

1 meeting performance requirements with respect to price re-
2 ductions and limiting price increases.

3 "(6) AREA FOR CONTRACTS.—

4 "(A) REGIONAL BASIS.—

5 "(i) IN GENERAL.—Except as provided in
6 clause (ii) and subject to subparagraph (B), the
7 contract entered into between the Secretary and a
8 pharmacy contractor shall require the contractor to
9 administer the benefits under this part in a region
10 determined by the Secretary under subparagraph
11 (B) or on a national basis.

12 "(ii) PARTIAL REGIONAL BASIS.—

13 "(I) IN GENERAL.—If determined appro-
14 priate by the Secretary, the Secretary may per-
15 mit the benefits to be administered in a partial
16 region determined appropriate by the Sec-
17 retary.

18 "(II) REQUIREMENTS.—If the Secretary
19 permits administration pursuant to subclause
20 (I), the Secretary shall ensure that the partial
21 region in which administration is effected is no
22 smaller than a State and is at least the size of
23 the commercial service area of the contractor
24 for that area.

25 "(B) DETERMINATION.—

26 "(i) IN GENERAL.—In determining regions for
27 contracts under this part, the Secretary shall—

28 "(I) take into account the number of indi-
29 viduals enrolled under this part in an area in
30 order to encourage participation by pharmacy
31 contractors; and

32 "(II) ensure that there are at least 10 dif-
33 ferent regions in the United States.

34 "(ii) NO ADMINISTRATIVE OR JUDICIAL RE-
35 VIEW.—The determination of administrative areas
36 under this paragraph shall not be subject to admin-
37 istrative or judicial review.

1 “(7) SUBMISSION OF BIDS.—

2 “(A) SUBMISSION.—

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

10 “(ii) BID THAT COVERS MULTIPLE AREAS.—

11 The Secretary shall permit an entity to submit a
12 single bid for multiple areas if the bid is applicable
13 to all such areas.

14 “(B) REQUIRED INFORMATION.—The bids de-
15 scribed in subparagraph (A) shall include—

16 “(i) a proposal for the estimated prices of cov-
17 ered outpatient prescription medicines and the pro-
18 jected annual increases in such prices, including
19 the additional reduction in price negotiated below
20 the Secretary’s maximum price and differentials be-
21 tween preferred and nonpreferred prices, if applica-
22 ble;

23 “(ii) a statement regarding the amount that
24 the entity will charge the Secretary for admin-
25 istering the benefits under the contract;

26 “(iii) a statement regarding whether the entity
27 will reduce the applicable coinsurance percentage
28 pursuant to section 1859E(a)(1)(A)(ii) and if so,
29 the amount of such reduction and how such reduc-
30 tion is tied to the performance requirements de-
31 scribed in subsection (c)(4)(A)(ii);

32 “(iv) a detailed description of the performance
33 requirements for which the administrative fee of
34 the entity will be subject to risk pursuant to sub-
35 section (c)(4)(A)(ii);

36 “(v) a detailed description of access to phar-
37 macy services provided by the entity, including in-



1 formation regarding whether the pharmacy contractor will use a preferred pharmacy network, and,
 2 if so, how the pharmacy contractor will ensure access to pharmacies that choose to be outside of that
 3 network, and whether there will be increased cost-sharing for beneficiaries if they obtain medicines at
 4 such pharmacies;
 5

6
 7
 8 “(vi) a detailed description of the procedures and standards the entity will use for—
 9

10 “(I) selecting preferred prescription medicines; and
 11

12 “(II) determining when and how often the list of preferred prescription medicines should
 13 be modified;
 14

15 “(vii) a detailed description of any ownership or shared financial interests with pharmaceutical
 16 manufacturers, pharmacies, and other entities involved in the administration or delivery of benefits
 17 under this part as proposed in the bid;
 18

19
 20 “(viii) a detailed description of the entity’s estimated marketing and advertising expenditures related to enrolling and retaining eligible beneficiaries; and
 21
 22
 23

24 “(ix) such other information that the Secretary determines is necessary in order to carry out
 25 this part, including information relating to the bidding process under this part.
 26
 27

28 The procedures under clause (vi) shall include the use
 29 of a pharmaceutical and therapeutics committee the members of which include practicing pharmacists.
 30

31 “(8) AWARDING OF CONTRACTS.—

32 “(A) NUMBER OF CONTRACTS.—The Secretary shall, consistent with the requirements of this part and the goals of providing quality care and of containing costs under this part, award in a competitive manner at least 2 contracts to administer benefits under this part in each area specified under paragraph (6), unless
 33
 34
 35
 36
 37



1 only 1 pharmacy contractor submitting a bid meets the
2 minimum standards specified under this part and by
3 the Secretary.

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

11 “(i) how well the contractor meets such min-
12 imum standards;

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

16 “(iii) the performance standards established
17 under subsection (c)(2) and performance require-
18 ments for which the administrative fee of the entity
19 will be subject to risk pursuant to subsection
20 (c)(4)(A)(ii);

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

24 “(v) factors relating to benefits, quality and
25 performance, beneficiary cost-sharing, and con-
26 sumer satisfaction;

27 “(vi) past performance and prior experience of
28 the contractor in administering a prescription med-
29 icine benefit program;

30 “(vii) effectiveness of the contractor in con-
31 taining costs through pricing incentives and utiliza-
32 tion management; and

33 “(viii) such other factors as the Secretary
34 deems necessary to evaluate the merits of each bid.

35 “(C) EXCEPTION TO CONFLICT OF INTEREST
36 RULES.—In awarding contracts with pharmacy contrac-
37 tors under this part, the Secretary may waive conflict

1 of interest laws generally applicable to Federal acqui-
2 sitions (subject to such safeguards as the Secretary may
3 find necessary to impose) in circumstances where the
4 Secretary finds that such waiver—

5 “(i) is not inconsistent with the—

6 “(I) purposes of the programs under this
7 part; or

8 “(II) best interests of beneficiaries en-
9 rolled under this part; and

10 “(ii) permits a sufficient level of competition
11 for such contracts, promotes efficiency of benefits
12 administration, or otherwise serves the objectives of
13 the program under this part.

14 “(D) NO ADMINISTRATIVE OR JUDICIAL RE-
15 VIEW.—The determination of the Secretary to award or
16 not award a contract to a pharmacy contractor under
17 this part shall not be subject to administrative or judi-
18 cial review.

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

20 “(A) AREAS NOT COVERED BY CONTRACTS.—The
21 Secretary shall develop procedures for the provision of
22 covered outpatient prescription medicines under this
23 part to each eligible beneficiary enrolled under this part
24 that resides in an area that is not covered by any con-
25 tract under this part.

26 “(B) BENEFICIARIES RESIDING IN DIFFERENT LO-
27 CATIONS.—The Secretary shall develop procedures to
28 ensure that each eligible beneficiary enrolled under this
29 part that resides in different areas in a year is provided
30 the benefits under this part throughout the entire year.

31 “(b) QUALITY, FINANCIAL, AND OTHER STANDARDS AND
32 PROGRAMS.—In consultation with appropriate pharmacy con-
33 tractors, pharmacists, and health care professionals with exper-
34 tise in prescribing, dispensing, and the appropriate use of pre-
35 scription medicines, the Secretary shall establish standards and
36 programs for the administration of this part to ensure appro-
37 priate prescribing, dispensing, and utilization of outpatient

1 medicines under this part, to avoid adverse medicine reactions,
2 and to continually reduce errors in the delivery of medically ap-
3 propriate covered benefits. The Secretary shall not award a
4 contract to a pharmacy contractor under this part unless the
5 Secretary finds that the contractor agrees to comply with such
6 standards and programs and other terms and conditions as the
7 Secretary shall specify. The standards and programs under this
8 subsection shall be applied to any administrative agreements
9 described in subsection (a) the Secretary enters into. Such
10 standards and programs shall include the following:

11 “(1) ACCESS.—

12 “(A) IN GENERAL.—The pharmacy contractor
13 shall ensure that covered outpatient prescription medi-
14 cines are accessible and convenient to eligible bene-
15 ficiaries enrolled under this part for whom benefits are
16 administered by the pharmacy contractor, including by
17 offering the services 24 hours a day and 7 days a week
18 for emergencies.

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

25 “(C) GUARANTEED ACCESS TO MEDICINES IN
26 RURAL AND HARD-TO-SERVE AREAS.—The Secretary
27 shall ensure that all beneficiaries have guaranteed ac-
28 cess to the full range of pharmaceuticals under this
29 part, and shall give special attention to access, phar-
30 macist counseling, and delivery in rural and hard-to-
31 serve areas, including through the use of incentives
32 such as bonus payments to retail pharmacists in rural
33 areas and extra payments to the pharmacy contractor
34 for the cost of rapid delivery of pharmaceuticals and
35 any other actions necessary.

36 “(D) PREFERRED PHARMACY NETWORKS.—



1 “(i) IN GENERAL.—If a pharmacy contractor
 2 uses a preferred pharmacy network to deliver bene-
 3 fits under this part, such network shall meet min-
 4 imum access standards established by the Sec-
 5 retary.

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

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

15 “(F) CONTINUITY OF CARE.—

16 “(i) IN GENERAL.—The pharmacy contractor
 17 shall ensure that, in the case of an eligible bene-
 18 ficiary who loses coverage under this part with such
 19 entity under circumstances that would permit a
 20 special election period (as established by the Sec-
 21 retary under section 1859C(b)(3)), the contractor
 22 will continue to provide coverage under this part to
 23 such beneficiary until the beneficiary enrolls and
 24 receives such coverage with another pharmacy con-
 25 tractor under this part or, if eligible, with a
 26 Medicare+ Choice organization.

