICATION FORMS.—The pharmacy contractor
3 shall comply with requirements of section 1851(h)
4 (relating to marketing material and application
5 forms) with respect to this part in the same manner
6 as such requirements apply under part C, except
7 that the provisions of paragraph (4)(A) of such sec-
8 tion shall not apply with respect to discounts or re-
9 bates provided in accordance with this part.

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

12 “(1) IN GENERAL.—The Secretary shall include
13 in a contract awarded under subsection (b) with a
14 pharmacy contractor such incentives for cost and
15 utilization management and quality improvement as
16 the Secretary may deem appropriate. The contract
17 may provide financial or other incentives to encour-
18 age greater savings to the program under this part.

19 “(2) PERFORMANCE STANDARDS.—The Sec-
20 retary shall provide for performance standards
21 (which may include monetary bonuses if the stand-
22 ards are met and penalties if the standards are not
23 met), including standards relating to the time taken
24 to answer member and pharmacy inquiries (written
25 or by telephone), the accuracy of responses, claims

1 processing accuracy, online system availability, ap-
2 peal procedure turnaround time, system availability,
3 the accuracy and timeliness of reports, and level of
4 beneficiary satisfaction.

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

7 “(A) financial incentives under which sav-
8 ings derived from the substitution of generic
9 and other preferred multi-source medicines in
10 lieu of nongeneric and nonpreferred medicines
11 are made available to pharmacy contractors,
12 pharmacies, beneficiaries, and the Federal
13 Medicare Prescription Medicine Trust Fund;
14 and

15 “(B) any other incentive that the Secretary
16 deems appropriate and likely to be effective in
17 managing costs or utilization or improving qual-
18 ity that does not reduce the access of bene-
19 ficiaries to medically necessary covered out-
20 patient medicines.

21 “(4) REQUIREMENTS FOR PROCEDURES.—

22 “(A) IN GENERAL.—The Secretary shall
23 establish procedures for making payments to
24 each pharmacy contractor with a contract under
25 this part for the administration of the benefits

1 under this part. The procedures shall provide
2 for the following:

3 “(i) ADMINISTRATIVE PAYMENT.—

4 Payment of administrative fees for such
5 administration.

6 “(ii) RISK REQUIREMENT.—An ad-

7 justment of a percentage (determined
8 under subparagraph (B)) of the adminis-
9 trative fee payments made to a pharmacy
10 contractor to ensure that the contractor, in
11 administering the benefits under this part,
12 pursues performance requirements estab-
13 lished by the Secretary, including the fol-
14 lowing:

15 “(I) QUALITY SERVICE.—The

16 contractor provides eligible bene-
17 ficiaries for whom it administers bene-
18 fits with quality services, as measured
19 by such factors as sustained pharmacy
20 network access, timeliness and accu-
21 racy of service delivery in claims proc-
22 essing and card production, pharmacy
23 and member service support access,
24 and timely action with regard to ap-

1 peals and current beneficiary service
2 surveys.

3 “(II) QUALITY CLINICAL CARE.—

4 The contractor provides such bene-
5 ficiaries with quality clinical care, as
6 measured by such factors as providing
7 notification to such beneficiaries and
8 to providers in order to prevent ad-
9 verse drug reactions and reduce medi-
10 cation errors and specific clinical sug-
11 gestions to improve health and patient
12 and prescriber education as appro-
13 priate.

14 “(III) CONTROL OF MEDICARE

15 COSTS.—The contractor contains costs
16 under this part to the Federal Medi-
17 care Prescription Medicine Trust
18 Fund and enrollees, as measured by
19 generic substitution rates, price dis-
20 counts, and other factors determined
21 appropriate by the Secretary that do
22 not reduce the access of beneficiaries
23 to medically necessary covered out-
24 patient prescription medicines.

1 “(B) PERCENTAGE OF PAYMENT TIED TO
2 RISK.—

3 “(i) IN GENERAL.—Subject to clause
4 (ii), the Secretary shall determine the per-
5 centage of the administrative payments to
6 a pharmacy contractor that will be tied to
7 the performance requirements described in
8 subparagraph (A)(ii).

9 “(ii) LIMITATION ON RISK TO ENSURE
10 PROGRAM STABILITY.—In order to provide
11 for program stability, the Secretary may
12 not establish a percentage to be adjusted
13 under this paragraph at a level that jeop-
14 ardizes the ability of a pharmacy con-
15 tractor to administer the benefits under
16 this part or administer such benefits in a
17 quality manner.

