

107TH CONGRESS
2^D SESSION

S. 2625

To amend title XVIII of the Social Security Act to provide coverage of outpatient prescription drugs under the medicare program.

IN THE SENATE OF THE UNITED STATES

JUNE 14, 2002

Mr. GRAHAM (for himself, Mr. MILLER, Mr. KENNEDY, Mr. ROCKEFELLER, Mr. DASCHLE, Mr. CLELAND, Mr. INOUE, Mr. REID, Ms. MIKULSKI, Mr. JOHNSON, Mr. LEAHY, Mrs. CLINTON, Mr. NELSON of Florida, Mr. SARBANES, Mr. BINGAMAN, Ms. STABENOW, Mr. WELLSTONE, Mr. HOLLINGS, Mrs. MURRAY, Mr. SCHUMER, Mr. AKAKA, Mrs. BOXER, Mr. REED, Mr. DODD, Mr. LEVIN, Mrs. CARNAHAN, Ms. CANTWELL, Mr. DURBIN, and Mr. DAYTON) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend title XVIII of the Social Security Act to provide coverage of outpatient prescription drugs under the medicare program.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Medicare Outpatient Prescription Drug Act of 2002”.

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

- Sec. 1. Short title; table of contents.
 Sec. 2. Medicare outpatient prescription drug benefit program.

“PART D—OUTPATIENT PRESCRIPTION DRUG BENEFIT PROGRAM

- “Sec. 1860. Definitions.
 “Sec. 1860A. Establishment of outpatient prescription drug benefit program.
 “Sec. 1860B. Enrollment under program.
 “Sec. 1860C. Enrollment in a plan.
 “Sec. 1860D. Providing information to beneficiaries.
 “Sec. 1860E. Premiums.
 “Sec. 1860F. Outpatient prescription drug benefits.
 “Sec. 1860G. Entities eligible to provide outpatient drug benefit.
 “Sec. 1860H. Minimum standards for eligible entities.
 “Sec. 1860I. Payments.
 “Sec. 1860J. Employer incentive program for employment-based retiree drug coverage.
 “Sec. 1860K. Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.
 “Sec. 1860L. Medicare Prescription Drug Advisory Committee.”.
 Sec. 3. Part D benefits under Medicare+Choice plans.
 Sec. 4. Additional assistance for low-income beneficiaries.
 Sec. 5. Medigap revisions.
 Sec. 6. HHS studies and report on uniform pharmacy benefit cards and systems for transferring prescriptions electronically.
 Sec. 7. GAO study and biennial reports on competition and savings.
 Sec. 8. Expansion of membership and duties of Medicare Payment Advisory Commission (MedPAC).

1 **SEC. 2. MEDICARE OUTPATIENT PRESCRIPTION DRUG BEN-**
 2 **EFIT PROGRAM.**

3 (a) ESTABLISHMENT.—Title XVIII of the Social Se-
 4 curity Act (42 U.S.C. 1395 et seq.) is amended by redesi-
 5 gnating part D as part E and by inserting after part C
 6 the following new part:

7 “PART D—OUTPATIENT PRESCRIPTION DRUG BENEFIT
 8 PROGRAM

9 “DEFINITIONS

10 “SEC. 1860. In this part:

11 “(1) COVERED OUTPATIENT DRUG.—

1 “(A) IN GENERAL.—Except as provided in
2 subparagraph (B), the term ‘covered outpatient
3 drug’ means any of the following products:

4 “(i) A drug which may be dispensed
5 only upon prescription, and—

6 “(I) which is approved for safety
7 and effectiveness as a prescription
8 drug under section 505 of the Federal
9 Food, Drug, and Cosmetic Act;

10 “(II)(aa) which was commercially
11 used or sold in the United States be-
12 fore the date of enactment of the
13 Drug Amendments of 1962 or which
14 is identical, similar, or related (within
15 the meaning of section 310.6(b)(1) of
16 title 21 of the Code of Federal Regu-
17 lations) to such a drug, and (bb)
18 which has not been the subject of a
19 final determination by the Secretary
20 that it is a ‘new drug’ (within the
21 meaning of section 201(p) of the Fed-
22 eral Food, Drug, and Cosmetic Act)
23 or an action brought by the Secretary
24 under section 301, 302(a), or 304(a)

1 of such Act to enforce section 502(f)
2 or 505(a) of such Act; or

3 “(III)(aa) which is described in
4 section 107(c)(3) of the Drug Amend-
5 ments of 1962 and for which the Sec-
6 retary has determined there is a com-
7 pelling justification for its medical
8 need, or is identical, similar, or re-
9 lated (within the meaning of section
10 310.6(b)(1) of title 21 of the Code of
11 Federal Regulations) to such a drug,
12 and (bb) for which the Secretary has
13 not issued a notice of an opportunity
14 for a hearing under section 505(e) of
15 the Federal Food, Drug, and Cos-
16 metic Act on a proposed order of the
17 Secretary to withdraw approval of an
18 application for such drug under such
19 section because the Secretary has de-
20 termined that the drug is less than ef-
21 fective for all conditions of use pre-
22 scribed, recommended, or suggested in
23 its labeling.

24 “(ii) A biological product which—

1 “(I) may only be dispensed upon
2 prescription;

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

6 “(III) is produced at an estab-
7 lishment licensed under such section
8 to produce such product.

9 “(iii) Insulin approved under appro-
10 priate Federal law, including needles, sy-
11 ringes, and disposable pumps for the ad-
12 ministration of such insulin.

13 “(iv) A prescribed drug or biological
14 product that would meet the requirements
15 of clause (i) or (ii) except that it is avail-
16 able over-the-counter in addition to being
17 available upon prescription.

18 “(B) EXCLUSION.—The term ‘covered out-
19 patient drug’ does not include any product—

20 “(i) except as provided in subpara-
21 graph (A)(iv), which may be distributed to
22 individuals without a prescription;

23 “(ii) for which payment is available
24 under part A or B or would be available
25 under part B but for the application of a

1 deductible under such part (unless pay-
2 ment for such product is not available be-
3 cause benefits under part A or B have
4 been exhausted), determined, except as
5 provided in subparagraph (C), without re-
6 gard to whether the beneficiary involved is
7 entitled to benefits under part A or en-
8 rolled under part B; or

9 “(iii) except for agents used to pro-
10 mote smoking cessation and agents used
11 for the treatment of obesity, for which cov-
12 erage may be excluded or restricted under
13 section 1927(d)(2).

14 “(C) CLARIFICATION REGARDING IMMUNO-
15 SUPPRESSIVE DRUGS.—In the case of a bene-
16 ficiary who is not eligible for any coverage
17 under part B of drugs described in section
18 1861(s)(2)(J) because of the requirements
19 under such section (and would not be so eligible
20 if the individual were enrolled under such part),
21 the term ‘covered outpatient drug’ shall include
22 such drugs if the drugs would otherwise be de-
23 scribed in subparagraph (A).

1 “(2) ELIGIBLE BENEFICIARY.—The term ‘eligi-
2 ble beneficiary’ means an individual that is entitled
3 to benefits under part A or enrolled under part B.

4 “(3) ELIGIBLE ENTITY.—The term ‘eligible en-
5 tity’ means any entity that the Secretary determines
6 to be appropriate to provide eligible beneficiaries
7 with covered outpatient drugs under a plan under
8 this part, including—

9 “(A) a pharmacy benefit management com-
10 pany;

11 “(B) a retail pharmacy delivery system;

12 “(C) a health plan or insurer;

13 “(D) a State (through mechanisms estab-
14 lished under a State plan under title XIX);

15 “(E) any other entity approved by the Sec-
16 retary; or

17 “(F) any combination of the entities de-
18 scribed in subparagraphs (A) through (E) if the
19 Secretary determines that such combination—

20 “(i) increases the scope or efficiency
21 of the provision of benefits under this part;

22 and

23 “(ii) is not anticompetitive.

24 “(4) MEDICARE+CHOICE ORGANIZATION;

25 MEDICARE+CHOICE PLAN.—The terms

1 ‘Medicare+Choice organization’ and
 2 ‘Medicare+Choice plan’ have the meanings given
 3 such terms in subsections (a)(1) and (b)(1), respec-
 4 tively, of section 1859 (relating to definitions relat-
 5 ing to Medicare+Choice organizations).

6 “(5) PRESCRIPTION DRUG ACCOUNT.—The
 7 term ‘Prescription Drug Account’ means the Pre-
 8 scription Drug Account (as established under section
 9 1860K) in the Federal Supplementary Medical In-
 10 surance Trust Fund under section 1841.

11 “ESTABLISHMENT OF OUTPATIENT PRESCRIPTION DRUG
 12 BENEFIT PROGRAM

13 “SEC. 1860A. (a) PROVISION OF BENEFIT.—

14 “(1) IN GENERAL.—Beginning in 2004, the
 15 Secretary shall provide for and administer an out-
 16 patient prescription drug benefit program under
 17 which each eligible beneficiary enrolled under this
 18 part shall be provided with coverage of covered out-
 19 patient drugs as follows:

20 “(A) MEDICARE+CHOICE PLAN.—If the el-
 21 igible beneficiary is eligible to enroll in a
 22 Medicare+Choice plan, the beneficiary—

23 “(i) may enroll in such a plan; and

24 “(ii) if so enrolled, shall obtain cov-
 25 erage of covered outpatient drugs through
 26 such plan.

1 “(B) MEDICARE PRESCRIPTION DRUG
2 PLAN.—If the eligible beneficiary is not enrolled
3 in a Medicare+Choice plan, the beneficiary
4 shall obtain coverage of covered outpatient
5 drugs through enrollment in a plan offered by
6 an eligible entity with a contract under this
7 part.

8 “(2) VOLUNTARY NATURE OF PROGRAM.—
9 Nothing in this part shall be construed as requiring
10 an eligible beneficiary to enroll in the program es-
11 tablished under this part.

12 “(3) SCOPE OF BENEFITS.—The program es-
13 tablished under this part shall provide for coverage
14 of all therapeutic classes of covered outpatient
15 drugs.

16 “(b) ACCESS TO ALTERNATIVE PRESCRIPTION DRUG
17 COVERAGE.—In the case of an eligible beneficiary who has
18 creditable prescription drug coverage (as defined in section
19 1860B(b)(1)(F)), such beneficiary—

20 “(1) may continue to receive such coverage and
21 not enroll under this part; and

22 “(2) pursuant to section 1860B(b)(1)(C), is
23 permitted to subsequently enroll under this part
24 without any penalty and obtain coverage of covered
25 outpatient drugs in the manner described in sub-

1 section (a) if the beneficiary involuntarily loses such
2 coverage.

3 “(c) FINANCING.—The costs of providing benefits
4 under this part shall be payable from the Prescription
5 Drug Account.

6 “ENROLLMENT UNDER PROGRAM

7 “SEC. 1860B. (a) ESTABLISHMENT OF PROCESS.—

8 “(1) PROCESS SIMILAR TO ENROLLMENT
9 UNDER PART B.—The Secretary shall establish a
10 process through which an eligible beneficiary (includ-
11 ing an eligible beneficiary enrolled in a
12 Medicare+Choice plan offered by a
13 Medicare+Choice organization) may make an elec-
14 tion to enroll under this part. Such process shall be
15 similar to the process for enrollment in part B under
16 section 1837, including the deeming provisions of
17 such section.

18 “(2) REQUIREMENT OF ENROLLMENT.—An eli-
19 gible beneficiary must enroll under this part in order
20 to be eligible to receive covered outpatient drugs
21 under this title.

22 “(b) SPECIAL ENROLLMENT PROCEDURES.—

23 “(1) LATE ENROLLMENT PENALTY.—

24 “(A) INCREASE IN PREMIUM.—Subject to
25 the succeeding provisions of this paragraph, in
26 the case of an eligible beneficiary whose cov-

1 erage period under this part began pursuant to
2 an enrollment after the beneficiary's initial en-
3 rollment period under part B (determined pur-
4 suant to section 1837(d)) and not pursuant to
5 the open enrollment period described in para-
6 graph (2), the Secretary shall establish proce-
7 dures for increasing the amount of the monthly
8 part D premium under section 1860E(a) appli-
9 cable to such beneficiary—

10 “(i) by an amount that is equal to 10
11 percent of such premium for each full 12-
12 month period (in the same continuous pe-
13 riod of eligibility) in which the eligible ben-
14 efiary could have been enrolled under this
15 part but was not so enrolled; or

16 “(ii) if determined appropriate by the
17 Secretary, by an amount that the Sec-
18 retary determines is actuarially sound for
19 each such period.

20 “(B) PERIODS TAKEN INTO ACCOUNT.—

21 For purposes of calculating any 12-month pe-
22 riod under subparagraph (A), there shall be
23 taken into account—

24 “(i) the months which elapsed be-
25 tween the close of the eligible beneficiary's

1 initial enrollment period and the close of
2 the enrollment period in which the bene-
3 ficiary enrolled; and

4 “(ii) in the case of an eligible bene-
5 ficiary who reenrolls under this part, the
6 months which elapsed between the date of
7 termination of a previous coverage period
8 and the close of the enrollment period in
9 which the beneficiary reenrolled.