27 “(ii) LIMITED PERIOD.—In no event shall a
 28 pharmacy contractor be required to provide the ex-
 29 tended coverage required under clause (i) beyond
 30 the date which is 30 days after the coverage with
 31 such contractor would have terminated but for this
 32 subparagraph.

33 “(2) ENROLLEE GUIDELINES.—The pharmacy con-
 34 tractor shall, consistent with State law, apply guidelines for
 35 counseling enrollees regarding—

36 “(A) the proper use of covered outpatient prescrip-
 37 tion medicine; and



1 “(B) interactions and contra-indications.

2 “(3) EDUCATION.—The pharmacy contractor shall
3 apply methods to identify and educate providers, phar-
4 macists, and enrollees regarding—

5 “(A) instances or patterns concerning the unneces-
6 sary or inappropriate prescribing or dispensing of cov-
7 ered outpatient prescription medicines;

8 “(B) instances or patterns of substandard care;

9 “(C) potential adverse reactions to covered out-
10 patient prescription medicines;

11 “(D) inappropriate use of antibiotics;

12 “(E) appropriate use of generic products; and

13 “(F) the importance of using covered outpatient
14 prescription medicines in accordance with the instruc-
15 tion of prescribing providers.

16 “(4) COORDINATION.—The pharmacy contractor shall
17 coordinate with State prescription medicine programs,
18 other pharmacy contractors, pharmacies, and other relevant
19 entities as necessary to ensure appropriate coordination of
20 benefits with respect to enrolled individuals when such indi-
21 vidual is traveling outside the home service area, and under
22 such other circumstances as the Secretary may specify.

23 “(5) COST DATA.—

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

27 “(B) The Secretary shall require, either directly or
28 through a pharmacy contractor, that participating
29 pharmacists, physicians, and manufacturers—

30 “(i) maintain their prescription medicine cost
31 data (including data on discounts) in a form and
32 manner specified by the Secretary;

33 “(ii) make such prescription medicine cost
34 data available for review and audit by the Sec-
35 retary; and

36 “(iii) certify that the prescription medicine
37 cost data are current, accurate, and complete, and



1 reflect all discounts obtained by the pharmacist or
2 physician in the purchasing of covered outpatient
3 prescription medicines.

4 Discounts referred to in subparagraphs (A) and (B) shall
5 include all volume discounts, manufacturer rebates, prompt
6 payment discounts, free goods, in-kind services, or any
7 other thing of financial value provided explicitly or implic-
8 itly in exchange for the purchase of a covered outpatient
9 prescription medicine.

10 "(6) REPORTING.—The pharmacy contractor shall
11 provide the Secretary with periodic reports on—

12 "(A) the contractor's costs of administering this
13 part;

14 "(B) utilization of benefits under this part;

15 "(C) marketing and advertising expenditures re-
16 lated to enrolling and retaining individuals under this
17 part; and

18 "(D) grievances and appeals.

19 "(7) RECORDS AND AUDITS.—The pharmacy con-
20 tractor shall maintain adequate records related to the ad-
21 ministration of benefits under this part and afford the Sec-
22 retary access to such records for auditing purposes.

23 "(8) APPROVAL OF MARKETING MATERIAL AND APPLI-
24 CATION FORMS.—The pharmacy contractor shall comply
25 with requirements of section 1851(h) (relating to mar-
26 keting material and application forms) with respect to this
27 part in the same manner as such requirements apply under
28 part C, except that the provisions of paragraph (4)(A) of
29 such section shall not apply with respect to discounts or re-
30 bates provided in accordance with this part.

31 "(c) INCENTIVES FOR COST AND UTILIZATION MANAGE-
32 MENT AND QUALITY IMPROVEMENT.—

33 "(1) IN GENERAL.—The Secretary shall include in a
34 contract awarded under subsection (b) with a pharmacy
35 contractor such incentives for cost and utilization manage-
36 ment and quality improvement as the Secretary may deem
37 appropriate. The contract may provide financial or other

1 incentives to encourage greater savings to the program
2 under this part.

3 “(2) PERFORMANCE STANDARDS.—The Secretary shall
4 provide for performance standards (which may include
5 monetary bonuses if the standards are met and penalties
6 if the standards are not met), including standards relating
7 to the time taken to answer member and pharmacy inquir-
8 ies (written or by telephone), the accuracy of responses,
9 claims processing accuracy, online system availability, ap-
10 peal procedure turnaround time, system availability, the ac-
11 curacy and timeliness of reports, and level of beneficiary
12 satisfaction.

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

15 “(A) financial incentives under which savings de-
16 rived from the substitution of generic and other pre-
17 ferred multi-source medicines in lieu of nongeneric and
18 nonpreferred medicines are made available to pharmacy
19 contractors, pharmacies, beneficiaries, and the Federal
20 Medicare Prescription Medicine Trust Fund; and

21 “(B) any other incentive that the Secretary deems
22 appropriate and likely to be effective in managing costs
23 or utilization or improving quality that does not reduce
24 the access of beneficiaries to medically necessary cov-
25 ered outpatient medicines.

26 “(4) REQUIREMENTS FOR PROCEDURES.—

27 “(A) IN GENERAL.—The Secretary shall establish
28 procedures for making payments to each pharmacy
29 contractor with a contract under this part for the ad-
30 ministration of the benefits under this part. The proce-
31 dures shall provide for the following:

32 “(i) ADMINISTRATIVE PAYMENT.—Payment of
33 administrative fees for such administration.

34 “(ii) RISK REQUIREMENT.—An adjustment of
35 a percentage (determined under subparagraph (B))
36 of the administrative fee payments made to a phar-
37 macy contractor to ensure that the contractor, in



1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37

administering the benefits under this part, pursues performance requirements established by the Secretary, including the following:

“(I) QUALITY SERVICE.—The contractor provides eligible beneficiaries for whom it administers benefits with quality services, as measured by such factors as sustained pharmacy network access, timeliness and accuracy of service delivery in claims processing and card production, pharmacy and member service support access, and timely action with regard to appeals and current beneficiary service surveys.

“(II) QUALITY CLINICAL CARE.—The contractor provides such beneficiaries with quality clinical care, as measured by such factors as providing notification to such beneficiaries and to providers in order to prevent adverse drug reactions and reduce medication errors and specific clinical suggestions to improve health and patient and prescriber education as appropriate.

“(III) CONTROL OF MEDICARE COSTS.—The contractor contains costs under this part to the Federal Medicare Prescription Medicine Trust Fund and enrollees, as measured by generic substitution rates, price discounts, and other factors determined appropriate by the Secretary that do not reduce the access of beneficiaries to medically necessary covered outpatient prescription medicines.

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

“(i) IN GENERAL.—Subject to clause (ii), the Secretary shall determine the percentage of the administrative payments to a pharmacy contractor that will be tied to the performance requirements described in subparagraph (A)(ii).



1 “(ii) LIMITATION ON RISK TO ENSURE PRO-
2 GRAM STABILITY.—In order to provide for program
3 stability, the Secretary may not establish a percent-
4 age to be adjusted under this paragraph at a level
5 that jeopardizes the ability of a pharmacy con-
6 tractor to administer the benefits under this part
7 or administer such benefits in a quality manner.

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

17 “(d) AUTHORITY RELATING TO PHARMACY PARTICIPA-
18 TION.—

19 “(1) IN GENERAL.—Subject to the succeeding provi-
20 sions of this subsection, a pharmacy contractor may estab-
21 lish consistent with this part conditions for the participa-
22 tion of pharmacies, including conditions relating to quality
23 (including reduction of medical errors) and technology.

24 “(2) AGREEMENTS WITH PHARMACIES.—Each phar-
25 macy contractor shall enter into a participation agreement
26 with any pharmacy that meets the requirements of this
27 subsection and section 1859E to furnish covered outpatient
28 prescription medicines to individuals enrolled under this
29 part.

30 “(3) TERMS OF AGREEMENT.—An agreement under
31 this subsection shall include the following terms and condi-
32 tions:

33 “(A) APPLICABLE REQUIREMENTS.—The phar-
34 macy shall meet (and throughout the contract period
35 continue to meet) all applicable Federal requirements
36 and State and local licensing requirements.

1 “(B) ACCESS AND QUALITY STANDARDS.—The
2 pharmacy shall comply with such standards as the Sec-
3 retary (and such a pharmacy contractor) shall establish
4 concerning the quality of, and enrolled individuals’ ac-
5 cess to, pharmacy services under this part. Such stand-
6 ards shall require the pharmacy—

7 “(i) not to refuse to dispense covered out-
8 patient prescription medicines to any individual en-
9 rolled under this part;

10 “(ii) to keep patient records (including records
11 on expenses) for all covered outpatient prescription
12 medicines dispensed to such enrolled individuals;

13 “(iii) to submit information (in a manner spec-
14 ified by the Secretary to be necessary to administer
15 this part) on all purchases of such medicines dis-
16 pensed to such enrolled individuals; and

17 “(iv) to comply with periodic audits to assure
18 compliance with the requirements of this part and
19 the accuracy of information submitted.