18 “(C) RISK ADJUSTMENT OF PAYMENTS
19 BASED ON ENROLLEES IN PLAN.—To the extent
20 that a pharmacy contractor is at risk under this
21 paragraph, the procedures established under
22 this paragraph may include a methodology for
23 risk adjusting the payments made to such con-
24 tractor based on the differences in actuarial
25 risk of different enrollees being served if the

1 Secretary determines such adjustments to be
2 necessary and appropriate.

3 “(d) AUTHORITY RELATING TO PHARMACY PARTICI-
4 PATION.—

5 “(1) IN GENERAL.—Subject to the succeeding
6 provisions of this subsection, a pharmacy contractor
7 may establish consistent with this part conditions for
8 the participation of pharmacies, including conditions
9 relating to quality (including reduction of medical
10 errors) and technology.

11 “(2) AGREEMENTS WITH PHARMACIES.—Each
12 pharmacy contractor shall enter into a participation
13 agreement with any pharmacy that meets the re-
14 quirements of this subsection and section 1859E to
15 furnish covered outpatient prescription medicines to
16 individuals enrolled under this part.

17 “(3) TERMS OF AGREEMENT.—An agreement
18 under this subsection shall include the following
19 terms and conditions:

20 “(A) APPLICABLE REQUIREMENTS.—The
21 pharmacy shall meet (and throughout the con-
22 tract period continue to meet) all applicable
23 Federal requirements and State and local li-
24 censing requirements.

1 “(B) ACCESS AND QUALITY STANDARDS.—
2 The pharmacy shall comply with such standards
3 as the Secretary (and such a pharmacy con-
4 tractor) shall establish concerning the quality
5 of, and enrolled individuals’ access to, phar-
6 macy services under this part. Such standards
7 shall require the pharmacy—

8 “(i) not to refuse to dispense covered
9 outpatient prescription medicines to any
10 individual enrolled under this part;

11 “(ii) to keep patient records (includ-
12 ing records on expenses) for all covered
13 outpatient prescription medicines dispensed
14 to such enrolled individuals;

15 “(iii) to submit information (in a
16 manner specified by the Secretary to be
17 necessary to administer this part) on all
18 purchases of such medicines dispensed to
19 such enrolled individuals; and

20 “(iv) to comply with periodic audits to
21 assure compliance with the requirements of
22 this part and the accuracy of information
23 submitted.

24 “(C) ADHERENCE TO NEGOTIATED
25 PRICES.—(i) The total charge for each medicine

1 dispensed by the pharmacy to an enrolled indi-
2 vidual under this part, without regard to wheth-
3 er the individual is financially responsible for
4 any or all of such charge, shall not exceed the
5 price negotiated under section 1859A(a) or, if
6 lower, negotiated under subsection (a)(5) (or, if
7 less, the retail price for the medicine involved)
8 with respect to such medicine plus a reasonable
9 dispensing fee determined contractually with
10 the pharmacy contractor.

11 “(ii) The pharmacy does not charge (or
12 collect from) an enrolled individual an amount
13 that exceeds the individual’s obligation (as de-
14 termined in accordance with the provisions of
15 this part) of the applicable price described in
16 clause (i).

17 “(D) ADDITIONAL REQUIREMENTS.—The
18 pharmacy shall meet such additional contract
19 requirements as the applicable pharmacy con-
20 tractor specifies under this section.

21 “(4) APPLICABILITY OF FRAUD AND ABUSE
22 PROVISIONS.—The provisions of section 1128
23 through 1128C (relating to fraud and abuse) apply
24 to pharmacies participating in the program under
25 this part.

1 “ELIGIBILITY; VOLUNTARY ENROLLMENT; COVERAGE

2 “SEC. 1859C. (a) ELIGIBILITY.—Each individual
3 who is entitled to hospital insurance benefits under part
4 A or is eligible to be enrolled in the medical insurance pro-
5 gram under part B is eligible to enroll in accordance with
6 this section for outpatient prescription medicine benefits
7 under this part.

8 “(b) VOLUNTARY ENROLLMENT.—

9 “(1) IN GENERAL.—An individual may enroll
10 under this part only in such manner and form as
11 may be prescribed by regulations, and only during
12 an enrollment period prescribed in or under this sub-
13 section.

14 “(2) INITIAL ENROLLMENT PERIOD.—

15 “(A) INDIVIDUALS CURRENTLY COV-
16 ERED.—In the case of an individual who satis-
17 fies subsection (a) as of November 1, 2005, the
18 initial general enrollment period shall begin on
19 August 1, 2005, and shall end on March 1,
20 2006.

21 “(B) INDIVIDUAL COVERED IN FUTURE.—

22 In the case of an individual who first satisfies
23 subsection (a) on or after November 1, 2005,
24 the individual’s initial enrollment period shall
25 begin on the first day of the third month before

1 the month in which such individual first satis-
2 fies such paragraph and shall end seven months
3 later. The Secretary shall apply rules similar to
4 the rule described in the second sentence of sec-
5 tion 1837(d).