10 “(C) PERIODS NOT TAKEN INTO AC-
11 COUNT.—

12 “(i) IN GENERAL.—For purposes of
13 calculating any 12-month period under
14 subparagraph (A), subject to clause (ii),
15 there shall not be taken into account
16 months for which the eligible beneficiary
17 can demonstrate that the beneficiary had
18 creditable prescription drug coverage (as
19 defined in subparagraph (F)).

20 “(ii) APPLICATION.—This subpara-
21 graph shall only apply with respect to a
22 coverage period the enrollment for which
23 occurs before the end of the 60-day period
24 that begins on the first day of the month
25 which includes—

1 “(I) in the case of a beneficiary
2 with coverage described in clause (ii)
3 of subparagraph (F), the date on
4 which the plan terminates, ceases to
5 provide, or reduces the value of the
6 prescription drug coverage under such
7 plan to below the actuarial value of
8 the coverage provided under the pro-
9 gram under this part; or

10 “(II) in the case of a beneficiary
11 with coverage described in clause (i),
12 (iii), or (iv) of subparagraph (F), the
13 date on which the beneficiary loses eli-
14 gibility for such coverage.

15 “(D) PERIODS TREATED SEPARATELY.—
16 Any increase in an eligible beneficiary’s monthly
17 part D premium under subparagraph (A) with
18 respect to a particular continuous period of eli-
19 gibility shall not be applicable with respect to
20 any other continuous period of eligibility which
21 the beneficiary may have.

22 “(E) CONTINUOUS PERIOD OF ELIGI-
23 BILITY.—

24 “(i) IN GENERAL.—Subject to clause
25 (ii), for purposes of this paragraph, an eli-

1 eligible beneficiary’s ‘continuous period of eli-
2 gibility’ is the period that begins with the
3 first day on which the beneficiary is eligi-
4 ble to enroll under section 1836 and ends
5 with the beneficiary’s death.

6 “(ii) SEPARATE PERIOD.—Any period
7 during all of which an eligible beneficiary
8 satisfied paragraph (1) of section 1836
9 and which terminated in or before the
10 month preceding the month in which the
11 beneficiary attained age 65 shall be a sepa-
12 rate ‘continuous period of eligibility’ with
13 respect to the beneficiary (and each such
14 period which terminates shall be deemed
15 not to have existed for purposes of subse-
16 quently applying this paragraph).

17 “(F) CREDITABLE PRESCRIPTION DRUG
18 COVERAGE DEFINED.—For purposes of this
19 part, the term ‘creditable prescription drug cov-
20 erage’ means any of the following:

21 “(i) MEDICAID PRESCRIPTION DRUG
22 COVERAGE.—Prescription drug coverage
23 under a medicaid plan under title XIX, in-
24 cluding through the Program of All-inclu-
25 sive Care for the Elderly (PACE) under

1 section 1934 and through a social health
2 maintenance organization (referred to in
3 section 4104(c) of the Balanced Budget
4 Act of 1997).

5 “(ii) PRESCRIPTION DRUG COVERAGE
6 UNDER A GROUP HEALTH PLAN.—Pre-
7 scription drug coverage under a group
8 health plan, including a health benefits
9 plan under the Federal Employees Health
10 Benefit Program under chapter 89 of title
11 5, United States Code, and a qualified re-
12 tiree prescription drug plan (as defined in
13 section 1860J(e)(3)), that provides cov-
14 erage of the cost of prescription drugs the
15 actuarial value of which (as defined by the
16 Secretary) to the beneficiary equals or ex-
17 ceeds the actuarial value of the benefits
18 provided to an individual enrolled in the
19 outpatient prescription drug benefit pro-
20 gram under this part.

21 “(iii) STATE PHARMACEUTICAL AS-
22 SISTANCE PROGRAM.—Coverage of pre-
23 scription drugs under a State pharma-
24 ceutical assistance program.

1 “(iv) VETERANS’ COVERAGE OF PRE-
2 SCRIPTION DRUGS.—Coverage of prescrip-
3 tion drugs for veterans, and survivors and
4 dependents of veterans, under chapter 17
5 of title 38, United States Code.

6 “(2) OPEN ENROLLMENT PERIOD FOR CUR-
7 RENT BENEFICIARIES IN WHICH LATE ENROLLMENT
8 PROCEDURES DO NOT APPLY.—

9 “(A) IN GENERAL.—The Secretary shall
10 establish an applicable period, which shall begin
11 on the date on which the Secretary first begins
12 to accept elections for enrollment under this
13 part, during which any eligible beneficiary may
14 enroll under this part without the application of
15 the late enrollment procedures established
16 under paragraph (1)(A).

17 “(B) OPEN ENROLLMENT PERIOD TO
18 BEGIN PRIOR TO JANUARY 1, 2004.—The Sec-
19 retary shall ensure that eligible beneficiaries are
20 permitted to enroll under this part prior to Jan-
21 uary 1, 2004, in order to ensure that coverage
22 under this part is effective as of such date.

23 “(3) SPECIAL ENROLLMENT PERIOD FOR BENE-
24 FICIARIES WHO INVOLUNTARILY LOSE CREDITABLE
25 PRESCRIPTION DRUG COVERAGE.—The Secretary

1 shall establish a special open enrollment period for
2 an eligible beneficiary that loses creditable prescrip-
3 tion drug coverage.

4 “(c) PERIOD OF COVERAGE.—

5 “(1) IN GENERAL.—Except as provided in para-
6 graph (2) and subject to paragraph (3), an eligible
7 beneficiary’s coverage under the program under this
8 part shall be effective for the period provided in sec-
9 tion 1838, as if that section applied to the program
10 under this part.

11 “(2) OPEN AND SPECIAL ENROLLMENT.—Sub-
12 ject to paragraph (3), an eligible beneficiary who en-
13 rolls under the program under this part pursuant to
14 paragraph (2) or (3) of subsection (b) shall be enti-
15 tled to the benefits under this part beginning on the
16 first day of the month following the month in which
17 such enrollment occurs.

18 “(3) LIMITATION.—Coverage under this part
19 shall not begin prior to January 1, 2004.

20 “(d) TERMINATION.—

21 “(1) IN GENERAL.—The causes of termination
22 specified in section 1838 shall apply to this part in
23 the same manner as such causes apply to part B.

24 “(2) COVERAGE TERMINATED BY TERMINATION
25 OF COVERAGE UNDER PARTS A AND B.—

1 “(A) IN GENERAL.—In addition to the
2 causes of termination specified in paragraph
3 (1), the Secretary shall terminate an individ-
4 ual’s coverage under this part if the individual
5 is no longer enrolled in either part A or B.

6 “(B) EFFECTIVE DATE.—The termination
7 described in subparagraph (A) shall be effective
8 on the effective date of termination of coverage
9 under part A or (if later) under part B.

10 “(3) PROCEDURES REGARDING TERMINATION
11 OF A BENEFICIARY UNDER A PLAN.—The Secretary
12 shall establish procedures for determining the status
13 of an eligible beneficiary’s enrollment under this
14 part if the beneficiary’s enrollment in a plan offered
15 by an eligible entity under this part is terminated by
16 the entity for cause (pursuant to procedures estab-
17 lished by the Secretary under section 1860C(a)(1)).

18 “ENROLLMENT IN A PLAN

19 “SEC. 1860C. (a) PROCESS.—

20 “(1) ESTABLISHMENT.—

21 “(A) IN GENERAL.—The Secretary shall
22 establish a process through which an eligible
23 beneficiary who is enrolled under this part but
24 not enrolled in a Medicare+Choice plan offered
25 by a Medicare+Choice organization shall make
26 an annual election to enroll in any plan offered

1 by an eligible entity that has been awarded a
2 contract under this part and serves the geo-
3 graphic area in which the beneficiary resides.
4 Such process shall include for the default en-
5 rollment in such a plan in the case of an eligible
6 beneficiary who is enrolled under this part but
7 who has failed to make an election of such a
8 plan.

9 “(B) RULES.—In establishing the process
10 under subparagraph (A), the Secretary shall—

11 “(i) use rules similar to the rules for
12 enrollment, disenrollment, and termination
13 of enrollment with a Medicare+Choice
14 plan under section 1851, including—

15 “(I) the establishment of special
16 election periods under subsection
17 (e)(4) of such section; and

18 “(II) the application of the guar-
19 anteed issue and renewal provisions of
20 subsection (g) of such section (other
21 than paragraph (3)(C)(i), relating to
22 default enrollment); and

23 “(ii) coordinate enrollments,
24 disenrollments, and terminations of enroll-
25 ment under part C with enrollments,

1 disenrollments, and terminations of enroll-
2 ment under this part.

3 “(2) FIRST ENROLLMENT PERIOD FOR PLAN
4 ENROLLMENT.—The process developed under para-
5 graph (1) shall—

6 “(A) ensure that eligible beneficiaries who
7 choose to enroll under this part are permitted
8 to enroll with an eligible entity prior to January
9 1, 2004, in order to ensure that coverage under
10 this part is effective as of such date; and

11 “(B) be coordinated with the open enroll-
12 ment period under section 1860B(b)(2)(A).

13 “(b) MEDICARE+CHOICE ENROLLEES.—

14 “(1) IN GENERAL.—An eligible beneficiary who
15 is enrolled under this part and enrolled in a
16 Medicare+Choice plan offered by a
17 Medicare+Choice organization shall receive coverage
18 of covered outpatient drugs under this part through
19 such plan.

20 “(2) RULES.—Enrollment in a
21 Medicare+Choice plan is subject to the rules for en-
22 rollment in such a plan under section 1851.

23 “PROVIDING INFORMATION TO BENEFICIARIES

24 “SEC. 1860D. (a) ACTIVITIES.—

25 “(1) IN GENERAL.—The Secretary shall con-
26 duct activities that are designed to broadly dissemi-

1 nate information to eligible beneficiaries (and pro-
2 spective eligible beneficiaries) regarding the coverage
3 provided under this part.

4 “(2) SPECIAL RULE FOR FIRST ENROLLMENT
5 UNDER THE PROGRAM.—To the extent practicable,
6 the activities described in paragraph (1) shall ensure
7 that eligible beneficiaries are provided with such in-
8 formation at least 30 days prior to the open enroll-
9 ment period described in section 1860B(b)(2)(A).

10 “(b) REQUIREMENTS.—

11 “(1) IN GENERAL.—The activities described in
12 subsection (a) shall—

13 “(A) be similar to the activities performed
14 by the Secretary under section 1851(d);

15 “(B) be coordinated with the activities per-
16 formed by the Secretary under such section and
17 under section 1804; and

18 “(C) provide for the dissemination of infor-
19 mation comparing the plans offered by eligible
20 entities under this part that are available to eli-
21 gible beneficiaries residing in an area.

22 “(2) COMPARATIVE INFORMATION.—The com-
23 parative information described in paragraph (1)(C)
24 shall include a comparison of the following:

1 “(A) BENEFITS.—The benefits provided
2 under the plan, including the prices bene-
3 ficiaries will be charged for covered outpatient
4 drugs, any preferred pharmacy networks used
5 by the eligible entity under the plan, and the
6 formularies and appeals processes under the
7 plan.

8 “(B) QUALITY AND PERFORMANCE.—To
9 the extent available, the quality and perform-
10 ance of the eligible entity offering the plan.

11 “(C) BENEFICIARY COST-SHARING.—The
12 cost-sharing required of eligible beneficiaries
13 under the plan.

14 “(D) CONSUMER SATISFACTION SUR-
15 VEYS.—To the extent available, the results of
16 consumer satisfaction surveys regarding the
17 plan and the eligible entity offering such plan.

18 “(E) ADDITIONAL INFORMATION.—Such
19 additional information as the Secretary may
20 prescribe.

21 “(3) INFORMATION STANDARDS.—The Sec-
22 retary shall develop standards to ensure that the in-
23 formation provided to eligible beneficiaries under
24 this part is complete, accurate, and uniform.

1 “(c) USE OF MEDICARE CONSUMER COALITIONS TO
2 PROVIDE INFORMATION.—

3 “(1) IN GENERAL.—The Secretary may con-
4 tract with Medicare Consumer Coalitions to conduct
5 the informational activities under—

6 “(A) this section;

7 “(B) section 1851(d); and

8 “(C) section 1804.

9 “(2) SELECTION OF COALITIONS.—If the Sec-
10 retary determines the use of Medicare Consumer
11 Coalitions to be appropriate, the Secretary shall—

12 “(A) develop and disseminate, in such
13 areas as the Secretary determines appropriate,
14 a request for proposals for Medicare Consumer
15 Coalitions to contract with the Secretary in
16 order to conduct any of the informational ac-
17 tivities described in paragraph (1); and

18 “(B) select a proposal of a Medicare Con-
19 sumer Coalition to conduct the informational
20 activities in each such area, with a preference
21 for broad participation by organizations with
22 experience in providing information to bene-
23 ficiaries under this title.

24 “(3) PAYMENT TO MEDICARE CONSUMER COA-
25 LITIONS.—The Secretary shall make payments to

1 Medicare Consumer Coalitions contracting under
2 this subsection in such amounts and in such manner
3 as the Secretary determines appropriate.