20 “(C) ADHERENCE TO NEGOTIATED PRICES.—(i)
21 The total charge for each medicine dispensed by the
22 pharmacy to an enrolled individual under this part,
23 without regard to whether the individual is financially
24 responsible for any or all of such charge, shall not ex-
25 ceed the price negotiated under section 1859A(a) or, if
26 lower, negotiated under subsection (a)(5) (or, if less,
27 the retail price for the medicine involved) with respect
28 to such medicine plus a reasonable dispensing fee de-
29 termined contractually with the pharmacy contractor.

30 “(ii) The pharmacy does not charge (or collect
31 from) an enrolled individual an amount that exceeds
32 the individual’s obligation (as determined in accordance
33 with the provisions of this part) of the applicable price
34 described in clause (i).

35 “(D) ADDITIONAL REQUIREMENTS.—The phar-
36 macy shall meet such additional contract requirements

1 as the applicable pharmacy contractor specifies under
2 this section.

3 "(4) APPLICABILITY OF FRAUD AND ABUSE PROVI-
4 SIONS.—The provisions of section 1128 through 1128C (re-
5 lating to fraud and abuse) apply to pharmacies partici-
6 pating in the program under this part.

7 "ELIGIBILITY; VOLUNTARY ENROLLMENT; COVERAGE

8 "SEC. 1859C. (a) ELIGIBILITY.—Each individual who is
9 entitled to hospital insurance benefits under part A or is eligi-
10 ble to be enrolled in the medical insurance program under part
11 B is eligible to enroll in accordance with this section for out-
12 patient prescription medicine benefits under this part.

13 "(b) VOLUNTARY ENROLLMENT.—

14 "(1) IN GENERAL.—An individual may enroll under
15 this part only in such manner and form as may be pre-
16 scribed by regulations, and only during an enrollment pe-
17 riod prescribed in or under this subsection.

18 "(2) INITIAL ENROLLMENT PERIOD.—

19 "(A) INDIVIDUALS CURRENTLY COVERED.—In the
20 case of an individual who satisfies subsection (a) as of
21 November 1, 2004, the initial general enrollment period
22 shall begin on August 1, 2004, and shall end on March
23 1, 2005.

24 "(B) INDIVIDUAL COVERED IN FUTURE.—In the
25 case of an individual who first satisfies subsection (a)
26 on or after November 1, 2004, the individual's initial
27 enrollment period shall begin on the first day of the
28 third month before the month in which such individual
29 first satisfies such paragraph and shall end seven
30 months later. The Secretary shall apply rules similar to
31 the rule described in the second sentence of section
32 1837(d).

33 "(3) SPECIAL ENROLLMENT PERIODS (WITHOUT PRE-
34 MIUM PENALTY).—

35 "(A) EMPLOYER COVERAGE AT TIME OF INITIAL
36 GENERAL ENROLLMENT PERIOD.—In the case of an in-
37 dividual who—

1 “(i) at the time the individual first satisfies
 2 subsection (a) is enrolled in a group health plan
 3 (including continuation coverage) that provides out-
 4 patient prescription medicine coverage by reason of
 5 the individual's (or the individual's spouse's) cur-
 6 rent (or, in the case of continuation coverage,
 7 former) employment status, and

8 “(ii) has elected not to enroll (or to be deemed
 9 enrolled) under this subsection during the individ-
 10 ual's initial enrollment period,

11 there shall be a special enrollment period of 6 months
 12 beginning with the first month that includes the date
 13 of the individual's (or individual's spouse's) retirement
 14 from or termination of current employment status with
 15 the employer that sponsors the plan, or, in the case of
 16 continuation coverage, that includes the date of termi-
 17 nation of such coverage, or that includes the date the
 18 plan substantially terminates outpatient prescription
 19 medicine coverage.

20 “(B) DROPPING OF RETIREE PRESCRIPTION MEDI-
 21 CINE COVERAGE.—In the case of an individual who—

22 “(i) at the time the individual first satisfies
 23 subsection (a) is enrolled in a group health plan
 24 that provides outpatient prescription medicine cov-
 25 erage other than by reason of the individual's (or
 26 the individual's spouse's) current employment; and

27 “(ii) has elected not to enroll (or to be deemed
 28 enrolled) under this subsection during the individ-
 29 ual's initial enrollment period,

30 there shall be a special enrollment period of 6 months
 31 beginning with the first month that includes the date
 32 that the plan substantially terminates outpatient pre-
 33 scription medicine coverage and ending 6 months later.

34 “(C) LOSS OF MEDICARE+ CHOICE PRESCRIPTION
 35 MEDICINE COVERAGE.—In the case of an individual
 36 who is enrolled under part C in a Medicare+ Choice
 37 plan that provides prescription medicine benefits, if



1 such enrollment is terminated because of the termi-
2 nation or reduction in service area of the plan, there
3 shall be a special enrollment period of 6 months begin-
4 ning with the first month that includes the date that
5 such plan is terminated or such reduction occurs and
6 ending 6 months later.

7 "(D) LOSS OF MEDICAID PRESCRIPTION MEDICINE
8 COVERAGE.—In the case of an individual who—

9 "(i) satisfies subsection (a);

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

14 "(iii) is not otherwise enrolled under this sub-
15 section at the time of such loss of eligibility,

16 there shall be a special enrollment period specified by
17 the Secretary of not less than 6 months beginning with
18 the first month that includes the date that the indi-
19 vidual loses such eligibility.

20 "(4) LATE ENROLLMENT WITH PREMIUM PENALTY.—

21 The Secretary shall permit an individual who satisfies sub-
22 section (a) to enroll other than during the initial enrollment
23 period under paragraph (2) or a special enrollment period
24 under paragraph (3). But, in the case of such an enroll-
25 ment, the amount of the monthly premium of the individual
26 is subject to an increase under section 1859C(e)(1).

27 "(5) INFORMATION.—

28 "(A) IN GENERAL.—The Secretary shall broadly
29 distribute information to individuals who satisfy sub-
30 section (a) on the benefits provided under this part.
31 The Secretary shall periodically make available infor-
32 mation on the cost differentials to enrollees for the use
33 of generic medicines and other medicines.

34 "(B) TOLL-FREE HOTLINE.—The Secretary shall
35 maintain a toll-free telephone hotline (which may be a
36 hotline already used by the Secretary under this title)
37 for purposes of providing assistance to beneficiaries in

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

5 "(6) ENROLLEE DEFINED.—For purposes of this part,
6 the term 'enrollee' means an individual enrolled for benefits
7 under this part.

8 "(c) COVERAGE PERIOD.—

9 "(1) IN GENERAL.—The period during which an indi-
10 vidual is entitled to benefits under this part (in this sub-
11 section referred to as the individual's 'coverage period')
12 shall begin on such a date as the Secretary shall establish
13 consistent with the type of coverage rules described in sub-
14 sections (a) and (e) of section 1838, except that in no case
15 shall a coverage period begin before January 1, 2005. No
16 payments may be made under this part with respect to the
17 expenses of an individual unless such expenses were in-
18 curred by such individual during a period which, with re-
19 spect to the individual, is a coverage period.

20 "(2) TERMINATION.—The Secretary shall provide for
21 the application of provisions under this subsection similar
22 to the provisions in section 1838(b).

23 "(d) PROVISION OF BENEFITS TO MEDICARE+ CHOICE
24 ENROLLEES.—In the case of an individual who is enrolled
25 under this part and is enrolled in a Medicare+Choice plan
26 under part C, the individual shall be provided the benefits
27 under this part through such plan and not through payment
28 under this part.

29 "(e) LATE ENROLLMENT PENALTIES; PAYMENT OF PRE-
30 MIUMS.—

31 "(1) LATE ENROLLMENT PENALTY.—

32 "(A) IN GENERAL.—In the case of a late enroll-
33 ment described in subsection (b)(4), subject to the suc-
34 ceeding provisions of this paragraph, the Secretary
35 shall establish procedures for increasing the amount of
36 the monthly premium under this part applicable to
37 such enrollee—



1 “(i) by an amount that is equal to 10 percent
 2 of such premium for each full 12-month period (in
 3 the same continuous period of eligibility) in which
 4 the enrollee could have been enrolled under this
 5 part but was not so enrolled; or

6 “(ii) if determined appropriate by the Sec-
 7 retary, by an amount that the Secretary determines
 8 is actuarially sound for each such period.

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

15 “(C) PERIODS NOT TAKEN INTO ACCOUNT.—

16 “(i) IN GENERAL.—For purposes of calcu-
 17 lating any 12-month period under subparagraph
 18 (A), subject to clause (ii), there shall not be taken
 19 into account months for which the enrollee can
 20 demonstrate that the enrollee was covered under a
 21 group health plan that provides coverage of the
 22 cost of prescription medicines whose actuarial value
 23 (as defined by the Secretary) to the enrollee equals
 24 or exceeds the actuarial value of the benefits pro-
 25 vided to an individual enrolled in the outpatient
 26 prescription medicine benefit program under this
 27 part.

28 “(ii) APPLICATION.—This subparagraph shall
 29 only apply with respect to a coverage period the en-
 30 rollment for which occurs before the end of the 60-
 31 day period that begins on the first day of the
 32 month which includes the date on which the plan
 33 terminates or reduces its service area (in a manner
 34 that results in termination of enrollment), ceases to
 35 provide, or reduces the value of the prescription
 36 medicine coverage under such plan to below the



1 value of the coverage provided under the program
2 under this part.