6 “(3) SPECIAL ENROLLMENT PERIODS (WITHOUT
7 PREMIUM PENALTY).—

8 “(A) EMPLOYER COVERAGE AT TIME OF
9 INITIAL GENERAL ENROLLMENT PERIOD.—In
10 the case of an individual who—

11 “(i) at the time the individual first
12 satisfies subsection (a) is enrolled in a
13 group health plan (including continuation
14 coverage) that provides outpatient pre-
15 scription medicine coverage by reason of
16 the individual’s (or the individual’s
17 spouse’s) current (or, in the case of con-
18 tinuation coverage, former) employment
19 status, and

20 “(ii) has elected not to enroll (or to be
21 deemed enrolled) under this subsection
22 during the individual’s initial enrollment
23 period,

24 there shall be a special enrollment period of 6
25 months beginning with the first month that in-

1 includes the date of the individual's (or individ-
2 ual's spouse's) retirement from or termination
3 of current employment status with the employer
4 that sponsors the plan, or, in the case of con-
5 tinuation coverage, that includes the date of
6 termination of such coverage, or that includes
7 the date the plan substantially terminates out-
8 patient prescription medicine coverage.

9 “(B) DROPPING OF RETIREE PRESCRIP-
10 TION MEDICINE COVERAGE.—In the case of an
11 individual who—

12 “(i) at the time the individual first
13 satisfies subsection (a) is enrolled in a
14 group health plan that provides outpatient
15 prescription medicine coverage other than
16 by reason of the individual's (or the indi-
17 vidual's spouse's) current employment; and

18 “(ii) has elected not to enroll (or to be
19 deemed enrolled) under this subsection
20 during the individual's initial enrollment
21 period,

22 there shall be a special enrollment period of 6
23 months beginning with the first month that in-
24 cludes the date that the plan substantially ter-

1 minates outpatient prescription medicine cov-
2 erage and ending 6 months later.

3 “(C) LOSS OF MEDICARE+CHOICE PRE-
4 SCRIPTION MEDICINE COVERAGE.—In the case
5 of an individual who is enrolled under part C in
6 a Medicare+Choice plan that provides prescrip-
7 tion medicine benefits, if such enrollment is ter-
8 minated because of the termination or reduction
9 in service area of the plan, there shall be a spe-
10 cial enrollment period of 6 months beginning
11 with the first month that includes the date that
12 such plan is terminated or such reduction oc-
13 curs and ending 6 months later.

14 “(D) LOSS OF MEDICAID PRESCRIPTION
15 MEDICINE COVERAGE.—In the case of an indi-
16 vidual who—

17 “(i) satisfies subsection (a);

18 “(ii) loses eligibility for benefits (that
19 include benefits for prescription medicine)
20 under a State plan after having been en-
21 rolled (or determined to be eligible) for
22 such benefits under such plan; and

23 “(iii) is not otherwise enrolled under
24 this subsection at the time of such loss of
25 eligibility,

1 there shall be a special enrollment period speci-
2 fied by the Secretary of not less than 6 months
3 beginning with the first month that includes the
4 date that the individual loses such eligibility.

5 “(4) LATE ENROLLMENT WITH PREMIUM PEN-
6 ALTY.—The Secretary shall permit an individual
7 who satisfies subsection (a) to enroll other than dur-
8 ing the initial enrollment period under paragraph (2)
9 or a special enrollment period under paragraph (3).
10 But, in the case of such an enrollment, the amount
11 of the monthly premium of the individual is subject
12 to an increase under section 1859C(e)(1).

13 “(5) INFORMATION.—

14 “(A) IN GENERAL.—The Secretary shall
15 broadly distribute information to individuals
16 who satisfy subsection (a) on the benefits pro-
17 vided under this part. The Secretary shall peri-
18 odically make available information on the cost
19 differentials to enrollees for the use of generic
20 medicines and other medicines.

21 “(B) TOLL-FREE HOTLINE.—The Sec-
22 retary shall maintain a toll-free telephone hot-
23 line (which may be a hotline already used by
24 the Secretary under this title) for purposes of
25 providing assistance to beneficiaries in the pro-

1 gram under this part, including responding to
2 questions concerning coverage, enrollment, ben-
3 efits, grievances and appeals procedures, and
4 other aspects of such program.

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

8 “(c) COVERAGE PERIOD.—

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

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

1 “(d) PROVISION OF BENEFITS TO
2 MEDICARE+CHOICE ENROLLEES.—In the case of an indi-
3 vidual who is enrolled under this part and is enrolled in
4 a Medicare+Choice plan under part C, the individual shall
5 be provided the benefits under this part through such plan
6 and not through payment under this part.

