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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Medicare Prescription Drug Coverage Act of 2001''.

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

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Prescription drug coverage was not a standard part of health insurance when the medicare pro-

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

(2) At least ⅔ of medicare beneficiaries have unreliable, inadequate, or no drug coverage at all.

(3) Seniors who do not have drug coverage typically pay 15 percent more for prescription drugs than individuals that have such coverage pay for such drugs, and often pay 2 times the best available price for such drugs.

(4) Although many medicare beneficiaries who lack prescription drug coverage have low incomes, more than ½ of such beneficiaries have incomes greater than 150 percent of the poverty line.

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

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

(7) The management of a medicare prescription drug benefit should mirror the practices employed by private entities in delivering prescription drugs. Discounts should be achieved through competition.

(8) All medicare beneficiaries should have access to a voluntary, reliable, affordable outpatient drug benefit as part of the medicare program that assists with the high cost of prescription drugs and protects them against excessive out-of-pocket costs.

(9) The addition of a medicare drug benefit should be consistent with an overall plan to strengthen and modernize the medicare program.

SEC. 3. MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT PROGRAM.

(a) ESTABLISHMENT.—Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended by redesignating part D as part E and by inserting after part C the following new part:

''PART D—OUTPATIENT PRESCRIPTION DRUG BENEFIT PROGRAM

''DEFINITIONS

''SEC. 1860. In this part:

''(1) COVERED OUTPATIENT DRUG.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'covered outpatient drug' means any of the following products:

"(i) A drug which may be dispensed only upon prescription, and—

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

"(II)(aa) which was commercially used or sold in the United States before the date of enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (bb) which has not been the subject of a final determination by the Secretary that it is a 'new drug' (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a)

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

''(III)(aa) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (bb) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling.

''(ii) A biological product which—

''(I) may only be dispensed upon prescription;

''(II) is licensed under section 351 of the Public Health Service Act; and

''(III) is produced at an establishment licensed under such section to produce such product.

''(iii) Insulin approved under appropriate Federal law, including needles, syringes, and disposable pumps for the administration of such insulin.

''(iv) A prescribed drug or biological product that would meet the requirements of clause (i) or (ii) but that it is available over-the-counter in addition to being available upon prescription.

''(B) EXCLUSION.—The term 'covered outpatient drug' does not include any product—

''(i) except as provided in subparagraph (A)(iv), which may be distributed to individuals without a prescription;

''(ii) that is covered under part A or B (unless coverage of such product is not

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

"(iii) except for agents used to promote smoking cessation, for which coverage may be excluded or restricted under section 1927(d)(2).

"(2) ELIGIBLE BENEFICIARY.—The term 'eligible beneficiary' means an individual that is entitled to benefits under part A or enrolled under part B.

"(3) ELIGIBLE ENTITY.—The term 'eligible entity' means any entity that the Secretary determines to be appropriate to provide eligible beneficiaries with covered outpatient drugs under a contract entered into under this part, including—

"(A) a pharmacy benefit management company;

"(B) a retail pharmacy delivery system;

"(C) a health plan or insurer;

"(D) a State (through mechanisms established under a State plan under title XIX);

"(E) any other entity approved by the Secretary; or

"(F) any combination of the entities described in subparagraphs (A) through (E) if the Secretary determines that such combination—

''(i) increases the scope or efficiency of the provision of benefits under this part; and

''(ii) is not anticompetitive.

''SUBPART 1—ESTABLISHMENT OF OUTPATIENT PRESCRIPTION DRUG BENEFIT PROGRAM

''ESTABLISHMENT OF OUTPATIENT PRESCRIPTION DRUG BENEFIT PROGRAM

''SEC. 1860A. (a) PROVISION OF BENEFIT.—Beginning on the date that is 1 year after the date of enactment of this Act, the Secretary shall provide for an outpatient prescription drug benefit program under which an eligible beneficiary shall be provided covered outpatient drugs.

''(b) VOLUNTARY NATURE OF PROGRAM.—Nothing in this part shall be construed as requiring an eligible beneficiary to enroll in the program established under this part.

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

''(d) FINANCING.—The costs of providing benefits under this part shall be payable from the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

''ENROLLMENT

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

''(1) ESTABLISHMENT OF PROCESS.—

''(A) IN GENERAL.—The Secretary shall establish a process through which an eligible beneficiary (including an eligible beneficiary enrolled in a Medicare+Choice plan offered by a Medicare+Choice organization) may make an election to enroll under this part. Such process shall be similar to the process for enrollment in part B under section 1837.

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

''(2) ENROLLMENT PROCEDURES.—

''(A) LATE ENROLLMENT PENALTY.—

''(i) IN GENERAL.—Subject to the succeeding provisions of this subparagraph, in the case of an eligible beneficiary whose coverage period under this part began pursuant to an enrollment after the beneficiary's initial enrollment period under part B (determined pursuant to section 1837(d)) and not pursuant to the open enrollment period described in subparagraph (B), the Secretary shall establish proce-

dures for increasing the amount of the monthly premium under section 1860D applicable to such beneficiary—

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

"(II) if determined appropriate by the Secretary, by an amount that the Secretary determines is actuarily sound for each such period.

"(ii) PERIODS TAKEN INTO ACCOUNT.—For purposes of calculating any 12-month period under clause (i), there shall be taken into account—

"(I) the months which elapsed between the close of the eligible beneficiary's initial enrollment period and the close of the enrollment period in which the beneficiary enrolled; and

"(II) in the case of an eligible beneficiary who reenrolls under this

part, the months which elapsed between the date of termination of a previous coverage period and the close of the enrollment period in which the beneficiary reenrolled.

''(iii) PERIODS NOT TAKEN INTO ACCOUNT.—

''(I) IN GENERAL.—For purposes of calculating any 12-month period under clause (i), subject to subclause (II), there shall not be taken into account months for which the eligible beneficiary can demonstrate that the beneficiary was covered under a group health plan, including a qualified retiree prescription drug plan (as defined in section 1860I(e)(3)) for which an incentive payment was paid under section 1860I, that provides coverage of the cost of prescription drugs whose actuarial value (as defined by the Secretary) to the beneficiary equals or exceeds the actuarial value of the benefits provided to an individual enrolled in the outpatient pre-

scription drug benefit program under this part.

''(II) APPLICATION.—This clause shall only apply with respect to a coverage period the enrollment for which occurs before the end of the 60-day period that begins on the first day of the month which includes the date on which the plan terminates, ceases to provide, or reduces the value of the prescription drug coverage under such plan to below the value of the coverage provided under the program under this part.

''(iv) PERIODS TREATED SEPARATELY.—Any increase in an eligible beneficiary's monthly premium under clause (i) with respect to a particular continuous period of eligibility shall not be applicable with respect to any other continuous period of eligibility which the beneficiary may have.