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

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

22 "PROVISION OF, AND ENTITLEMENT TO, BENEFITS

23 "SEC. 1859D. (a) BENEFITS.—Subject to the succeeding
24 provisions of this section, the benefits provided to an enrollee
25 by the program under this part shall consist of the following:

26 "(1) COVERED OUTPATIENT PRESCRIPTION MEDICINE
27 BENEFITS.—Entitlement to have payment made on the in-
28 dividual's behalf for covered outpatient prescription medi-
29 cines.

30 "(2) LIMITATION ON COST-SHARING FOR PART B OUT-
31 PATIENT PRESCRIPTION MEDICINES.—

32 "(A) IN GENERAL.—Once an enrollee has incurred
33 aggregate countable cost-sharing (as defined in sub-
34 paragraph (B)) equal to the stop-loss limit specified in
35 subsection (c)(4) for expenses in a year, entitlement to
36 the elimination of cost-sharing otherwise applicable
37 under part B for additional expenses incurred in the

1 year for outpatient prescription medicines or biologicals
2 for which payment is made under part B.

3 "(B) COUNTABLE COST-SHARING DEFINED.—For
4 purposes of this part, the term 'countable cost-sharing'
5 means—

6 "(i) out-of-pocket expenses for outpatient pre-
7 scription medicines with respect to which benefits
8 are payable under part B, and

9 "(ii) cost-sharing under subsections (c) (3) (B)
10 and (c) (3) (C) (i).

11 "(b) COVERED OUTPATIENT PRESCRIPTION MEDICINE
12 DEFINED.—

13 "(1) IN GENERAL.—Except as provided in paragraph
14 (2), for purposes of this part the term 'covered outpatient
15 prescription medicine' means any of the following products:

16 "(A) A medicine which may be dispensed only
17 upon prescription, and—

18 "(i) which is approved for safety and effective-
19 ness as a prescription medicine under section 505
20 of the Federal Food, Drug, and Cosmetic Act;

21 "(ii) (I) which was commercially used or sold in
22 the United States before the date of enactment of
23 the Drug Amendments of 1962 or which is iden-
24 tical, similar, or related (within the meaning of sec-
25 tion 310.6(b)(1) of title 21 of the Code of Federal
26 Regulations) to such a medicine, and (II) which
27 has not been the subject of a final determination
28 by the Secretary that it is a 'new drug' (within the
29 meaning of section 201(p) of the Federal Food,
30 Drug, and Cosmetic Act) or an action brought by
31 the Secretary under section 301, 302(a), or 304(a)
32 of such Act to enforce section 502(f) or 505(a) of
33 such Act; or

34 "(iii) (I) which is described in section 107(c)(3)
35 of the Drug Amendments of 1962 and for which
36 the Secretary has determined there is a compelling
37 justification for its medical need, or is identical,



1 similar, or related (within the meaning of section
2 310.6(b)(1) of title 21 of the Code of Federal Reg-
3 ulations) to such a medicine, and (II) for which the
4 Secretary has not issued a notice of an opportunity
5 for a hearing under section 505(e) of the Federal
6 Food, Drug, and Cosmetic Act on a proposed order
7 of the Secretary to withdraw approval of an appli-
8 cation for such medicine under such section be-
9 cause the Secretary has determined that the medi-
10 cine is less than effective for all conditions of use
11 prescribed, recommended, or suggested in its label-
12 ing.

13 “(B) A biological product which—

14 “(i) may only be dispensed upon prescription;

15 “(ii) is licensed under section 351 of the Pub-
16 lic Health Service Act; and

17 “(iii) is produced at an establishment licensed
18 under such section to produce such product.

19 “(C) Insulin approved under appropriate Federal
20 law, and needles, syringes, and disposable pumps for
21 the administration of such insulin.

22 “(D) A prescribed medicine or biological product
23 that would meet the requirements of subparagraph (A)
24 or (B) but that is available over-the-counter in addition
25 to being available upon prescription, but only if the
26 particular dosage form or strength prescribed and re-
27 quired for the individual is not available over-the-
28 counter.

29 “(E) Smoking cessation agents (as specified by the
30 Secretary).

31 “(2) EXCLUSION.—The term ‘covered outpatient pre-
32 scription medicine’ does not include—

33 “(A) medicines or classes of medicines, or their
34 medical uses, which may be excluded from coverage or
35 otherwise restricted under section 1927(d)(2), other
36 than subparagraph (E) thereof (relating to smoking
37 cessation agents), as the Secretary may specify and



1 does not include such other medicines, classes, and uses
2 as the Secretary may specify consistent with the goals
3 of providing quality care and containing costs under
4 this part;

5 "(B) except as provided in paragraphs (1)(D) and
6 (1)(E), any product which may be distributed to indi-
7 viduals without a prescription;

8 "(C) any product when furnished as part of, or as
9 incident to, a diagnostic service or any other item or
10 service for which payment may be made under this
11 title; or

12 "(D) any product that is covered under part B of
13 this title.

14 "(c) PAYMENT OF BENEFITS.—

15 "(1) COVERED OUTPATIENT PRESCRIPTION MEDI-
16 CINES.—There shall be paid from the Federal Medicare
17 Prescription Medicine Trust Fund, in the case of each en-
18 rollee who incurs expenses for medicines with respect to
19 which benefits are payable under this part under subsection
20 (a)(1), amounts equal to the sum of—

21 "(A) the price for which the medicine is made
22 available under this part (consistent with sections
23 1859A and 1859B), reduced by any applicable cost-
24 sharing under paragraphs (2) and (3); and

25 "(B) a reasonable dispensing fee.

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

28 "(2) DEDUCTIBLE.—The amount of payment under
29 paragraph (1) for expenses incurred in a year, beginning
30 with 2005, shall be reduced by an annual deductible equal
31 to the amount specified in section 1859(2) (subject to ad-
32 justment under paragraph (8)). Only expenses for count-
33 able cost-sharing (as defined in subsection (a)(2)(B)) shall
34 be taken into account in applying this paragraph.

35 "(3) COINSURANCE.—

36 "(A) IN GENERAL.—The amount of payment
37 under paragraph (1) for expenses incurred in a year

1 shall be further reduced (subject to the stop-loss limit
2 under paragraph (4)) by coinsurance as provided under
3 this paragraph.

4 "(B) PREFERRED MEDICINES.—The coinsurance
5 under this paragraph in the case of a preferred medi-
6 cine (including a medicine treated as a preferred medi-
7 cine under paragraph (5)), is equal to 20 percent of the
8 price applicable under paragraph (1)(A) (or such lower
9 percentage as may be provided for under section
10 1859E(a)(1)(A)(ii)). In this part, the term 'preferred
11 medicine' means, with respect to medicines classified
12 within a therapeutic class, those medicines which have
13 been designated as a preferred medicine by the Sec-
14 retary or the pharmacy contractor involved with respect
15 to that class and (in the case of a nongeneric medicine)
16 with respect to which a contract has been negotiated
17 under this part.

18 "(C) NONPREFERRED MEDICINES.—The coinsur-
19 ance under this paragraph in the case of a nonpre-
20 ferred medicine that is not treated as a preferred medi-
21 cine under paragraph (5) is equal to the sum of—

22 "(i) 20 percent of the price for lowest price
23 preferred medicine that is within the same thera-
24 peutic class; and

25 "(ii) the amount by which—

26 "(I) the price at which the nonpreferred
27 medicine is made available to the enrollee; ex-
28 ceeds

29 "(II) the price of such lowest price pre-
30 ferred medicine.

31 "(4) NO COINSURANCE ONCE OUT-OF-POCKET EX-
32 PENDITURES EQUAL STOP-LOSS LIMIT.—Once an enrollee
33 has incurred aggregate countable cost-sharing under para-
34 graph (3) (including cost-sharing under part B attributable
35 to outpatient prescription drugs or biologicals) equal to the
36 amount specified in section 1859(4) (subject to adjustment
37 under paragraph (8)) for expenses in a year—



1 “(A) there shall be no coinsurance under para-
2 graph (3) for additional expenses incurred in the year
3 involved; and

4 “(B) there shall be no coinsurance under part B
5 for additional expenses incurred in the year involved for
6 outpatient prescription drugs and biologicals.

7 “(5) APPEALS RIGHTS RELATING TO COVERAGE OF
8 NONPREFERRED MEDICINES.—

9 “(A) PROCEDURES REGARDING THE DETERMINA-
10 TION OF MEDICINES THAT ARE MEDICALLY NEC-
11 ESSARY.—Each pharmacy contractor shall have in
12 place procedures on a case-by-case basis to treat a non-
13 preferred medicine as a preferred medicine under this
14 part if the preferred medicine is determined to be not
15 as effective for the enrollee or to have significant ad-
16 verse effect on the enrollee. Such procedures shall re-
17 quire that such determinations are based on profes-
18 sional medical judgment, the medical condition of the
19 enrollee, and other medical evidence.

