108TH CONGRESS
1ST SESSION

S. 7

To amend title XVIII of the Social Security Act to provide coverage of outpatient prescription drugs under the medicare program and to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JANUARY 7, 2003

Mr. DASCHLE (for himself, Mr. ROCKEFELLER, Ms. STABENOW, Mr. SCHUMER, Mr. KENNEDY, Mrs. CLINTON, Mr. AKAKA, Mr. CORZINE, Mr. DURBIN, Ms. MIKULSKI, Mr. LEAHY, Mr. LEVIN, Mr. JOHNSON, Mr. REED, Mr. SARBANES, Mr. DAYTON, Mr. LAUTENBERG, and Mr. REID) 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 and to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals, and for other purposes.

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 title may be cited as the ''Prescription Drug Benefit and Cost Containment Act of 2003''.

(b) TABLE OF CONTENTS.—The table of contents of this title 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 program 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 who have such coverage.

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

(5) 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.

(6) 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.

(7) Generic pharmaceuticals are approved by the Food and Drug Administration on the basis of scientific testing and other information establishing that pharmaceuticals are therapeutically equivalent to brand-name pharmaceuticals, ensuring consumers a safe, efficacious, and cost-effective alternative to brand-name innovator pharmaceuticals.

(8) The Congressional Budget Office estimates that—

(A) the use of generic pharmaceuticals for brand-name pharmaceuticals could save purchasers of pharmaceuticals between $8,000,000,000 and $10,000,000,000 each year; and

(B) generic pharmaceuticals cost between 25 percent and 60 percent less than brand-name pharmaceuticals, resulting in an estimated average savings of $15 to $30 on each prescription.

(9) Expanding access to generic pharmaceuticals can help consumers, especially senior citizens and the uninsured, have access to more affordable prescription drugs.

TITLE I—MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT PROGRAM

SEC. 101. 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 re-

lated (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 and syringes for the administration of such insulin.

''(iv) A prescribed drug or biological product that would meet the requirements of clause (i) or (ii) except 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) for which payment is available under part A or B or would be available under part B but for the application of a deductible under such part (unless payment for such product is not available because benefits under part A or B have been exhausted), determined, except as provided in subparagraph (C), without regard to whether the beneficiary involved is entitled to benefits under part A or enrolled under part B; or

''(iii) except for agents used to promote smoking cessation and agents used for the treatment of obesity, 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 plan 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 or under a State pharmaceutical assistance program);

''(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.

''(4) MEDICARE+CHOICE ORGANIZATION; MEDICARE+CHOICE PLAN.—The terms 'Medicare+Choice organization' and 'Medicare+Choice plan' have the meanings given such terms in subsections (a)(1) and (b)(1), respectively, of section 1859 (relating to definitions relating to Medicare+Choice organizations).

''(5) PRESCRIPTION DRUG ACCOUNT.—The term 'Prescription Drug Account' means the Prescription Drug Account (as established under section 1860K) in the Federal Supplementary Medical Insurance Trust Fund under section 1841.

''ESTABLISHMENT OF OUTPATIENT PRESCRIPTION DRUG BENEFIT PROGRAM

''SEC. 1860A. (a) PROVISION OF BENEFIT.—

''(1) IN GENERAL.—As soon as the Prescription Drug Benefit and Cost Containment Act of 2003 can be implemented after the date of enactment of that Act, the Secretary shall provide for and admin-

ister an outpatient prescription drug benefit program under which each eligible beneficiary enrolled under this part shall be provided with coverage of covered outpatient drugs as follows:

"(A) MEDICARE+CHOICE PLAN.—If the eligible beneficiary is eligible to enroll in a Medicare+Choice plan, the beneficiary—

"(i) may enroll in such a plan; and

"(ii) if so enrolled, shall obtain coverage of covered outpatient drugs through such plan.

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

"(2) 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.

"(3) SCOPE OF BENEFITS.—The program established under this part shall provide for coverage

of all therapeutic classes of covered outpatient drugs.

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

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

''(2) pursuant to section 1860B(b)(1)(C), is permitted to subsequently enroll under this part without any penalty and obtain coverage of covered outpatient drugs in the manner described in subsection (a) if the beneficiary involuntarily loses such coverage.

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

''ENROLLMENT UNDER PROGRAM

''SEC. 1860B. (a) ESTABLISHMENT OF PROCESS.—

''(1) PROCESS SIMILAR TO ENROLLMENT UNDER PART B.—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, including the deeming provisions of such section.

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

''(b) SPECIAL ENROLLMENT PROCEDURES.—

''(1) LATE ENROLLMENT PENALTY.—

''(A) INCREASE IN PREMIUM.—Subject to the succeeding provisions of this paragraph, 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 paragraph (2), the Secretary shall establish procedures for increasing the amount of the monthly part D premium under section 1860E(a) applicable to such beneficiary by an amount that the Secretary determines is actuarially sound 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.

''(B) PERIODS TAKEN INTO ACCOUNT.—For purposes of calculating any 12-month period under subparagraph (A), 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.

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

''(i) IN GENERAL.—For purposes of calculating any 12-month period under subparagraph (A), subject to clause (ii), there shall not be taken into account months for which the eligible beneficiary can demonstrate that the beneficiary had

creditable prescription drug coverage (as defined in subparagraph (F)).