''(v) CONTINUOUS PERIOD OF ELIGIBILITY.—

"(I) IN GENERAL.—Subject to subclause (II), for purposes of this subparagraph, an eligible beneficiary's 'continuous period of eligibility' is the period that begins with the first day on which the beneficiary is eligible to enroll under section 1836 and ends with the beneficiary's death.

"(II) SEPARATE PERIOD.—Any period during all of which an eligible beneficiary satisfied paragraph (1) of section 1836 and which terminated in or before the month preceding the month in which the beneficiary attained age 65 shall be a separate 'continuous period of eligibility' with respect to the beneficiary (and each such period which terminates shall be deemed not to have existed for purposes of subsequently applying this subparagraph).

"(B) OPEN ENROLLMENT PERIOD FOR CURRENT BENEFICIARIES IN WHICH LATE ENROLLMENT PROCEDURES DO NOT APPLY.—The Secretary shall establish an applicable period,

which shall begin on the date on which the Secretary first begins to accept elections for enrollment under this part, during which any eligible beneficiary may enroll under this part without the application of the late enrollment procedures established under subparagraph (A)(i).

''(3) PERIOD OF COVERAGE.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), an eligible beneficiary's coverage under the program under this part shall be effective for the period provided in section 1838, as if that section applied to the program under this part.

''(B) OPEN ENROLLMENT.—An eligible beneficiary who enrolls under the program under this part pursuant to paragraph (2)(B) shall be entitled to the benefits under this part beginning on the first day of the month following the month in which such enrollment occurs.

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

''(4) PART D COVERAGE TERMINATED BY TERMINATION OF COVERAGE UNDER PARTS A AND B.—

''(A) IN GENERAL.—In addition to the causes of termination specified in section 1838, the Secretary shall terminate an individual's coverage under this part if the individual is no longer enrolled in either part A or part B.

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

''(b) ENROLLMENT WITH ELIGIBLE ENTITY.—

''(1) PROCESS.—

''(A) IN GENERAL.—The Secretary shall establish a process through which an eligible beneficiary who is enrolled under this part but not enrolled in a Medicare+Choice plan offered by a Medicare+Choice organization shall make an annual election to enroll with any eligible entity that has been awarded a contract under this part and serves the geographic area in which the beneficiary resides.

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

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

''(2) MEDICARE+CHOICE ENROLLEES.—An eligible beneficiary who is enrolled under this part and enrolled in a Medicare+Choice plan offered by a Medicare+Choice organization shall receive coverage of covered outpatient drugs under this part through such plan.

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

''PROVIDING INFORMATION TO BENEFICIARIES

''SEC. 1860C. (a) ACTIVITIES.—

''(1) IN GENERAL.—The Secretary shall conduct activities that are designed to broadly disseminate information to eligible beneficiaries (and prospective eligible beneficiaries) regarding the coverage provided under this part.

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

formation at least 30 days prior to the first enrollment period described in section 1860B(c).

''(b) REQUIREMENTS.—

''(1) IN GENERAL.—The activities described in subsection (a) shall—

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

''(B) be coordinated with the activities performed by the Secretary under such section and under section 1804; and

''(C) provide for the dissemination of information comparing the eligible entities that are available to eligible beneficiaries residing in an area under this part.

''(2) COMPARATIVE INFORMATION.—The comparative information described in paragraph (1)(B) shall include the following:

''(A) BENEFITS.—A comparison of the benefits provided by each eligible entity, including a comparison of the pharmacy networks used by each eligible entity and the formularies and appeals processes implemented by each entity.

"(B) QUALITY AND PERFORMANCE.—To the extent available, the quality and performance of each eligible entity.

"(C) BENEFICIARY COSTS.—The cost-sharing required of eligible beneficiaries enrolled in each eligible entity.

"(D) CONSUMER SATISFACTION SURVEYS.—To the extent available, the results of consumer satisfaction surveys regarding each eligible entity.

"(E) ADDITIONAL INFORMATION.—Such additional information as the Secretary may prescribe.

"(3) INFORMATION STANDARDS.—The Secretary shall develop standards to ensure that the information provided to eligible beneficiaries under this part is complete, accurate, and uniform.

"(c) USE OF MEDICARE CONSUMER COALITIONS TO PROVIDE INFORMATION.—

"(1) IN GENERAL.—The Secretary may contract with Medicare Consumer Coalitions to conduct the informational activities—

"(A) under this section;

"(B) under section 1851(d); and

"(C) under section 1804.

''(2) SELECTION OF COALITIONS.—If the Secretary determines the use of Medicare Consumer Coalitions to be appropriate, the Secretary shall—

''(A) develop and disseminate, in such areas as the Secretary determines appropriate, a request for proposals for Medicare Consumer Coalitions to contract with the Secretary in order to conduct any of the informational activities described in paragraph (1); and

''(B) select a proposal of a Medicare Consumer Coalition to conduct the informational activities in each such area, with a preference for broad participation by organizations with experience in providing information to beneficiaries under this title.

''(3) PAYMENT TO MEDICARE CONSUMER COALITIONS.—The Secretary shall make payments to Medicare Consumer Coalitions contracting under this subsection in such amounts and in such manner as the Secretary determines appropriate.

''(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary such sums as may be necessary to contract with Medicare Consumer Coalitions under this section.

''(5) MEDICARE CONSUMER COALITION DEFINED.—In this subsection, the term 'Medicare Consumer Coalition' means an entity that is a nonprofit organization operated under the direction of a board of directors that is primarily composed of beneficiaries under this title.

''PREMIUMS

''SEC. 1860D. (a) ANNUAL ESTABLISHMENT OF MONTHLY PREMIUM RATES.—

''(1) PREMIUM.—The Secretary shall, during September of each year (beginning with the first September after the day that is 1 year after the date of enactment of the Medicare Prescription Drug Coverage Act of 2001), determine and promulgate a monthly premium rate for the succeeding year in accordance with the provisions of this subsection.

''(2) ACTUARIAL DETERMINATIONS.—

''(A) DETERMINATION OF ANNUAL BENEFIT AND ADMINISTRATIVE COSTS.—The Secretary shall estimate annually for the succeeding year the amount equal to the total of the benefits and administrative costs that will be payable from the Federal Supplementary Medical Insurance Trust Fund for providing covered outpatient drugs in such calendar year

with respect to enrollees in the program under this part.

''(B) DETERMINATION OF MONTHLY PREMIUM RATES.—

''(i) IN GENERAL.—The Secretary shall determine the monthly premium rate with respect to such enrollees for such succeeding year, which shall be 1/12 of the applicable percent of the amount determined under subparagraph (A), divided by the total number of such enrollees, and rounded (if such rate is not a multiple of 10 cents) to the nearest multiple of 10 cents.

''(ii) DEFINITION OF APPLICABLE PERCENT.—For purposes of clause (i), the term 'applicable percent' means—

''(I) 45 percent, in the case of premiums paid by an eligible beneficiary enrolled in the program under this part; and

''(II) 66.66 percent, in the case of premiums paid for such a beneficiary by an employer (as defined in section 1860I(e)(2)) that the beneficiary formerly worked for.