20 “(B) PROCEDURES REGARDING DENIALS OF
21 CARE.—Such contractor shall have in place procedures
22 to ensure—

23 “(i) a timely internal review for resolution of
24 denials of coverage (in whole or in part and includ-
25 ing those regarding the coverage of nonpreferred
26 medicines) in accordance with the medical exigen-
27 cies of the case and a timely resolution of com-
28 plaints, by enrollees in the plan, or by providers,
29 pharmacists, and other individuals acting on behalf
30 of each such enrollee (with the enrollee’s consent)
31 in accordance with requirements (as established by
32 the Secretary) that are comparable to such require-
33 ments for Medicare+Choice organizations under
34 part C;

35 “(ii) that the entity complies in a timely man-
36 ner with requirements established by the Secretary
37 that (I) provide for an external review by an inde-



1 pendent entity selected by the Secretary of denials
2 of coverage described in clause (i) not resolved in
3 the favor of the beneficiary (or other complainant)
4 under the process described in such clause and (II)
5 are comparable to the external review requirements
6 established for Medicare+ Choice organizations
7 under part C; and

8 “(iii) that enrollees are provided with informa-
9 tion regarding the appeals procedures under this
10 part at the time of enrollment with a pharmacy
11 contractor under this part and upon request there-
12 after.

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

20 “(7) PERMITTING APPLICATION UNDER PART B OF
21 NEGOTIATED PRICES.—For purposes of making payment
22 under part B for medicines that would be covered out-
23 patient prescription medicines but for the exclusion under
24 subparagraph (B) or (C) of subsection (b)(2), the Secretary
25 may elect to apply the payment basis used for payment of
26 covered outpatient prescription medicines under this part
27 instead of the payment basis otherwise used under such
28 part, if it results in a lower cost to the program.

29 “(8) INFLATION ADJUSTMENT.—

30 “(A) IN GENERAL.—With respect to expenses in-
31 curred in a year after 2005—

32 “(i) the deductible under paragraph (2) is
33 equal to the deductible determined under such
34 paragraph (or this subparagraph) for the previous
35 year increased by the percentage increase in per
36 capita program expenditures (as estimated in ad-

1 vance for the year involved under subparagraph
2 (B)); and

3 "(ii) the stop-loss limit under paragraph (3) is
4 equal to the stop-loss limit determined under such
5 paragraph (or this subparagraph) for the previous
6 year increased by such percentage increase.

7 The Secretary shall adjust such percentage increase in
8 subsequent years to take into account misestimations
9 made of the per capita program expenditures under
10 clauses (i) and (ii) in previous years. Any increase
11 under this subparagraph that is not a multiple of \$10
12 shall be rounded to the nearest multiple of \$10.

13 "(B) ESTIMATION OF INCREASE IN PER CAPITA
14 PROGRAM EXPENDITURES.—The Secretary shall before
15 the beginning of each year (beginning with 2006) esti-
16 mate the percentage increase in average per capita ag-
17 gregate expenditures from the Federal Medicare Pre-
18 scription Medicine Trust Fund for the year involved
19 compared to the previous year.

20 "(C) RECONCILIATION.—The Secretary shall also
21 compute (beginning with 2007) the actual percentage
22 increase in such aggregate expenditures in order to
23 provide for reconciliation of deductibles, stop-loss lim-
24 its, and premiums under the second sentence of sub-
25 paragraph (A) and under section 1859D(d)(2).

26 "(d) AMOUNT OF PREMIUMS.—

27 "(1) MONTHLY PREMIUM RATE IN 2005.—The monthly
28 premium rate in 2005 for prescription medicine benefits
29 under this part is the amount specified in section 1859(1).

30 "(2) INFLATION ADJUSTMENT FOR SUBSEQUENT
31 YEARS.—The monthly premium rate for a year after 2005
32 for prescription medicine benefits under this part is equal
33 to the monthly premium rate for the previous year under
34 this subsection increased by the percentage increase in per
35 capita program expenditures (as estimated in advance for
36 the year involved under subsection (c)(8)(B)). The Sec-
37 retary shall adjust such percentage in subsequent years to



1 take into account misestimations made of the per capita
2 program expenditures under the previous sentence in pre-
3 vious years. Any increase under this paragraph that is not
4 a multiple of \$1 shall be rounded to the nearest multiple
5 of \$1.

6 "ADMINISTRATION; QUALITY ASSURANCE

7 "SEC. 1859E. (a) RULES RELATING TO PROVISION OF
8 BENEFITS.—

9 "(1) PROVISION OF BENEFITS.—

10 "(A) IN GENERAL.—In providing benefits under
11 this part, the Secretary (directly or through the con-
12 tracts with pharmacy contractors) shall employ mecha-
13 nisms to provide benefits appropriately and efficiently,
14 and those mechanisms may include—

15 "(i) the use of—

16 "(I) price negotiations (consistent with
17 subsection (b));

18 "(II) reduced coinsurance (below 20 per-
19 cent) to encourage the utilization of appro-
20 priate preferred medicines; and

21 "(III) methods to reduce medication errors
22 and encourage appropriate use of medications;
23 and

24 "(ii) permitting pharmacy contractors, as ap-
25 proved by the Secretary, to make exceptions to sec-
26 tion 1859D(c)(3)(C) (relating to cost-sharing for
27 non-preferred medicines) to secure best prices for
28 enrollees so long as the payment amount under sec-
29 tion 1859D(c)(1) does not equal zero.

30 "(B) CONSTRUCTION.—Nothing in this subsection
31 shall be construed to prevent the Secretary (directly or
32 through the contracts with pharmacy contractors) from
33 using incentives to encourage enrollees to select generic
34 or other cost-effective medicines, so long as—

35 "(i) such incentives are designed not to result
36 in any increase in the aggregate expenditures under

1 the Federal Medicare Prescription Medicine Trust
2 Fund; and

3 “(ii) a beneficiary’s coinsurance shall be no
4 greater than 20 percent in the case of a preferred
5 medicine (including a nonpreferred medicine treat-
6 ed as a preferred medicine under section
7 1859D(c)(5)).

8 “(2) CONSTRUCTION.—Nothing in this part shall pre-
9 clude the Secretary or a pharmacy contractor from—

10 “(A) educating prescribing providers, pharmacists,
11 and enrollees about medical and cost benefits of pre-
12 ferred medicines;

13 “(B) requesting prescribing providers to consider a
14 preferred medicine prior to dispensing of a nonpre-
15 ferred medicine, as long as such request does not un-
16 duly delay the provision of the medicine;

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

26 “(D) using price negotiations to achieve reduced
27 prices on covered outpatient prescription medicines, in-
28 cluding new medicines, medicines for which there are
29 few therapeutic alternatives, and medicines of par-
30 ticular clinical importance to individuals enrolled under
31 this part; and

32 “(E) utilizing information on medicine prices of
33 OECD countries and of other payors in the United
34 States in the negotiation of prices under this part.

35 “(b) PRICE NEGOTIATIONS PROCESS.—

36 “(1) REQUIREMENTS WITH RESPECT TO PREFERRED
37 MEDICINES.—Negotiations of contracts with manufacturers



1 with respect to covered outpatient prescription medicines
2 under this part shall be conducted in a manner so that—

3 “(A) there is at least a contract for a medicine
4 within each therapeutic class (as defined by the Sec-
5 retary in consultation with such Medicare Prescription
6 Medicine Advisory Committee);

7 “(B) if there is more than 1 medicine available in
8 a therapeutic class, there are contracts for at least 2
9 medicines within such class unless determined clinically
10 inappropriate in accordance with standards established
11 by the Secretary; and

12 “(C) if there are more than 2 medicines available
13 in a therapeutic class, there is a contract for at least
14 2 medicines within such class and a contract for ge-
15 neric medicine substitute if available unless determined
16 clinically inappropriate in accordance with standards
17 established by the Secretary.

18 “(2) ESTABLISHMENT OF THERAPEUTIC CLASSES.—
19 The Secretary, in consultation with the Medicare Prescrip-
20 tion Medicine Advisory Committee (established under sec-
21 tion 1859H), shall establish for purposes of this part thera-
22 peutic classes and assign to such classes covered outpatient
23 prescription medicines.

24 “(3) DISCLOSURE CONCERNING PREFERRED MEDI-
25 CINES.—The Secretary shall provide, through pharmacy
26 contractors or otherwise, for disclosure to current and pro-
27 spective enrollees and to participating providers and phar-
28 macies in each service area a list of the preferred medicines
29 and differences in applicable cost-sharing between such
30 medicines and nonpreferred medicines.

31 “(4) NO REVIEW.—The Secretary’s establishment of
32 therapeutic classes and the assignment of medicines to such
33 classes and the Secretary’s determination of what is a
34 breakthrough medicine are not subject to administrative or
35 judicial review.

36 “(c) CONFIDENTIALITY.—The Secretary shall ensure that
37 the confidentiality of individually identifiable health information

1 relating to the provision of benefits under this part is pro-
2 tected, consistent with the standards for the privacy of such in-
3 formation promulgated by the Secretary under the Health In-
4 surance Portability and Accountability Act of 1996, or any sub-
5 sequent comprehensive and more protective set of confiden-
6 tiality standards enacted into law or promulgated by the Sec-
7 retary. Nothing in this subsection shall be construed as pre-
8 venting the coordination of data with a State prescription medi-
9 cine program so long as such program has in place confiden-
10 tiality standards that are equal to or exceed the standards used
11 by the Secretary.

12 "(d) FRAUD AND ABUSE SAFEGUARDS.—The Secretary,
13 through the Office of the Inspector General, is authorized and
14 directed to issue regulations establishing appropriate safe-
15 guards to prevent fraud and abuse under this part. Such safe-
16 guards, at a minimum, should include compliance programs,
17 certification data, audits, and recordkeeping practices. In devel-
18 oping such regulations, the Secretary shall consult with the At-
19 torney General and other law enforcement and regulatory agen-
20 cies.