7 “(e) LATE ENROLLMENT PENALTIES; PAYMENT OF
8 PREMIUMS.—

9 “(1) LATE ENROLLMENT PENALTY.—

10 “(A) IN GENERAL.—In the case of a late
11 enrollment described in subsection (b)(4), sub-
12 ject to the succeeding provisions of this para-
13 graph, the Secretary shall establish procedures
14 for increasing the amount of the monthly pre-
15 mium under this part applicable to such en-
16 rollee by an amount that the Secretary deter-
17 mines is actuarially sound for each such period.

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

24 “(C) PERIODS NOT TAKEN INTO AC-
25 COUNT.—

1 “(i) IN GENERAL.—For purposes of
2 calculating any 12-month period under
3 subparagraph (A), subject to clause (ii),
4 there shall not be taken into account
5 months for which the enrollee can dem-
6 onstrate that the enrollee was covered
7 under a group health plan that provides
8 coverage of the cost of prescription medi-
9 cines whose actuarial value (as defined by
10 the Secretary) to the enrollee equals or ex-
11 ceeds the actuarial value of the benefits
12 provided to an individual enrolled in the
13 outpatient prescription medicine benefit
14 program under this part.

15 “(ii) APPLICATION.—This subpara-
16 graph shall only apply with respect to a
17 coverage period the enrollment for which
18 occurs before the end of the 60-day period
19 that begins on the first day of the month
20 which includes the date on which the plan
21 terminates or reduces its service area (in a
22 manner that results in termination of en-
23 rollment), ceases to provide, or reduces the
24 value of the prescription medicine coverage
25 under such plan to below the value of the

1 coverage provided under the program
2 under this part.

3 “(2) INCORPORATION OF PREMIUM PAYMENT
4 AND GOVERNMENT CONTRIBUTIONS PROVISIONS.—
5 The provisions of sections 1840 and 1844(a)(1) shall
6 apply to enrollees under this part in the same man-
7 ner as they apply to individuals 65 years of age or
8 older enrolled under part B. For purposes of this
9 subsection, any reference in a section referred to in
10 a previous subsection to the Federal Supplementary
11 Medical Insurance Trust Fund is deemed a reference
12 to the Federal Medicare Prescription Medicine Trust
13 Fund.

14 “(f) ELECTION OF PHARMACY CONTRACTOR TO AD-
15 MINISTER BENEFITS.—The Secretary shall establish a
16 process whereby each individual enrolled under this part
17 and residing in a region may elect the pharmacy con-
18 tractor that will administer the benefits under this part
19 with respect to the individual. Such process shall permit
20 the individual to make an initial election and to change
21 such an election on at least an annual basis and under
22 such other circumstances as the Secretary shall specify.

23 “PROVISION OF, AND ENTITLEMENT TO, BENEFITS

24 “SEC. 1859D. (a) BENEFITS.—Subject to the suc-
25 ceeding provisions of this section, the benefits provided to

1 an enrollee by the program under this part shall consist
2 of the following:

3 “(1) COVERED OUTPATIENT PRESCRIPTION
4 MEDICINE BENEFITS.—Entitlement to have payment
5 made on the individual’s behalf for covered out-
6 patient prescription medicines.

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

9 “(A) IN GENERAL.—Once an enrollee has
10 incurred aggregate countable cost-sharing (as
11 defined in subparagraph (B)) equal to the stop-
12 loss limit specified in subsection (c)(4) for ex-
13 penses in a year, entitlement to the elimination
14 of cost-sharing otherwise applicable under part
15 B for additional expenses incurred in the year
16 for outpatient prescription medicines or
17 biologicals for which payment is made under
18 part B.

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

22 “(i) out-of-pocket expenses for out-
23 patient prescription medicines with respect
24 to which benefits are payable under part
25 B, and

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

3 “(b) COVERED OUTPATIENT PRESCRIPTION MEDI-
4 CINE DEFINED.—

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

9 “(A) A medicine which may be dispensed
10 only upon prescription, and—

11 “(i) which is approved for safety and
12 effectiveness as a prescription medicine
13 under section 505 of the Federal Food,
14 Drug, and Cosmetic Act;

15 “(ii)(I) which was commercially used
16 or sold in the United States before the
17 date of enactment of the Drug Amend-
18 ments of 1962 or which is identical, simi-
19 lar, or related (within the meaning of sec-
20 tion 310.6(b)(1) of title 21 of the Code of
21 Federal Regulations) to such a medicine,
22 and

23 “(II) which has not been the subject of
24 a final determination by the Secretary that
25 it is a ‘new drug’ (within the meaning of

1 section 201(p) of the Federal Food, Drug,
2 and Cosmetic Act) or an action brought by
3 the Secretary under section 301, 302(a),
4 or 304(a) of such Act to enforce section
5 502(f) or 505(a) of such Act; or