4 “(4) AUTHORIZATION OF APPROPRIATIONS.—
5 There are authorized to be appropriated to the Sec-
6 retary such sums as may be necessary to contract
7 with Medicare Consumer Coalitions under this sec-
8 tion.

9 “(5) MEDICARE CONSUMER COALITION DE-
10 FINED.—In this subsection, the term ‘Medicare Con-
11 sumer Coalition’ means an entity that is a nonprofit
12 organization operated under the direction of a board
13 of directors that is primarily composed of bene-
14 ficiaries under this title.

15 “PREMIUMS
16 “SEC. 1860E. (a) ANNUAL ESTABLISHMENT OF
17 MONTHLY PART D PREMIUM RATES.—

18 “(1) IN GENERAL.—The Secretary shall, during
19 September of each year (beginning in 2003), deter-
20 mine and promulgate a monthly part D premium
21 rate for the succeeding year.

22 “(2) AMOUNT.—The Secretary shall determine
23 the monthly part D premium rate for the succeeding
24 year as follows:

25 “(A) PREMIUM FOR 2004.—The monthly
26 part D premium rate for 2004 shall be \$25.

1 “(B) INFLATION ADJUSTMENT OF PRE-
2 MIUM FOR 2005 AND SUBSEQUENT YEARS.—

3 “(i) IN GENERAL.—Subject to clause
4 (ii), in the case of any calendar year begin-
5 ning after 2004, the monthly part D pre-
6 mium rate for the year shall be the amount
7 described in subparagraph (A) increased
8 by an amount equal to—

9 “(I) such dollar amount, multi-
10 plied by

11 “(II) the percentage (if any) by
12 which the amount of the average an-
13 nual per capita aggregate expendi-
14 tures payable from the Prescription
15 Drug Account for the year (as esti-
16 mated under section 1860J(e)(2)(C))
17 exceeds the amount of such expendi-
18 tures in 2004.

19 “(ii) ROUNDING.—If the monthly part
20 D premium rate determined under clause
21 (i) is not a multiple of \$1, such rate shall
22 be rounded to the nearest multiple of \$1.

23 “(b) COLLECTION OF PART D PREMIUM.—The
24 monthly part D premium applicable to an eligible bene-
25 ficiary under this part (after application of any increase

1 under section 1860B(b)(1)) shall be collected and credited
 2 to the Prescription Drug Account in the same manner as
 3 the monthly premium determined under section 1839 is
 4 collected and credited to the Federal Supplementary Med-
 5 ical Insurance Trust Fund under section 1840.

6 “OUTPATIENT PRESCRIPTION DRUG BENEFITS

7 “SEC. 1860F. (a) REQUIREMENT.—A plan offered by
 8 an eligible entity under this part shall provide eligible
 9 beneficiaries enrolled in such plan with—

10 “(1) coverage of covered outpatient drugs—

11 “(A) without the application of any deduct-
 12 ible; and

13 “(B) with the cost-sharing described in
 14 subsection (b); and

15 “(2) access to negotiated prices for such drugs
 16 under subsection (c).

17 “(b) COST-SHARING.—

18 “(1) THREE-TIERED COPAYMENT STRUCTURE
 19 FOR DRUGS INCLUDED IN THE FORMULARY.—

20 “(A) IN GENERAL.—Subject to the suc-
 21 ceeding provisions of this subsection, in the case
 22 of a covered outpatient drug that is dispensed
 23 in a year to an eligible beneficiary and that is
 24 included in the formulary established by the eli-
 25 gible entity (pursuant to section 1860H(c)) for
 26 the plan, the beneficiary shall be responsible for

1 a copayment for the drug in an amount equal
2 to the following:

3 “(i) GENERIC DRUGS.—In the case of
4 a generic covered outpatient drug, \$10 for
5 each prescription (as defined by the Sec-
6 retary in consultation with the Medicare
7 Prescription Drug Advisory Committee es-
8 tablished under section 1860L) of such
9 drug.

10 “(ii) PREFERRED BRAND NAME
11 DRUGS.—In the case of a preferred brand
12 name covered outpatient drug (including a
13 drug treated as a preferred brand name
14 drug under subparagraph (C)), \$40 for
15 each prescription (as so defined) of such
16 drug.

17 “(iii) NONPREFERRED BRAND NAME
18 DRUG.—In the case of a nonpreferred
19 brand name covered outpatient drug (that
20 is not treated as a preferred brand name
21 drug under subparagraph (C)), \$60 for
22 each prescription (as so defined) of such
23 drug.

24 “(B) REDUCTION BY ELIGIBLE ENTITY.—
25 An eligible entity offering a plan under this

1 part may reduce the applicable copayment
2 amount that an eligible beneficiary enrolled in
3 the plan is subject to under subparagraph (A)
4 if the Secretary determines that such
5 reduction—

6 “(i) is tied to the performance re-
7 quirements described in section
8 1860I(b)(1)(C); and

9 “(ii) will not result in an increase in
10 the expenditures made from the Prescrip-
11 tion Drug Account.

12 “(C) TREATMENT OF MEDICALLY NEC-
13 ESSARY NONPREFERRED AND NONFORMULARY
14 DRUGS.—The eligible entity shall treat a non-
15 preferred brand name drug and a nonformulary
16 drug as a preferred brand name drug under
17 subparagraph (A)(ii) if such nonpreferred or
18 nonformulary drug, as the case may be, is de-
19 termined (pursuant to subparagraph (D) or (E)
20 of section 1860H(a)(3)) to be medically nec-
21 essary.

22 “(2) AUTHORITY FOR INCREASED COST-SHAR-
23 ING FOR NONFORMULARY DRUGS.—Pursuant to sec-
24 tion 1860H(c)(3)(A), an eligible entity offering a
25 plan under this part may require cost-sharing for a

1 nonformulary drug that is higher than the copay-
2 ment amount described in paragraph (1)(A)(iii).

3 “(3) COST-SHARING MAY NOT EXCEED NEGO-
4 TIATED PRICE.—

5 “(A) IN GENERAL.—If the amount of cost-
6 sharing for a covered outpatient drug that
7 would otherwise be required under this sub-
8 section (but for this paragraph) is greater than
9 the applicable amount, then the amount of such
10 cost-sharing shall be reduced to an amount
11 equal to such applicable amount.

12 “(B) APPLICABLE AMOUNT DEFINED.—
13 For purposes of subparagraph (A), the term
14 ‘applicable amount’ means an amount equal
15 to—

16 “(i) in the case of generic drugs and
17 preferred brand name drugs, the nego-
18 tiated price for the drug (as reported to
19 the Secretary pursuant to section
20 1860H(a)(5)(A)) less \$5; and

21 “(ii) in the case of nonpreferred brand
22 name drugs and nonformulary drugs, the
23 negotiated price for the drug (as so re-
24 ported).

1 “(4) NO COST-SHARING ONCE EXPENSES EQUAL
2 ANNUAL OUT-OF-POCKET LIMIT.—

3 “(A) IN GENERAL.—An eligible entity of-
4 fering a plan under this part shall provide cov-
5 erage of covered outpatient drugs without any
6 cost-sharing if the individual has incurred costs
7 (as described in subparagraph (C)) for covered
8 outpatient drugs in a year equal to the annual
9 out-of-pocket limit specified in subparagraph
10 (B).

11 “(B) ANNUAL OUT-OF-POCKET LIMIT.—
12 Subject to paragraph (5), for purposes of this
13 part, the ‘annual out-of-pocket limit’ specified
14 in this subparagraph is equal to \$4,000.

15 “(C) APPLICATION.—In applying subpara-
16 graph (A)—

17 “(i) incurred costs shall only include
18 costs incurred for the cost-sharing de-
19 scribed in this subsection; but

20 “(ii) such costs shall be treated as in-
21 curred without regard to whether the indi-
22 vidual or another person, including a State
23 program or other third-party coverage, has
24 paid for such costs.

1 “(5) INFLATION ADJUSTMENT FOR COPAYMENT
2 AMOUNTS AND ANNUAL OUT-OF-POCKET LIMIT.—

3 “(A) IN GENERAL.—For any year after
4 2005—

5 “(i) the copayment amounts described
6 in clauses (i), (ii), and (iii) of paragraph
7 (1)(A) are equal to the copayment amounts
8 determined under such paragraph (or this
9 paragraph) for the previous year increased
10 by the annual percentage increase de-
11 scribed in subparagraph (B); and

12 “(ii) the annual out-of-pocket limit
13 specified in paragraph (4)(B) is equal to
14 the annual out-of-pocket limit determined
15 under such paragraph (or this paragraph)
16 for the previous year increased by the an-
17 nual percentage increase described in sub-
18 paragraph (B).

19 “(B) ANNUAL PERCENTAGE INCREASE.—
20 The annual percentage increase specified in this
21 subparagraph for a year is equal to the annual
22 percentage increase in the prices of covered out-
23 patient drugs (including both price inflation
24 and price changes due to changes in therapeutic
25 mix), as determined by the Secretary for the

1 12-month period ending in July of the previous
2 year.

3 “(C) ROUNDING.—If any amount deter-
4 mined under subparagraph (A) is not a multiple
5 of \$1, such amount shall be rounded to the
6 nearest multiple of \$1.

7 “(c) ACCESS TO NEGOTIATED PRICES.—Under a
8 plan offered by an eligible entity with a contract under
9 this part, the eligible entity offering such plan shall pro-
10 vide eligible beneficiaries enrolled in such plan with access
11 to negotiated prices (including applicable discounts) used
12 for payment for covered outpatient drugs, regardless of
13 the fact that only partial benefits may be payable under
14 the coverage with respect to such drugs because of the
15 application of the cost-sharing under subsection (b).

16 “ENTITIES ELIGIBLE TO PROVIDE OUTPATIENT DRUG
17 BENEFIT

18 “SEC. 1860G. (a) ESTABLISHMENT OF PANELS OF
19 PLANS AVAILABLE IN AN AREA.—

20 “(1) IN GENERAL.—The Secretary shall estab-
21 lish procedures under which the Secretary—

22 “(A) accepts bids submitted by eligible en-
23 tities for the plans which such entities intend to
24 offer in an area established under subsection
25 (b); and

1 “(B) awards contracts to such entities to
2 provide such plans to eligible beneficiaries in
3 the area.

4 “(2) COMPETITIVE PROCEDURES.—Competitive
5 procedures (as defined in section 4(5) of the Office
6 of Federal Procurement Policy Act (41 U.S.C.
7 403(5))) shall be used to enter into contracts under
8 this part.

9 “(b) AREA FOR CONTRACTS.—

10 “(1) REGIONAL BASIS.—

11 “(A) IN GENERAL.—Except as provided in
12 subparagraph (B) and subject to paragraph (2),
13 the contract entered into between the Secretary
14 and an eligible entity with respect to a plan
15 shall require the eligible entity to provide cov-
16 erage of covered outpatient drugs under the
17 plan in a region determined by the Secretary
18 under paragraph (2).

19 “(B) PARTIAL REGIONAL BASIS.—

20 “(i) IN GENERAL.—If determined ap-
21 propriate by the Secretary, the Secretary
22 may permit the coverage described in sub-
23 paragraph (A) to be provided in a partial
24 region determined appropriate by the Sec-
25 retary.

1 “(ii) REQUIREMENTS.—If the Sec-
2 retary permits coverage pursuant to clause
3 (i), the Secretary shall ensure that the par-
4 tial region in which coverage is provided
5 is—

6 “(I) at least the size of the com-
7 mercial service area of the eligible en-
8 tity for that area; and

9 “(II) not smaller than a State.

10 “(2) DETERMINATION.—

11 “(A) IN GENERAL.—In determining re-
12 gions for contracts under this part, the Sec-
13 retary shall—

14 “(i) take into account the number of
15 eligible beneficiaries in an area in order to
16 encourage participation by eligible entities;
17 and

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

20 “(B) NO ADMINISTRATIVE OR JUDICIAL
21 REVIEW.—The determination of coverage areas
22 under this part shall not be subject to adminis-
23 trative or judicial review.

24 “(c) SUBMISSION OF BIDS.—

25 “(1) SUBMISSION.—

1 “(A) IN GENERAL.—Subject to subpara-
2 graph (B), each eligible entity desiring to offer
3 a plan under this part in an area shall submit
4 a bid with respect to such plan to the Secretary
5 at such time, in such manner, and accompanied
6 by such information as the Secretary may rea-
7 sonably require.

8 “(B) BID THAT COVERS MULTIPLE
9 AREAS.—The Secretary shall permit an eligible
10 entity to submit a single bid for multiple areas
11 if the bid is applicable to all such areas.