21 "FEDERAL MEDICARE PRESCRIPTION MEDICINE TRUST FUND
22 "SEC. 1859F. (a) ESTABLISHMENT.—There is hereby cre-
23 ated on the books of the Treasury of the United States a trust
24 fund to be known as the 'Federal Medicare Prescription Medi-
25 cine Trust Fund' (in this section referred to as the 'Trust
26 Fund'). The Trust Fund shall consist of such gifts and be-
27 quests as may be made as provided in section 201(i)(1), and
28 such amounts as may be deposited in, or appropriated to, such
29 fund as provided in this part.

30 "(b) APPLICATION OF SMI TRUST FUND PROVISIONS.—
31 The provisions of subsections (b) through (i) of section 1841
32 shall apply to this part and the Trust Fund in the same man-
33 ner as they apply to part B and the Federal Supplementary
34 Medical Insurance Trust Fund, respectively.

1 "COMPENSATION FOR EMPLOYERS COVERING RETIREE
2 MEDICINE COSTS

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

16 "(b) REQUIREMENTS.—To receive payment under this sec-
17 tion, a group health plan shall comply with the following re-
18 quirements:

19 "(1) COMPLIANCE WITH REQUIREMENTS.—The group
20 health plan shall comply with the requirements of this Act
21 and other reasonable, necessary, and related requirements
22 that are needed to administer this section, as determined
23 by the Secretary.

24 "(2) ANNUAL ASSURANCES AND NOTICE BEFORE TER-
25 MINATION.—The sponsor of the plan shall—

26 "(A) annually attest, and provide such assurances
27 as the Secretary may require, that the coverage offered
28 under the group health plan meets the requirements of
29 this section and will continue to meet such require-
30 ments for the duration of the sponsor's participation in
31 the program under this section; and

32 "(B) guarantee that it will give notice to the Sec-
33 retary and covered enrollees—

34 "(i) at least 120 days before terminating its
35 plan, and

36 "(ii) immediately upon determining that the
37 actuarial value of the prescription medicine benefit

1 under the plan falls below the actuarial value re-
2 quired under subsection (a).

3 "(3) BENEFICIARY INFORMATION.—The sponsor of
4 the plan shall report to the Secretary, for each calendar
5 quarter for which it seeks a payment under this section, the
6 names and social security numbers of all enrollees described
7 in subsection (a) covered under such plan during such
8 quarter and the dates (if less than the full quarter) during
9 which each such individual was covered.

10 "(4) AUDITS.—The sponsor or plan seeking payment
11 under this section shall agree to maintain, and to afford
12 the Secretary access to, such records as the Secretary may
13 require for purposes of audits and other oversight activities
14 necessary to ensure the adequacy of prescription medicine
15 coverage, the accuracy of payments made, and such other
16 matters as may be appropriate.

17 "(c) PAYMENT.—

18 "(1) IN GENERAL.—The sponsor of a group health
19 plan that meets the requirements of subsection (b) with re-
20 spect to a quarter in a calendar year shall be entitled to
21 have payment made on a quarterly basis of the amount
22 specified in paragraph (2) for each individual described in
23 subsection (a) who during the quarter is covered under the
24 plan and was not enrolled in the insurance program under
25 this part.

26 "(2) AMOUNT OF PAYMENT.—

27 "(A) IN GENERAL.—The amount of the payment
28 for a quarter shall approximate, for each such covered
29 individual, $\frac{2}{3}$ of the sum of the monthly Government
30 contribution amounts (computed under subparagraph
31 (B)) for each of the 3 months in the quarter.

32 "(B) COMPUTATION OF MONTHLY GOVERNMENT
33 CONTRIBUTION AMOUNT.—For purposes of subpara-
34 graph (A), the monthly Government contribution
35 amount for a month in a year is equal to the amount
36 by which—



1 “(i) $\frac{1}{12}$ of the average per capita aggregate
2 expenditures, as estimated under section
3 1859D(c)(8) for the year involved; exceeds

4 “(ii) the monthly premium rate under section
5 1859D(d) for the month involved.

6 “MEDICARE PRESCRIPTION MEDICINE ADVISORY COMMITTEE

7 “SEC. 1859H. (a) ESTABLISHMENT OF COMMITTEE.—

8 There is established a Medicare Prescription Medicine Advisory
9 Committee (in this section referred to as the ‘Committee’).

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

12 “(1) the development of guidelines for the implementa-
13 tion and administration of the outpatient prescription medi-
14 cine benefit program under this part; and

15 “(2) the development of—

16 “(A) standards required of pharmacy contractors
17 under section 1859D(c)(5) for determining if a medi-
18 cine is as effective for an enrollee or has a significant
19 adverse effect on an enrollee under this part;

20 “(B) standards for—

21 “(i) defining therapeutic classes;

22 “(ii) adding new therapeutic classes;

23 “(iii) assigning to such classes covered out-
24 patient prescription medicines; and

25 “(iv) identifying breakthrough medicines;

26 “(C) procedures to evaluate the bids submitted by
27 pharmacy contractors under this part;

28 “(D) procedures for negotiations, and standards
29 for entering into contracts, with manufacturers, includ-
30 ing identifying medicines or classes of medicines where
31 Secretarial negotiation is most likely to yield savings
32 under this part significantly above those that which
33 could be achieved by a pharmacy contractor; and

34 “(E) procedures to ensure that pharmacy contrac-
35 tors with a contract under this part are in compliance
36 with the requirements under this part.

1 For purposes of this part, a medicine is a 'breakthrough medi-
2 cine' if the Secretary, in consultation with the Committee, de-
3 termines it is a new product that will make a significant and
4 major improvement by reducing physical or mental illness, re-
5 ducing mortality, or reducing disability, and that no other
6 product is available to beneficiaries that achieves similar results
7 for the same condition. The Committee may consider cost-effec-
8 tiveness in establishing standards for defining therapeutic
9 classes and assigning drugs to such classes under subparagraph
10 (B).

11 "(c) STRUCTURE AND MEMBERSHIP OF THE COM-
12 MITTEE.—

13 "(1) STRUCTURE.—The Committee shall be composed
14 of 19 members who shall be appointed by the Secretary.

15 "(2) MEMBERSHIP.—

16 "(A) IN GENERAL.—The members of the Com-
17 mittee shall be chosen on the basis of their integrity,
18 impartiality, and good judgment, and shall be individ-
19 uals who are, by reason of their education, experience,
20 and attainments, exceptionally qualified to perform the
21 duties of members of the Committee.

22 "(B) SPECIFIC MEMBERS.—Of the members ap-
23 pointed under paragraph (1)—

24 "(i) 5 shall be chosen to represent practicing
25 physicians, 2 of whom shall be gerontologists;

26 "(ii) 2 shall be chosen to represent practicing
27 nurse practitioners;

28 "(iii) 4 shall be chosen to represent practicing
29 pharmacists;

30 "(iv) 1 shall be chosen to represent the Cen-
31 ters for Medicare & Medicaid Services;

32 "(v) 4 shall be chosen to represent actuaries,
33 pharmacoeconomists, researchers, and other appro-
34 priate experts;

35 "(vi) 1 shall be chosen to represent emerging
36 medicine technologies;



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

3 “(viii) 1 shall be chosen to represent individ-
4 uals enrolled under this part.

5 “(d) TERMS OF APPOINTMENT.—Each member of the
6 Committee shall serve for a term determined appropriate by the
7 Secretary. The terms of service of the members initially ap-
8 pointed shall begin on January 1, 2004.

9 “(e) CHAIRPERSON.—The Secretary shall designate a
10 member of the Committee as Chairperson. The term as Chair-
11 person shall be for a 1-year period.

12 “(f) COMMITTEE PERSONNEL MATTERS.—

13 “(1) MEMBERS.—

14 “(A) COMPENSATION.—Each member of the Com-
15 mittee who is not an officer or employee of the Federal
16 Government shall be compensated at a rate equal to
17 the daily equivalent of the annual rate of basic pay pre-
18 scribed for level IV of the Executive Schedule under
19 section 5315 of title 5, United States Code, for each
20 day (including travel time) during which such member
21 is engaged in the performance of the duties of the
22 Committee. All members of the Committee who are of-
23 ficers or employees of the United States shall serve
24 without compensation in addition to that received for
25 their services as officers or employees of the United
26 States.

27 “(B) TRAVEL EXPENSES.—The members of the
28 Committee shall be allowed travel expenses, including
29 per diem in lieu of subsistence, at rates authorized for
30 employees of agencies under subchapter I of chapter 57
31 of title 5, United States Code, while away from their
32 homes or regular places of business in the performance
33 of services for the Committee.

34 “(2) STAFF.—The Committee may appoint such per-
35 sonnel as the Committee considers appropriate.

36 “(g) OPERATION OF THE COMMITTEE.—



1 “(1) MEETINGS.—The Committee shall meet at the
2 call of the Chairperson (after consultation with the other
3 members of the Committee) not less often than quarterly
4 to consider a specific agenda of issues, as determined by
5 the Chairperson after such consultation.

6 “(2) QUORUM.—Ten members of the Committee shall
7 constitute a quorum for purposes of conducting business.

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

11 “(i) TRANSFER OF PERSONNEL, RESOURCES, AND AS-
12 SETS.—For purposes of carrying out its duties, the Secretary
13 and the Committee may provide for the transfer to the Com-
14 mittee of such civil service personnel in the employ of the De-
15 partment of Health and Human Services (including the Centers
16 for Medicare & Medicaid Services), and such resources and as-
17 sets of the Department used in carrying out this title, as the
18 Committee requires.