6 “(iii)(I) which is described in section
7 107(c)(3) of the Drug Amendments of
8 1962 and for which the Secretary has de-
9 termined there is a compelling justification
10 for its medical need, or is identical, simi-
11 lar, or related (within the meaning of sec-
12 tion 310.6(b)(1) of title 21 of the Code of
13 Federal Regulations) to such a medicine,
14 and

15 (II) for which the Secretary has not
16 issued a notice of an opportunity for a
17 hearing under section 505(e) of the Fed-
18 eral Food, Drug, and Cosmetic Act on a
19 proposed order of the Secretary to with-
20 draw approval of an application for such
21 medicine under such section because the
22 Secretary has determined that the medi-
23 cine is less than effective for all conditions
24 of use prescribed, recommended, or sug-
25 gested in its labeling.

1 “(B) A biological product which—

2 “(i) may only be dispensed upon pre-
3 scription;

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

6 “(iii) is produced at an establishment
7 licensed under such section to produce
8 such product.

9 “(C) Insulin approved under appropriate
10 Federal law, and needles, syringes, and dispos-
11 able pumps for the administration of such insu-
12 lin.

13 “(D) A prescribed medicine or biological
14 product that would meet the requirements of
15 subparagraph (A) or (B) but that is available
16 over-the-counter in addition to being available
17 upon prescription, but only if the particular
18 dosage form or strength prescribed and re-
19 quired for the individual is not available over-
20 the-counter.

21 “(E) Smoking cessation agents (as speci-
22 fied by the Secretary).

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

1 “(A) medicines or classes of medicines, or
2 their medical uses, which may be excluded from
3 coverage or otherwise restricted under section
4 1927(d)(2), other than subparagraph (E) there-
5 of (relating to smoking cessation agents), as the
6 Secretary may specify and does not include
7 such other medicines, classes, and uses as the
8 Secretary may specify consistent with the goals
9 of providing quality care and containing costs
10 under this part;

11 “(B) except as provided in paragraphs
12 (1)(D) and (1)(E), any product which may be
13 distributed to individuals without a prescrip-
14 tion;

15 “(C) any product when furnished as part
16 of, or as incident to, a diagnostic service or any
17 other item or service for which payment may be
18 made under this title; or

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

21 “(c) PAYMENT OF BENEFITS.—

22 “(1) COVERED OUTPATIENT PRESCRIPTION
23 MEDICINES.—There shall be paid from the Federal
24 Medicare Prescription Medicine Trust Fund, in the
25 case of each enrollee who incurs expenses for medi-

1 cines with respect to which benefits are payable
2 under this part under subsection (a)(1), amounts
3 equal to the sum of—

4 “(A) the price for which the medicine is
5 made available under this part (consistent with
6 sections 1859A and 1859B), reduced by any
7 applicable cost-sharing under paragraphs (2)
8 and (3); and

9 “(B) a reasonable dispensing fee.

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

12 “(2) DEDUCTIBLE.—The amount of payment
13 under paragraph (1) for expenses incurred in a year,
14 beginning with 2006, shall be reduced by an annual
15 deductible equal to the amount specified in section
16 1859(2) (subject to adjustment under paragraph
17 (8)). Only expenses for countable cost-sharing (as
18 defined in subsection (a)(2)(B)) shall be taken into
19 account in applying this paragraph.

20 “(3) COINSURANCE.—

21 “(A) IN GENERAL.—The amount of pay-
22 ment under paragraph (1) for expenses in-
23 curred in a year shall be further reduced (sub-
24 ject to the stop-loss limit under paragraph (4))

1 by coinsurance as provided under this para-
2 graph.

3 “(B) PREFERRED MEDICINES.—The coin-
4 surance under this paragraph in the case of a
5 preferred medicine (including a medicine treat-
6 ed as a preferred medicine under paragraph
7 (5)), is equal to 20 percent of the price applica-
8 ble under paragraph (1)(A) (or such lower per-
9 centage as may be provided for under section
10 1859E(a)(1)(A)(ii)). In this part, the term ‘pre-
11 ferred medicine’ means, with respect to medi-
12 cines classified within a therapeutic class, those
13 medicines which have been designated as a pre-
14 ferred medicine by the Secretary or the phar-
15 macy contractor involved with respect to that
16 class and (in the case of a nongeneric medicine)
17 with respect to which a contract has been nego-
18 tiated under this part.

19 “(C) NONPREFERRED MEDICINES.—The
20 coinsurance under this paragraph in the case of
21 a nonpreferred medicine that is not treated as
22 a preferred medicine under paragraph (5) is
23 equal to the sum of—

1 “(i) 20 percent of the price for lowest
2 price preferred medicine that is within the
3 same therapeutic class; and

4 “(ii) the amount by which—

5 “(I) the price at which the non-
6 preferred medicine is made available
7 to the enrollee; exceeds

8 “(II) the price of such lowest
9 price preferred medicine.