''(3) PUBLICATION OF ASSUMPTIONS.—The Secretary shall publish, together with the promulgation of the monthly premium rates for the succeeding year, a statement setting forth the actuarial assumptions and bases employed in arriving at the amounts and rates determined under paragraphs (1) and (2).

''(b) COLLECTION OF PREMIUM.—The monthly premium applicable to an eligible beneficiary under this part shall be collected and credited to the Federal Supplementary Medical Insurance Trust Fund in the same manner as the monthly premium determined under section 1839 is collected and credited to such Trust Fund under section 1840.

''COST-SHARING

''SEC. 1860E. (a) DEDUCTIBLE.—

''(1) IN GENERAL.—Subject to paragraph (2), no payments shall be made under this part on behalf of an eligible beneficiary until the beneficiary has met a $250 deductible.

''(2) WAIVER OF DEDUCTIBLE FOR GENERIC DRUGS.—

''(A) IN GENERAL.—An eligible entity may provide that generic drugs are not subject to the deductible described in paragraph (1) if the

Secretary determines that the waiver of the deductible—

"(i) is tied to the performance measures and other incentives applicable to the entity pursuant to section 1860H(a); and

"(ii) will not result in an increase in the expenditures made from the Federal Supplementary Medical Insurance Trust Fund.

"(B) CREDIT FOR AMOUNTS PAID.—If the deductible is waived pursuant to subparagraph (A), any coinsurance paid by an eligible beneficiary for the generic drug shall be credited toward the annual deductible.

"(b) COINSURANCE.—

"(1) ESTABLISHMENT.—

"(A) IN GENERAL.—Subject to paragraph (2), if any covered outpatient drug is provided to an eligible beneficiary in a year after the beneficiary has met any deductible requirement under subsection (a) for the year, the beneficiary shall be responsible for making payments for the drug in an amount equal to the applicable percentage of the cost of the drug.

"(B) APPLICABLE PERCENTAGE DEFINED.—For purposes of subparagraph (A), the 'applicable percentage' means, with respect to any covered outpatient drug provided to an eligible beneficiary in a year—

"(i) 50 percent to the extent the out-of-pocket expenses of the beneficiary for such drug, when added to the out-of-pocket expenses of the beneficiary for covered outpatient drugs previously provided in the year, do not exceed $3,500;

"(ii) 25 percent to the extent such expenses, when so added, exceed $3,500 but do not exceed $4,000; and

"(iii) 0 percent to the extent such expenses, when so added, would exceed $4,000.

"(C) OUT-OF-POCKET EXPENSES DEFINED.—For purposes of subparagraph (B), the term 'out-of-pocket expenses' means expenses incurred as a result of the application of the deductible under subsection (a) and the coinsurance required under this subsection.

"(2) REDUCTION BY ELIGIBLE ENTITY.—An eligible entity may reduce the applicable percentage

that an eligible beneficiary is subject to under paragraph (1) if the Secretary determines that such reduction—

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

''(B) will not result in an increase in the expenditures made from the Federal Supplementary Medical Insurance Trust Fund.

''(c) INFLATION ADJUSTMENT.—

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

''(A) such dollar amount, multiplied by

''(B) the percentage (if any) by which the amount of average per capita expenditures under this part in the preceding calendar year exceeds the amount of such expenditures in 2003.

''(2) ROUNDING.—If any dollar amount after being increased under paragraph (1) is not a multiple of $5, such dollar amount shall be rounded to the nearest multiple of $5.

''SELECTION OF ENTITIES TO PROVIDE OUTPATIENT DRUG BENEFIT

''SEC. 1860F. (a) ESTABLISHMENT OF BIDDING PROCESS.—

''(1) IN GENERAL.—The Secretary shall establish procedures under which the Secretary accepts bids submitted by eligible entities and awards contracts to such entities in order to administer and deliver the benefits provided under this part to eligible beneficiaries in an area.

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

''(b) AREA FOR CONTRACTS.—

''(1) REGIONAL BASIS.—

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

''(B) PARTIAL REGIONAL BASIS.—

''(i) IN GENERAL.—If determined appropriate by the Secretary, the Secretary may permit the coverage described in subparagraph (A) to be provided on a partial regional basis.

''(ii) REQUIREMENTS.—If the Secretary permits coverage pursuant to clause (i), the Secretary shall ensure that the partial region in which coverage is provided is—

''(I) at least the size of the commercial service area of the eligible entity for that area; and

''(II) not smaller than a State.

''(2) DETERMINATION.—

''(A) IN GENERAL.—In determining coverage areas under this part, the Secretary shall—

''(i) take into account the number of eligible beneficiaries in an area in order to encourage participation by eligible entities; and

''(ii) ensure that there are at least 10 different coverage areas in the United States.

"(B) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—The determination of coverage areas under this part shall not be subject to administrative or judicial review.

"(c) SUBMISSION OF BIDS.—

"(1) IN GENERAL.—Each eligible entity desiring to provide covered outpatient drugs under this part shall submit a bid to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

"(2) REQUIRED INFORMATION.—The bids described in paragraph (1) shall include—

"(A) a proposal for the estimated prices of covered outpatient drugs and the projected annual increases in such prices, including differentials between formulary and nonformulary prices, if applicable;

"(B) the amount that the entity will charge the Secretary for administering and delivering the benefits under such contract;

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

"(D) a statement regarding whether the entity will reduce the applicable coinsurance

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

''(E) a detailed description of—

''(i) the risk corridors tied to performance measures and other incentives that the entity will accept under the contract; and

''(ii) how the entity will meet such measures and incentives;

''(F) a detailed description of proposed contracts with local pharmacy providers designed to ensure access, including compensation for local pharmacists' services;

''(G) a detailed description of any ownership or shared financial interests with other entities involved in the delivery of the benefit as proposed;

''(H) a detailed description of the entity's estimated marketing and advertising expenditures related to enrolling and retaining eligible beneficiaries; and

''(I) such other information that the Secretary determines is necessary in order to carry out this part, including information relating to the bidding process under this part.

''(d) ACCESS.—

''(1) IN GENERAL.—The Secretary shall ensure that an eligible entity—

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

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

''(2) AREAS NOT COVERED BY CONTRACTS.—The Secretary shall develop procedures for the provision of covered outpatient drugs under this part to each eligible beneficiary that resides in an area that is not covered by any contract under this part.

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

''(4) SPECIAL ATTENTION TO RURAL AND HARD-TO-SERVE AREAS.—

''(A) IN GENERAL.—The Secretary shall ensure that all eligible beneficiaries have access to the full range of benefits under this part, and shall give special attention to access, pharmacist counseling, and delivery in rural and

hard-to-serve areas (as the Secretary may define by regulation).

