

107TH CONGRESS
1ST SESSION

S. 10

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

JANUARY 22, 2001

Mr. DASCHLE (for himself, Mr. BAUCUS, Mr. GRAHAM, Mr. KENNEDY, Mr. AKAKA, Mr. BIDEN, Mr. BINGAMAN, Mrs. BOXER, Mr. BYRD, Mrs. CARNAHAN, Mr. CLELAND, Mrs. CLINTON, Mr. CORZINE, Mr. DAYTON, Mr. DODD, Mr. DORGAN, Mr. DURBIN, Mr. HOLLINGS, Mr. INOUYE, Mr. JOHNSON, Mr. KERRY, Mr. LEAHY, Mr. LEVIN, Mrs. LINCOLN, Ms. MIKULSKI, Mrs. MURRAY, Mr. NELSON of Florida, Mr. REED, Mr. REID, Mr. ROCKEFELLER, Mr. SARBANES, and Mr. SCHUMER) 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 Prescription Drug Coverage Act of 2001”.

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

- Sec. 1. Short title; table of contents.
 Sec. 2. Findings.
 Sec. 3. Medicare outpatient prescription drug benefit program.

“PART D—OUTPATIENT PRESCRIPTION DRUG BENEFIT PROGRAM

“Sec. 1860. Definitions.

“SUBPART 1—ESTABLISHMENT OF OUTPATIENT PRESCRIPTION DRUG
 BENEFIT PROGRAM

“Sec. 1860A. Establishment of outpatient prescription drug benefit pro-
 gram.

“Sec. 1860B. Enrollment.

“Sec. 1860C. Providing information to beneficiaries.

“Sec. 1860D. Premiums.

“Sec. 1860E. Cost-sharing.

“Sec. 1860F. Selection of entities to provide outpatient drug benefit.

“Sec. 1860G. Conditions for awarding contract.

“Sec. 1860H. Payments.

“Sec. 1860I. Employer incentive program for employment-based retiree
 drug coverage.

“Sec. 1860J. Procedures for partial year implementation.

“Sec. 1860K. Appropriations.

“SUBPART 2—MEDICARE PHARMACY AND THERAPEUTICS (P&T) ADVISORY
 COMMITTEE

“Sec. 1860M. Medicare Pharmacy and Therapeutics (P&T) Advisory Com-
 mittee.”.

- Sec. 4. Part D benefits under Medicare+Choice plans.
 Sec. 5. Exclusion of part D costs from determination of part B monthly pre-
 mium.
 Sec. 6. Additional assistance for low-income beneficiaries.
 Sec. 7. Medigap revisions.
 Sec. 8. Comprehensive immunosuppressive drug coverage for transplant pa-
 tients.
 Sec. 9. HHS studies and report to Congress regarding outpatient prescription
 drug benefit program.
 Sec. 10. GAO study and biennial reports on competition and savings.
 Sec. 11. MedPAC study and annual reports on the pharmaceutical market,
 pharmacies, and beneficiary access.
 Sec. 12. Appropriations.

3 **SEC. 2. FINDINGS.**

4 Congress makes the following findings:

- 5 (1) Prescription drug coverage was not a stand-
 6 ard part of health insurance when the medicare pro-

1 gram under title XVIII of the Social Security Act
2 was enacted in 1965. Since 1965, however, drug cov-
3 erage has become a key component of most private
4 and public health insurance coverage, except for the
5 medicare program.

6 (2) At least $\frac{2}{3}$ of medicare beneficiaries have
7 unreliable, inadequate, or no drug coverage at all.

8 (3) Seniors who do not have drug coverage typi-
9 cally pay 15 percent more for prescription drugs
10 than individuals that have such coverage pay for
11 such drugs, and often pay 2 times the best available
12 price for such drugs.

13 (4) Although many medicare beneficiaries who
14 lack prescription drug coverage have low incomes,
15 more than $\frac{1}{2}$ of such beneficiaries have incomes
16 greater than 150 percent of the poverty line.

17 (5) The number of private firms offering retiree
18 health coverage is declining.

19 (6) The premiums for medicare supplemental
20 policies (medigap policies) that provide prescription
21 drug coverage are too expensive for most medicare
22 beneficiaries and are highest for older senior citizens
23 who need prescription drug coverage the most and
24 typically have the lowest incomes.

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) but that it is available
16 over-the-counter in addition to being avail-
17 able 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) that is covered under part A or
24 B (unless coverage of such product is not

1 available because benefits under part A or
2 B have been exhausted); or

3 “(iii) except for agents used to pro-
4 mote smoking cessation, for which cov-
5 erage may be excluded or restricted under
6 section 1927(d)(2).

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

10 “(3) ELIGIBLE ENTITY.—The term ‘eligible en-
11 tity’ means any entity that the Secretary determines
12 to be appropriate to provide eligible beneficiaries
13 with covered outpatient drugs under a contract en-
14 tered into under this part, including—

15 “(A) a pharmacy benefit management com-
16 pany;

17 “(B) a retail pharmacy delivery system;

18 “(C) a health plan or insurer;

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

21 “(E) any other entity approved by the Sec-
22 retary; or

23 “(F) any combination of the entities de-
24 scribed in subparagraphs (A) through (E) if the
25 Secretary determines that such combination—

1 “(i) increases the scope or efficiency
2 of the provision of benefits under this part;
3 and

4 “(ii) is not anticompetitive.

5 “SUBPART 1—ESTABLISHMENT OF OUTPATIENT
6 PRESCRIPTION DRUG BENEFIT PROGRAM

7 “ESTABLISHMENT OF OUTPATIENT PRESCRIPTION DRUG
8 BENEFIT PROGRAM

9 “SEC. 1860A. (a) PROVISION OF BENEFIT.—Begin-
10 ning on the date that is 1 year after the date of enactment
11 of this Act, the Secretary shall provide for an outpatient
12 prescription drug benefit program under which an eligible
13 beneficiary shall be provided covered outpatient drugs.

14 “(b) VOLUNTARY NATURE OF PROGRAM.—Nothing
15 in this part shall be construed as requiring an eligible ben-
16 eficiary to enroll in the program established under this
17 part.

18 “(c) SCOPE OF BENEFITS.—The program established
19 under this part shall provide for coverage of all therapeutic
20 classes of covered outpatient drugs.

21 “(d) FINANCING.—The costs of providing benefits
22 under this part shall be payable from the Federal Supple-
23 mentary Medical Insurance Trust Fund established under
24 section 1841.

25 “ENROLLMENT

26 “SEC. 1860B. (a) ENROLLMENT UNDER PART D.—

1 “(1) ESTABLISHMENT OF PROCESS.—

2 “(A) IN GENERAL.—The Secretary shall
3 establish a process through which an eligible
4 beneficiary (including an eligible beneficiary en-
5 rolled in a Medicare+Choice plan offered by a
6 Medicare+Choice organization) may make an
7 election to enroll under this part. Such process
8 shall be similar to the process for enrollment in
9 part B under section 1837.

10 “(B) REQUIREMENT OF ENROLLMENT.—
11 An eligible beneficiary must enroll under this
12 part in order to be eligible to receive covered
13 outpatient drugs under this title.

14 “(2) ENROLLMENT PROCEDURES.—

15 “(A) LATE ENROLLMENT PENALTY.—

16 “(i) IN GENERAL.—Subject to the
17 succeeding provisions of this subparagraph,
18 in the case of an eligible beneficiary whose
19 coverage period under this part began pur-
20 suant to an enrollment after the bene-
21 ficiary’s initial enrollment period under
22 part B (determined pursuant to section
23 1837(d)) and not pursuant to the open en-
24 rollment period described in subparagraph
25 (B), the Secretary shall establish proce-

1 dures for increasing the amount of the
2 monthly premium under section 1860D ap-
3 plicable to such beneficiary—

4 “(I) by an amount that is equal
5 to 10 percent of such premium for
6 each full 12-month period (in the
7 same continuous period of eligibility)
8 in which the eligible beneficiary could
9 have been enrolled under this part but
10 was not so enrolled; or

11 “(II) if determined appropriate
12 by the Secretary, by an amount that
13 the Secretary determines is actuarially
14 sound for each such period.

15 “(ii) PERIODS TAKEN INTO AC-
16 COUNT.—For purposes of calculating any
17 12-month period under clause (i), there
18 shall be taken into account—

19 “(I) the months which elapsed
20 between the close of the eligible bene-
21 ficiary’s initial enrollment period and
22 the close of the enrollment period in
23 which the beneficiary enrolled; and

24 “(II) in the case of an eligible
25 beneficiary who reenrolls under this

1 part, the months which elapsed be-
2 tween the date of termination of a
3 previous coverage period and the close
4 of the enrollment period in which the
5 beneficiary reenrolled.

6 “(iii) PERIODS NOT TAKEN INTO AC-
7 COUNT.—

8 “(I) IN GENERAL.—For purposes
9 of calculating any 12-month period
10 under clause (i), subject to subclause
11 (II), there shall not be taken into ac-
12 count months for which the eligible
13 beneficiary can demonstrate that the
14 beneficiary was covered under a group
15 health plan, including a qualified re-
16 tiree prescription drug plan (as de-
17 fined in section 1860I(e)(3)) for which
18 an incentive payment was paid under
19 section 1860I, that provides coverage
20 of the cost of prescription drugs
21 whose actuarial value (as defined by
22 the Secretary) to the beneficiary
23 equals or exceeds the actuarial value
24 of the benefits provided to an indi-
25 vidual enrolled in the outpatient pre-

1 prescription drug benefit program under
2 this part.