12 “(2) REQUIRED INFORMATION.—The bids de-
13 scribed in paragraph (1) shall include—

14 “(A) a proposal for the estimated prices of
15 covered outpatient drugs and the projected an-
16 nual increases in such prices, including differen-
17 tials between formulary and nonformulary
18 prices, if applicable;

19 “(B) a statement regarding the amount
20 that the entity will charge the Secretary for
21 managing, administering, and delivering the
22 benefits under the contract;

23 “(C) a statement regarding whether the
24 entity will reduce the applicable cost-sharing
25 amount pursuant to section 1860F(b)(1)(B)

1 and if so, the amount of such reduction and
2 how such reduction is tied to the performance
3 requirements described in section
4 1860I(b)(1)(C);

5 “(D) a detailed description of the perform-
6 ance requirements for which the payments to
7 the entity will be subject to risk pursuant to
8 section 1860I(b)(1)(C);

9 “(E) a detailed description of access to
10 pharmacy services provided under the plan, in-
11 cluding information regarding—

12 “(i) whether the entity will use a pre-
13 ferred pharmacy network under the plan;
14 and

15 “(ii) if a preferred pharmacy network
16 is used, whether the entity will offer access
17 to pharmacies that are outside such net-
18 work and if such access is provided, rules
19 for accessing such pharmacies;

20 “(F) with respect to the formulary used by
21 the entity, a detailed description of the proce-
22 dures and standards the entity will use for—

23 “(i) adding new drugs to a thera-
24 peutic class within the formulary; and

1 “(ii) determining when and how often
2 the formulary should be modified;

3 “(G) a detailed description of any owner-
4 ship or shared financial interests with other en-
5 tities involved in the delivery of the benefit as
6 proposed under the plan;

7 “(H) a detailed description of the entity’s
8 estimated marketing and advertising expendi-
9 tures related to enrolling eligible beneficiaries
10 under the plan and retaining such enrollment;
11 and

12 “(I) such other information that the Sec-
13 retary determines is necessary in order to carry
14 out this part, including information relating to
15 the bidding process under this part.

16 “(d) ACCESS TO BENEFITS IN CERTAIN AREAS.—

17 “(1) AREAS NOT COVERED BY CONTRACTS.—

18 The Secretary shall develop procedures for the provi-
19 sion of covered outpatient drugs under this part to
20 each eligible beneficiary enrolled under this part that
21 resides in an area that is not covered by any con-
22 tract under this part.

23 “(2) BENEFICIARIES RESIDING IN DIFFERENT
24 LOCATIONS.—The Secretary shall develop procedures
25 to ensure that each eligible beneficiary enrolled

1 under this part that resides in different areas in a
2 year is provided the benefits under this part
3 throughout the entire year.

4 “(e) AWARDING OF CONTRACTS.—

5 “(1) NUMBER OF CONTRACTS.—The Secretary
6 shall, consistent with the requirements of this part
7 and the goal of containing costs under this title,
8 award in a competitive manner at least 2 contracts
9 to offer a plan in an area, unless only 1 bidding en-
10 tity (and the plan offered by the entity) meets the
11 minimum standards specified under this part and by
12 the Secretary.

13 “(2) DETERMINATION.—In determining which
14 of the eligible entities that submitted bids that meet
15 the minimum standards specified under this part
16 and by the Secretary to award a contract, the Sec-
17 retary shall consider the comparative merits of each
18 bid, as determined on the basis of the past perform-
19 ance of the entity and other relevant factors, with
20 respect to—

21 “(A) how well the entity (and the plan of-
22 fered by the entity) meet such minimum stand-
23 ards;

24 “(B) the amount that the entity will
25 charge the Secretary for managing, admin-

1 istering, and delivering the benefits under the
2 contract;

3 “(C) the performance requirements for
4 which the payments to the entity will be subject
5 to risk pursuant to section 1860I(b)(1)(C);

6 “(D) the proposed negotiated prices of cov-
7 ered outpatient drugs and annual increases in
8 such prices;

9 “(E) the factors described in section
10 1860D(b)(2);

11 “(F) prior experience of the entity in man-
12 aging, administering, and delivering a prescrip-
13 tion drug benefit program;

14 “(G) effectiveness of the entity and plan in
15 containing costs through pricing incentives and
16 utilization management; and

17 “(H) such other factors as the Secretary
18 deems necessary to evaluate the merits of each
19 bid.

20 “(3) EXCEPTION TO CONFLICT OF INTEREST
21 RULES.—In awarding contracts under this part, the
22 Secretary may waive conflict of interest laws gen-
23 erally applicable to Federal acquisitions (subject to
24 such safeguards as the Secretary may find necessary

1 to impose) in circumstances where the Secretary
2 finds that such waiver—

3 “(A) is not inconsistent with the—

4 “(i) purposes of the programs under
5 this title; or

6 “(ii) best interests of beneficiaries en-
7 rolled under this part; and

8 “(B) permits a sufficient level of competi-
9 tion for such contracts, promotes efficiency of
10 benefits administration, or otherwise serves the
11 objectives of the program under this part.

12 “(4) NO ADMINISTRATIVE OR JUDICIAL RE-
13 VIEW.—The determination of the Secretary to award
14 or not award a contract to an eligible entity with re-
15 spect to a plan under this part shall not be subject
16 to administrative or judicial review.

17 “(f) APPROVAL OF MARKETING MATERIAL AND AP-
18 PPLICATION FORMS.—The provisions of section 1851(h)
19 shall apply to marketing material and application forms
20 under this part in the same manner as such provisions
21 apply to marketing material and application forms under
22 part C.

23 “(g) DURATION OF CONTRACTS.—Each contract
24 awarded under this part shall be for a term of at least

1 2 years but not more than 5 years, as determined by the
2 Secretary.

3 “MINIMUM STANDARDS FOR ELIGIBLE ENTITIES

4 “SEC. 1860H. (a) IN GENERAL.—The Secretary
5 shall not award a contract to an eligible entity under this
6 part unless the Secretary finds that the eligible entity
7 agrees to comply with such terms and conditions as the
8 Secretary shall specify, including the following:

9 “(1) QUALITY AND FINANCIAL STANDARDS.—

10 The eligible entity meets the quality and financial
11 standards specified by the Secretary.

12 “(2) PROCEDURES TO ENSURE PROPER UTILI-
13 ZATION, COMPLIANCE, AND AVOIDANCE OF ADVERSE
14 DRUG REACTIONS.—

15 “(A) IN GENERAL.—The eligible entity has
16 in place drug utilization review procedures to
17 ensure—

18 “(i) the appropriate utilization by eli-
19 gible beneficiaries enrolled in the plan cov-
20 ered by the contract of the benefits to be
21 provided under the plan;

22 “(ii) the avoidance of adverse drug re-
23 actions among such beneficiaries, including
24 problems due to therapeutic duplication,
25 drug-disease contraindications, drug-drug
26 interactions (including serious interactions

1 with nonprescription or over-the-counter
2 drugs), incorrect drug dosage or duration
3 of drug treatment, drug-allergy inter-
4 actions, and clinical abuse and misuse; and

5 “(iii) the reasonable application of
6 peer-reviewed medical literature pertaining
7 to improvements in pharmaceutical safety
8 and appropriate use of drugs.

9 “(B) AUTHORITY TO USE CERTAIN COM-
10 PENDIA AND LITERATURE.—The eligible entity
11 may use the compendia and literature referred
12 to in clauses (i) and (ii), respectively, of section
13 1927(g)(1)(B) as a source for the utilization re-
14 view under subparagraph (A).

15 “(3) PATIENT PROTECTIONS.—

16 “(A) ACCESS.—

17 “(i) IN GENERAL.—The eligible entity
18 ensures that the covered outpatient drugs
19 are accessible and convenient to eligible
20 beneficiaries enrolled in the plan covered
21 by the contract, including by offering the
22 services 24 hours a day and 7 days a week
23 for emergencies.

24 “(ii) AGREEMENTS WITH PHAR-
25 MACIES.—The eligible entity shall enter

1 into a participation agreement with any
2 pharmacy that meets the requirements of
3 subsection (d) to furnish covered prescrip-
4 tion drugs to eligible beneficiaries under
5 this part. Such agreements shall include
6 the payment of a reasonable dispensing fee
7 for covered outpatient drugs dispensed to a
8 beneficiary under the agreement.

9 “(iii) PREFERRED PHARMACY NET-
10 WORKS.—If the eligible entity utilizes a
11 preferred pharmacy network, the network
12 complies with the standards under sub-
13 section (e).

14 “(B) ENSURING THAT BENEFICIARIES ARE
15 NOT OVERCHARGED.—The eligible entity has
16 procedures in place to ensure that each phar-
17 macy with a participation agreement under this
18 part with the entity complies with the require-
19 ments under subsection (d)(1)(C) (relating to
20 adherence to negotiated prices).

21 “(C) CONTINUITY OF CARE.—

22 “(i) IN GENERAL.—The eligible entity
23 ensures that, in the case of an eligible ben-
24 eficiary who loses coverage under this part
25 with such entity under circumstances that

1 would permit a special election period (as
2 established by the Secretary under section
3 1860C(a)(1)), the entity will continue to
4 provide coverage under this part to such
5 beneficiary until the beneficiary enrolls and
6 receives such coverage with another eligible
7 entity under this part or, if eligible, with a
8 Medicare+Choice organization.

9 “(ii) LIMITED PERIOD.—In no event
10 shall an eligible entity be required to pro-
11 vide the extended coverage required under
12 clause (i) beyond the date which is 30 days
13 after the coverage with such entity would
14 have terminated but for this subparagraph.

15 “(D) PROCEDURES REGARDING THE DE-
16 TERMINATION OF DRUGS THAT ARE MEDICALLY
17 NECESSARY.—

18 “(i) IN GENERAL.—The eligible entity
19 has in place procedures on a case-by-case
20 basis to treat a nonpreferred brand name
21 drug as a preferred brand name drug and
22 a nonformulary drug as a preferred brand
23 name drug under this part if the nonpre-
24 ferred brand name drug or the nonfor-

1 mulary drug, as the case may be, is
2 determined—

3 “(I) to be not as effective for the
4 enrollee in preventing or slowing the
5 deterioration of, or improving or
6 maintaining, the health of the en-
7 rollee; or

8 “(II) to have a significant ad-
9 verse effect on the enrollee.

10 “(ii) REQUIREMENT.—The procedures
11 under clause (i) shall require that deter-
12 minations under such clause are based on
13 professional medical judgment, the medical
14 condition of the enrollee, and other medical
15 evidence.

16 “(E) PROCEDURES REGARDING APPEAL
17 RIGHTS WITH RESPECT TO DENIALS OF
18 CARE.—The eligible entity has in place proce-
19 dures to ensure—

20 “(i) a timely internal review for reso-
21 lution of denials of coverage (in whole or
22 in part and including those regarding the
23 coverage of nonpreferred brand name
24 drugs and nonformulary drugs as preferred
25 brand name drugs) in accordance with the

1 medical exigencies of the case and a timely
2 resolution of complaints, by enrollees in
3 the plan, or by providers, pharmacists, and
4 other individuals acting on behalf of each
5 such enrollee (with the enrollee’s consent)
6 in accordance with requirements (as estab-
7 lished by the Secretary) that are com-
8 parable to such requirements for
9 Medicare+Choice organizations under part
10 C (and are not less favorable to the en-
11 rollee than such requirements under such
12 part as in effect on the date of enactment
13 of the Medicare Outpatient Prescription
14 Drug Act of 2002);

15 “(ii) that the entity complies in a
16 timely manner with requirements estab-
17 lished by the Secretary that (I) provide for
18 an external review by an independent enti-
19 ty selected by the Secretary of denials of
20 coverage described in clause (i) not re-
21 solved in the favor of the beneficiary (or
22 other complainant) under the process de-
23 scribed in such clause, and (II) are com-
24 parable to the external review requirements
25 established for Medicare+Choice organiza-

1 tions under part C (and are not less favor-
2 able to the enrollee than such requirements
3 under such part as in effect on the date of
4 enactment of the Medicare Outpatient Pre-
5 scription Drug Act of 2002); and

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

11 “(F) PROCEDURES REGARDING PATIENT
12 CONFIDENTIALITY.—Insofar as an eligible enti-
13 ty maintains individually identifiable medical
14 records or other health information regarding
15 eligible beneficiaries enrolled in the plan that is
16 covered by the contract, the entity has in place
17 procedures to—

18 “(i) safeguard the privacy of any indi-
19 vidually identifiable beneficiary informa-
20 tion;

21 “(ii) maintain such records and infor-
22 mation in a manner that is accurate and
23 timely;

1 “(iii) ensure timely access by such
2 beneficiaries to such records and informa-
3 tion; and

4 “(iv) otherwise comply with applicable
5 laws relating to patient confidentiality.

6 “(G) PROCEDURES REGARDING TRANSFER
7 OF MEDICAL RECORDS.—

8 “(i) IN GENERAL.—The eligible entity
9 has in place procedures for the timely
10 transfer of records and information de-
11 scribed in subparagraph (F) (with respect
12 to a beneficiary who loses coverage under
13 this part with the entity and enrolls with
14 another entity (including a
15 Medicare+Choice organization) under this
16 part) to such other entity.

17 “(ii) PATIENT CONFIDENTIALITY.—
18 The procedures described in clause (i) shall
19 comply with the patient confidentiality pro-
20 cedures described in subparagraph (F).

21 “(H) PROCEDURES REGARDING MEDICAL
22 ERRORS.—The eligible entity has in place pro-
23 cedures for—

1 “(i) working with the Secretary to
2 deter medical errors related to the provi-
3 sion of covered outpatient drugs; and

4 “(ii) ensuring that pharmacies with a
5 contract with the entity have in place pro-
6 cedures to deter medical errors related to
7 the provision of covered outpatient drugs.