''(B) SPECIAL ATTENTION DEFINED.—For purposes of subparagraph (A), the term 'special attention' may include bonus payments to retail pharmacists in rural areas, extra payments to eligible entities for the cost of rapid delivery of pharmaceuticals, and any other actions the Secretary determines are necessary to ensure full access to benefits under this part by eligible beneficiaries residing in rural and hard-to-serve areas.

''(C) GAO REPORT.—Not later than 2 years after the date of enactment of the Medicare Prescription Drug Coverage Act of 2001, the Comptroller General of the United States shall submit to Congress a report on the access to benefits under this part by eligible beneficiaries residing in rural and hard-to-serve areas, together with any recommendations of the Comptroller General regarding any additional steps the Secretary may need to take to ensure the access of medicare beneficiaries to such benefits.

''(e) AWARDING OF CONTRACTS.—

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

''(2) DETERMINATION.—In determining which of the eligible entities that submitted bids that meet the minimum standards specified under this part and by the Secretary (including the terms and conditions described in section 1860G) to award a contract, the Secretary shall consider the comparative merits of each bid, as determined on the basis of the past performance of the entity and other relevant factors, with respect to—

''(A) how well the entity meets such minimum standards;

''(B) the amount that the entity will charge the Secretary for administering and delivering the benefits under the contract;

''(C) the proposed prices of covered outpatient drugs and annual increases in such prices;

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

"(E) the factors described in section 1860C(b)(2);

"(F) prior experience in administering a prescription drug benefit program;

"(G) effectiveness in containing costs through pricing incentives and utilization management; and

"(H) such other factors as the Secretary deems necessary to evaluate the merits of each bid.

"(3) EXCEPTION TO CONFLICT OF INTEREST RULES.—In awarding contracts under this part, the Secretary may waive conflict of interest laws generally applicable to Federal acquisitions (subject to such safeguards as the Secretary may find necessary to impose) in circumstances where the Secretary finds that such waiver—

"(A) is not inconsistent with the—

"(i) purposes of the programs under this title; or

"(ii) best interests of enrolled individuals; and

''(B) permits a sufficient level of competition for such contracts, promotes efficiency of benefits administration, or otherwise serves the objectives of the program under this part.

''(4) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—The determination of the Secretary to award or not award a contract to an eligible entity under this part shall not be subject to administrative or judicial review.

''(f) APPROVAL OF MARKETING MATERIAL AND APPLICATION FORMS.—The provisions of section 1851(h) shall apply to marketing material and application forms under this part in the same manner as such provisions apply to marketing material and application forms under part C.

''(g) DURATION OF CONTRACTS.—Each contract under this part shall be for a term of at least 2 years but not more than 5 years, as determined by the Secretary.

''CONDITIONS FOR AWARDING CONTRACT

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

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

''(2) PROCEDURES TO ENSURE PROPER UTILIZATION, COMPLIANCE, AND AVOIDANCE OF ADVERSE DRUG REACTIONS.—The eligible entity has in place drug utilization review procedures to ensure—

''(A) the appropriate utilization by eligible beneficiaries of the benefits to be provided under the contract; and

''(B) the avoidance of adverse drug reactions among eligible beneficiaries enrolled with the entity, including problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse and misuse.

''(3) COST-EFFECTIVE PROVISION OF BENEFITS.—

''(A) IN GENERAL.—In providing the benefits under a contract under this part, an eligible entity may—

"(i) employ mechanisms to provide the benefits economically, including the use of—

"(I) formularies (pursuant to subparagraph (B));

"(II) alternative methods of distribution; and

"(III) generic drug substitution;

"(ii) use mechanisms to encourage eligible beneficiaries to select cost-effective drugs or less costly means of receiving drugs, including the use of pharmacy incentive programs, therapeutic interchange programs, and disease management programs; and

"(iii) encourage pharmacy providers to—

"(I) inform beneficiaries of the differentials in price between generic and nongeneric drug equivalents; and

"(II) provide medication therapy management programs in order to enhance beneficiaries' understanding of the appropriate use of medications and to reduce the risk of potential ad-

verse events associated with medications.

''(B) FORMULARIES.—If an eligible entity uses a formulary under this part, such formulary shall comply with standards established by the Secretary in consultation with the Medicare Pharmacy and Therapeutics Advisory Committee established under section 1860M. Such standards shall require that the eligible entity—

''(i) use a pharmacy and therapeutic committee (that meets the standards for a pharmacy and therapeutic committee established by the Secretary in consultation with the Medicare Pharmacy and Therapeutics Advisory Committee established under section 1860M) to develop and implement the formulary;

''(ii) include in the formulary—

''(I) at least 1 drug from each therapeutic class (as defined by the entity's pharmacy and therapeutic committee in accordance with standards established by the Secretary in consultation with the Medicare Phar-

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

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

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

''(iii) develop procedures for the—

''(I) addition of new therapeutic classes to the formulary;

''(II) addition of new drugs to an existing therapeutic class; and

''(III) modification of the formulary;

''(iv) provide for coverage of otherwise covered non-formulary drugs when recommended by a prescribing provider; and

''(v) disclose to current and prospective beneficiaries and to providers in the service area the nature of the formulary restrictions, including information regarding the drugs included in the formulary,

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

''(C) CONSTRUCTION.—Nothing in this paragraph shall be construed as precluding an eligible entity from—

''(i) requiring cost-sharing for nonformulary drugs that is higher than the cost-sharing established in section 1860E(b), except that such entity shall provide for coverage of a nonformulary drug at the same cost-sharing level as a drug within the formulary if such nonformulary drug is recommended by a prescribing provider;

''(ii) educating prescribing providers, pharmacists, and beneficiaries about the medical and cost benefits of formulary drugs (including generic drugs); or

''(iii) requiring prescribing providers to consider a formulary drug prior to dispensing of a nonformulary drug, as long as such requirement does not unduly delay the provision of the drug.

''(4) PATIENT PROTECTIONS.—

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

and convenient to eligible beneficiaries covered under the contract, including by doing the following:

''(i) SERVICES DURING EMERGENCIES.—Offering services 24 hours a day and 7 days a week for emergencies.

''(ii) AGREEMENTS WITH PHARMACIES.—Entering into participation agreements under subsection (b) with pharmacies, that include terms that—

''(I) secure the participation of sufficient numbers of pharmacies to ensure convenient access (including adequate emergency access); and

''(II) permit the participation of any pharmacy in the service area that meets the participation requirements described in subsection (b).

''(B) CONTINUITY OF CARE.—

''(i) IN GENERAL.—The eligible entity ensures that, in the case of an eligible beneficiary who loses coverage under this part with such entity under circumstances that would permit a special election period (as established by the Secretary under section

1860B(b)), the entity will continue to provide coverage under this part to such beneficiary until the beneficiary enrolls and receives such coverage with another eligible entity under this part.

''(ii) LIMITED PERIOD.—In no event shall an eligible entity be required to provide the extended coverage required under clause (i) beyond the date which is 30 days after the coverage with such entity would have terminated but for this subparagraph.