3 “(II) APPLICATION.—This clause
4 shall only apply with respect to a cov-
5 erage period the enrollment for which
6 occurs before the end of the 60-day
7 period that begins on the first day of
8 the month which includes the date on
9 which the plan terminates, ceases to
10 provide, or reduces the value of the
11 prescription drug coverage under such
12 plan to below the value of the cov-
13 erage provided under the program
14 under this part.

15 “(iv) PERIODS TREATED SEPA-
16 RATELY.—Any increase in an eligible bene-
17 ficiary’s monthly premium under clause (i)
18 with respect to a particular continuous pe-
19 riod of eligibility shall not be applicable
20 with respect to any other continuous period
21 of eligibility which the beneficiary may
22 have.

23 “(v) CONTINUOUS PERIOD OF ELIGI-
24 BILITY.—

1 “(I) IN GENERAL.—Subject to
2 subclause (II), for purposes of this
3 subparagraph, an eligible beneficiary’s
4 ‘continuous period of eligibility’ is the
5 period that begins with the first day
6 on which the beneficiary is eligible to
7 enroll under section 1836 and ends
8 with the beneficiary’s death.

9 “(II) SEPARATE PERIOD.—Any
10 period during all of which an eligible
11 beneficiary satisfied paragraph (1) of
12 section 1836 and which terminated in
13 or before the month preceding the
14 month in which the beneficiary at-
15 tained age 65 shall be a separate ‘con-
16 tinuous period of eligibility’ with re-
17 spect to the beneficiary (and each
18 such period which terminates shall be
19 deemed not to have existed for pur-
20 poses of subsequently applying this
21 subparagraph).

22 “(B) OPEN ENROLLMENT PERIOD FOR
23 CURRENT BENEFICIARIES IN WHICH LATE EN-
24 ROLLMENT PROCEDURES DO NOT APPLY.—The
25 Secretary shall establish an applicable period,

1 which shall begin on the date on which the Sec-
2 retary first begins to accept elections for enroll-
3 ment under this part, during which any eligible
4 beneficiary may enroll under this part without
5 the application of the late enrollment proce-
6 dures established under subparagraph (A)(i).

7 “(3) PERIOD OF COVERAGE.—

8 “(A) IN GENERAL.—Except as provided in
9 subparagraph (B), an eligible beneficiary’s cov-
10 erage under the program under this part shall
11 be effective for the period provided in section
12 1838, as if that section applied to the program
13 under this part.

14 “(B) OPEN ENROLLMENT.—An eligible
15 beneficiary who enrolls under the program
16 under this part pursuant to paragraph (2)(B)
17 shall be entitled to the benefits under this part
18 beginning on the first day of the month fol-
19 lowing the month in which such enrollment oc-
20 curs.

21 “(C) LIMITATION.—Coverage under this
22 part shall not begin prior to the date that is 1
23 year after the date of enactment of this Act.

24 “(4) PART D COVERAGE TERMINATED BY TER-
25 MINATION OF COVERAGE UNDER PARTS A AND B.—

1 “(A) IN GENERAL.—In addition to the
2 causes of termination specified in section 1838,
3 the Secretary shall terminate an individual’s
4 coverage under this part if the individual is no
5 longer enrolled in either part A or part 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 “(b) ENROLLMENT WITH ELIGIBLE ENTITY.—

11 “(1) PROCESS.—

12 “(A) IN GENERAL.—The Secretary shall
13 establish a process through which an eligible
14 beneficiary who is enrolled under this part but
15 not enrolled in a Medicare+Choice plan offered
16 by a Medicare+Choice organization shall make
17 an annual election to enroll with any eligible en-
18 tity that has been awarded a contract under
19 this part and serves the geographic area in
20 which the beneficiary resides.

21 “(B) RULES.—In establishing the process
22 under subparagraph (A), the Secretary shall
23 use rules similar to the rules for enrollment and
24 disenrollment with a Medicare+Choice plan

1 under section 1851 (including special election
2 periods under subsection (e)(4) of such section).

3 “(2) MEDICARE+CHOICE ENROLLEES.—An eli-
4 gible beneficiary who is enrolled under this part and
5 enrolled in a Medicare+Choice plan offered by a
6 Medicare+Choice organization shall receive coverage
7 of covered outpatient drugs under this part through
8 such plan.

9 “(c) FIRST ENROLLMENT PERIOD.—The processes
10 developed under subsections (a) and (b) shall ensure that
11 eligible beneficiaries are permitted to enroll under this
12 part and with an eligible entity prior to the date that is
13 1 year after the date of enactment of this Act, in order
14 to ensure that coverage under this part is effective as of
15 such date.

16 “PROVIDING INFORMATION TO BENEFICIARIES

17 “SEC. 1860C. (a) ACTIVITIES.—

18 “(1) IN GENERAL.—The Secretary shall con-
19 duct activities that are designed to broadly dissemi-
20 nate information to eligible beneficiaries (and pro-
21 spective eligible beneficiaries) regarding the coverage
22 provided under this part.

23 “(2) SPECIAL RULE FOR FIRST ENROLLMENT
24 UNDER THE PROGRAM.—To the extent practicable,
25 the activities described in paragraph (1) shall ensure
26 that eligible beneficiaries are provided with such in-

1 formation at least 30 days prior to the first enroll-
2 ment period described in section 1860B(c).

3 “(b) REQUIREMENTS.—

4 “(1) IN GENERAL.—The activities described in
5 subsection (a) shall—

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

8 “(B) be coordinated with the activities per-
9 formed by the Secretary under such section and
10 under section 1804; and

11 “(C) provide for the dissemination of infor-
12 mation comparing the eligible entities that are
13 available to eligible beneficiaries residing in an
14 area under this part.

15 “(2) COMPARATIVE INFORMATION.—The com-
16 parative information described in paragraph (1)(B)
17 shall include the following:

18 “(A) BENEFITS.—A comparison of the
19 benefits provided by each eligible entity, includ-
20 ing a comparison of the pharmacy networks
21 used by each eligible entity and the formularies
22 and appeals processes implemented by each en-
23 tity.

1 “(B) QUALITY AND PERFORMANCE.—To
2 the extent available, the quality and perform-
3 ance of each eligible entity.

4 “(C) BENEFICIARY COSTS.—The cost-shar-
5 ing required of eligible beneficiaries enrolled in
6 each eligible entity.

7 “(D) CONSUMER SATISFACTION SUR-
8 VEYS.—To the extent available, the results of
9 consumer satisfaction surveys regarding each
10 eligible entity.

11 “(E) ADDITIONAL INFORMATION.—Such
12 additional information as the Secretary may
13 prescribe.

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

18 “(c) USE OF MEDICARE CONSUMER COALITIONS TO
19 PROVIDE INFORMATION.—

20 “(1) IN GENERAL.—The Secretary may con-
21 tract with Medicare Consumer Coalitions to conduct
22 the informational activities—

23 “(A) under this section;

24 “(B) under section 1851(d); and

25 “(C) under section 1804.

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

4 “(A) develop and disseminate, in such
5 areas as the Secretary determines appropriate,
6 a request for proposals for Medicare Consumer
7 Coalitions to contract with the Secretary in
8 order to conduct any of the informational ac-
9 tivities described in paragraph (1); and

10 “(B) select a proposal of a Medicare Con-
11 sumer Coalition to conduct the informational
12 activities in each such area, with a preference
13 for broad participation by organizations with
14 experience in providing information to bene-
15 ficiaries under this title.

16 “(3) PAYMENT TO MEDICARE CONSUMER COA-
17 LITIONS.—The Secretary shall make payments to
18 Medicare Consumer Coalitions contracting under
19 this subsection in such amounts and in such manner
20 as the Secretary determines appropriate.

21 “(4) AUTHORIZATION OF APPROPRIATIONS.—
22 There are authorized to be appropriated to the Sec-
23 retary such sums as may be necessary to contract
24 with Medicare Consumer Coalitions under this sec-
25 tion.

1 with respect to enrollees in the program under
2 this part.

3 “(B) DETERMINATION OF MONTHLY PRE-
4 MIUM RATES.—

5 “(i) IN GENERAL.—The Secretary
6 shall determine the monthly premium rate
7 with respect to such enrollees for such suc-
8 ceeding year, which shall be $\frac{1}{12}$ of the ap-
9 plicable percent of the amount determined
10 under subparagraph (A), divided by the
11 total number of such enrollees, and round-
12 ed (if such rate is not a multiple of 10
13 cents) to the nearest multiple of 10 cents.

14 “(ii) DEFINITION OF APPLICABLE
15 PERCENT.—For purposes of clause (i), the
16 term ‘applicable percent’ means—

17 “(I) 45 percent, in the case of
18 premiums paid by an eligible bene-
19 ficiary enrolled in the program under
20 this part; and

21 “(II) 66.66 percent, in the case
22 of premiums paid for such a bene-
23 ficiary by an employer (as defined in
24 section 1860I(e)(2)) that the bene-
25 ficiary formerly worked for.

1 Secretary determines that the waiver of the
2 deductible—

3 “(i) is tied to the performance meas-
4 ures and other incentives applicable to the
5 entity pursuant to section 1860H(a); and

6 “(ii) will not result in an increase in
7 the expenditures made from the Federal
8 Supplementary Medical Insurance Trust
9 Fund.

10 “(B) CREDIT FOR AMOUNTS PAID.—If the
11 deductible is waived pursuant to subparagraph
12 (A), any coinsurance paid by an eligible bene-
13 ficiary for the generic drug shall be credited to-
14 ward the annual deductible.

15 “(b) COINSURANCE.—

16 “(1) ESTABLISHMENT.—

17 “(A) IN GENERAL.—Subject to paragraph
18 (2), if any covered outpatient drug is provided
19 to an eligible beneficiary in a year after the
20 beneficiary has met any deductible requirement
21 under subsection (a) for the year, the bene-
22 ficiary shall be responsible for making payments
23 for the drug in an amount equal to the applica-
24 ble percentage of the cost of the drug.