8 “(4) PROCEDURES TO CONTROL FRAUD, ABUSE,
9 AND WASTE.—The eligible entity has in place proce-
10 dures to control fraud, abuse, and waste.

11 “(5) REPORTING REQUIREMENTS.—

12 “(A) IN GENERAL.—The eligible entity
13 provides the Secretary with reports containing
14 information regarding the following:

15 “(i) The negotiated prices that the eli-
16 gible entity is paying for covered out-
17 patient drugs.

18 “(ii) The prices that eligible bene-
19 ficiaries enrolled in the plan that is covered
20 by the contract will be charged for covered
21 outpatient drugs.

22 “(iii) The management costs of pro-
23 viding such benefits.

24 “(iv) Utilization of such benefits.

1 “(v) Marketing and advertising ex-
2 penditures related to enrolling and retain-
3 ing eligible beneficiaries.

4 “(B) TIMEFRAME FOR SUBMITTING RE-
5 PORTS.—

6 “(i) IN GENERAL.—The eligible entity
7 shall submit a report described in subpara-
8 graph (A) to the Secretary within 3
9 months after the end of each 12-month pe-
10 riod in which the eligible entity has a con-
11 tract under this part. Such report shall
12 contain information concerning the benefits
13 provided during such 12-month period.

14 “(ii) LAST YEAR OF CONTRACT.—In
15 the case of the last year of a contract
16 under this part, the Secretary may require
17 that a report described in subparagraph
18 (A) be submitted 3 months prior to the
19 end of the contract. Such report shall con-
20 tain information concerning the benefits
21 provided between the period covered by the
22 most recent report under this subpara-
23 graph and the date that a report is sub-
24 mitted under this clause.

1 “(C) CONFIDENTIALITY OF INFORMA-
2 TION.—

3 “(i) IN GENERAL.—Notwithstanding
4 any other provision of law and subject to
5 clause (ii), information disclosed by an eli-
6 gible entity pursuant to subparagraph (A)
7 (except for information described in clause
8 (ii) of such subparagraph) is confidential
9 and shall only be used by the Secretary for
10 the purposes of, and to the extent nec-
11 essary, to carry out this part.

12 “(ii) UTILIZATION DATA.—Subject to
13 patient confidentiality laws, the Secretary
14 shall make information disclosed by an eli-
15 gible entity pursuant to subparagraph
16 (A)(iv) (regarding utilization data) avail-
17 able for research purposes. The Secretary
18 may charge a reasonable fee for making
19 such information available.

20 “(6) APPROVAL OF MARKETING MATERIAL AND
21 APPLICATION FORMS.—The eligible entity complies
22 with the requirements described in section 1860G(f).

23 “(7) RECORDS AND AUDITS.—The eligible enti-
24 ty maintains adequate records related to the admin-
25 istration of the benefits under this part and affords

1 the Secretary access to such records for auditing
2 purposes.

3 “(b) SPECIAL RULES REGARDING COST-EFFECTIVE
4 PROVISION OF BENEFITS.—In providing the benefits
5 under a contract under this part, an eligible entity shall—

6 “(1) employ mechanisms to provide the benefits
7 economically, such as through the use of—

8 “(A) alternative methods of distribution;

9 “(B) preferred pharmacy networks (pursu-
10 ant to subsection (e)); and

11 “(C) generic drug substitution;

12 “(2) use mechanisms to encourage eligible bene-
13 ficiaries to select cost-effective drugs or less costly
14 means of receiving drugs, such as through the use
15 of—

16 “(A) pharmacy incentive programs;

17 “(B) therapeutic interchange programs;

18 and

19 “(C) disease management programs;

20 “(3) encourage pharmacy providers to—

21 “(A) inform beneficiaries of the differen-
22 tials in price between generic and brand name
23 drug equivalents; and

24 “(B) provide medication therapy manage-
25 ment programs in order to enhance bene-

1 ficiaries’ understanding of the appropriate use
2 of medications and to reduce the risk of poten-
3 tial adverse events associated with medications;
4 and

5 “(4) develop and implement a formulary in ac-
6 cordance with subsection (c).

7 “(c) REQUIREMENTS FOR FORMULARIES.—

8 “(1) IN GENERAL.—The formulary developed
9 and implemented by the eligible entity shall comply
10 with standards established by the Secretary in con-
11 sultation with the Medicare Prescription Drug Advi-
12 sory Committee established under section 1860L.

13 “(2) REQUIREMENTS FOR STANDARDS.—The
14 standards established under paragraph (1) shall re-
15 quire that the eligible entity—

16 “(A) use a pharmacy and therapeutic com-
17 mittee (that meets the standards for a phar-
18 macy and therapeutic committee established by
19 the Secretary in consultation with such Medi-
20 care Prescription Drug Advisory Committee) to
21 develop and implement the formulary;

22 “(B) assign all brand name drugs included
23 in the formulary to either the preferred cat-
24 egory or nonpreferred category of drugs;

25 “(C) include—

1 “(i) all generic covered outpatient
2 drugs in the formulary;

3 “(ii) at least 1 brand name covered
4 outpatient drug from each therapeutic
5 class (as defined by the Secretary in con-
6 sultation with such Medicare Prescription
7 Drug Advisory Committee) as a preferred
8 brand name drug in the formulary; and

9 “(iii) if there is more than 1 brand
10 name covered outpatient drug available in
11 a therapeutic class, at least 1 such drug as
12 a preferred brand name drug in the for-
13 mulary and at least 1 such drug as a non-
14 preferred brand name drug in the for-
15 mulary;

16 “(D) develop procedures for the modifica-
17 tion of the formulary, including for the addition
18 of new drugs to an existing therapeutic class;

19 “(E) pursuant to section 1860F(b)(1)(C),
20 provide for coverage of nonpreferred brand
21 name drugs and nonformulary drugs at the pre-
22 ferred rate when determined under subpara-
23 graph (D) or (E) of subsection (a)(3) to be
24 medically necessary;

1 “(F) disclose to current and prospective
2 beneficiaries and to providers in the service
3 area the nature of the formulary restrictions,
4 including information regarding the drugs in-
5 cluded in the formulary and any difference in
6 the cost-sharing for—

7 “(i) drugs included in the formulary;

8 and

9 “(ii) for drugs not included in the for-
10 mulary; and

11 “(G) provide a reasonable amount of notice
12 to beneficiaries enrolled in the plan that is cov-
13 ered by the contract under this part of any
14 change in the formulary.

15 “(3) CONSTRUCTION.—Nothing in this part
16 shall be construed as precluding an eligible entity
17 from—

18 “(A) except as provided in section
19 1860F(b)(1)(C) (relating to the coverage of
20 medically necessary drugs at the preferred
21 rate), requiring cost-sharing for nonformulary
22 drugs that is higher than the copayment
23 amount established in section
24 1860F(b)(1)(A)(iii);

1 “(B) educating prescribing providers, phar-
2 macists, and beneficiaries about the medical
3 and cost benefits of drugs included in the for-
4 mulary (including generic drugs); or

5 “(C) requesting prescribing providers to
6 consider a drug included in the formulary prior
7 to dispensing of a drug not so included or a
8 preferred brand name drug prior to dispensing
9 of a nonpreferred brand name drug, as long as
10 such a request does not unduly delay the provi-
11 sion of the drug.

12 “(d) TERMS OF PARTICIPATION AGREEMENT WITH
13 PHARMACIES.—

14 “(1) IN GENERAL.—A participation agreement
15 between an eligible entity and a pharmacy under this
16 part (pursuant to subsection (a)(3)(A)(ii)) shall in-
17 clude the following terms and conditions:

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

23 “(B) ACCESS AND QUALITY STANDARDS.—
24 The pharmacy shall comply with such standards
25 as the Secretary (and the eligible entity) shall

1 establish concerning the quality of, and enrolled
2 beneficiaries' access to, pharmacy services
3 under this part. Such standards shall require
4 the pharmacy—

5 “(i) not to refuse to dispense covered
6 outpatient drugs to any eligible beneficiary
7 enrolled under this part;

8 “(ii) to keep patient records (includ-
9 ing records on expenses) for all covered
10 outpatient drugs dispensed to such enrolled
11 beneficiaries;

12 “(iii) to submit information (in a
13 manner specified by the Secretary to be
14 necessary to administer this part) on all
15 purchases of such drugs dispensed to such
16 enrolled beneficiaries; and

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

21 “(C) ENSURING THAT BENEFICIARIES ARE
22 NOT OVERCHARGED.—

23 “(i) ADHERENCE TO NEGOTIATED
24 PRICES.—The total charge for each cov-
25 ered outpatient drug dispensed by the

1 pharmacy to a beneficiary enrolled in the
2 plan, without regard to whether the indi-
3 vidual is financially responsible for any or
4 all of such charge, shall not exceed the ne-
5 gotiated price for the drug (as reported to
6 the Secretary pursuant to subsection
7 (a)(5)(A)).

8 “(ii) ADHERENCE TO BENEFICIARY
9 OBLIGATION.—The pharmacy may not
10 charge (or collect from) such beneficiary
11 an amount that exceed’s the cost-sharing
12 that the beneficiary is responsible for
13 under this part (as determined under sec-
14 tion 1860F(b) using the negotiated price
15 of the drug).

16 “(D) ADDITIONAL REQUIREMENTS.—The
17 pharmacy shall meet such additional contract
18 requirements as the eligible entity specifies
19 under this section.

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

25 “(e) PREFERRED PHARMACY NETWORKS.—

1 “(1) IN GENERAL.—If an eligible entity uses a
2 preferred pharmacy network to deliver benefits
3 under this part, such network shall meet minimum
4 access standards established by the Secretary.

5 “(2) STANDARDS.—In establishing standards
6 under paragraph (1), the Secretary shall take into
7 account reasonable distances to pharmacy services in
8 both urban and rural areas.

9 “PAYMENTS

10 “SEC. 1860I. (a) PROCEDURES FOR PAYMENTS TO
11 ELIGIBLE ENTITIES.—The Secretary shall establish pro-
12 cedures for making payments to each eligible entity with
13 a contract under this part for the management, adminis-
14 tration, and delivery of the benefits under this part.

15 “(b) REQUIREMENTS FOR PROCEDURES.—

16 “(1) IN GENERAL.—The procedures established
17 under subsection (a) shall provide for the following:

18 “(A) MANAGEMENT PAYMENT.—Payment
19 for the management, administration, and deliv-
20 ery of the benefits under this part.

21 “(B) REIMBURSEMENT FOR NEGOTIATED
22 COSTS OF DRUGS PROVIDED.—Payments for the
23 negotiated costs of covered outpatient drugs
24 provided to eligible beneficiaries enrolled under
25 this part and in a plan offered by the eligible

1 entity, reduced by any applicable cost-sharing
2 under section 1860F(b).

3 “(C) RISK REQUIREMENT TO ENSURE PUR-
4 SUIT OF PERFORMANCE REQUIREMENTS.—An
5 adjustment of a percentage (as determined
6 under paragraph (2)) of the payments made to
7 an entity under subparagraph (A) to ensure
8 that the entity, in managing, administering,
9 and delivering the benefits under this part, pur-
10 sues performance requirements established by
11 the Secretary, including the following:

12 “(i) CONTROL OF MEDICARE AND
13 BENEFICIARY COSTS.—The entity contains
14 costs to the Prescription Drug Account
15 and to eligible beneficiaries enrolled under
16 this part and in the plan offered by the en-
17 tity, as measured by generic substitution
18 rates, price discounts, and other factors
19 determined appropriate by the Secretary
20 that do not reduce the access of such bene-
21 ficiaries to medically necessary covered
22 outpatient drugs.

23 “(ii) QUALITY CLINICAL CARE.—The
24 entity provides such beneficiaries with

1 quality clinical care, as measured by such
2 factors as—

3 “(I) the level of adverse drug re-
4 actions and medical errors among
5 such beneficiaries; and

6 “(II) providing specific clinical
7 suggestions to improve health and pa-
8 tient and prescriber education as ap-
9 propriate.

10 “(iii) QUALITY SERVICE.—The entity
11 provides such beneficiaries with quality
12 services, as measured by such factors as
13 sustained pharmacy network access, timeli-
14 ness and accuracy of service delivery in
15 claims processing and card production,
16 pharmacy and member service support ac-
17 cess, response time in mail delivery service,
18 and timely action with regard to appeals
19 and current beneficiary service surveys.

20 “(2) PERCENTAGE OF PAYMENT TIED TO
21 RISK.—

22 “(A) IN GENERAL.—Subject to subpara-
23 graph (B), the Secretary shall determine the
24 percentage (which may be up to 100 percent) of
25 the payments made to an entity under subpara-

1 graph (A) that will be tied to the performance
2 requirements described in paragraph (1)(C).

3 “(B) LIMITATION ON RISK TO ENSURE
4 PROGRAM STABILITY.—In order to provide for
5 program stability, the Secretary may not estab-
6 lish a percentage to be adjusted under this sub-
7 section at a level that jeopardizes the ability of
8 an eligible entity to administer and deliver the
9 benefits under this part or administer and de-
10 liver such benefits in a quality manner.