''(C) PROCEDURES REGARDING DENIALS OF CARE.—The eligible entity has in place procedures to ensure—

''(i) a timely internal and external review and resolution of denials of coverage (in whole or in part) and complaints (including those regarding the use of formularies under paragraph (3)) by eligible beneficiaries, or by providers, pharmacists, and other individuals acting on behalf of each such beneficiary (with the beneficiary's consent) in accordance with requirements (as established by the Secretary) that are comparable to such re-

quirements for Medicare+Choice organizations under part C; and

"(ii) that beneficiaries are provided with information regarding the appeals procedures under this part at the time of enrollment.

"(D) PROCEDURES REGARDING PATIENT CONFIDENTIALITY.—Insofar as an eligible entity maintains individually identifiable medical records or other health information regarding eligible beneficiaries under a contract entered into under this part, the entity has in place procedures to—

"(i) safeguard the privacy of any individually identifiable beneficiary information;

"(ii) maintain such records and information in a manner that is accurate and timely;

"(iii) ensure timely access by such beneficiaries to such records and information; and

"(iv) otherwise comply with applicable laws relating to patient confidentiality.

''(E) PROCEDURES REGARDING TRANSFER OF MEDICAL RECORDS.—

''(i) IN GENERAL.—The eligible entity has in place procedures for the timely transfer of records and information described in subparagraph (D) (with respect to a beneficiary who loses coverage under this part with the entity and enrolls with another entity under this part) to such other entity.

''(ii) PATIENT CONFIDENTIALITY.—The procedures described in clause (i) shall comply with the patient confidentiality procedures described in subparagraph (D).

''(F) PROCEDURES REGARDING MEDICAL ERRORS.—The eligible entity has in place procedures for working with the Secretary to deter medical errors related to the provision of covered outpatient drugs.

''(5) PROCEDURES TO CONTROL FRAUD, ABUSE, AND WASTE.—The eligible entity has in place procedures to control fraud, abuse, and waste.

''(6) REPORTING REQUIREMENTS.—

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

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

''(ii) The prices that eligible beneficiaries enrolled with the entity will be charged for covered outpatient drugs.

''(iii) The administrative costs of providing such benefits.

''(iv) Utilization of such benefits.

''(v) Marketing and advertising expenditures related to enrolling and retaining eligible beneficiaries.

''(B) TIMEFRAME FOR SUBMITTING REPORTS.—

''(i) IN GENERAL.—The eligible entity shall submit a report described in subparagraph (A) to the Secretary within 3 months after the end of each 12-month period in which the eligible entity has a contract under this part. Such report shall contain information concerning the benefits provided during such 12-month period.

"(ii) LAST YEAR OF CONTRACT.—In the case of the last year of a contract under this section, the Secretary may require that a report described in subparagraph (A) be submitted 3 months prior to the end of the contract. Such report shall contain information concerning the benefits provided between the period covered by the most recent report under this subparagraph and the date that a report is submitted under this clause.

"(C) CONFIDENTIALITY OF INFORMATION.—

"(i) IN GENERAL.—Notwithstanding any other provision of law and subject to clause (ii), information disclosed by an eligible entity pursuant to subparagraph (A) is confidential and shall only be used by the Secretary for the purposes of, and to the extent necessary, to carry out this part.

"(ii) UTILIZATION DATA.—Subject to patient confidentiality laws, the Secretary shall make information disclosed by an eligible entity pursuant to subparagraph

(A)(iv) (regarding utilization data) available for research purposes. The Secretary may charge a reasonable fee for making such information available.

''(7) APPROVAL OF MARKETING MATERIAL AND APPLICATION FORMS.—The eligible entity will comply with the requirements described in section 1860F(f).

''(8) RECORDS AND AUDITS.—The eligible entity maintains adequate records related to the administration of the benefit under this part and affords the Secretary access to such records for auditing purposes.

''(b) PHARMACY PARTICIPATION AGREEMENTS.—

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

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

''(A) LICENSING.—The pharmacy and pharmacists shall meet (and throughout the

contract period will continue to meet) all applicable State and local licensing requirements.

''(B) LIMITATION ON CHARGES.—Pharmacies participating under this part shall not charge an eligible beneficiary enrolled with the eligible entity more than—

''(i) the negotiated price for an individual drug (as reported to the Secretary pursuant to subsection (a)(6)(A)); or

''(ii) the amount of the beneficiary's obligation (as determined in accordance with the provisions of this part) of the negotiated price of such drug.

''(C) PERFORMANCE STANDARDS.—The pharmacy shall comply with performance standards relating to—

''(i) measures for quality assurance, reduction of medical errors, and compliance with the drug utilization review procedures described in subsection (a)(2);

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

''(iii) other requirements as the Secretary may impose to ensure integrity, effi-

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

''PAYMENTS

''SEC. 1860H. (a) PAYMENTS TO ELIGIBLE ENTITIES.—

''(1) PROCEDURES.—

''(A) IN GENERAL.—The Secretary shall establish procedures for making payments to an eligible entity under a contract entered into under this part for the administration and delivery of the benefits under this part.

''(B) ENTITIES ONLY SUBJECT TO LIMITED RISK.—Under the procedures established under subparagraph (A), an eligible entity shall only be at risk to the extent that the entity is at risk under paragraph (2).

''(2) RISK CORRIDORS TIED TO PERFORMANCE MEASURES AND OTHER INCENTIVES.—

''(A) IN GENERAL.—The procedures established under paragraph (1) may include the use of—

''(i) risk corridors tied to performance measures that have been agreed to between the eligible entity and the Secretary under the contract; and

"(ii) any other incentives that the Secretary determines appropriate.

"(B) PHASE-IN OF RISK CORRIDORS TIED TO PERFORMANCE MEASURES.—The Secretary may phase-in the use of risk corridors tied to performance measures if the Secretary determines such phase-in to be appropriate.

"(C) PAYMENTS SUBJECT TO INCENTIVES.—If a contract under this part includes the use of risk corridors tied to performance measures or other incentives pursuant to subparagraph (A), payments to eligible entities under such contract shall be subject to such risk corridors tied to performance measures and other incentives.

"(3) RISK ADJUSTMENT.—To the extent that eligible entities are at risk because of the risk corridors or other incentives described in paragraph (2)(A), the procedures established under paragraph (1) may include a methodology for adjusting the payments made to such entities based on the differences in actuarial risk of different enrollees being served if the Secretary determines such adjustments to be necessary and appropriate.

''(b) SECONDARY PAYER PROVISIONS.—The provisions of section 1862(b) shall apply to the benefits provided under this part.

''EMPLOYER INCENTIVE PROGRAM FOR EMPLOYMENT-BASED RETIREE DRUG COVERAGE

''SEC. 1860I. (a) PROGRAM AUTHORITY.—The Secretary is authorized to develop and implement a program under this section called the 'Employer Incentive Program' that encourages employers and other sponsors of employment-based health care coverage to provide adequate prescription drug benefits to retired individuals by subsidizing, in part, the sponsor's cost of providing coverage under qualifying plans.