1 “(B) APPLICABLE PERCENTAGE DE-
2 FINED.—For purposes of subparagraph (A), the
3 ‘applicable percentage’ means, with respect to
4 any covered outpatient drug provided to an eli-
5 gible beneficiary in a year—

6 “(i) 50 percent to the extent the out-
7 of-pocket expenses of the beneficiary for
8 such drug, when added to the out-of-pocket
9 expenses of the beneficiary for covered out-
10 patient drugs previously provided in the
11 year, do not exceed \$3,500;

12 “(ii) 25 percent to the extent such ex-
13 penses, when so added, exceed \$3,500 but
14 do not exceed \$4,000; and

15 “(iii) 0 percent to the extent such ex-
16 penses, when so added, would exceed
17 \$4,000.

18 “(C) OUT-OF-POCKET EXPENSES DE-
19 FINED.—For purposes of subparagraph (B),
20 the term ‘out-of-pocket expenses’ means ex-
21 penses incurred as a result of the application of
22 the deductible under subsection (a) and the co-
23 insurance required under this subsection.

24 “(2) REDUCTION BY ELIGIBLE ENTITY.—An el-
25 igible entity may reduce the applicable percentage

1 that an eligible beneficiary is subject to under para-
2 graph (1) if the Secretary determines that such
3 reduction—

4 “(A) is tied to the performance measures
5 and other incentives applicable to the entity
6 pursuant to section 1860H(a); and

7 “(B) will not result in an increase in the
8 expenditures made from the Federal Supple-
9 mentary Medical Insurance Trust Fund.

10 “(c) INFLATION ADJUSTMENT.—

11 “(1) IN GENERAL.—In the case of any calendar
12 year beginning after 2004, each of the dollar
13 amounts in subsections (a)(1) and (b)(1)(B) shall be
14 increased by an amount equal to—

15 “(A) such dollar amount, multiplied by

16 “(B) the percentage (if any) by which the
17 amount of average per capita expenditures
18 under this part in the preceding calendar year
19 exceeds the amount of such expenditures in
20 2003.

21 “(2) ROUNDING.—If any dollar amount after
22 being increased under paragraph (1) is not a mul-
23 tiple of \$5, such dollar amount shall be rounded to
24 the nearest multiple of \$5.

1 “SELECTION OF ENTITIES TO PROVIDE OUTPATIENT
2 DRUG BENEFIT

3 “SEC. 1860F. (a) ESTABLISHMENT OF BIDDING
4 PROCESS.—

5 “(1) IN GENERAL.—The Secretary shall estab-
6 lish procedures under which the Secretary accepts
7 bids submitted by eligible entities and awards con-
8 tracts to such entities in order to administer and de-
9 liver the benefits provided under this part to eligible
10 beneficiaries in an area.

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

16 “(b) AREA FOR CONTRACTS.—

17 “(1) REGIONAL BASIS.—

18 “(A) IN GENERAL.—Except as provided in
19 subparagraph (B) and subject to paragraph (2),
20 the contract entered into between the Secretary
21 and an eligible entity shall require the eligible
22 entity to provide covered outpatient drugs on a
23 regional basis.

24 “(B) PARTIAL REGIONAL BASIS.—

1 “(i) IN GENERAL.—If determined ap-
2 propriate by the Secretary, the Secretary
3 may permit the coverage described in sub-
4 paragraph (A) to be provided on a partial
5 regional basis.

6 “(ii) REQUIREMENTS.—If the Sec-
7 retary permits coverage pursuant to clause
8 (i), the Secretary shall ensure that the par-
9 tial region in which coverage is provided
10 is—

11 “(I) at least the size of the com-
12 mercial service area of the eligible en-
13 tity for that area; and

14 “(II) not smaller than a State.

15 “(2) DETERMINATION.—

16 “(A) IN GENERAL.—In determining cov-
17 erage areas under this part, the Secretary
18 shall—

19 “(i) take into account the number of
20 eligible beneficiaries in an area in order to
21 encourage participation by eligible entities;
22 and

23 “(ii) ensure that there are at least 10
24 different coverage areas in the United
25 States.

1 “(B) NO ADMINISTRATIVE OR JUDICIAL
2 REVIEW.—The determination of coverage areas
3 under this part shall not be subject to adminis-
4 trative or judicial review.

5 “(c) SUBMISSION OF BIDS.—

6 “(1) IN GENERAL.—Each eligible entity desir-
7 ing to provide covered outpatient drugs under this
8 part shall submit a bid to the Secretary at such
9 time, in such manner, and accompanied by such in-
10 formation as the Secretary may reasonably require.

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

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

18 “(B) the amount that the entity will
19 charge the Secretary for administering and de-
20 livering the benefits under such contract;

21 “(C) a statement regarding whether the
22 entity will waive the deductible for generic
23 drugs pursuant to section 1860E(a)(2);

24 “(D) a statement regarding whether the
25 entity will reduce the applicable coinsurance

1 percentage pursuant to section 1860E(b)(2)
2 and if so, the amount of such reduction;

3 “(E) a detailed description of—

4 “(i) the risk corridors tied to perform-
5 ance measures and other incentives that
6 the entity will accept under the contract;
7 and

8 “(ii) how the entity will meet such
9 measures and incentives;

10 “(F) a detailed description of proposed
11 contracts with local pharmacy providers de-
12 signed to ensure access, including compensation
13 for local pharmacists’ services;

14 “(G) a detailed description of any owner-
15 ship or shared financial interests with other en-
16 tities involved in the delivery of the benefit as
17 proposed;

18 “(H) a detailed description of the entity’s
19 estimated marketing and advertising expendi-
20 tures related to enrolling and retaining eligible
21 beneficiaries; and

22 “(I) such other information that the Sec-
23 retary determines is necessary in order to carry
24 out this part, including information relating to
25 the bidding process under this part.

1 “(d) ACCESS.—

2 “(1) IN GENERAL.—The Secretary shall ensure
3 that an eligible entity—

4 “(A) complies with the access requirements
5 described in section 1860G(a)(4)(A); and

6 “(B) makes available to each beneficiary
7 covered under the contract the full scope of the
8 benefits required under this part.

9 “(2) AREAS NOT COVERED BY CONTRACTS.—

10 The Secretary shall develop procedures for the provi-
11 sion of covered outpatient drugs under this part to
12 each eligible beneficiary that resides in an area that
13 is not covered by any contract under this part.

14 “(3) BENEFICIARIES RESIDING IN DIFFERENT
15 LOCATIONS.—The Secretary shall develop procedures
16 to ensure that each eligible beneficiary that resides
17 in different areas in a year is provided the benefits
18 under this part throughout the entire year.

19 “(4) SPECIAL ATTENTION TO RURAL AND
20 HARD-TO-SERVE AREAS.—

21 “(A) IN GENERAL.—The Secretary shall
22 ensure that all eligible beneficiaries have access
23 to the full range of benefits under this part,
24 and shall give special attention to access, phar-
25 macist counseling, and delivery in rural and

1 hard-to-serve areas (as the Secretary may de-
2 fine by regulation).

3 “(B) SPECIAL ATTENTION DEFINED.—For
4 purposes of subparagraph (A), the term ‘special
5 attention’ may include bonus payments to retail
6 pharmacists in rural areas, extra payments to
7 eligible entities for the cost of rapid delivery of
8 pharmaceuticals, and any other actions the Sec-
9 retary determines are necessary to ensure full
10 access to benefits under this part by eligible
11 beneficiaries residing in rural and hard-to-serve
12 areas.

13 “(C) GAO REPORT.—Not later than 2
14 years after the date of enactment of the Medi-
15 care Prescription Drug Coverage Act of 2001,
16 the Comptroller General of the United States
17 shall submit to Congress a report on the access
18 to benefits under this part by eligible bene-
19 ficiaries residing in rural and hard-to-serve
20 areas, together with any recommendations of
21 the Comptroller General regarding any addi-
22 tional steps the Secretary may need to take to
23 ensure the access of medicare beneficiaries to
24 such benefits.

25 “(e) AWARDING OF CONTRACTS.—

1 “(1) NUMBER OF CONTRACTS.—The Secretary
2 shall, consistent with the requirements of this part
3 and the goal of containing costs under this title,
4 award in a competitive manner at least 2 contracts
5 in an area, unless only 1 bidding entity meets the
6 minimum standards specified under this part and by
7 the Secretary.

8 “(2) DETERMINATION.—In determining which
9 of the eligible entities that submitted bids that meet
10 the minimum standards specified under this part
11 and by the Secretary (including the terms and condi-
12 tions described in section 1860G) to award a con-
13 tract, the Secretary shall consider the comparative
14 merits of each bid, as determined on the basis of the
15 past performance of the entity and other relevant
16 factors, with respect to—

17 “(A) how well the entity meets such min-
18 imum standards;

19 “(B) the amount that the entity will
20 charge the Secretary for administering and de-
21 livering the benefits under the contract;

22 “(C) the proposed prices of covered out-
23 patient drugs and annual increases in such
24 prices;

1 “(D) the proposed risk corridors tied to
2 performance measures and other incentives that
3 the entity will be subject to under the contract;

4 “(E) the factors described in section
5 1860C(b)(2);

6 “(F) prior experience in administering a
7 prescription drug benefit program;

8 “(G) effectiveness in containing costs
9 through pricing incentives and utilization man-
10 agement; and

11 “(H) such other factors as the Secretary
12 deems necessary to evaluate the merits of each
13 bid.