11 “(3) RISK ADJUSTMENT OF PAYMENTS BASED
12 ON ENROLLEES IN PLAN.—To the extent that an eli-
13 gible entity is at risk under this subsection, the pro-
14 cedures established under subsection (a) may include
15 a methodology for risk adjusting the payments made
16 to such entity based on the differences in actuarial
17 risk of different enrollees being served if the Sec-
18 retary determines such adjustments to be necessary
19 and appropriate.

20 “(4) PASS-THROUGH OF REBATES AND PRICE
21 CONCESSIONS OBTAINED BY THE ELIGIBLE ENTI-
22 TY.—The Secretary, if determined by the Secretary
23 to be in the best interests of the medicare program
24 or eligible beneficiaries, may establish procedures for
25 reducing the amount of payments to an eligible enti-

1 ty under subsection (a) to take into account any re-
2 bates or price concessions obtained by the entity
3 from manufacturers of covered outpatient drugs.

4 “(c) PAYMENTS TO MEDICARE+CHOICE ORGANIZA-
5 TIONS.—For provisions related to payments to
6 Medicare+Choice organizations for the administration
7 and delivery of benefits under this part to eligible bene-
8 ficiaries enrolled in a Medicare+Choice plan offered by the
9 organization, see section 1853(c)(8).

10 “(d) SECONDARY PAYER PROVISIONS.—The provi-
11 sions of section 1862(b) shall apply to the benefits pro-
12 vided under this part.

13 “EMPLOYER INCENTIVE PROGRAM FOR EMPLOYMENT-
14 BASED RETIREE DRUG COVERAGE

15 “SEC. 1860J. (a) PROGRAM AUTHORITY.—The Sec-
16 retary is authorized to develop and implement a program
17 under this section to be known as the ‘Employer Incentive
18 Program’ that encourages employers and other sponsors
19 of employment-based health care coverage to provide ade-
20 quate prescription drug benefits to retired individuals by
21 subsidizing, in part, the sponsor’s cost of providing cov-
22 erage under qualifying plans.

23 “(b) SPONSOR REQUIREMENTS.—In order to be eligi-
24 ble to receive an incentive payment under this section with
25 respect to coverage of an individual under a qualified re-

1 tiree prescription drug plan (as defined in subsection
2 (e)(3)), a sponsor shall meet the following requirements:

3 “(1) ASSURANCES.—The sponsor shall—

4 “(A) annually attest, and provide such as-
5 surances as the Secretary may require, that the
6 coverage offered by the sponsor is a qualified
7 retiree prescription drug plan, and will remain
8 such a plan for the duration of the sponsor’s
9 participation in the program under this section;
10 and

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

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 drug benefit under the plan falls below the
18 actuarial value of the outpatient prescrip-
19 tion drug benefit under this part.

20 “(2) BENEFICIARY INFORMATION.—The spon-
21 sor shall report to the Secretary, for each calendar
22 quarter for which it seeks an incentive payment
23 under this section, the names and social security
24 numbers of all retirees (and their spouses and de-
25 pendants) covered under such plan during such

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

3 “(3) AUDITS.—The sponsor and the employ-
4 ment-based retiree health coverage plan seeking in-
5 centive payments under this section shall agree to
6 maintain, and to afford the Secretary access to, such
7 records as the Secretary may require for purposes of
8 audits and other oversight activities necessary to en-
9 sure the adequacy of prescription drug coverage, the
10 accuracy of incentive payments made, and such
11 other matters as may be appropriate.

12 “(4) OTHER REQUIREMENTS.—The sponsor
13 shall provide such other information, and comply
14 with such other requirements, as the Secretary may
15 find necessary to administer the program under this
16 section.

17 “(c) INCENTIVE PAYMENTS.—

18 “(1) IN GENERAL.—A sponsor that meets the
19 requirements of subsection (b) with respect to a
20 quarter in a calendar year shall be entitled to have
21 payment made by the Secretary on a quarterly basis
22 (to the sponsor or, at the sponsor’s direction, to the
23 appropriate employment-based health plan) of an in-
24 centive payment, in the amount determined in para-

1 graph (2), for each retired individual (or spouse or
2 dependent) who—

3 “(A) was covered under the sponsor’s
4 qualified retiree prescription drug plan during
5 such quarter; and

6 “(B) was eligible for, but was not enrolled
7 in, the outpatient prescription drug benefit pro-
8 gram under this part.

9 “(2) AMOUNT OF PAYMENT.—

10 “(A) IN GENERAL.—The amount of the
11 payment for a quarter shall be, for each indi-
12 vidual described in paragraph (1), $\frac{2}{3}$ of the
13 sum of the monthly Government contribution
14 amounts (computed under subparagraph (B))
15 for each of the 3 months in the quarter.

16 “(B) COMPUTATION OF MONTHLY GOV-
17 ERNMENT CONTRIBUTION AMOUNT.—For pur-
18 poses of subparagraph (A), the monthly Gov-
19 ernment contribution amount for a month in a
20 year is equal to the amount by which—

21 “(i) $\frac{1}{12}$ of the amount estimated
22 under subparagraph (C) for the year in-
23 volved; exceeds

24 “(ii) the monthly Part D premium
25 under section 1860E(a) (determined with-

1 out regard to any increase under section
2 1860B(b)(1)) for the month involved.

3 “(C) ESTIMATE OF AVERAGE ANNUAL PER
4 CAPITA AGGREGATE EXPENDITURES.—

5 “(i) IN GENERAL.—The Secretary
6 shall for each year after 2003 estimate for
7 that year an amount equal to average an-
8 nual per capita aggregate expenditures
9 payable from the Prescription Drug Ac-
10 count for that year.

11 “(ii) TIMEFRAME FOR ESTIMATION.—
12 The Secretary shall make the estimate de-
13 scribed in clause (i) for a year before the
14 beginning of that year.

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

19 “(d) CIVIL MONEY PENALTIES.—A sponsor, health
20 plan, or other entity that the Secretary determines has,
21 directly or through its agent, provided information in con-
22 nection with a request for an incentive payment under this
23 section that the entity knew or should have known to be
24 false shall be subject to a civil monetary penalty in an
25 amount up to 3 times the total incentive amounts under

1 subsection (e) that were paid (or would have been payable)
2 on the basis of such information.

3 “(e) DEFINITIONS.—In this section:

4 “(1) EMPLOYMENT-BASED RETIREE HEALTH
5 COVERAGE.—The term ‘employment-based retiree
6 health coverage’ means health insurance or other
7 coverage, whether provided by voluntary insurance
8 coverage or pursuant to statutory or contractual ob-
9 ligation, of health care costs for retired individuals
10 (or for such individuals and their spouses and de-
11 pendents) based on their status as former employees
12 or labor union members.

13 “(2) EMPLOYER.—The term ‘employer’ has the
14 meaning given the term in section 3(5) of the Em-
15 ployee Retirement Income Security Act of 1974 (ex-
16 cept that such term shall include only employers of
17 2 or more employees).

18 “(3) QUALIFIED RETIREE PRESCRIPTION DRUG
19 PLAN.—The term ‘qualified retiree prescription drug
20 plan’ means health insurance coverage included in
21 employment-based retiree health coverage that—

22 “(A) provides coverage of the cost of pre-
23 scription drugs with an actuarial value (as de-
24 fined by the Secretary) to each retired bene-
25 ficiary that equals or exceeds the actuarial

1 value of the benefits provided to an individual
 2 enrolled in the outpatient prescription drug
 3 benefit program under this part; and

4 “(B) does not deny, limit, or condition the
 5 coverage or provision of prescription drug bene-
 6 fits for retired individuals based on age or any
 7 health status-related factor described in section
 8 2702(a)(1) of the Public Health Service Act.

9 “(4) SPONSOR.—The term ‘sponsor’ has the
 10 meaning given the term ‘plan sponsor’ in section
 11 3(16)(B) of the Employer Retirement Income Secu-
 12 rity Act of 1974.

13 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
 14 are authorized to be appropriated from time to time, out
 15 of any moneys in the Treasury not otherwise appropriated,
 16 such sums as may be necessary to carry out the program
 17 under this section.

18 “PRESCRIPTION DRUG ACCOUNT IN THE FEDERAL
 19 SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND

20 “SEC. 1860K. (a) ESTABLISHMENT.—

21 “(1) IN GENERAL.—There is created within the
 22 Federal Supplementary Medical Insurance Trust
 23 Fund established by section 1841 an account to be
 24 known as the ‘Prescription Drug Account’ (in this
 25 section referred to as the ‘Account’).

1 “(2) FUNDS.—The Account shall consist of
2 such gifts and bequests as may be made as provided
3 in section 201(i)(1), and such amounts as may be
4 deposited in, or appropriated to, the account as pro-
5 vided in this part.

6 “(3) SEPARATE FROM REST OF TRUST FUND.—
7 Funds provided under this part to the Account shall
8 be kept separate from all other funds within the
9 Federal Supplementary Medical Insurance Trust
10 Fund.

11 “(b) PAYMENTS FROM ACCOUNT.—

12 “(1) IN GENERAL.—The Managing Trustee
13 shall pay from time to time from the Account such
14 amounts as the Secretary certifies are necessary to
15 make payments to operate the program under this
16 part, including payments to eligible entities under
17 section 1860I, payments to Medicare+Choice orga-
18 nizations under section 1853(c)(8), and payments
19 with respect to administrative expenses under this
20 part in accordance with section 201(g).

21 “(2) TREATMENT IN RELATION TO PART B PRE-
22 MIUM.—Amounts payable from the Account shall not
23 be taken into account in computing actuarial rates
24 or premium amounts under section 1839.

1 “(c) APPROPRIATIONS TO COVER BENEFITS AND
2 ADMINISTRATIVE COSTS.—

3 “(1) IN GENERAL.—Subject to paragraph (2),
4 there are appropriated to the Account in a fiscal
5 year, out of any moneys in the Treasury not other-
6 wise appropriated, an amount equal to the amount
7 by which the benefits and administrative costs of
8 providing the benefits under this part in the year ex-
9 ceed the premiums collected under section 1860E(b)
10 for the year.

11 “(2) LIMITATION.—No amounts shall be appro-
12 priated, and no amounts expended, for expenses in-
13 curred for providing coverage of covered outpatient
14 drugs after January 1, 2011. The Secretary may
15 make payments on or after such date for expenses
16 incurred to the extent such expenses were incurred
17 for providing coverage of covered outpatient drugs
18 prior to such date.

19 “MEDICARE PRESCRIPTION DRUG ADVISORY COMMITTEE

20 “SEC. 1860L. (a) ESTABLISHMENT OF COM-
21 MITTEE.—There is established a Medicare Prescription
22 Drug Advisory Committee (in this section referred to as
23 the ‘Committee’).

24 “(b) FUNCTIONS OF COMMITTEE.—On and after
25 March 1, 2003, the Committee shall advise the Secretary
26 on policies related to—

1 “(1) the development of guidelines for the im-
2 plementation and administration of the outpatient
3 prescription drug benefit program under this part;
4 and

5 “(2) the development of—

6 “(A) standards for a pharmacy and thera-
7 peutics committee required of eligible entities
8 under section 1860H(e)(2)(A);

9 “(B) standards required under subpara-
10 graphs (D) and (E) of section 1860H(a)(3) for
11 determining if a drug is medically necessary;

12 “(C) standards for—

13 “(i) establishing therapeutic classes;

14 “(ii) adding new therapeutic classes to
15 a formulary; and

16 “(iii) defining a prescription of cov-
17 ered outpatient drugs for purposes of ap-
18 plying cost-sharing under section
19 1860F(b);

20 “(D) procedures to evaluate the bids sub-
21 mitted by eligible entities under this part; and

22 “(E) procedures to ensure that eligible en-
23 tities with a contract under this part are in
24 compliance with the requirements under this
25 part.

1 “(c) STRUCTURE AND MEMBERSHIP OF THE COM-
2 MITTEE.—

3 “(1) STRUCTURE.—The Committee shall be
4 composed of 19 members who shall be appointed by
5 the Secretary.

6 “(2) MEMBERSHIP.—

7 “(A) IN GENERAL.—The members of the
8 Committee shall be chosen on the basis of their
9 integrity, impartiality, and good judgment, and
10 shall be individuals who are, by reason of their
11 education, experience, attainments, and under-
12 standing of pharmaceutical cost control and
13 quality enhancement, exceptionally qualified to
14 perform the duties of members of the Com-
15 mittee.

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

18 “(i) five shall be chosen to represent
19 physicians, 2 of whom shall be geriatrici-
20 cians;

21 “(ii) two shall be chosen to represent
22 nurse practitioners;

23 “(iii) four shall be chosen to represent
24 pharmacists;

1 “(iv) one shall be chosen to represent
2 the Centers for Medicare & Medicaid Serv-
3 ices;

4 “(v) four shall be chosen to represent
5 actuaries, pharmacoeconomists, research-
6 ers, and other appropriate experts;

7 “(vi) one shall be chosen to represent
8 emerging drug technologies;

9 “(vii) one shall be closed to represent
10 the Food and Drug Administration; and

11 “(viii) one shall be chosen to represent
12 individuals enrolled under this part.