''(b) SPONSOR REQUIREMENTS.—In order to be eligible to receive an incentive payment under this section with respect to coverage of an individual under a qualified retiree prescription drug plan (as defined in subsection (f)(3)), a sponsor shall meet the following requirements:

''(1) ASSURANCES.—The sponsor shall—

''(A) annually attest, and provide such assurances as the Secretary may require, that the coverage offered by the sponsor is a qualified retiree prescription drug plan, and will remain such a plan for the duration of the sponsor's participation in the program under this section; and

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

''(i) at least 120 days before terminating its plan; and

''(ii) immediately upon determining that the actuarial value of the prescription drug benefit under the plan falls below the actuarial value of the outpatient prescription drug benefit under this part.

''(2) BENEFICIARY INFORMATION.—The sponsor shall report to the Secretary, for each calendar quarter for which it seeks an incentive payment under this section, the names and social security numbers of all retirees (and their spouses and dependents) covered under such plan during such quarter and the dates (if less than the full quarter) during which each such individual was covered.

''(3) AUDITS.—The sponsor and the employment-based retiree health coverage plan seeking incentive payments under this section shall agree to maintain, and to afford the Secretary access to, such records as the Secretary may require for purposes of audits and other oversight activities necessary to ensure the adequacy of prescription drug coverage, the

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

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

''(c) INCENTIVE PAYMENTS.—

''(1) IN GENERAL.—A sponsor that meets the requirements of subsection (b) with respect to a quarter in a calendar year shall be entitled to have payment made by the Secretary on a quarterly basis (to the sponsor or, at the sponsor's direction, to the appropriate employment-based health plan) of an incentive payment, in the amount determined in paragraph (2), for each retired individual (or spouse) who—

''(A) was covered under the sponsor's qualified retiree prescription drug plan during such quarter; and

''(B) was eligible for, but was not enrolled in, the outpatient prescription drug benefit program under this part.

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

scribed in paragraph (1) for a month shall be equal to ⅔ of the monthly premium amount payable by an eligible beneficiary enrolled under this part, as set for the calendar year pursuant to section 1860D(a)(2).

''(3) PAYMENT DATE.—The incentive under this section with respect to a calendar quarter shall be payable as of the end of the next succeeding calendar quarter.

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

''(e) DEFINITIONS.—In this section:

''(1) EMPLOYMENT-BASED RETIREE HEALTH COVERAGE.—The term 'employment-based retiree health coverage' means health insurance or other coverage of health care costs for retired individuals (or for such individuals and their spouses and de-

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

''(2) EMPLOYER.—The term 'employer' has the meaning given the term in section 3(5) of the Employee Retirement Income Security Act of 1974 (except that such term shall include only employers of 2 or more employees).

''(3) QUALIFIED RETIREE PRESCRIPTION DRUG PLAN.—The term 'qualified retiree prescription drug plan' means health insurance coverage included in employment-based retiree health coverage that—

''(A) provides coverage of the cost of prescription drugs whose actuarial value (as defined by the Secretary) to each retired beneficiary equals or exceeds the actuarial value of the benefits provided to an individual enrolled in the outpatient prescription drug benefit program under this part; and

''(B) does not deny, limit, or condition the coverage or provision of prescription drug benefits for retired individuals based on age or any health status-related factor described in section 2702(a)(1) of the Public Health Service Act.

''(4) SPONSOR.—The term 'sponsor' has the meaning given the term 'plan sponsor' in section

3(16)(B) of the Employer Retirement Income Security Act of 1974.

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

''PROCEDURES FOR PARTIAL YEAR IMPLEMENTATION

''SEC. 1860J. If the Secretary first implements the program under this part on a day other that January 1 of a year, the Secretary shall establish procedures for implementing the program during the period between the date of implementation and December 31 of such year, including procedures—

''(1) for prorating premiums, deductibles, and coinsurance under the program during such period; and

''(2) relating to requirements and payments under the Medicare+Choice program during such period.

''APPROPRIATIONS

''SEC. 1860K. There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, to the Federal Supplementary Medical Insurance Trust Fund established under section 1841, an amount equal to the amount by which

the benefits and administrative costs of providing the benefits under this part exceed the premiums collected under section 1860D.

''SUBPART 2—MEDICARE PHARMACY AND THERAPEUTICS (P&T) ADVISORY COMMITTEE

''MEDICARE PHARMACY AND THERAPEUTICS (P&T) ADVISORY COMMITTEE

''SEC. 1860M. (a) ESTABLISHMENT OF COMMITTEE.—There is established a Medicare Pharmacy and Therapeutics Advisory Committee (in this section referred to as the 'Committee').

''(b) FUNCTIONS OF COMMITTEE.—On and after January 1, 2002, the Committee shall advise the Secretary on policies related to—

''(1) the development of guidelines for the implementation and administration of the outpatient prescription drug benefit program under this part; and

''(2) the development of—

''(A) standards for a pharmacy and therapeutics committee required of eligible entities under section 1860G(a)(3)(B)(i);

''(B) standards for—

''(i) defining therapeutic classes;

''(ii) adding new therapeutic classes to a formulary;

''(iii) adding new drugs to a therapeutic class within a formulary; and

''(iv) when and how often a formulary should be modified;

''(C) procedures to evaluate the bids submitted by eligible entities under this part; and

''(D) procedures to ensure that eligible entities with a contract under this part are in compliance with the requirements under this part.

''(c) STRUCTURE AND MEMBERSHIP OF THE COMMITTEE.—

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

''(2) MEMBERSHIP.—

''(A) IN GENERAL.—The members of the Committee shall be chosen on the basis of their integrity, impartiality, and good judgment, and shall be individuals who are, by reason of their education, experience, and attainments, exceptionally qualified to perform the duties of members of the Committee.

''(B) SPECIFIC MEMBERS.—Of the members appointed under paragraph (1)—

''(i) eleven shall be chosen to represent physicians;

''(ii) four shall be chosen to represent pharmacists;

''(iii) one shall be chosen to represent the Health Care Financing Administration;

''(iv) two shall be chosen to represent actuaries and pharmacoeconomists; and

''(v) one shall be chosen to represent emerging drug technologies.

''(d) TERMS OF APPOINTMENT.—Each member of the Committee shall serve for a term determined appropriate by the Secretary. The terms of service of the members initially appointed shall begin on January 1, 2002.

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

''(f) COMPENSATION AND TRAVEL EXPENSES.—

''(1) COMPENSATION OF MEMBERS.—Each member of the Committee who is not an officer or employee of the Federal Government shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV

of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which such member is engaged in the performance of the duties of the Committee. All members of the Committee who are officers or employees of the United States shall serve without compensation in addition to that received for their services as officers or employees of the United States.