14 “(3) EXCEPTION TO CONFLICT OF INTEREST
15 RULES.—In awarding contracts under this part, the
16 Secretary may waive conflict of interest laws gen-
17 erally applicable to Federal acquisitions (subject to
18 such safeguards as the Secretary may find necessary
19 to impose) in circumstances where the Secretary
20 finds that such waiver—

21 “(A) is not inconsistent with the—

22 “(i) purposes of the programs under
23 this title; or

24 “(ii) best interests of enrolled individ-
25 uals; and

1 “(B) permits a sufficient level of competi-
2 tion for such contracts, promotes efficiency of
3 benefits administration, or otherwise serves the
4 objectives of the program under this part.

5 “(4) NO ADMINISTRATIVE OR JUDICIAL RE-
6 VIEW.—The determination of the Secretary to award
7 or not award a contract to an eligible entity under
8 this part shall not be subject to administrative or ju-
9 dicial review.

10 “(f) APPROVAL OF MARKETING MATERIAL AND AP-
11 PLICATION FORMS.—The provisions of section 1851(h)
12 shall apply to marketing material and application forms
13 under this part in the same manner as such provisions
14 apply to marketing material and application forms under
15 part C.

16 “(g) DURATION OF CONTRACTS.—Each contract
17 under this part shall be for a term of at least 2 years
18 but not more than 5 years, as determined by the Sec-
19 retary.

20 “CONDITIONS FOR AWARDING CONTRACT

21 “SEC. 1860G. (a) IN GENERAL.—The Secretary shall
22 not award a contract to an eligible entity under this part
23 unless the Secretary finds that the eligible entity agrees
24 to comply with such terms and conditions as the Secretary
25 shall specify, including the following:

1 “(1) QUALITY AND FINANCIAL STANDARDS.—
2 The eligible entity meets the quality and financial
3 standards specified by the Secretary.

4 “(2) PROCEDURES TO ENSURE PROPER UTILI-
5 ZATION, COMPLIANCE, AND AVOIDANCE OF ADVERSE
6 DRUG REACTIONS.—The eligible entity has in place
7 drug utilization review procedures to ensure—

8 “(A) the appropriate utilization by eligible
9 beneficiaries of the benefits to be provided
10 under the contract; and

11 “(B) the avoidance of adverse drug reac-
12 tions among eligible beneficiaries enrolled with
13 the entity, including problems due to thera-
14 peutic duplication, drug-disease contraindica-
15 tions, drug-drug interactions (including serious
16 interactions with nonprescription or over-the-
17 counter drugs), incorrect drug dosage or dura-
18 tion of drug treatment, drug-allergy inter-
19 actions, and clinical abuse and misuse.

20 “(3) COST-EFFECTIVE PROVISION OF BENE-
21 FITS.—

22 “(A) IN GENERAL.—In providing the bene-
23 fits under a contract under this part, an eligible
24 entity may—

1 “(i) employ mechanisms to provide
2 the benefits economically, including the use
3 of—

4 “(I) formularies (pursuant to
5 subparagraph (B));

6 “(II) alternative methods of dis-
7 tribution; and

8 “(III) generic drug substitution;

9 “(ii) use mechanisms to encourage eli-
10 gible beneficiaries to select cost-effective
11 drugs or less costly means of receiving
12 drugs, including the use of pharmacy in-
13 centive programs, therapeutic interchange
14 programs, and disease management pro-
15 grams; and

16 “(iii) encourage pharmacy providers
17 to—

18 “(I) inform beneficiaries of the
19 differentials in price between generic
20 and nongeneric drug equivalents; and

21 “(II) provide medication therapy
22 management programs in order to en-
23 hance beneficiaries’ understanding of
24 the appropriate use of medications
25 and to reduce the risk of potential ad-

1 verse events associated with medica-
2 tions.

3 “(B) FORMULARIES.—If an eligible entity
4 uses a formulary under this part, such for-
5 mulary shall comply with standards established
6 by the Secretary in consultation with the Medi-
7 care Pharmacy and Therapeutics Advisory
8 Committee established under section 1860M.
9 Such standards shall require that the eligible
10 entity—

11 “(i) use a pharmacy and therapeutic
12 committee (that meets the standards for a
13 pharmacy and therapeutic committee es-
14 tablished by the Secretary in consultation
15 with the Medicare Pharmacy and Thera-
16 peutics Advisory Committee established
17 under section 1860M) to develop and im-
18 plement the formulary;

19 “(ii) include in the formulary—

20 “(I) at least 1 drug from each
21 therapeutic class (as defined by the
22 entity’s pharmacy and therapeutic
23 committee in accordance with stand-
24 ards established by the Secretary in
25 consultation with the Medicare Phar-

1 macy and Therapeutics Advisory
2 Committee established under section
3 1860M);

4 “(II) if there is more than 1 drug
5 available in a therapeutic class, at
6 least 2 drugs from such class; and

7 “(III) if there are more than 2
8 drugs available in a therapeutic class,
9 at least 2 drugs from such class and
10 a generic drug substitute if available;

11 “(iii) develop procedures for the—

12 “(I) addition of new therapeutic
13 classes to the formulary;

14 “(II) addition of new drugs to an
15 existing therapeutic class; and

16 “(III) modification of the for-
17 mulary;

18 “(iv) provide for coverage of otherwise
19 covered non-formulary drugs when rec-
20 ommended by a prescribing provider; and

21 “(v) disclose to current and prospec-
22 tive beneficiaries and to providers in the
23 service area the nature of the formulary
24 restrictions, including information regard-
25 ing the drugs included in the formulary,

1 coinsurance, and any difference in the
2 cost-sharing for different types of drugs.

3 “(C) CONSTRUCTION.—Nothing in this
4 paragraph shall be construed as precluding an
5 eligible entity from—

6 “(i) requiring cost-sharing for nonfor-
7 mulary drugs that is higher than the cost-
8 sharing established in section 1860E(b),
9 except that such entity shall provide for
10 coverage of a nonformulary drug at the
11 same cost-sharing level as a drug within
12 the formulary if such nonformulary drug is
13 recommended by a prescribing provider;

14 “(ii) educating prescribing providers,
15 pharmacists, and beneficiaries about the
16 medical and cost benefits of formulary
17 drugs (including generic drugs); or

18 “(iii) requiring prescribing providers
19 to consider a formulary drug prior to dis-
20 pensing of a nonformulary drug, as long as
21 such requirement does not unduly delay
22 the provision of the drug.

23 “(4) PATIENT PROTECTIONS.—

24 “(A) ACCESS.—The eligible entity ensures
25 that the covered outpatient drugs are accessible

1 and convenient to eligible beneficiaries covered
2 under the contract, including by doing the fol-
3 lowing:

4 “(i) SERVICES DURING EMER-
5 GENCIES.—Offering services 24 hours a
6 day and 7 days a week for emergencies.

7 “(ii) AGREEMENTS WITH PHAR-
8 MACIES.—Entering into participation
9 agreements under subsection (b) with
10 pharmacies, that include terms that—

11 “(I) secure the participation of
12 sufficient numbers of pharmacies to
13 ensure convenient access (including
14 adequate emergency access); and

15 “(II) permit the participation of
16 any pharmacy in the service area that
17 meets the participation requirements
18 described in subsection (b).

19 “(B) CONTINUITY OF CARE.—

20 “(i) IN GENERAL.—The eligible entity
21 ensures that, in the case of an eligible ben-
22 eficiary who loses coverage under this part
23 with such entity under circumstances that
24 would permit a special election period (as
25 established by the Secretary under section

1 1860B(b)), the entity will continue to pro-
2 vide coverage under this part to such bene-
3 ficiary until the beneficiary enrolls and re-
4 ceives such coverage with another eligible
5 entity under this part.

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

12 “(C) PROCEDURES REGARDING DENIALS
13 OF CARE.—The eligible entity has in place pro-
14 cedures to ensure—

15 “(i) a timely internal and external re-
16 view and resolution of denials of coverage
17 (in whole or in part) and complaints (in-
18 cluding those regarding the use of
19 formularies under paragraph (3)) by eligi-
20 ble beneficiaries, or by providers, phar-
21 macists, and other individuals acting on
22 behalf of each such beneficiary (with the
23 beneficiary’s consent) in accordance with
24 requirements (as established by the Sec-
25 retary) that are comparable to such re-

1 requirements for Medicare+Choice organiza-
2 tions under part C; and

3 “(ii) that beneficiaries are provided
4 with information regarding the appeals
5 procedures under this part at the time of
6 enrollment.

7 “(D) PROCEDURES REGARDING PATIENT
8 CONFIDENTIALITY.—Insofar as an eligible enti-
9 ty maintains individually identifiable medical
10 records or other health information regarding
11 eligible beneficiaries under a contract entered
12 into under this part, the entity has in place pro-
13 cedures to—

14 “(i) safeguard the privacy of any indi-
15 vidually identifiable beneficiary informa-
16 tion;

17 “(ii) maintain such records and infor-
18 mation in a manner that is accurate and
19 timely;

20 “(iii) ensure timely access by such
21 beneficiaries to such records and informa-
22 tion; and

23 “(iv) otherwise comply with applicable
24 laws relating to patient confidentiality.

1 “(E) PROCEDURES REGARDING TRANSFER
2 OF MEDICAL RECORDS.—

3 “(i) IN GENERAL.—The eligible entity
4 has in place procedures for the timely
5 transfer of records and information de-
6 scribed in subparagraph (D) (with respect
7 to a beneficiary who loses coverage under
8 this part with the entity and enrolls with
9 another entity under this part) to such
10 other entity.

11 “(ii) PATIENT CONFIDENTIALITY.—
12 The procedures described in clause (i) shall
13 comply with the patient confidentiality pro-
14 cedures described in subparagraph (D).

15 “(F) PROCEDURES REGARDING MEDICAL
16 ERRORS.—The eligible entity has in place pro-
17 cedures for working with the Secretary to deter
18 medical errors related to the provision of cov-
19 ered outpatient drugs.