10 “(4) NO COINSURANCE ONCE OUT-OF-POCKET
11 EXPENDITURES EQUAL STOP-LOSS LIMIT.—Once an
12 enrollee has incurred aggregate countable cost-shar-
13 ing under paragraph (3) (including cost-sharing
14 under part B attributable to outpatient prescription
15 drugs or biologicals) equal to the amount specified
16 in section 1859(4) (subject to adjustment under
17 paragraph (8)) for expenses in a year—

18 “(A) there shall be no coinsurance under
19 paragraph (3) for additional expenses incurred
20 in the year involved; and

21 “(B) there shall be no coinsurance under
22 part B for additional expenses incurred in the
23 year involved for outpatient prescription drugs
24 and biologicals.

1 “(5) APPEALS RIGHTS RELATING TO COVERAGE
2 OF NONPREFERRED MEDICINES.—

3 “(A) PROCEDURES REGARDING THE DE-
4 TERMINATION OF MEDICINES THAT ARE MEDI-
5 CALLY NECESSARY.—Each pharmacy contractor
6 shall have in place procedures on a case-by-case
7 basis to treat a nonpreferred medicine as a pre-
8 ferred medicine under this part if the preferred
9 medicine is determined to be not as effective for
10 the enrollee or to have significant adverse effect
11 on the enrollee. Such procedures shall require
12 that such determinations are based on profes-
13 sional medical judgment, the medical condition
14 of the enrollee, and other medical evidence.

15 “(B) PROCEDURES REGARDING DENIALS
16 OF CARE.—Such contractor shall have in place
17 procedures to ensure—

18 “(i) a timely internal review for reso-
19 lution of denials of coverage (in whole or
20 in part and including those regarding the
21 coverage of nonpreferred medicines) in ac-
22 cordance with the medical exigencies of the
23 case and a timely resolution of complaints,
24 by enrollees in the plan, or by providers,
25 pharmacists, and other individuals acting

1 on behalf of each such enrollee (with the
2 enrollee’s consent) in accordance with re-
3 quirements (as established by the Sec-
4 retary) that are comparable to such re-
5 quirements for Medicare+Choice organiza-
6 tions under part C;

7 “(ii) that the entity complies in a
8 timely manner with requirements estab-
9 lished by the Secretary that (I) provide for
10 an external review by an independent enti-
11 ty selected by the Secretary of denials of
12 coverage described in clause (i) not re-
13 solved in the favor of the beneficiary (or
14 other complainant) under the process de-
15 scribed in such clause and (II) are com-
16 parable to the external review requirements
17 established for Medicare+Choice organiza-
18 tions under part C; and

19 “(iii) that enrollees are provided with
20 information regarding the appeals proce-
21 dures under this part at the time of enroll-
22 ment with a pharmacy contractor under
23 this part and upon request thereafter.

24 “(6) TRANSFER OF FUNDS TO COVER COSTS OF

25 PART B PRESCRIPTION MEDICINE CATASTROPHIC

1 BENEFIT.—With respect to benefits described in
2 subsection (a)(2), there shall transferred from the
3 Federal Medicare Prescription Medicine Trust Fund
4 to the Federal Supplementary Medical Insurance
5 Trust Fund amounts equivalent to the elimination of
6 cost-sharing described in such subsection.

7 “(7) PERMITTING APPLICATION UNDER PART B
8 OF NEGOTIATED PRICES.—For purposes of making
9 payment under part B for medicines that would be
10 covered outpatient prescription medicines but for the
11 exclusion under subparagraph (B) or (C) of sub-
12 section (b)(2), the Secretary may elect to apply the
13 payment basis used for payment of covered out-
14 patient prescription medicines under this part in-
15 stead of the payment basis otherwise used under
16 such part, if it results in a lower cost to the pro-
17 gram.

18 “(8) INFLATION ADJUSTMENT.—

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

21 “(i) the deductible under paragraph
22 (2) is equal to the deductible determined
23 under such paragraph (or this subpara-
24 graph) for the previous year increased by
25 the percentage increase in per capita pro-

1 gram expenditures (as estimated in ad-
2 vance for the year involved under subpara-
3 graph (B)); and

4 “(ii) the stop-loss limit under para-
5 graph (3) is equal to the stop-loss limit de-
6 termined under such paragraph (or this
7 subparagraph) for the previous year in-
8 creased by such percentage increase.