13 “(d) TERMS OF APPOINTMENT.—Each member of
14 the Committee shall serve for a term determined appro-
15 priate by the Secretary. The terms of service of the mem-
16 bers initially appointed shall begin on January 1, 2003.

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

20 “(f) COMMITTEE PERSONNEL MATTERS.—

21 “(1) MEMBERS.—

22 “(A) COMPENSATION.—Each member of
23 the Committee who is not an officer or em-
24 ployee of the Federal Government shall be com-
25 pensated at a rate equal to the daily equivalent

1 of the annual rate of basic pay prescribed for
2 level IV of the Executive Schedule under section
3 5315 of title 5, United States Code, for each
4 day (including travel time) during which such
5 member is engaged in the performance of the
6 duties of the Committee. All members of the
7 Committee who are officers or employees of the
8 United States shall serve without compensation
9 in addition to that received for their services as
10 officers or employees of the United States.

11 “(B) TRAVEL EXPENSES.—The members
12 of the Committee shall be allowed travel ex-
13 penses, including per diem in lieu of subsist-
14 ence, at rates authorized for employees of agen-
15 cies under subchapter I of chapter 57 of title 5,
16 United States Code, while away from their
17 homes or regular places of business in the per-
18 formance of services for the Committee.

19 “(2) STAFF.—The Committee may appoint
20 such personnel as the Committee considers appro-
21 priate.

22 “(g) OPERATION OF THE COMMITTEE.—

23 “(1) MEETINGS.—The Committee shall meet at
24 the call of the Chairperson (after consultation with
25 the other members of the Committee) not less often

1 than quarterly to consider a specific agenda of
2 issues, as determined by the Chairperson after such
3 consultation.

4 “(2) QUORUM.—Ten members of the Com-
5 mittee shall constitute a quorum for purposes of
6 conducting business.

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

10 “(i) TRANSFER OF PERSONNEL, RESOURCES, AND
11 ASSETS.—For purposes of carrying out its duties, the Sec-
12 retary and the Committee may provide for the transfer
13 to the Committee of such civil service personnel in the em-
14 ploy of the Department of Health and Human Services
15 (including the Centers for Medicare & Medicaid Services),
16 and such resources and assets of the Department used in
17 carrying out this title, as the Committee requires.

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

21 (b) EXCLUSIONS FROM COVERAGE.—

22 (1) APPLICATION TO PART D.—Section 1862(a)
23 of the Social Security Act (42 U.S.C. 1395y(a)) is
24 amended in the matter preceding paragraph (1) by

1 striking “part A or part B” and inserting “part A,
2 B, or D”.

3 (2) PRESCRIPTION DRUGS NOT EXCLUDED
4 FROM COVERAGE IF REASONABLE AND NEC-
5 ESSARY.—Section 1862(a)(1) of the Social Security
6 Act (42 U.S.C. 1395y(a)(1)) is amended—

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

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

11 (C) by adding at the end the following new
12 subparagraph:

13 “(J) in the case of prescription drugs cov-
14 ered under part D, which are not reasonable
15 and necessary to prevent or slow the deteriora-
16 tion of, or improve or maintain, the health of
17 eligible beneficiaries;”.

18 (c) CONFORMING AMENDMENTS TO FEDERAL SUP-
19 PLEMENTARY MEDICAL INSURANCE TRUST FUND.—Sec-
20 tion 1841 of the Social Security Act (42 U.S.C. 1395t)
21 is amended—

22 (1) in the last sentence of subsection (a)—

23 (A) by striking “and” before “such
24 amounts”; and

1 (B) by inserting before the period the fol-
2 lowing: “, and such amounts as may be depos-
3 ited in, or appropriated to, the Prescription
4 Drug Account established by section 1860K”;

5 (2) in subsection (g), by inserting after “by this
6 part,” the following: “the payments provided for
7 under part D (in which case the payments shall be
8 made from the Prescription Drug Account in the
9 Trust Fund),”;

10 (3) in subsection (h), by inserting after
11 “1840(d)” the following: “and section 1860E(b) (in
12 which case the payments shall be made from the
13 Prescription Drug Account in the Trust Fund)”;
14 and

15 (4) in subsection (i), by inserting after “section
16 1840(b)(1)” the following: “, section 1860E(b) (in
17 which case the payments shall be made from the
18 Prescription Drug Account in the Trust Fund),”.

19 (d) CONFORMING REFERENCES TO PREVIOUS PART
20 D.—

21 (1) IN GENERAL.—Any reference in law (in ef-
22 fect before the date of enactment of this Act) to part
23 D of title XVIII of the Social Security Act is deemed
24 a reference to part E of such title (as in effect after
25 such date).

1 (2) SECRETARIAL SUBMISSION OF LEGISLATIVE
2 PROPOSAL.—Not later than 6 months after the date
3 of enactment of this Act, the Secretary of Health
4 and Human Services shall submit to Congress a leg-
5 islative proposal providing for such technical and
6 conforming amendments in the law as are required
7 by the provisions of this Act.

8 **SEC. 3. PART D BENEFITS UNDER MEDICARE+CHOICE**
9 **PLANS.**

10 (a) ELIGIBILITY, ELECTION, AND ENROLLMENT.—
11 Section 1851 of the Social Security Act (42 U.S.C.
12 1395w–21) is amended—

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

15 (2) in subsection (i)(1), by striking “parts A
16 and B” and inserting “parts A, B, and D”.

17 (b) VOLUNTARY BENEFICIARY ENROLLMENT FOR
18 DRUG COVERAGE.—Section 1852(a)(1)(A) of the Social
19 Security Act (42 U.S.C. 1395w–22(a)(1)(A)) is amended
20 by inserting “(and under part D to individuals also en-
21 rolled under that part)” after “parts A and B”.

22 (c) ACCESS TO SERVICES.—Section 1852(d)(1) of the
23 Social Security Act (42 U.S.C. 1395w–22(d)(1)) is
24 amended—

1 (1) in subparagraph (D), by striking “and” at
2 the end;

3 (2) in subparagraph (E), by striking the period
4 at the end and inserting “; and”; and

5 (3) by adding at the end the following new sub-
6 paragraph:

7 “(F) in the case of covered outpatient
8 drugs (as defined in section 1860(1)) provided
9 to individuals enrolled under part D, the orga-
10 nization complies with the access requirements
11 applicable under part D.”.

12 (d) PAYMENTS TO ORGANIZATIONS FOR PART D
13 BENEFITS.—

14 (1) IN GENERAL.—Section 1853(a)(1)(A) of the
15 Social Security Act (42 U.S.C. 1395w-23(a)(1)(A))
16 is amended—

17 (A) by inserting “determined separately for
18 the benefits under parts A and B and under
19 part D (for individuals enrolled under that
20 part)” after “as calculated under subsection
21 (c)”;

22 (B) by striking “that area, adjusted for
23 such risk factors” and inserting “that area. In
24 the case of payment for the benefits under

1 parts A and B, such payment shall be adjusted
2 for such risk factors as”; and

3 (C) by inserting before the last sentence
4 the following: “In the case of the payments
5 under subsection (c)(8) for the provision of cov-
6 erage of covered outpatient drugs to individuals
7 enrolled under part D, such payment shall be
8 adjusted for the risk factors of each enrollee as
9 the Secretary determines to be feasible and ap-
10 propriate to ensure actuarial equivalence.”.

11 (2) AMOUNT.—Section 1853(c) of the Social
12 Security Act (42 U.S.C. 1395w–23(c)) is amended—

13 (A) in paragraph (1), in the matter pre-
14 ceding subparagraph (A), by inserting “for ben-
15 efits under parts A and B” after “capitation
16 rate”; and

17 (B) by adding at the end the following new
18 paragraph:

19 “(8) CAPITATION RATE FOR PART D BENE-
20 FITS.—

21 “(A) IN GENERAL.—In the case of a
22 Medicare+Choice plan that provides coverage
23 of covered outpatient drugs to an individual en-
24 rolled under part D, the capitation rate for
25 such coverage shall be the amount described in

1 subparagraph (B). Such payments shall be
2 made in the same manner and at the same time
3 as the payments to the Medicare+Choice orga-
4 nization offering the plan for benefits under
5 parts A and B are otherwise made, but such
6 payments shall be payable from the Prescrip-
7 tion Drug Account in the Federal Supple-
8 mentary Medical Insurance Trust Fund under
9 section 1841.

10 “(B) AMOUNT.—The amount described in
11 this paragraph is an amount equal to $\frac{1}{12}$ of the
12 average annual per capita aggregate expendi-
13 tures payable from the Prescription Drug Ac-
14 count for the year (as estimated under section
15 1860J(c)(2)(C)).”.

16 (e) LIMITATION ON ENROLLEE LIABILITY.—Section
17 1854(e) of the Social Security Act (42 U.S.C. 1395w-
18 24(e)) is amended by adding at the end the following new
19 paragraph:

20 “(5) SPECIAL RULE FOR PART D BENEFITS.—

21 With respect to outpatient prescription drug benefits
22 under part D, a Medicare+Choice organization may
23 not require that an enrollee pay any deductible or
24 pay a cost-sharing amount that exceeds the amount

1 of cost-sharing applicable for such benefits for an el-
 2 ible beneficiary under part D.”.

3 (f) REQUIREMENT FOR ADDITIONAL BENEFITS.—
 4 Section 1854(f)(1) of the Social Security Act (42 U.S.C.
 5 1395w–24(f)(1)) is amended by adding at the end the fol-
 6 lowing new sentence: “Such determination shall be made
 7 separately for the benefits under parts A and B and for
 8 prescription drug benefits under part D.”.

9 (g) EFFECTIVE DATE.—The amendments made by
 10 this section shall apply to items and services provided
 11 under a Medicare+Choice plan on or after January 1,
 12 2004.

13 **SEC. 4. ADDITIONAL ASSISTANCE FOR LOW-INCOME BENE-**
 14 **FICIARIES.**

15 (a) INCLUSION IN MEDICARE COST-SHARING.—Sec-
 16 tion 1905(p)(3) of the Social Security Act (42 U.S.C.
 17 1396d(p)(3)) is amended—

18 (1) in subparagraph (A)—

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

21 (B) in clause (ii), by inserting “and” at
 22 the end; and

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

25 “(iii) premiums under section 1860E(a).”; and

1 (2) in subparagraph (B), by inserting “and
2 cost-sharing described in section 1860F(b)” after
3 “section 1813”.

4 (b) EXPANSION OF MEDICAL ASSISTANCE.—Section
5 1902(a)(10)(E) of the Social Security Act (42 U.S.C.
6 1396a(a)(10)(E)) is amended—

7 (1) in clause (iii)—

8 (A) by striking “section 1905(p)(3)(A)(ii)”
9 and inserting “clauses (ii) and (iii) of section
10 1905(p)(3)(A) and for medicare cost-sharing
11 described in section 1905(p)(3)(B) (but only in-
12 sofar as it relates to benefits provided under
13 part D of title XVIII),”; and

14 (B) by striking “and” at the end;

15 (2) by redesignating clause (iv) as clause (vi);

16 and

17 (3) by inserting after clause (iii) the following
18 new clauses:

19 “(iv) for making medical assistance avail-
20 able for medicare cost-sharing described in sec-
21 tion 1905(p)(3)(A)(iii) and for medicare cost-
22 sharing described in section 1905(p)(3)(B) (but
23 only insofar as it relates to benefits provided
24 under part D of title XVIII) for individuals who
25 would be qualified medicare beneficiaries de-

1 scribed in section 1905(p)(1) but for the fact
2 that their income exceeds 120 percent but does
3 not exceed 135 percent of such official poverty
4 line for a family of the size involved;

5 “(v) for making medical assistance avail-
6 able for medicare cost-sharing described in sec-
7 tion 1905(p)(3)(A)(iii) on a linear sliding scale
8 based on the income of such individuals for in-
9 dividuals who would be qualified medicare bene-
10 ficiaries described in section 1905(p)(1) but for
11 the fact that their income exceeds 135 percent
12 but does not exceed 150 percent of such official
13 poverty line for a family of the size involved;
14 and”.

15 (c) NONAPPLICABILITY OF RESOURCE REQUIRE-
16 MENTS TO MEDICARE PART D COST-SHARING.—Section
17 1905(p)(1) of the Social Security Act (42 U.S.C.
18 1396d(p)(1)) is amended by adding at the end the fol-
19 lowing flush sentence:

20 “In determining if an individual is a qualified medicare
21 beneficiary under this paragraph, subparagraph (C) shall
22 not be applied for purposes of providing the individual
23 with medicare cost-sharing described in section
24 1905(p)(3)(A)(iii) or for medicare cost-sharing described

1 in section 1905(p)(3)(B) (but only insofar as it relates to
2 benefits provided under part D of title XVIII).”.

3 (d) NONAPPLICABILITY OF PAYMENT DIFFERENTIAL
4 REQUIREMENTS TO MEDICARE PART D COST-SHAR-
5 ING.—Section 1902(n)(2) of the Social Security Act (42
6 U.S.C. 1396a(n)(2)) is amended by adding at the end the
7 following new sentence: “The preceding sentence shall not
8 apply to the cost-sharing described in section 1860F(b).”.