20 “(5) PROCEDURES TO CONTROL FRAUD, ABUSE,
21 AND WASTE.—The eligible entity has in place proce-
22 dures to control fraud, abuse, and waste.

23 “(6) REPORTING REQUIREMENTS.—

1 “(A) IN GENERAL.—The eligible entity
2 provides the Secretary with reports containing
3 information regarding the following:

4 “(i) The prices that the eligible entity
5 is paying for covered outpatient drugs.

6 “(ii) The prices that eligible bene-
7 ficiaries enrolled with the entity will be
8 charged for covered outpatient drugs.

9 “(iii) The administrative costs of pro-
10 viding such benefits.

11 “(iv) Utilization of such benefits.

12 “(v) Marketing and advertising ex-
13 penditures related to enrolling and retain-
14 ing eligible beneficiaries.

15 “(B) TIMEFRAME FOR SUBMITTING RE-
16 PORTS.—

17 “(i) IN GENERAL.—The eligible entity
18 shall submit a report described in subpara-
19 graph (A) to the Secretary within 3
20 months after the end of each 12-month pe-
21 riod in which the eligible entity has a con-
22 tract under this part. Such report shall
23 contain information concerning the benefits
24 provided during such 12-month period.

1 “(ii) LAST YEAR OF CONTRACT.—In
2 the case of the last year of a contract
3 under this section, the Secretary may re-
4 quire that a report described in subpara-
5 graph (A) be submitted 3 months prior to
6 the end of the contract. Such report shall
7 contain information concerning the benefits
8 provided between the period covered by the
9 most recent report under this subpara-
10 graph and the date that a report is sub-
11 mitted under this clause.

12 “(C) CONFIDENTIALITY OF INFORMA-
13 TION.—

14 “(i) IN GENERAL.—Notwithstanding
15 any other provision of law and subject to
16 clause (ii), information disclosed by an eli-
17 gible entity pursuant to subparagraph (A)
18 is confidential and shall only be used by
19 the Secretary for the purposes of, and to
20 the extent necessary, to carry out this
21 part.

22 “(ii) UTILIZATION DATA.—Subject to
23 patient confidentiality laws, the Secretary
24 shall make information disclosed by an eli-
25 gible entity pursuant to subparagraph

1 (A)(iv) (regarding utilization data) avail-
2 able for research purposes. The Secretary
3 may charge a reasonable fee for making
4 such information available.

5 “(7) APPROVAL OF MARKETING MATERIAL AND
6 APPLICATION FORMS.—The eligible entity will com-
7 ply with the requirements described in section
8 1860F(f).

9 “(8) RECORDS AND AUDITS.—The eligible enti-
10 ty maintains adequate records related to the admin-
11 istration of the benefit under this part and affords
12 the Secretary access to such records for auditing
13 purposes.

14 “(b) PHARMACY PARTICIPATION AGREEMENTS.—

15 “(1) IN GENERAL.—A pharmacy that meets the
16 requirements of this subsection shall be eligible to
17 enter an agreement with an eligible entity to furnish
18 covered outpatient drugs and pharmacists’ services
19 to eligible beneficiaries enrolled with such entity and
20 residing in the service area.

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

24 “(A) LICENSING.—The pharmacy and
25 pharmacists shall meet (and throughout the

1 contract period will continue to meet) all appli-
2 cable State and local licensing requirements.

3 “(B) LIMITATION ON CHARGES.—Phar-
4 macies participating under this part shall not
5 charge an eligible beneficiary enrolled with the
6 eligible entity more than—

7 “(i) the negotiated price for an indi-
8 vidual drug (as reported to the Secretary
9 pursuant to subsection (a)(6)(A)); or

10 “(ii) the amount of the beneficiary’s
11 obligation (as determined in accordance
12 with the provisions of this part) of the ne-
13 gotiated price of such drug.

14 “(C) PERFORMANCE STANDARDS.—The
15 pharmacy shall comply with performance stand-
16 ards relating to—

17 “(i) measures for quality assurance,
18 reduction of medical errors, and compli-
19 ance with the drug utilization review proce-
20 dures described in subsection (a)(2);

21 “(ii) systems to ensure compliance
22 with the patient confidentiality standards
23 applicable under subsection (a)(4)(D); and

24 “(iii) other requirements as the Sec-
25 retary may impose to ensure integrity, effi-

1 ciency, and the quality of the program
2 under this part.

3 “PAYMENTS

4 “SEC. 1860H. (a) PAYMENTS TO ELIGIBLE ENTI-
5 TIES.—

6 “(1) PROCEDURES.—

7 “(A) IN GENERAL.—The Secretary shall
8 establish procedures for making payments to an
9 eligible entity under a contract entered into
10 under this part for the administration and de-
11 livery of the benefits under this part.

12 “(B) ENTITIES ONLY SUBJECT TO LIM-
13 ITED RISK.—Under the procedures established
14 under subparagraph (A), an eligible entity shall
15 only be at risk to the extent that the entity is
16 at risk under paragraph (2).

17 “(2) RISK CORRIDORS TIED TO PERFORMANCE
18 MEASURES AND OTHER INCENTIVES.—

19 “(A) IN GENERAL.—The procedures estab-
20 lished under paragraph (1) may include the use
21 of—

22 “(i) risk corridors tied to performance
23 measures that have been agreed to between
24 the eligible entity and the Secretary under
25 the contract; and

1 “(ii) any other incentives that the
2 Secretary determines appropriate.

3 “(B) PHASE-IN OF RISK CORRIDORS TIED
4 TO PERFORMANCE MEASURES.—The Secretary
5 may phase-in the use of risk corridors tied to
6 performance measures if the Secretary deter-
7 mines such phase-in to be appropriate.

8 “(C) PAYMENTS SUBJECT TO INCEN-
9 TIVES.—If a contract under this part includes
10 the use of risk corridors tied to performance
11 measures or other incentives pursuant to sub-
12 paragraph (A), payments to eligible entities
13 under such contract shall be subject to such
14 risk corridors tied to performance measures and
15 other incentives.

16 “(3) RISK ADJUSTMENT.—To the extent that
17 eligible entities are at risk because of the risk cor-
18 ridors or other incentives described in paragraph
19 (2)(A), the procedures established under paragraph
20 (1) may include a methodology for adjusting the
21 payments made to such entities based on the dif-
22 ferences in actuarial risk of different enrollees being
23 served if the Secretary determines such adjustments
24 to be necessary and appropriate.

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

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

5 “(ii) immediately upon determining
6 that the actuarial value of the prescription
7 drug benefit under the plan falls below the
8 actuarial value of the outpatient prescrip-
9 tion drug benefit under this part.

10 “(2) BENEFICIARY INFORMATION.—The spon-
11 sor shall report to the Secretary, for each calendar
12 quarter for which it seeks an incentive payment
13 under this section, the names and social security
14 numbers of all retirees (and their spouses and de-
15 pendents) covered under such plan during such
16 quarter and the dates (if less than the full quarter)
17 during which each such individual was covered.

18 “(3) AUDITS.—The sponsor and the employ-
19 ment-based retiree health coverage plan seeking in-
20 centive payments under this section shall agree to
21 maintain, and to afford the Secretary access to, such
22 records as the Secretary may require for purposes of
23 audits and other oversight activities necessary to en-
24 sure the adequacy of prescription drug coverage, the

1 accuracy of incentive payments made, and such
2 other matters as may be appropriate.

3 “(4) OTHER REQUIREMENTS.—The sponsor
4 shall provide such other information, and comply
5 with such other requirements, as the Secretary may
6 find necessary to administer the program under this
7 section.

8 “(c) INCENTIVE PAYMENTS.—

9 “(1) IN GENERAL.—A sponsor that meets the
10 requirements of subsection (b) with respect to a
11 quarter in a calendar year shall be entitled to have
12 payment made by the Secretary on a quarterly basis
13 (to the sponsor or, at the sponsor’s direction, to the
14 appropriate employment-based health plan) of an in-
15 centive payment, in the amount determined in para-
16 graph (2), for each retired individual (or spouse)
17 who—

18 “(A) was covered under the sponsor’s
19 qualified retiree prescription drug plan during
20 such quarter; and

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

24 “(2) AMOUNT OF INCENTIVE.—The payment
25 under this section with respect to each individual de-

1 scribed in paragraph (1) for a month shall be equal
2 to $\frac{2}{3}$ of the monthly premium amount payable by an
3 eligible beneficiary enrolled under this part, as set
4 for the calendar year pursuant to section
5 1860D(a)(2).

6 “(3) PAYMENT DATE.—The incentive under
7 this section with respect to a calendar quarter shall
8 be payable as of the end of the next succeeding cal-
9 endar quarter.

10 “(d) CIVIL MONEY PENALTIES.—A sponsor, health
11 plan, or other entity that the Secretary determines has,
12 directly or through its agent, provided information in con-
13 nection with a request for an incentive payment under this
14 section that the entity knew or should have known to be
15 false shall be subject to a civil monetary penalty in an
16 amount up to 3 times the total incentive amounts under
17 subsection (c) that were paid (or would have been payable)
18 on the basis of such information.

19 “(e) DEFINITIONS.—In this section:

20 “(1) EMPLOYMENT-BASED RETIREE HEALTH
21 COVERAGE.—The term ‘employment-based retiree
22 health coverage’ means health insurance or other
23 coverage of health care costs for retired individuals
24 (or for such individuals and their spouses and de-

1 pendents) based on their status as former employees
2 or labor union members.

3 “(2) EMPLOYER.—The term ‘employer’ has the
4 meaning given the term in section 3(5) of the Em-
5 ployee Retirement Income Security Act of 1974 (ex-
6 cept that such term shall include only employers of
7 2 or more employees).