9 The Secretary shall adjust such percentage in-
10 crease in subsequent years to take into account
11 misestimations made of the per capita program
12 expenditures under clauses (i) and (ii) in pre-
13 vious years. Any increase under this subpara-
14 graph that is not a multiple of \$10 shall be
15 rounded to the nearest multiple of \$10.

16 “(B) ESTIMATION OF INCREASE IN PER
17 CAPITA PROGRAM EXPENDITURES.—The Sec-
18 retary shall before the beginning of each year
19 (beginning with 2007) estimate the percentage
20 increase in average per capita aggregate ex-
21 penditures from the Federal Medicare Prescrip-
22 tion Medicine Trust Fund for the year involved
23 compared to the previous year.

24 “(C) RECONCILIATION.—The Secretary
25 shall also compute (beginning with 2008) the

1 actual percentage increase in such aggregate
2 expenditures in order to provide for reconcili-
3 ation of deductibles, stop-loss limits, and pre-
4 miums under the second sentence of subpara-
5 graph (A) and under section 1859D(d)(2).

6 “(d) AMOUNT OF PREMIUMS.—

7 “(1) MONTHLY PREMIUM RATE IN 2006.—The
8 monthly premium rate in 2006 for prescription med-
9 icine benefits under this part is the amount specified
10 in section 1859(1).

11 “(2) INFLATION ADJUSTMENT FOR SUBSE-
12 QUENT YEARS.—The monthly premium rate for a
13 year after 2006 for prescription medicine benefits
14 under this part is equal to the monthly premium
15 rate for the previous year under this subsection in-
16 creased by the percentage increase in per capita pro-
17 gram expenditures (as estimated in advance for the
18 year involved under subsection (c)(8)(B)). The Sec-
19 retary shall adjust such percentage in subsequent
20 years to take into account misestimations made of
21 the per capita program expenditures under the pre-
22 vious sentence in previous years. Any increase under
23 this paragraph that is not a multiple of \$1 shall be
24 rounded to the nearest multiple of \$1.

1 “ADMINISTRATION; QUALITY ASSURANCE

2 “SEC. 1859E. (a) RULES RELATING TO PROVISION
3 OF BENEFITS.—

4 “(1) PROVISION OF BENEFITS.—

5 “(A) IN GENERAL.—In providing benefits
6 under this part, the Secretary (directly or
7 through the contracts with pharmacy contrac-
8 tors) shall employ mechanisms to provide bene-
9 fits appropriately and efficiently, and those
10 mechanisms may include—

11 “(i) the use of—

12 “(I) price negotiations (con-
13 sistent with subsection (b));

14 “(II) reduced coinsurance (below
15 20 percent) to encourage the utiliza-
16 tion of appropriate preferred medi-
17 cines; and

18 “(III) methods to reduce medica-
19 tion errors and encourage appropriate
20 use of medications; and

21 “(ii) permitting pharmacy contractors,
22 as approved by the Secretary, to make ex-
23 ceptions to section 1859D(c)(3)(C) (relat-
24 ing to cost-sharing for non-preferred medi-
25 cines) to secure best prices for enrollees so

1 long as the payment amount under section
2 1859D(c)(1) does not equal zero.

3 “(B) CONSTRUCTION.—Nothing in this
4 subsection shall be construed to prevent the
5 Secretary (directly or through the contracts
6 with pharmacy contractors) from using incen-
7 tives to encourage enrollees to select generic or
8 other cost-effective medicines, so long as—

9 “(i) such incentives are designed not
10 to result in any increase in the aggregate
11 expenditures under the Federal Medicare
12 Prescription Medicine Trust Fund; and

13 “(ii) a beneficiary’s coinsurance shall
14 be no greater than 20 percent in the case
15 of a preferred medicine (including a non-
16 preferred medicine treated as a preferred
17 medicine under section 1859D(c)(5)).

18 “(2) CONSTRUCTION.—Nothing in this part
19 shall preclude the Secretary or a pharmacy con-
20 tractor from—

21 “(A) educating prescribing providers, phar-
22 macists, and enrollees about medical and cost
23 benefits of preferred medicines;

24 “(B) requesting prescribing providers to
25 consider a preferred medicine prior to dis-

1 pensing of a nonpreferred medicine, as long as
2 such request does not unduly delay the provi-
3 sion of the medicine;

4 “(C) using mechanisms to encourage en-
5 rollees under this part to select cost-effective
6 medicines or less costly means of receiving or
7 administering medicines, including the use of
8 therapeutic interchange programs, disease man-
9 agement programs, and notification to the bene-
10 ficiary that a more affordable generic medicine
11 equivalent was not selected by the prescribing
12 provider and a statement of the lost cost sav-
13 ings to the beneficiary;

14 “(D) using price negotiations to achieve re-
15 duced prices on covered outpatient prescription
16 medicines, including new medicines, medicines
17 for which there are few therapeutic alternatives,
18 and medicines of particular clinical importance
19 to individuals enrolled under this part; and

20 “(E) utilizing information on medicine
21 prices of OECD countries and of other payors
22 in the United States in the negotiation of prices
23 under this part.