9 (e) 100 PERCENT FEDERAL MEDICAL ASSISTANCE
10 PERCENTAGE.—The first sentence of section 1905(b) of
11 the Social Security Act (42 U.S.C. 1396d(b)) is
12 amended—

13 (1) by striking “and” before “(4)”; and

14 (2) by inserting before the period at the end the
15 following: “, and (5) the Federal medical assistance
16 percentage shall be 100 percent with respect to med-
17 ical assistance provided under clauses (iv) and (v) of
18 section 1902(a)(10)(E)”.

19 (f) TREATMENT OF TERRITORIES.—Section 1108(g)
20 of the Social Security Act (42 U.S.C. 1308(g)) is amended
21 by adding at the end the following new paragraph:

22 “(3) Notwithstanding the preceding provisions of this
23 subsection, with respect to fiscal year 2004 and any fiscal
24 year thereafter, the amount otherwise determined under
25 this subsection (and subsection (f)) for the fiscal year for

1 a Commonwealth or territory shall be increased by the
2 ratio (as estimated by the Secretary) of—

3 “(A) the aggregate amount of payments made
4 to the 50 States and the District of Columbia for
5 the fiscal year under title XIX that are attributable
6 to making medical assistance available for individ-
7 uals described in clauses (i), (iii), (iv), and (v) of
8 section 1902(a)(10)(E) for payment of medicare
9 cost-sharing described in section 1905(p)(3)(A)(iii)
10 and for medicare cost-sharing described in section
11 1905(p)(3)(B) (but only insofar as it relates to bene-
12 fits provided under part D of title XVIII); to

13 “(B) the aggregate amount of total payments
14 made to such States and District for the fiscal year
15 under such title.”.

16 (g) CONFORMING AMENDMENTS.—Section 1933 of
17 the Social Security Act (42 U.S.C. 1396u-3) is
18 amended—

19 (1) in subsection (a), by striking “section
20 1902(a)(10)(E)(iv)” and inserting “section
21 1902(a)(10)(E)(vi)”;

22 (2) in subsection (c)(2)(A)—

23 (A) in clause (i), by striking “section
24 1902(a)(10)(E)(iv)(I)” and inserting “section
25 1902(a)(10)(E)(vi)(I)”; and

1 (B) in clause (ii), by striking “section
2 1902(a)(10)(E)(iv)(II)” and inserting “section
3 1902(a)(10)(E)(vi)(II)”;

4 (3) in subsection (d), by striking “section
5 1902(a)(10)(E)(iv)” and inserting “section
6 1902(a)(10)(E)(vi)”;

7 (4) in subsection (e), by striking “section
8 1902(a)(10)(E)(iv)” and inserting “section
9 1902(a)(10)(E)(vi)”.

10 (h) EFFECTIVE DATE.—The amendments made by
11 this section shall apply for medical assistance provided
12 under section 1902(a)(10)(E) of the Social Security Act
13 (42 U.S.C. 1396a(a)(10)(E)) on and after January 1,
14 2004.

15 **SEC. 5. MEDIGAP REVISIONS.**

16 Section 1882 of the Social Security Act (42 U.S.C.
17 1395ss) is amended by adding at the end the following
18 new subsection:

19 “(v) MODERNIZED BENEFIT PACKAGES FOR MEDI-
20 CARE SUPPLEMENTAL POLICIES.—

21 “(1) REVISION OF BENEFIT PACKAGES.—

22 “(A) IN GENERAL.—Notwithstanding sub-
23 section (p), the benefit packages classified as
24 ‘H’, ‘I’, and ‘J’ under the standards established
25 by subsection (p)(2) (including the benefit

1 package classified as ‘J’ with a high deductible
2 feature, as described in subsection (p)(11))
3 shall be revised so that—

4 “(i) the coverage of outpatient pre-
5 scription drugs available under such ben-
6 efit packages is replaced with coverage of
7 outpatient prescription drugs that com-
8 plements but does not duplicate the cov-
9 erage of outpatient prescription drugs that
10 is otherwise available under this title;

11 “(ii) the revised benefit packages pro-
12 vide a range of coverage options for out-
13 patient prescription drugs for beneficiaries,
14 but do not provide coverage for more than
15 90 percent of the cost-sharing amount ap-
16 plicable to an individual under section
17 1860F(b);

18 “(iii) uniform language and defini-
19 tions are used with respect to such revised
20 benefits;

21 “(iv) uniform format is used in the
22 policy with respect to such revised benefits;

23 “(v) such revised standards meet any
24 additional requirements imposed by the
25 amendments made by the Medicare Out-

1 patient Prescription Drug Act of 2002;
2 and

3 “(vi) except as revised under the pre-
4 ceding clauses or as provided under sub-
5 section (p)(1)(E), the benefit packages are
6 identical to the benefit packages that were
7 available on the date of enactment of the
8 Medicare Outpatient Prescription Drug
9 Act of 2002.

10 “(B) MANNER OF REVISION.—The benefit
11 packages revised under this section shall be re-
12 vised in the manner described in subparagraph
13 (E) of subsection (p)(1), except that for pur-
14 poses of subparagraph (C) of such subsection,
15 the standards established under this subsection
16 shall take effect not later than January 1,
17 2004.

18 “(2) CONSTRUCTION OF BENEFITS IN OTHER
19 MEDICARE SUPPLEMENTAL POLICIES.—Nothing in
20 the benefit packages classified as ‘A’ through ‘G’
21 under the standards established by subsection (p)(2)
22 (including the benefit package classified as ‘F’ with
23 a high deductible feature, as described in subsection
24 (p)(11)) shall be construed as providing coverage for

1 benefits for which payment may be made under part
2 D.

3 “(3) GUARANTEED ISSUANCE AND RENEWAL
4 OF REVISED POLICIES.—The provisions of sub-
5 sections (q) and (s), including provisions of sub-
6 section (s)(3) (relating to special enrollment periods
7 in cases of termination or disenrollment), shall apply
8 to medicare supplemental policies revised under this
9 subsection in the same manner as such provisions
10 apply to medicare supplemental policies issued under
11 the standards established under subsection (p).

12 “(4) OPPORTUNITY OF CURRENT POLICY-
13 HOLDERS TO PURCHASE REVISED POLICIES.—

14 “(A) IN GENERAL.—No medicare supple-
15 mental policy of an issuer with a benefit pack-
16 age that is revised under paragraph (1) shall be
17 deemed to meet the standards in subsection (c)
18 unless the issuer—

19 “(i) provides written notice during the
20 60-day period immediately preceding the
21 period established for the open enrollment
22 period established under section
23 1860B(b)(2)(A), to each individual who is
24 a policyholder or certificate holder of a
25 medicare supplemental policy issued by

1 that issuer (at the most recent available
2 address of that individual) of the offer de-
3 scribed in clause (ii) and of the fact that
4 such individual will no longer be covered
5 under such policy as of January 1, 2004;
6 and

7 “(ii) offers the policyholder or certifi-
8 cate holder under the terms described in
9 subparagraph (B), during at least the pe-
10 riod established under section
11 1860B(b)(2)(A), a medicare supplemental
12 policy with the benefit package that the
13 Secretary determines is most comparable
14 to the policy in which the individual is en-
15 rolled with coverage effective as of the date
16 on which the individual is first entitled to
17 benefits under part D.

18 “(B) TERMS OF OFFER DESCRIBED.—The
19 terms described in this subparagraph are terms
20 which do not—

21 “(i) deny or condition the issuance or
22 effectiveness of a medicare supplemental
23 policy described in subparagraph (A)(ii)
24 that is offered and is available for issuance
25 to new enrollees by such issuer;

1 “(ii) discriminate in the pricing of
2 such policy because of health status, claims
3 experience, receipt of health care, or med-
4 ical condition; or

5 “(iii) impose an exclusion of benefits
6 based on a preexisting condition under
7 such policy.

8 “(5) ELIMINATION OF OBSOLETE POLICIES
9 WITH NO GRANDFATHERING.—No person may sell,
10 issue, or renew a medicare supplemental policy with
11 a benefit package that is classified as ‘H’, ‘I’, or ‘J’
12 (or with a benefit package classified as ‘J’ with a
13 high deductible feature) that has not been revised
14 under this subsection on or after January 1, 2004.

15 “(6) PENALTIES.—Each penalty under this sec-
16 tion shall apply with respect to policies revised under
17 this subsection as if such policies were issued under
18 the standards established under subsection (p), in-
19 cluding the penalties under subsections (a), (d),
20 (p)(8), (p)(9), (q)(5), (r)(6)(A), (s)(4), and
21 (t)(2)(D).”.

1 **SEC. 6. HHS STUDIES AND REPORT ON UNIFORM PHAR-**
2 **MACY BENEFIT CARDS AND SYSTEMS FOR**
3 **TRANSFERRING PRESCRIPTIONS ELECTRONI-**
4 **CALLY.**

5 (a) STUDIES.—The Secretary of Health and Human
6 Services shall conduct a study to determine the feasibility
7 and advisability of—

8 (1) establishing a uniform format for pharmacy
9 benefit cards provided to beneficiaries by eligible en-
10 tities under the outpatient prescription drug benefit
11 program under part D of title XVIII of the Social
12 Security Act (as added by section 2); and

13 (2) developing systems to electronically transfer
14 prescriptions under such program from the pre-
15 scriber to the pharmacist.

16 (b) REPORT.—Not later than 2 years after the date
17 of enactment of this Act, the Secretary of Health and
18 Human Services shall submit to Congress a report on the
19 results of the studies conducted under subsection (a) to-
20 gether with any recommendations for legislation that the
21 Secretary determines to be appropriate as a result of such
22 studies.

23 **SEC. 7. GAO STUDY AND BIENNIAL REPORTS ON COMPETI-**
24 **TION AND SAVINGS.**

25 (a) ONGOING STUDY.—The Comptroller General of
26 the United States shall conduct an ongoing study and

1 analysis of the outpatient prescription drug benefit pro-
2 gram under part D of title XVIII of the Social Security
3 Act (as added by section 2), including an analysis of—

4 (1) the extent to which the competitive bidding
5 process under such program fosters maximum com-
6 petition and efficiency; and

7 (2) the savings to the medicare program result-
8 ing from such outpatient prescription drug benefit
9 program, including the reduction in the number or
10 length of hospital visits.

11 (b) INITIAL REPORT ON COMPETITIVE BIDDING
12 PROCESS.—Not later than 9 months after the date of en-
13 actment of this Act, the Comptroller General of the United
14 States shall submit to Congress a report on the results
15 of the portion of the study conducted pursuant to sub-
16 section (a)(1).

17 (c) BIENNIAL REPORTS.—Not later than January 1,
18 2005, and biennially thereafter, the Comptroller General
19 of the United States shall submit to Congress a report
20 on the results of the study conducted under subsection (a)
21 together with such recommendations for legislation and
22 administrative action as the Comptroller General deter-
23 mines appropriate.

1 **SEC. 8. EXPANSION OF MEMBERSHIP AND DUTIES OF MEDI-**
2 **CARE PAYMENT ADVISORY COMMISSION**
3 **(MEDPAC).**

4 (a) EXPANSION OF MEMBERSHIP.—

5 (1) IN GENERAL.—Section 1805(c) of the So-
6 cial Security Act (42 U.S.C. 1395b–6(c)) is
7 amended—

8 (A) in paragraph (1), by striking “17” and
9 inserting “19”; and

10 (B) in paragraph (2)(B), by inserting “ex-
11 perts in the area of pharmacology and prescrip-
12 tion drug benefit programs,” after “other
13 health professionals,”.

14 (2) INITIAL TERMS OF ADDITIONAL MEM-
15 BERS.—

16 (A) IN GENERAL.—For purposes of stag-
17 gering the initial terms of members of the
18 Medicare Payment Advisory Commission under
19 section 1805(c)(3) of the Social Security Act
20 (42 U.S.C. 1395b–6(c)(3)), the initial terms of
21 the 2 additional members of the Commission
22 provided for by the amendment under para-
23 graph (1)(A) are as follows:

24 (i) One member shall be appointed for
25 1 year.

1 (ii) One member shall be appointed
2 for 2 years.

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

5 (b) EXPANSION OF DUTIES.—Section 1805(b)(2) of
6 the Social Security Act (42 U.S.C. 1395b–6(b)(2)) is
7 amended by adding at the end the following new subpara-
8 graph:

9 “(D) PRESCRIPTION MEDICINE BENEFIT
10 PROGRAM.—Specifically, the Commission shall
11 review, with respect to the outpatient prescrip-
12 tion drug benefit program under part D, the
13 impact of such program on—

14 “(i) the pharmaceutical market, in-
15 cluding costs and pricing of pharma-
16 ceuticals, beneficiary access to such phar-
17 maceuticals, and trends in research and
18 development;

19 “(ii) franchise, independent, and rural
20 pharmacies; and

21 “(iii) beneficiary access to outpatient
22 prescription drugs, including an assess-
23 ment of out-of-pocket spending, generic

1 and brand name drug utilization, and
2 pharmacists' services.”.

○