8 “(3) QUALIFIED RETIREE PRESCRIPTION DRUG
9 PLAN.—The term ‘qualified retiree prescription drug
10 plan’ means health insurance coverage included in
11 employment-based retiree health coverage that—

12 “(A) provides coverage of the cost of pre-
13 scription drugs whose actuarial value (as de-
14 fined by the Secretary) to each retired bene-
15 ficiary equals or exceeds the actuarial value of
16 the benefits provided to an individual enrolled
17 in the outpatient prescription drug benefit pro-
18 gram under this part; and

19 “(B) does not deny, limit, or condition the
20 coverage or provision of prescription drug bene-
21 fits for retired individuals based on age or any
22 health status-related factor described in section
23 2702(a)(1) of the Public Health Service Act.

24 “(4) SPONSOR.—The term ‘sponsor’ has the
25 meaning given the term ‘plan sponsor’ in section

1 3(16)(B) of the Employer Retirement Income Secu-
2 rity Act of 1974.

3 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
4 are authorized to be appropriated from time to time, out
5 of any moneys in the Treasury not otherwise appropriated,
6 such sums as may be necessary to carry out the program
7 under this section.

8 “PROCEDURES FOR PARTIAL YEAR IMPLEMENTATION

9 “SEC. 1860J. If the Secretary first implements the
10 program under this part on a day other than January 1
11 of a year, the Secretary shall establish procedures for im-
12 plementing the program during the period between the
13 date of implementation and December 31 of such year,
14 including procedures—

15 “(1) for prorating premiums, deductibles, and
16 coinsurance under the program during such period;
17 and

18 “(2) relating to requirements and payments
19 under the Medicare+Choice program during such
20 period.

21 “APPROPRIATIONS

22 “SEC. 1860K. There are authorized to be appro-
23 priated from time to time, out of any moneys in the Treas-
24 ury not otherwise appropriated, to the Federal Supple-
25 mentary Medical Insurance Trust Fund established under
26 section 1841, an amount equal to the amount by which

1 the benefits and administrative costs of providing the ben-
 2 efits under this part exceed the premiums collected under
 3 section 1860D.

4 “SUBPART 2—MEDICARE PHARMACY AND
 5 THERAPEUTICS (P&T) ADVISORY COMMITTEE

6 “MEDICARE PHARMACY AND THERAPEUTICS (P&T)
 7 ADVISORY COMMITTEE

8 “SEC. 1860M. (a) ESTABLISHMENT OF COM-
 9 MITTEE.—There is established a Medicare Pharmacy and
 10 Therapeutics Advisory Committee (in this section referred
 11 to as the ‘Committee’).

12 “(b) FUNCTIONS OF COMMITTEE.—On and after
 13 January 1, 2002, the Committee shall advise the Sec-
 14 retary on policies related to—

15 “(1) the development of guidelines for the im-
 16 plementation and administration of the outpatient
 17 prescription drug benefit program under this part;
 18 and

19 “(2) the development of—

20 “(A) standards for a pharmacy and thera-
 21 peutics committee required of eligible entities
 22 under section 1860G(a)(3)(B)(i);

23 “(B) standards for—

24 “(i) defining therapeutic classes;

1 “(ii) adding new therapeutic classes to
2 a formulary;

3 “(iii) adding new drugs to a thera-
4 peutic class within a formulary; and

5 “(iv) when and how often a formulary
6 should be modified;

7 “(C) procedures to evaluate the bids sub-
8 mitted by eligible entities under this part; and

9 “(D) procedures to ensure that eligible en-
10 tities with a contract under this part are in
11 compliance with the requirements under this
12 part.

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

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

18 “(2) MEMBERSHIP.—

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

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

3 “(i) eleven shall be chosen to rep-
4 resent physicians;

5 “(ii) four shall be chosen to represent
6 pharmacists;

7 “(iii) one shall be chosen to represent
8 the Health Care Financing Administration;

9 “(iv) two shall be chosen to represent
10 actuaries and pharmacoeconomists; and

11 “(v) one shall be chosen to represent
12 emerging drug technologies.

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, 2002.

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

20 “(f) COMPENSATION AND TRAVEL EXPENSES.—

21 “(1) COMPENSATION OF MEMBERS.—Each
22 member of the Committee who is not an officer or
23 employee of the Federal Government shall be com-
24 pensated at a rate equal to the daily equivalent of
25 the annual rate of basic pay prescribed for level IV

1 of the Executive Schedule under section 5315 of title
2 5, United States Code, for each day (including travel
3 time) during which such member is engaged in the
4 performance of the duties of the Committee. All
5 members of the Committee who are officers or em-
6 ployees of the United States shall serve without com-
7 pensation in addition to that received for their serv-
8 ices as officers or employees of the United States.

9 “(2) TRAVEL EXPENSES.—The members of the
10 Committee shall be allowed travel expenses, includ-
11 ing per diem in lieu of subsistence, at rates author-
12 ized for employees of agencies under subchapter I of
13 chapter 57 of title 5, United States Code, while
14 away from their homes or regular places of business
15 in the performance of services for the Committee.

16 “(g) OPERATION OF THE COMMITTEE.—

17 “(1) MEETINGS.—The Committee shall meet at
18 the call of the Chairman (after consultation with the
19 other members of the Committee) not less often
20 than quarterly to consider a specific agenda of
21 issues, as determined by the Chairman after such
22 consultation.

23 “(2) QUORUM.—Ten members of the Com-
24 mittee shall constitute a quorum for purposes of
25 conducting business.

1 “(h) FEDERAL ADVISORY COMMITTEE ACT.—Section
2 14 of the Federal Advisory Committee Act (5 U.S.C.
3 App.) shall not apply to the Committee.

4 “(i) TRANSFER OF PERSONNEL, RESOURCES, AND
5 ASSETS.—For purposes of carrying out its duties, the Sec-
6 retary and the Committee may provide for the transfer
7 to the Committee of such civil service personnel in the em-
8 ploy of the Department of Health and Human Services,
9 and such resources and assets of the Department used in
10 carrying out this title, as the Committee requires.

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

14 (b) EXCLUSIONS FROM COVERAGE.—

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

20 (2) PRESCRIPTION DRUGS NOT EXCLUDED
21 FROM COVERAGE IF APPROPRIATELY PRESCRIBED.—
22 Section 1862(a)(1) of the Social Security Act (42
23 U.S.C. 1395y(a)(1)) is amended—

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

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

3 (C) by adding at the end the following new
4 subparagraph:

5 “(J) in the case of prescription drugs cov-
6 ered under part D, which are not prescribed in
7 accordance with such part;”.

8 (c) CONFORMING REFERENCES TO PREVIOUS PART
9 D.—

10 (1) IN GENERAL.—Any reference in law (in ef-
11 fect before the date of enactment of this Act) to part
12 D of title XVIII of the Social Security Act is deemed
13 a reference to part E of such title (as in effect after
14 such date).

15 (2) SECRETARIAL SUBMISSION OF LEGISLATIVE
16 PROPOSAL.—Not later than 6 months after the date
17 of enactment of this Act, the Secretary of Health
18 and Human Services shall submit to the appropriate
19 committees of Congress a legislative proposal pro-
20 viding for such technical and conforming amend-
21 ments in the law as are required by the provisions
22 of this Act.

1 **SEC. 4. PART D BENEFITS UNDER MEDICARE+CHOICE**
2 **PLANS.**

3 (a) **ELIGIBILITY, ELECTION, AND ENROLLMENT.**—
4 Section 1851 of the Social Security Act (42 U.S.C.
5 1395w–21) is amended—

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

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

10 (b) **VOLUNTARY BENEFICIARY ENROLLMENT FOR**
11 **DRUG COVERAGE.**—Section 1852(a)(1)(A) of such Act
12 (42 U.S.C. 1395w–22(a)(1)(A)) is amended by inserting
13 “(and under part D to individuals also enrolled under that
14 part)” after “parts A and B”.

15 (c) **ACCESS TO SERVICES.**—Section 1852(d)(1) of
16 such Act (42 U.S.C. 1395w–22(d)(1)) is amended—

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

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

21 (3) by adding at the end the following new sub-
22 paragraph:

23 “(F) in the case of covered outpatient
24 drugs provided to individuals enrolled under
25 part D (as defined in section 1860(1)), the or-

1 organization complies with the access require-
2 ments applicable under part D.”.

3 (d) PAYMENTS TO ORGANIZATIONS.—Section
4 1853(a)(1)(A) of such Act (42 U.S.C. 1395w-
5 23(a)(1)(A)) is amended—

6 (1) by inserting “determined separately for the
7 benefits under parts A and B and under part D (for
8 individuals enrolled under that part)” after “as cal-
9 culated under subsection (c)”;

10 (2) by striking “that area, adjusted for such
11 risk factors” and inserting “that area. In the case
12 of payment for the benefits under parts A and B,
13 such payment shall be adjusted for such risk factors
14 as”; and

15 (3) by inserting before the last sentence the fol-
16 lowing: “In the case of the payments for the benefits
17 under part D, such payment shall initially be ad-
18 justed for the risk factors of each enrollee as the
19 Secretary determines to be feasible and appropriate
20 to ensure actuarial equivalence. By 2006, the adjust-
21 ments to payments for benefits under part D shall
22 be for the same risk factors used to adjust payments
23 for the benefits under parts A and B.”.