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

''(g) OPERATION OF THE COMMITTEE.—

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

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

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

''(i) TRANSFER OF PERSONNEL, RESOURCES, AND ASSETS.—For purposes of carrying out its duties, the Secretary and the Committee may provide for the transfer to the Committee of such civil service personnel in the employ of the Department of Health and Human Services, and such resources and assets of the Department used in carrying out this title, as the Committee requires.

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

(b) EXCLUSIONS FROM COVERAGE.—

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

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

(A) in subparagraph (H), by striking ''and'' at the end;

(B) in subparagraph (I), by striking the semicolon at the end and inserting ", and"; and

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

"(J) in the case of prescription drugs covered under part D, which are not prescribed in accordance with such part;".

(c) CONFORMING REFERENCES TO PREVIOUS PART D.—

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

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

SEC. 4. PART D BENEFITS UNDER MEDICARE+CHOICE PLANS.

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

(1) in subsection (a)(1)(A), by striking ''parts A and B'' and inserting ''parts A, B, and D''; and

(2) in subsection (i)(1), by striking ''parts A and B'' and inserting ''parts A, B, and D''.

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

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

(1) in subparagraph (D), by striking ''and'' at the end;

(2) in subparagraph (E), by striking the period at the end and inserting ''; and''; and

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

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

ganization complies with the access requirements applicable under part D.''.

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

(1) by inserting ''determined separately for the benefits under parts A and B and under part D (for individuals enrolled under that part)'' after ''as calculated under subsection (c)'';

(2) by striking ''that area, adjusted for such risk factors'' and inserting ''that area. In the case of payment for the benefits under parts A and B, such payment shall be adjusted for such risk factors as''; and

(3) by inserting before the last sentence the following: ''In the case of the payments for the benefits under part D, such payment shall initially be adjusted for the risk factors of each enrollee as the Secretary determines to be feasible and appropriate to ensure actuarial equivalence. By 2006, the adjustments to payments for benefits under part D shall be for the same risk factors used to adjust payments for the benefits under parts A and B.''.

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

(1) in paragraph (1), in the matter preceding subparagraph (A), by inserting ''for benefits under parts A and B'' after ''capitation rate''; and

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

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

''(A) DRUGS DISPENSED BEFORE 2004.—In the case of prescription drugs dispensed on or after the date that is 1 year after the date of enactment of the Medicare Prescription Drug Coverage Act of 2001 and before January 1, 2004, the capitation rate shall be based on the projected national per capita costs for prescription drug benefits under part D and associated claims processing costs for beneficiaries enrolled under part D and not enrolled with a Medicare+Choice organization under this part.

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

pensed in 2004 or a subsequent year, the capitation rate shall be equal to the capitation rate for the preceding year increased by the Secretary's estimate of the projected per capita rate of growth in expenditures under this title for an individual enrolled under part D for such subsequent year.''.

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

''(5) SPECIAL RULE FOR PART D BENEFITS.—With respect to outpatient prescription drug benefits under part D, a Medicare+Choice organization may not require that an enrollee pay a deductible or a coinsurance percentage that exceeds the deductible or coinsurance percentage applicable for such benefits for an eligible beneficiary under part D.''.

(g) REQUIREMENT FOR ADDITIONAL BENEFITS.—Section 1854(f)(1) of such Act (42 U.S.C. 1395w–24(f)(1)) is amended by adding at the end the following new sentence: ''Such determination shall be made separately for the benefits under parts A and B and for prescription drug benefits under part D.''.

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

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

SEC. 5. EXCLUSION OF PART D COSTS FROM DETERMINATION OF PART B MONTHLY PREMIUM.

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

(1) by striking ''attributable to the application of section'' and inserting ''attributable to—

''(1) the application of section'';

(2) by striking the period and inserting ''; and''; and

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

''(2) the program under part D providing payment for covered outpatient drugs (including costs associated with making payments to employers and other sponsors of employment-based health care coverage under the Employer Incentive Program under section 1860I).''.

SEC. 6. ADDITIONAL ASSISTANCE FOR LOW-INCOME BENEFICIARIES.

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

(1) in subparagraph (A)—

(A) in clause (i), by striking ''and'' at the end;

(B) in clause (ii), by inserting ''and'' at the end; and

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

''(iii) premiums under section 1860D.'';

(2) in subparagraph (B), by striking ''section 1813'' and inserting ''sections 1813 and 1860E(b)''; and

(3) in subparagraph (C), by striking ''section 1813 and section 1833(b)'' and inserting ''sections 1813, 1833(b), and 1860E(a)''.

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

(1) in clause (iii)—

(A) by striking ''section 1905(p)(3)(A)(ii)'' and inserting ''clauses (ii) and (iii) of section 1905(p)(3)(A), for the coinsurance described in section 1860E(b), and for the deductible described in section 1860E(a)''; and

(B) by striking ''and'' at the end;

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

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

''(iv) for making medical assistance available for Medicare cost-sharing described in section 1905(p)(3)(A)(iii), for the coinsurance described in section 1860E(b), and for the deductible described in section 1860E(a) for individuals who would be qualified Medicare beneficiaries described in section 1905(p)(1) but for the fact that their income exceeds 120 percent but does not exceed 135 percent of such official poverty line for a family of the size involved;

''(v) for making medical assistance available for Medicare cost-sharing described in section 1905(p)(3)(A)(iii) on a linear sliding scale based on the income of such individuals for individuals who would be qualified Medicare beneficiaries described in section 1905(p)(1) but for the fact that their income exceeds 135 percent but does not exceed 175 percent of such official poverty line for a family of the size involved; and''.

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

1396d(p)(1)) is amended by adding at the end the following flush sentence:

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

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

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

(1) by striking ''and'' before ''(3)''; and

(2) by inserting before the period at the end the following: '', and (4) the Federal medical assistance percentage shall be 100 percent with respect to medical assistance provided under clauses (iv) and (v) of section 1902(a)(10)(E)''.

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

''(3) Notwithstanding the preceding provisions of this subsection, with respect to the first fiscal quarter that begins on or after the date that is 1 year after the date of enactment of the Medicare Prescription Drug Coverage Act of 2001 and any fiscal year thereafter, the amount otherwise determined under this subsection (and subsection (f)) for the fiscal year for a Commonwealth or territory shall be increased by the ratio (as estimated by the Secretary) of—

''(A) the aggregate amount of payments made to the 50 States and the District of Columbia for the fiscal year under title XIX that are attributable to making medical assistance available for individuals described in clauses (i), (iii), (iv), and (v) of section 1902(a)(10)(E) for payment of Medicare cost-sharing that consists of premiums under section 1860D, coinsurance described in section 1860E(b), or deductibles described in section 1860E(a); to

''(B) the aggregate amount of total payments made to such States and District for the fiscal year under such title.''.