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

22 (b) APPLICATION OF GENERAL EXCLUSIONS FROM COV-
23 ERAGE.—

24 (1) APPLICATION TO PART D.—Section 1862(a) (42
25 U.S.C. 1395y(a)) is amended in the matter preceding para-
26 graph (1) by striking “part A or part B” and inserting
27 “part A, B, or D”.

28 (2) PRESCRIPTION MEDICINES NOT EXCLUDED FROM
29 COVERAGE IF APPROPRIATELY PRESCRIBED.—Section
30 1862(a)(1) (42 U.S.C. 1395y(a)(1)) is amended—

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

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

35 (C) by adding at the end the following new sub-
36 paragraph:

1 “(J) in the case of prescription medicines covered
2 under part D, which are not prescribed in accordance
3 with such part.”.

4 (c) CONFORMING AMENDMENTS.—(1) Part C of title
5 XVIII is amended—

6 (A) in section 1851(a)(2)(B) (42 U.S.C. 1395w-
7 21(a)(2)(B)), by striking “1859(b)(3)” and inserting
8 “1858(b)(3)”;

9 (B) in section 1851(a)(2)(C) (42 U.S.C. 1395w-
10 21(a)(2)(C)), by striking “1859(b)(2)” and inserting
11 “1858(b)(2)”;

12 (C) in section 1852(a)(1) (42 U.S.C. 1395w-
13 22(a)(1)), by striking “1859(b)(3)” and inserting
14 “1858(b)(3)”;

15 (D) in section 1852(a)(3)(B)(ii) (42 U.S.C. 1395w-
16 22(a)(3)(B)(ii)), by striking “1859(b)(2)(B)” and inserting
17 “1858(b)(2)(B)”;

18 (E) in section 1853(a)(1)(A) (42 U.S.C. 1395w-
19 23(a)(1)(A)), by striking “1859(e)(4)” and inserting
20 “1858(e)(4)”;

21 (F) in section 1853(a)(3)(D) (42 U.S.C. 1395w-
22 23(a)(3)(D)), by striking “1859(e)(4)” and inserting
23 “1858(e)(4)”.

24 (2) Section 1171(a)(5)(D) (42 U.S.C. 1320d(a)(5)(D)) is
25 amended by striking “or (C)” and inserting “(C), or (D)”.

26 **SEC. 102. PROVISION OF MEDICARE OUTPATIENT PRE-**
27 **SCRIPTION MEDICINE COVERAGE UNDER**
28 **THE MEDICARE+CHOICE PROGRAM.**

29 (a) REQUIRING AVAILABILITY OF AN ACTUARIALLY
30 EQUIVALENT PRESCRIPTION MEDICINE BENEFIT.—Section
31 1851 (42 U.S.C. 1395w-21) is amended by adding at the end
32 the following new subsection:

33 “(j) AVAILABILITY OF PRESCRIPTION MEDICINE BENE-
34 FITS.—

35 “(1) IN GENERAL.—Notwithstanding any other provi-
36 sion of this part, each Medicare+ Choice organization that
37 makes available a Medicare+ Choice plan described in sec-

1 tion 1851(a)(2)(A) shall make available such a plan that
2 offers coverage of covered outpatient prescription medicines
3 that is at least actuarially equivalent to the benefits pro-
4 vided under part D. Information respecting such benefits
5 shall be made available in the same manner as information
6 on other benefits provided under this part is made avail-
7 able. Nothing in this paragraph shall be construed as re-
8 quiring the offering of such coverage separate from cov-
9 erage that includes benefits under parts A and B.

10 “(2) TREATMENT OF PRESCRIPTION MEDICINE EN-
11 ROLLEES.—In the case of a Medicare+ Choice eligible indi-
12 vidual who is enrolled under part D, the benefits described
13 in paragraph (1) shall be treated in the same manner as
14 benefits described in part B for purposes of coverage and
15 payment and any reference in this part to the Federal Sup-
16 plementary Medical Insurance Trust Fund shall be deemed,
17 with respect to such benefits, to be a reference to the Fed-
18 eral Medicare Prescription Medicine Trust Fund.”.

19 (b) APPLICATION OF QUALITY STANDARDS.—Section
20 1852(e)(2)(A) (42 U.S.C. 1395w-22(e)(2)(A)) is amended—

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

22 (2) by striking the period at the end of clause (xii)
23 and inserting “. and”; and

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

25 “(xiii) comply with the standards, and apply
26 the programs, under section 1859B(b) for covered
27 outpatient prescription medicines under the plan.”.

28 (c) PAYMENT SEPARATE FROM PAYMENT FOR PART A
29 AND B BENEFITS.—Section 1853 (42 U.S.C. 1395w-23) is
30 amended—

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

33 (2) by adding at the end the following new subsection:

34 “(j) PAYMENT FOR PRESCRIPTION MEDICINE COVERAGE
35 OPTION.—

36 “(1) IN GENERAL.—In the case of a Medicare+ Choice
37 plan that provides prescription medicine benefits described

1 in section 1851(j)(1), the amount of payment otherwise
2 made to the Medicare+Choice organization offering the
3 plan shall be increased by the amount described in para-
4 graph (2). Such payments shall be made in the same man-
5 ner and time as the amount otherwise paid, but such
6 amount shall be payable from the Federal Medicare Pre-
7 scription Medicine Trust Fund.

8 “(2) AMOUNT.—The amount described in this para-
9 graph is the monthly Government contribution amount
10 computed under section 1859G(c)(2)(B), but subject to ad-
11 justment under paragraph (3). Such amount shall be uni-
12 form geographically and shall not vary based on the
13 Medicare+Choice payment area involved.

14 “(3) RISK ADJUSTMENT.—The Secretary shall estab-
15 lish a methodology for the adjustment of the payment
16 amount under this subsection in a manner that takes into
17 account the relative risks for use of outpatient prescription
18 medicines by Medicare+Choice enrollees. Such methodology
19 shall be designed in a manner so that the total payments
20 under this title (including part D) are not changed as a re-
21 sult of the application of such methodology.”

22 (d) SEPARATE APPLICATION OF ADJUSTED COMMUNITY
23 RATE (ACR).—Section 1854 (42 U.S.C. 1395w-24) is amend-
24 ed by adding at the end the following:

25 “(i) APPLICATION TO PRESCRIPTION MEDICINE COV-
26 ERAGE.—The Secretary shall apply the previous provisions of
27 this section (including the computation of the adjusted commu-
28 nity rate) separately with respect to prescription medicine bene-
29 fits described in section 1851(j)(1).”

30 (f) CONFORMING AMENDMENTS.—

31 (1) Section 1851 (42 U.S.C. 1395w-21) is amended—

32 (A) in subsection (a)(1)(A), by striking “parts A
33 and B” and inserting “parts A, B, and D”; and

34 (B) in subsection (i) by inserting “(and, if applica-
35 ble, part D)” after “parts A and B”.

36 (2) Section 1852(a)(1)(A) (42 U.S.C. 1395w-
37 22(a)(1)(A)) is amended by inserting “(and under part D

1 to individuals also enrolled under such part)" after "parts
2 A and B".

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

5 (A) by striking "and" at the end of subparagraph
6 (D);

7 (B) by striking the period at the end of subpara-
8 graph (E) and inserting "; and"; and

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

10 "(F) the plan for part D benefits guarantees cov-
11 erage of any specifically named prescription medicine
12 for an enrollee to the extent that it would be required
13 to be covered under part D.

14 In carrying out subparagraph (F), a Medicare+ Choice or-
15 ganization has the same authority to enter into contracts
16 with respect to coverage of preferred medicines as the Sec-
17 retary has under part D, but subject to an independent
18 contractor appeal or other appeal process that would be ap-
19 plicable to determinations by such a pharmacy contractor
20 consistent with section 1859D(c)(5).".

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

24 "(5) LIMITATION ON COST-SHARING.—In no event
25 may a Medicare+ Choice organization include a require-
26 ment that an enrollee pay cost-sharing in excess of the
27 cost-sharing otherwise permitted under part D.".

28 **SEC. 103. MEDIGAP REVISIONS.**

29 (a) REQUIRED COVERAGE OF COVERED OUTPATIENT
30 PRESCRIPTION MEDICINES.—Section 1882(p)(2)(B) (42
31 U.S.C. 1395ss(p)(2)(B)) is amended by inserting before "and"
32 at the end the following: "including a requirement that an ap-
33 propriate number of policies provide coverage of medicines
34 which complements but does not duplicate the medicine benefits
35 that beneficiaries are otherwise eligible for benefits under part
36 D of this title (with the Secretary and the National Association
37 of Insurance Commissioners determining the appropriate level

1 of medicine benefits that each benefit package must provide
2 and ensuring that policies providing such coverage are afford-
3 able for beneficiaries;”

4 (b) EFFECTIVE DATE.—The amendment made by sub-
5 section (a) shall take effect on January 1, 2005.

6 (c) TRANSITION PROVISIONS.—

7 (1) IN GENERAL.—If the Secretary of Health and
8 Human Services identifies a State as requiring a change to
9 its statutes or regulations to conform its regulatory pro-
10 gram to the amendments made by this section, the State
11 regulatory program shall not be considered to be out of
12 compliance with the requirements of section 1882 of the
13 Social Security Act due solely to failure to make such
14 change until the date specified in paragraph (4).