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

4 (1) in paragraph (1), in the matter preceding
5 subparagraph (A), by inserting “for benefits under
6 parts A and B” after “capitation rate”; and

7 (2) by adding at the end the following new
8 paragraph:

9 “(8) PAYMENT FOR PART D BENEFITS.—The
10 Secretary shall determine a capitation rate for part
11 D benefits (for individuals enrolled under such part)
12 as follows:

13 “(A) DRUGS DISPENSED BEFORE 2004.—In
14 the case of prescription drugs dispensed on or
15 after the date that is 1 year after the date of
16 enactment of the Medicare Prescription Drug
17 Coverage Act of 2001 and before January 1,
18 2004, the capitation rate shall be based on the
19 projected national per capita costs for prescrip-
20 tion drug benefits under part D and associated
21 claims processing costs for beneficiaries enrolled
22 under part D and not enrolled with a
23 Medicare+Choice organization under this part.

24 “(B) DRUGS DISPENSED IN SUBSEQUENT
25 YEARS.—In the case of prescription drugs dis-

1 pensed in 2004 or a subsequent year, the capi-
2 tation rate shall be equal to the capitation rate
3 for the preceding year increased by the Sec-
4 retary’s estimate of the projected per capita
5 rate of growth in expenditures under this title
6 for an individual enrolled under part D for such
7 subsequent year.”.

8 (f) LIMITATION ON ENROLLEE LIABILITY.—Section
9 1854(e) of such Act (42 U.S.C. 1395w–24(e)) is amended
10 by adding at the end the following new paragraph:

11 “(5) SPECIAL RULE FOR PART D BENEFITS.—
12 With respect to outpatient prescription drug benefits
13 under part D, a Medicare+Choice organization may
14 not require that an enrollee pay a deductible or a co-
15 insurance percentage that exceeds the deductible or
16 coinsurance percentage applicable for such benefits
17 for an eligible beneficiary under part D.”.

18 (g) REQUIREMENT FOR ADDITIONAL BENEFITS.—
19 Section 1854(f)(1) of such Act (42 U.S.C. 1395w–
20 24(f)(1)) is amended by adding at the end the following
21 new sentence: “Such determination shall be made sepa-
22 rately for the benefits under parts A and B and for pre-
23 scription drug benefits under part D.”.

24 (h) EFFECTIVE DATE.—The amendments made by
25 this section shall apply to items and services provided

1 under a Medicare+Choice plan on or after the date that
 2 is 1 year after the date of enactment of this Act.

3 **SEC. 5. EXCLUSION OF PART D COSTS FROM DETERMINA-**
 4 **TION OF PART B MONTHLY PREMIUM.**

5 Section 1839(g) of the Social Security Act (42 U.S.C.
 6 1395r(g)) is amended—

7 (1) by striking “attributable to the application
 8 of section” and inserting “attributable to—
 9 “(1) the application of section”;

10 (2) by striking the period and inserting “;
 11 and”; and

12 (3) by adding at the end the following new
 13 paragraph:

14 “(2) the program under part D providing pay-
 15 ment for covered outpatient drugs (including costs
 16 associated with making payments to employers and
 17 other sponsors of employment-based health care cov-
 18 erage under the Employer Incentive Program under
 19 section 1860I).”.

20 **SEC. 6. ADDITIONAL ASSISTANCE FOR LOW-INCOME BENE-**
 21 **FICIARIES.**

22 (a) INCLUSION IN MEDICARE COST-SHARING.—Sec-
 23 tion 1905(p)(3) of the Social Security Act (42 U.S.C.
 24 1396d(p)(3)) is amended—

25 (1) in subparagraph (A)—

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

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

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

7 “(iii) premiums under section 1860D.”;

8 (2) in subparagraph (B), by striking “section
9 1813” and inserting “sections 1813 and 1860E(b)”;
10 and

11 (3) in subparagraph (C), by striking “section
12 1813 and section 1833(b)” and inserting “sections
13 1813, 1833(b), and 1860E(a)”.

14 (b) EXPANSION OF MEDICAL ASSISTANCE.—Section
15 1902(a)(10)(E) of the Social Security Act (42 U.S.C.
16 1396a(a)(10)(E)) is amended—

17 (1) in clause (iii)—

18 (A) by striking “section 1905(p)(3)(A)(ii)”
19 and inserting “clauses (ii) and (iii) of section
20 1905(p)(3)(A), for the coinsurance described in
21 section 1860E(b), and for the deductible de-
22 scribed in section 1860E(a)”;

23 (B) by striking “and” at the end;

24 (2) by redesignating clause (iv) as clause (vi);
25 and

1 (3) by inserting after clause (iii) the following
2 new clauses:

3 “(iv) for making medical assistance avail-
4 able for Medicare cost-sharing described in sec-
5 tion 1905(p)(3)(A)(iii), for the coinsurance de-
6 scribed in section 1860E(b), and for the de-
7 ductible described in section 1860E(a) for indi-
8 viduals who would be qualified Medicare bene-
9 ficiaries described in section 1905(p)(1) but for
10 the fact that their income exceeds 120 percent
11 but does not exceed 135 percent of such official
12 poverty line for a family of the size involved;

13 “(v) for making medical assistance avail-
14 able for Medicare cost-sharing described in sec-
15 tion 1905(p)(3)(A)(iii) on a linear sliding scale
16 based on the income of such individuals for in-
17 dividuals who would be qualified Medicare bene-
18 ficiaries described in section 1905(p)(1) but for
19 the fact that their income exceeds 135 percent
20 but does not exceed 175 percent of such official
21 poverty line for a family of the size involved;
22 and”.

23 (c) NONAPPLICABILITY OF RESOURCE REQUIRE-
24 MENTS TO MEDICARE PART D COST-SHARING.—Section
25 1905(p)(1) of the Social Security Act (42 U.S.C.

1 1396d(p)(1)) is amended by adding at the end the fol-
2 lowing flush sentence:

3 “In determining if an individual is a qualified medicare
4 beneficiary under this paragraph, subparagraph (C) shall
5 not be applied for purposes of providing the individual
6 with medicare cost-sharing that consists of premiums
7 under section 1860D, coinsurance described in section
8 1860E(b), or deductibles described in section 1860E(a).”.

9 (d) NONAPPLICABILITY OF PAYMENT DIFFERENTIAL
10 REQUIREMENTS TO MEDICARE PART D COST-SHAR-
11 ING.—Section 1902(n)(2) of the Social Security Act (42
12 U.S.C. 1396a(n)(2)) is amended by adding at the end the
13 following new sentence: “The preceding sentence shall not
14 apply to coinsurance described in section 1860E(b) or
15 deductibles described in section 1860E(a).”.

16 (e) 100 PERCENT FEDERAL MEDICAL ASSISTANCE
17 PERCENTAGE.—The first sentence of section 1905(b) of
18 the Social Security Act (42 U.S.C. 1396d(b)) is
19 amended—

20 (1) by striking “and” before “(3)”; and

21 (2) by inserting before the period at the end the
22 following: “, and (4) the Federal medical assistance
23 percentage shall be 100 percent with respect to med-
24 ical assistance provided under clauses (iv) and (v) of
25 section 1902(a)(10)(E)”.

1 (f) TREATMENT OF TERRITORIES.—Section 1108(g)
2 of such Act (42 U.S.C. 1308(g)) is amended by adding
3 at the end the following new paragraph:

4 “(3) Notwithstanding the preceding provisions of this
5 subsection, with respect to the first fiscal quarter that be-
6 gins on or after the date that is 1 year after the date
7 of enactment of the Medicare Prescription Drug Coverage
8 Act of 2001 and any fiscal year thereafter, the amount
9 otherwise determined under this subsection (and sub-
10 section (f)) for the fiscal year for a Commonwealth or ter-
11 ritory shall be increased by the ratio (as estimated by the
12 Secretary) of—

13 “(A) the aggregate amount of payments made
14 to the 50 States and the District of Columbia for
15 the fiscal year under title XIX that are attributable
16 to making medical assistance available for individ-
17 uals described in clauses (i), (iii), (iv), and (v) of
18 section 1902(a)(10)(E) for payment of Medicare
19 cost-sharing that consists of premiums under section
20 1860D, coinsurance described in section 1860E(b),
21 or deductibles described in section 1860E(a); to

22 “(B) the aggregate amount of total payments
23 made to such States and District for the fiscal year
24 under such title.”.

1 (g) CONFORMING AMENDMENTS.—Section 1933 of
2 the Social Security Act (42 U.S.C. 1396u–3) is
3 amended—

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

7 (2) in subsection (c)(2)(A)—

8 (A) in clause (i), by striking “section
9 1902(a)(10)(E)(iv)(I)” and inserting “section
10 1902(a)(10)(E)(vi)(I)”;

11 (B) in clause (ii), by striking “section
12 1902(a)(10)(E)(iv)(II)” and inserting “section
13 1902(a)(10)(E)(vi)(II)”;

14 (3) in subsection (d), by striking “section
15 1902(a)(10)(E)(iv)” and inserting “section
16 1902(a)(10)(E)(vi)”;

17 (4) in subsection (e), by striking “section
18 1902(a)(10)(E)(iv)” and inserting “section
19 1902(a)(10)(E)(vi)”.

20 (h) EFFECTIVE DATE.—The amendments made by
21 this section shall apply for medical assistance provided
22 under section 1902(a)(10)(E) of the Social Security Act
23 (42 U.S.C. 1396a(a)(10)(E)) on and after the date that
24 is 1 year after the date of enactment of this Act.