24 “(b) PRICE NEGOTIATIONS PROCESS.—

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

6 “(A) there is at least a contract for a med-
7 icine within each therapeutic class (as defined
8 by the Secretary in consultation with such
9 Medicare Prescription Medicine Advisory Com-
10 mittee);

11 “(B) if there is more than 1 medicine
12 available in a therapeutic class, there are con-
13 tracts for at least 2 medicines within such class
14 unless determined clinically inappropriate in ac-
15 cordance with standards established by the Sec-
16 retary; and

17 “(C) if there are more than 2 medicines
18 available in a therapeutic class, there is a con-
19 tract for at least 2 medicines within such class
20 and a contract for generic medicine substitute
21 if available unless determined clinically inappro-
22 priate in accordance with standards established
23 by the Secretary.

24 “(2) ESTABLISHMENT OF THERAPEUTIC CLASS-
25 ES.—The Secretary, in consultation with the Medi-

1 care Prescription Medicine Advisory Committee (es-
2 tablished under section 1859H), shall establish for
3 purposes of this part therapeutic classes and assign
4 to such classes covered outpatient prescription medi-
5 cines.

6 “(3) DISCLOSURE CONCERNING PREFERRED
7 MEDICINES.—The Secretary shall provide, through
8 pharmacy contractors or otherwise, for—

9 “(A) disclosure to current and prospective
10 enrollees and to participating providers and
11 pharmacies in each service area a list of the
12 preferred medicines and differences in applica-
13 ble cost-sharing between such medicines and
14 nonpreferred medicines; and

15 “(B) advance disclosure to current enroll-
16 ees and to participating providers and phar-
17 macies in each service area of changes to any
18 such list of preferred medicines and differences
19 in applicable cost-sharing.

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

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

15 “(d) FRAUD AND ABUSE SAFEGUARDS.—The Sec-
16 retary, through the Office of the Inspector General, is au-
17 thorized and directed to issue regulations establishing ap-
18 propriate safeguards to prevent fraud and abuse under
19 this part. Such safeguards, at a minimum, should include
20 compliance programs, certification data, audits, and rec-
21 ordkeeping practices. In developing such regulations, the
22 Secretary shall consult with the Attorney General and
23 other law enforcement and regulatory agencies.

1 “FEDERAL MEDICARE PRESCRIPTION MEDICINE TRUST
2 FUND

3 “SEC. 1859F. (a) ESTABLISHMENT.—There is here-
4 by created on the books of the Treasury of the United
5 States a trust fund to be known as the ‘Federal Medicare
6 Prescription Medicine Trust Fund’ (in this section re-
7 ferred to as the ‘Trust Fund’). The Trust Fund shall con-
8 sist of the following:

9 “(1) Amounts estimated by the Secretary of the
10 Treasury that would have been paid from the gen-
11 eral fund of the Treasury but for the amendments
12 and repeals made by section 101 of the Honor Thy
13 Parents Act of 2003.

14 “(2) Such gifts and bequests as may be made
15 as provided in section 201(i)(1).

16 “(3) Such amounts as may be deposited in, or
17 appropriated to, such fund as provided in this 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 “COMPENSATION FOR EMPLOYERS COVERING RETIREE
2 MEDICINE COSTS

3 “SEC. 1859G. (a) IN GENERAL.—In the case of an
4 individual who is eligible to be enrolled under this part
5 and is a participant or beneficiary under a group health
6 plan that provides outpatient prescription medicine cov-
7 erage to retirees the actuarial value of which is not less
8 than the actuarial value of the coverage provided under
9 this part, the Secretary shall make payments to such plan
10 subject to the provisions of this section. Such payments
11 shall be treated as payments under this part for purposes
12 of sections 1859F and 1859C(e)(2). In applying the pre-
13 vious sentence with respect to section 1859C(e)(2), the
14 amount of the Government contribution referred to in sec-
15 tion 1844(a)(1)(A) is deemed to be equal to the aggregate
16 amount of the payments made under this section.

17 “(b) REQUIREMENTS.—To receive payment under
18 this section, a group health plan shall comply with the fol-
19 lowing requirements:

20 “(1) COMPLIANCE WITH REQUIREMENTS.—The
21 group health plan shall comply with the require-
22 ments of this Act and other reasonable, necessary,
23 and related requirements that are needed to admin-
24 ister this section, as determined by the Secretary.

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 (b) 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 (c) 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. 202. 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 (e) 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 (f) 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. 203. 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. 204. 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.

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