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

(1) in subsection (a), by striking ''section 1902(a)(10)(E)(iv)'' and inserting ''section 1902(a)(10)(E)(vi)'';

(2) in subsection (c)(2)(A)—

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

(B) in clause (ii), by striking ''section 1902(a)(10)(E)(iv)(II)'' and inserting ''section 1902(a)(10)(E)(vi)(II)'';

(3) in subsection (d), by striking ''section 1902(a)(10)(E)(iv)'' and inserting ''section 1902(a)(10)(E)(vi)''; and

(4) in subsection (e), by striking ''section 1902(a)(10)(E)(iv)'' and inserting ''section 1902(a)(10)(E)(vi)''.

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

SEC. 7. MEDIGAP REVISIONS.

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

''(v) MODERNIZED BENEFIT PACKAGES FOR MEDICARE SUPPLEMENTAL POLICIES.—

''(1) PROMULGATION OF MODEL REGULATION.—

''(A) NAIC MODEL REGULATION.—If, within 6 months after the date of enactment of the Medicare Prescription Drug Coverage Act of 2001, the National Association of Insurance Commissioners (in this subsection referred to as the 'NAIC') changes the 1991 NAIC Model Regulation (described in subsection (p)) to revise the benefit packages classified as 'H', 'I', and 'J' under the standards established by subsection (p)(2) (including the benefit package classified as 'J' with a high deductible feature, as described in subsection (p)(11)) so that—

''(i) the coverage for outpatient prescription drugs available under such benefit packages is replaced with coverage for outpatient prescription drugs that compliments but does not duplicate the benefits for outpatient prescription drugs that

beneficiaries are otherwise entitled to under this title;

"(ii) the revised benefit packages provide a range of coverage options for outpatient prescription drugs for beneficiaries, but do not provide coverage for—

"(I) the deductible under section 1860E(a); or

"(II) more than 90 percent of the coinsurance applicable to an individual under section 1860E(b);

"(iii) uniform language and definitions are used with respect to such revised benefits;

"(iv) uniform format is used in the policy with respect to such revised benefits; and

"(v) such revised standards meet any additional requirements imposed by the Medicare Prescription Drug Coverage Act of 2001;

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

tion Drug Coverage Act of 2001, as if the reference to the Model Regulation adopted on June 6, 1979, were a reference to the 1991 NAIC Model Regulation as changed under this subparagraph (such changed regulation referred to in this section as the '2002 NAIC Model Regulation').

''(B) REGULATION BY THE SECRETARY.—If the NAIC does not make the changes in the 1991 NAIC Model Regulation within the 6-month period specified in subparagraph (A), the Secretary shall promulgate, not later than 6 months after the end of such period, a regulation and subsection (g)(2)(A) shall be applied in each State, effective for policies issued to policy holders on and after the date that is 1 year after the date of enactment of the Medicare Prescription Drug Coverage Act of 2001, as if the reference to the Model Regulation adopted on June 6, 1979, were a reference to the 1991 NAIC Model Regulation as changed by the Secretary under this subparagraph (such changed regulation referred to in this section as the '2002 Federal Regulation').

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

''(D) MODIFICATION OF STANDARDS IF MEDICARE BENEFITS CHANGE.—If benefits (including deductibles and coinsurance) under part D of this title are changed and the Secretary determines, in consultation with the NAIC, that changes in the 2002 NAIC Model Regulation or 2002 Federal Regulation are needed to reflect such changes, the preceding provisions of this paragraph shall apply to the modification of standards previously established in the same manner as they applied to the original establishment of such standards.

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

benefits for which payment may be made under part D.

''(3) APPLICATION OF PROVISIONS AND CONFORMING REFERENCES.—

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

''(i) any reference to the model regulation applicable under that subsection shall be deemed to be a reference to the applicable 2002 NAIC Model Regulation or 2002 Federal Regulation; and

''(ii) any reference to a date under such paragraphs of subsection (p) shall be deemed to be a reference to the appropriate date under this subsection.

''(B) OTHER REFERENCES.—Any reference to a provision of subsection (p) or a date applicable under such subsection shall also be considered to be a reference to the appropriate provision or date under this subsection.''.

SEC. 8. COMPREHENSIVE IMMUNOSUPPRESSIVE DRUG COVERAGE FOR TRANSPLANT PATIENTS.

(a) IN GENERAL.—Section 1861(s)(2)(J) of the Social Security Act (42 U.S.C. 1395x(s)(2)(J)), as amended by section 113(a) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (as enacted into law by section 1(a)(6) of Public Law 106–554), is amended by striking '', to an individual who receives'' and all that follows before the semicolon at the end and inserting ''to an individual who has received an organ transplant''.

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

SEC. 9. HHS STUDIES AND REPORT TO CONGRESS REGARDING OUTPATIENT PRESCRIPTION DRUG BENEFIT PROGRAM.

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

(1) WAIVER OR REDUCTION OF LATE ENROLLMENT PENALTY.—The feasibility and advisability of establishing an annual open enrollment period under the outpatient prescription drug benefit program under part D of title XVIII of the Social Security Act (as added by section 3) in which the late enrollment penalty under section 1860B(a)(2)(A) of the

Social Security Act (as so added) would be reduced or would not be applied. Such study shall include a projection of the costs if open enrollment was allowed with a reduced penalty or without a penalty.

(2) UNIFORM FORMAT FOR PHARMACY BENEFIT CARDS.—The feasibility and advisability of establishing a uniform format for pharmacy benefit cards provided to beneficiaries by eligible entities under such outpatient prescription drug benefit program.

(3) DEVELOPMENT OF SYSTEMS TO ELECTRONICALLY TRANSFER PRESCRIPTIONS.—The feasibility and advisability of developing systems to electronically transfer prescriptions under such outpatient prescription drug benefit program from the prescriber to the pharmacist.

(b) REPORT.—Not later than 9 months after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report on the results of the studies conducted under subsection (a), together with any recommendations for legislation that the Secretary determines to be appropriate as a result of such studies.

SEC. 10. GAO STUDY AND BIENNIAL REPORTS ON COMPETITION AND SAVINGS.

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

(1) the extent to which the competitive bidding process under such program fosters maximum competition and efficiency; and

(2) the savings to the medicare program resulting from such outpatient prescription drug benefit program, including the reduction in the number or length of hospital visits.

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

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

together with any recommendations for legislation that the Comptroller General determines to be appropriate as a result of such study.

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

(a) ONGOING STUDY.—The Medicare Payment Advisory Commission shall conduct an ongoing study and analysis of the outpatient prescription drug benefit program under part D of title XVIII of the Social Security Act (as added by section 3), including an analysis of the impact of such program on—

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

(2) franchise, independent, and rural pharmacies; and

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

(A) out-of-pocket spending;

(B) generic and brand-name utilization; and

(C) pharmacists' services.

(b) REPORT.—Not later than January 1, 2004, and annually thereafter, the Medicare Payment Advisory Commission shall submit to Congress a report on the results of the study conducted under subsection (a), together with any recommendations for legislation that such Commission determines to be appropriate as a result of such study.

SEC. 12. APPROPRIATIONS.

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

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