1 **SEC. 7. MEDIGAP REVISIONS.**

2 Section 1882 of the Social Security Act (42 U.S.C.
3 1395ss) is amended by adding at the end the following
4 new subsection:

5 “(v) MODERNIZED BENEFIT PACKAGES FOR MEDI-
6 CARE SUPPLEMENTAL POLICIES.—

7 “(1) PROMULGATION OF MODEL REGULA-
8 TION.—

9 “(A) NAIC MODEL REGULATION.—If,
10 within 6 months after the date of enactment of
11 the Medicare Prescription Drug Coverage Act
12 of 2001, the National Association of Insurance
13 Commissioners (in this subsection referred to as
14 the ‘NAIC’) changes the 1991 NAIC Model
15 Regulation (described in subsection (p)) to re-
16 vise the benefit packages classified as ‘H’, ‘I’,
17 and ‘J’ under the standards established by sub-
18 section (p)(2) (including the benefit package
19 classified as ‘J’ with a high deductible feature,
20 as described in subsection (p)(11)) so that—

21 “(i) the coverage for outpatient pre-
22 scription drugs available under such ben-
23 efit packages is replaced with coverage for
24 outpatient prescription drugs that com-
25 pliments but does not duplicate the bene-
26 fits for outpatient prescription drugs that

1 beneficiaries are otherwise entitled to
2 under this title;

3 “(ii) the revised benefit packages pro-
4 vide a range of coverage options for out-
5 patient prescription drugs for beneficiaries,
6 but do not provide coverage for—

7 “(I) the deductible under section
8 1860E(a); or

9 “(II) more than 90 percent of
10 the coinsurance applicable to an indi-
11 vidual under section 1860E(b);

12 “(iii) uniform language and defini-
13 tions are used with respect to such revised
14 benefits;

15 “(iv) uniform format is used in the
16 policy with respect to such revised benefits;
17 and

18 “(v) such revised standards meet any
19 additional requirements imposed by the
20 Medicare Prescription Drug Coverage Act
21 of 2001;

22 subsection (g)(2)(A) shall be applied in each
23 State, effective for policies issued to policy hold-
24 ers on and after the date that is 1 year after
25 the date of enactment of the Medicare Prescrip-

1 tion Drug Coverage Act of 2001, as if the ref-
2 erence to the Model Regulation adopted on
3 June 6, 1979, were a reference to the 1991
4 NAIC Model Regulation as changed under this
5 subparagraph (such changed regulation referred
6 to in this section as the ‘2002 NAIC Model
7 Regulation’).

8 “(B) REGULATION BY THE SECRETARY.—

9 If the NAIC does not make the changes in the
10 1991 NAIC Model Regulation within the 6-
11 month period specified in subparagraph (A), the
12 Secretary shall promulgate, not later than 6
13 months after the end of such period, a regula-
14 tion and subsection (g)(2)(A) shall be applied in
15 each State, effective for policies issued to policy
16 holders on and after the date that is 1 year
17 after the date of enactment of the Medicare
18 Prescription Drug Coverage Act of 2001, as if
19 the reference to the Model Regulation adopted
20 on June 6, 1979, were a reference to the 1991
21 NAIC Model Regulation as changed by the Sec-
22 retary under this subparagraph (such changed
23 regulation referred to in this section as the
24 ‘2002 Federal Regulation’).

1 “(C) CONSULTATION WITH WORKING
2 GROUP.—In promulgating standards under this
3 paragraph, the NAIC or Secretary shall consult
4 with a working group similar to the working
5 group described in subsection (p)(1)(D).

6 “(D) MODIFICATION OF STANDARDS IF
7 MEDICARE BENEFITS CHANGE.—If benefits (in-
8 cluding deductibles and coinsurance) under part
9 D of this title are changed and the Secretary
10 determines, in consultation with the NAIC, that
11 changes in the 2002 NAIC Model Regulation or
12 2002 Federal Regulation are needed to reflect
13 such changes, the preceding provisions of this
14 paragraph shall apply to the modification of
15 standards previously established in the same
16 manner as they applied to the original estab-
17 lishment of such standards.

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) APPLICATION OF PROVISIONS AND CON-
4 FORMING REFERENCES.—

5 “(A) APPLICATION OF PROVISIONS.—The
6 provisions of paragraphs (4) through (10) of
7 subsection (p) shall apply under this section,
8 except that—

9 “(i) any reference to the model regu-
10 lation applicable under that subsection
11 shall be deemed to be a reference to the
12 applicable 2002 NAIC Model Regulation or
13 2002 Federal Regulation; and

14 “(ii) any reference to a date under
15 such paragraphs of subsection (p) shall be
16 deemed to be a reference to the appro-
17 priate date under this subsection.

18 “(B) OTHER REFERENCES.—Any reference
19 to a provision of subsection (p) or a date appli-
20 cable under such subsection shall also be con-
21 sidered to be a reference to the appropriate pro-
22 vision or date under this subsection.”.

1 **SEC. 8. COMPREHENSIVE IMMUNOSUPPRESSIVE DRUG**
2 **COVERAGE FOR TRANSPLANT PATIENTS.**

3 (a) **IN GENERAL.**—Section 1861(s)(2)(J) of the So-
4 cial Security Act (42 U.S.C. 1395x(s)(2)(J)), as amended
5 by section 113(a) of the Medicare, Medicaid, and SCHIP
6 Benefits Improvement and Protection Act of 2000 (as en-
7 acted into law by section 1(a)(6) of Public Law 106–554),
8 is amended by striking “, to an individual who receives”
9 and all that follows before the semicolon at the end and
10 inserting “to an individual who has received an organ
11 transplant”.

12 (b) **EFFECTIVE DATE.**—The amendment made by
13 subsection (a) shall apply to drugs furnished on or after
14 the date of enactment of this Act.

15 **SEC. 9. HHS STUDIES AND REPORT TO CONGRESS REGARD-**
16 **ING OUTPATIENT PRESCRIPTION DRUG BEN-**
17 **EFIT PROGRAM.**

18 (a) **STUDIES.**—The Secretary of Health and Human
19 Services shall conduct a study on the following:

20 (1) **WAIVER OR REDUCTION OF LATE ENROLL-**
21 **MENT PENALTY.**—The feasibility and advisability of
22 establishing an annual open enrollment period under
23 the outpatient prescription drug benefit program
24 under part D of title XVIII of the Social Security
25 Act (as added by section 3) in which the late enroll-
26 ment penalty under section 1860B(a)(2)(A) of the

1 Social Security Act (as so added) would be reduced
2 or would not be applied. Such study shall include a
3 projection of the costs if open enrollment was al-
4 lowed with a reduced penalty or without a penalty.

5 (2) UNIFORM FORMAT FOR PHARMACY BENEFIT
6 CARDS.—The feasibility and advisability of estab-
7 lishing a uniform format for pharmacy benefit cards
8 provided to beneficiaries by eligible entities under
9 such outpatient prescription drug benefit program.

10 (3) DEVELOPMENT OF SYSTEMS TO ELEC-
11 TRONICALLY TRANSFER PRESCRIPTIONS.—The feasi-
12 bility and advisability of developing systems to elec-
13 tronically transfer prescriptions under such out-
14 patient prescription drug benefit program from the
15 prescriber to the pharmacist.

16 (b) REPORT.—Not later than 9 months 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.

1 **SEC. 10. GAO STUDY AND BIENNIAL REPORTS ON COMPETI-**
2 **TION AND SAVINGS.**

3 (a) ONGOING STUDY.—The Comptroller General of
4 the United States shall conduct an ongoing study and
5 analysis of the outpatient prescription drug benefit pro-
6 gram under part D of title XVIII of the Social Security
7 Act (as added by section 3), including an analysis of—

8 (1) the extent to which the competitive bidding
9 process under such program fosters maximum com-
10 petition and efficiency; and

11 (2) the savings to the medicare program result-
12 ing from such outpatient prescription drug benefit
13 program, including the reduction in the number or
14 length of hospital visits.

15 (b) INITIAL REPORT ON COMPETITIVE BIDDING
16 PROCESS.—Not later than 9 months after the date of en-
17 actment of this Act, the Comptroller General shall submit
18 to Congress a report on the extent to which the competi-
19 tive bidding process under the outpatient prescription
20 drug benefit program under part D of title XVIII of the
21 Social Security Act (as added by section 3) is expected
22 to foster maximum competition and efficiency.

23 (c) BIENNIAL REPORTS.—Not later than January 1,
24 2004, and biennially thereafter, the Comptroller General
25 of the United States shall submit to Congress a report
26 on the results of the study conducted under subsection (a),

1 together with any recommendations for legislation that the
2 Comptroller General determines to be appropriate as a re-
3 sult of such study.

4 **SEC. 11. MEDPAC STUDY AND ANNUAL REPORTS ON THE**
5 **PHARMACEUTICAL MARKET, PHARMACIES,**
6 **AND BENEFICIARY ACCESS.**

7 (a) ONGOING STUDY.—The Medicare Payment Advi-
8 sory Commission shall conduct an ongoing study and anal-
9 ysis of the outpatient prescription drug benefit program
10 under part D of title XVIII of the Social Security Act (as
11 added by section 3), including an analysis of the impact
12 of such program on—

13 (1) the pharmaceutical market, including costs
14 and pricing of pharmaceuticals, beneficiary access to
15 such pharmaceuticals, and trends in research and
16 development;

17 (2) franchise, independent, and rural phar-
18 macies; and

19 (3) beneficiary access to outpatient prescription
20 drugs, including an assessment of—

21 (A) out-of-pocket spending;

22 (B) generic and brand-name utilization;

23 and

24 (C) pharmacists' services.

1 (b) REPORT.—Not later than January 1, 2004, and
2 annually thereafter, the Medicare Payment Advisory Com-
3 mission shall submit to Congress a report on the results
4 of the study conducted under subsection (a), together with
5 any recommendations for legislation that such Commis-
6 sion determines to be appropriate as a result of such
7 study.

8 **SEC. 12. APPROPRIATIONS.**

9 In addition to amounts otherwise appropriated to the
10 Secretary of Health and Human Services, there are au-
11 thorized to be appropriated to the Secretary for fiscal year
12 2002 and each subsequent fiscal year such sums as may
13 be necessary to administer the outpatient prescription
14 drug benefit program under part D of title XVIII of the
15 Social Security Act (as added by section 3).

○