15 (2) NAIC STANDARDS.—If, within 9 months after the
16 date of enactment of this Act, the National Association of
17 Insurance Commissioners (in this subsection referred to as
18 the “NAIC”) modifies its NAIC Model Regulation relating
19 to section 1882 of the Social Security Act (referred to in
20 such section as the 1991 NAIC Model Regulation, as sub-
21 sequently modified) to conform to the amendments made
22 by this section, such revised regulation incorporating the
23 modifications shall be considered to be the applicable NAIC
24 model regulation (including the revised NAIC model regula-
25 tion and the 1991 NAIC Model Regulation) for the pur-
26 poses of such section.

27 (3) SECRETARY STANDARDS.—If the NAIC does not
28 make the modifications described in paragraph (2) within
29 the period specified in such paragraph, the Secretary of
30 Health and Human Services shall make the modifications
31 described in such paragraph and such revised regulation in-
32 corporating the modifications shall be considered to be the
33 appropriate regulation for the purposes of such section.

34 (4) DATE SPECIFIED.—

35 (A) IN GENERAL.—Subject to subparagraph (B),
36 the date specified in this paragraph for a State is the
37 earlier of—



1 (i) the date the State changes its statutes or
2 regulations to conform its regulatory program to
3 the changes made by this section; or

4 (ii) 1 year after the date the NAIC or the Sec-
5 retary first makes the modifications under para-
6 graph (2) or (3), respectively.

7 (B) ADDITIONAL LEGISLATIVE ACTION RE-
8 QUIRED.—In the case of a State which the Secretary
9 identifies as—

10 (i) requiring State legislation (other than leg-
11 islation appropriating funds) to conform its regu-
12 latory program to the changes made in this section;
13 but

14 (ii) having a legislature which is not scheduled
15 to meet in 2003 in a legislative session in which
16 such legislation may be considered;

17 the date specified in this paragraph is the first day of
18 the first calendar quarter beginning after the close of
19 the first legislative session of the State legislature that
20 begins on or after January 1, 2003. For purposes of
21 the previous sentence, in the case of a State that has
22 a 2-year legislative session, each year of such session
23 shall be deemed to be a separate regular session of the
24 State legislature.

25 **SEC. 104. TRANSITIONAL ASSISTANCE FOR LOW INCOME**
26 **BENEFICIARIES.**

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

30 (1) in subparagraph (A)—

31 (A) by striking “and” at the end of clause (i),

32 (B) by adding “and” at the end of clause (ii), and

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

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

35 (2) in subparagraph (B), by inserting “and section
36 1859D(c)(3)(B) and 1859D(c)(3)(C)(i)” after “1813”; and



1 (3) in subparagraph (C), by striking "and section
2 1833(b)" and inserting ", section 1833(b), and section
3 1859D(c)(2)".

4 (b) EXPANDED SLMB ELIGIBILITY.—Section
5 1902(a)(10)(E) (42 U.S.C. 1396a(a)(10)(E)) is amended—

6 (1) by striking "and" at the end of clause (iii);

7 (2) by adding "and" at the end of clause (iv); and

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

9 "(v)(I) for making medical assistance available for
10 medicare cost-sharing described in section
11 1905(p)(3)(A)(iii) and medicare cost-sharing described
12 in section 1905(p)(3)(B) and section 1905(p)(3)(C) but
13 only insofar as it relates to benefits provided under
14 part D of title XVIII, subject to section 1905(p)(4), for
15 individuals who are described in subparagraphs (A) and
16 (B) of section 1905(p)(1) or would be so described but
17 for the fact that their income exceeds 100 percent, but
18 is less than 150 percent, of the official poverty line (re-
19 ferred to in such section) for a family of the size in-
20 volved;

21 "(II) subject to section 1905(p)(4), for individuals
22 who are described in subparagraphs (A) and (B) of sec-
23 tion 1905(p)(1) or would be so described but for the
24 fact that their income exceeds 150 percent, but is less
25 than 175 percent, of the official poverty line (referred
26 to in such section) for a family of the size involved, for
27 making medical assistance available for medicare cost-
28 sharing described in section 1905(p)(3)(A)(iii) and
29 medicare cost-sharing described in section
30 1905(p)(3)(B) and section 1905(p)(3)(C) but only inso-
31 far as it relates to benefits provided under part D of
32 title XVIII, and the assistance for medicare cost-shar-
33 ing described in section 1905(p)(3)(A)(iii) is reduced
34 (on a sliding scale based on income) from 100 percent
35 to 0 percent as the income increases from 150 percent
36 to 175 percent of such poverty line;"

1 (c) FEDERAL FINANCING.—The third sentence of section
2 1905(b) (42 U.S.C. 1396d(b)) is amended by inserting before
3 the period at the end the following: “and with respect to
4 amounts expended that are attributable to section
5 1902(a)(10)(E)(v)”.

6 (d) TREATMENT OF TERRITORIES.—

7 (1) IN GENERAL.—Section 1905(p) (42 U.S.C.
8 1396d(p)) is amended—

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

11 (B) by inserting after paragraph (4) the following
12 new paragraph:

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

15 “(i) the provisions of paragraph (3) insofar as they re-
16 late to section 1859D and the provisions of section
17 1902(a)(10)(E)(v) shall not apply to residents of such
18 State; and

19 “(ii) if the State establishes a plan described in sub-
20 paragraph (B) (for providing medical assistance with re-
21 spect to the provision of prescription medicines to medicare
22 beneficiaries), the amount otherwise determined under sec-
23 tion 1108(f) (as increased under section 1108(g)) for the
24 State shall be increased by the amount specified in sub-
25 paragraph (C).

26 “(B) The plan described in this subparagraph is a plan
27 that—

28 “(i) provides medical assistance with respect to the
29 provision of covered outpatient medicines (as defined in
30 section 1859D(b)) to low-income medicare beneficiaries;
31 and

32 “(ii) assures that additional amounts received by the
33 State that are attributable to the operation of this para-
34 graph are used only for such assistance.

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

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

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

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

5 “(I) 2005, is equal to \$25,000,000; or

6 “(II) a subsequent year, is equal to the aggregate
7 amount specified in this clause for the previous year in-
8 creased by annual percentage increase specified in section
9 1859D(c)(8)(B) for the year involved.

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

13 (2) CONFORMING AMENDMENT.—Section 1108(f) (42
14 U.S.C. 1308(f)) is amended by inserting “and section
15 1905(p)(5)(A)(ii)” after “Subject to subsection (g)”.

16 (e) APPLICATION OF COST-SHARING.—Section 1902(n)(2)
17 (42 U.S.C. 1396a(n)(2)) is amended by adding at the end the
18 following: “The previous sentence shall not apply to medicare
19 cost-sharing relating to benefits under part D of title XVIII.”.

20 (f) EFFECTIVE DATE.—The amendments made by this
21 section apply to medical assistance for premiums and cost-shar-
22 ing incurred on or after January 1, 2005, with regard to
23 whether regulations to implement such amendments are pro-
24 mulgated by such date.

25 **SEC. 105. EXPANSION OF MEMBERSHIP AND DUTIES OF**
26 **MEDICARE PAYMENT ADVISORY COMMIS-**
27 **SION (MEDPAC).**

28 (a) EXPANSION OF MEMBERSHIP.—

29 (1) IN GENERAL.—Section 1805(c) (42 U.S.C. 1395b-
30 6(c)) is amended—

31 (A) in paragraph (1), by striking “17” and insert-
32 ing “19”; and

33 (B) in paragraph (2)(B), by inserting “experts in
34 the area of pharmacology and prescription medicine
35 benefit programs,” after “other health professionals.”.

36 (2) INITIAL TERMS OF ADDITIONAL MEMBERS.—

1 (A) IN GENERAL.—For purposes of staggering the
 2 initial terms of members of the Medicare Payment Ad-
 3 visory Commission under section 1805(c)(3) of the So-
 4 cial Security Act (42 U.S.C. 1395b-6(c)(3)), the initial
 5 terms of the 2 additional members of the Commission
 6 provided for by the amendment under paragraph (1)(A)
 7 are as follows:

- 8 (i) One member shall be appointed for 1 year.
- 9 (ii) One member shall be appointed for 2
 10 years.

11 (B) COMMENCEMENT OF TERMS.—Such terms
 12 shall begin on January 1, 2003.

13 (b) EXPANSION OF DUTIES.—Section 1805(b)(2) (42
 14 U.S.C. 1395b-6(b)(2)) is amended by adding at the end the
 15 following new subparagraph:

16 “(D) PRESCRIPTION MEDICINE BENEFIT PRO-
 17 GRAM.—Specifically, the Commission shall review, with
 18 respect to the prescription medicine benefit program
 19 under part D, the following:

20 “(i) The methodologies used for the manage-
 21 ment of costs and utilization of prescription medi-
 22 cines.

23 “(ii) The prices negotiated and paid, including
 24 trends in such prices and applicable discounts and
 25 comparisons with prices under section
 26 1859E(a)(2)(E).

27 “(iii) The relationship of pharmacy acquisition
 28 costs to the prices so negotiated and paid.

29 “(iv) The methodologies used to ensure access
 30 to covered outpatient prescription medicines and to
 31 ensure quality in the appropriate dispensing and
 32 utilization of such medicines.

33 “(v) The impact of the program on promoting
 34 the development of breakthrough medicines.”