''(ii) APPLICATION.—This subparagraph 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—

''(I) in the case of a beneficiary with coverage described in clause (ii) of subparagraph (F), 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 actuarial value of the coverage provided under the program under this part; or

''(II) in the case of a beneficiary with coverage described in clause (i), (iii), or (iv) of subparagraph (F), the date on which the beneficiary loses eligibility for such coverage.

''(D) PERIODS TREATED SEPARATELY.—Any increase in an eligible beneficiary's monthly part D premium under subparagraph (A) 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.

''(E) CONTINUOUS PERIOD OF ELIGIBILITY.—

''(i) IN GENERAL.—Subject to clause (ii), for purposes of this paragraph, 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 paragraph).

"(F) CREDITABLE PRESCRIPTION DRUG COVERAGE DEFINED.—For purposes of this part, the term 'creditable prescription drug coverage' means any of the following:

"(i) MEDICAID PRESCRIPTION DRUG COVERAGE.—Prescription drug coverage under a medicaid plan under title XIX, including through the Program of All-inclusive Care for the Elderly (PACE) under section 1934 and through a social health maintenance organization (referred to in section 4104(c) of the Balanced Budget Act of 1997), but only if the coverage provides coverage of the cost of prescription drugs the actuarial value of which (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 prescription drug benefit program under this part.

"(ii) PRESCRIPTION DRUG COVERAGE UNDER A GROUP HEALTH PLAN.—Prescription drug coverage under a group health plan, including a health benefits plan under the Federal Employees Health

Benefit Program under chapter 89 of title 5, United States Code, and a qualified retiree prescription drug plan (as defined in section 1860J(e)(3)), but only if the coverage provides coverage of the cost of prescription drugs the actuarial value of which (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 prescription drug benefit program under this part.

''(iii) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—Coverage of prescription drugs under a State pharmaceutical assistance program, but only if the coverage provides coverage of the cost of prescription drugs the actuarial value of which (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 prescription drug benefit program under this part.

''(iv) VETERANS' COVERAGE OF PRESCRIPTION DRUGS.—Coverage of prescription drugs for veterans, and survivors and

dependents of veterans, under chapter 17 of title 38, United States Code, but only if the coverage provides coverage of the cost of prescription drugs the actuarial value of which (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 prescription drug benefit program under this part.

''(2) OPEN ENROLLMENT PERIOD FOR CURRENT BENEFICIARIES IN WHICH LATE ENROLLMENT PROCEDURES DO NOT APPLY.—

''(A) IN GENERAL.—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 paragraph (1)(A).

''(B) OPEN ENROLLMENT.—An eligible beneficiary who enrolls under the program under this part pursuant to subparagraph (A) shall be entitled to the benefits under this part beginning on the first day of the month fol-

lowing the month in which such enrollment occurs.

''(3) SPECIAL ENROLLMENT PERIOD FOR BENEFICIARIES WHO INVOLUNTARILY LOSE CREDITABLE PRESCRIPTION DRUG COVERAGE.—The Secretary shall establish a special open enrollment period for an eligible beneficiary that loses creditable prescription drug coverage.

''(c) PERIOD OF COVERAGE.—

''(1) IN GENERAL.—Except as provided in paragraph (2) and subject to paragraph (3), 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.

''(2) OPEN AND SPECIAL ENROLLMENT.—Subject to paragraph (3), an eligible beneficiary who enrolls under the program under this part pursuant to paragraph (2) or (3) of subsection (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.

''(3) LIMITATION.—Coverage under this part shall not begin prior to the date the Secretary determines, in accordance with section 1860A(a)(1), that

the Prescription Drug Benefit and Cost Containment Act of 2003 shall be implemented.

''(d) TERMINATION.—

''(1) IN GENERAL.—The causes of termination specified in section 1838 shall apply to this part in a similar manner as such causes apply to part B.

''(2) COVERAGE TERMINATED BY TERMINATION OF COVERAGE UNDER PARTS A AND B.—

''(A) IN GENERAL.—In addition to the causes of termination specified in paragraph (1), the Secretary shall terminate an individual's coverage under this part if the individual is no longer enrolled in either part A or 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.

''(3) PROCEDURES REGARDING TERMINATION OF A BENEFICIARY UNDER A PLAN.—The Secretary shall establish procedures for determining the status of an eligible beneficiary's enrollment under this part if the beneficiary's enrollment in a plan offered by an eligible entity under this part is terminated by the entity for cause (pursuant to procedures established by the Secretary under section 1860C(a)(1)).

''ENROLLMENT IN A PLAN

''SEC. 1860C. (a) PROCESS.—

''(1) ESTABLISHMENT.—

''(A) ELECTION.—

''(i) 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—

''(I) shall make an annual election to enroll in any plan offered by an eligible entity that has been awarded a contract under this part and serves the geographic area in which the beneficiary resides; and

''(II) may make an annual election to change the election under this clause.

''(ii) DEFAULT ENROLLMENT.—Such process shall include for the default enrollment in such a plan in the case of an eligible beneficiary who is enrolled under this part but who has failed to make an election of such a plan.

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

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

''(I) the establishment of special election periods under subsection (e)(4) of such section; and

''(II) the application of the guaranteed issue and renewal provisions of subsection (g) of such section (other than paragraph (3)(C)(i), relating to default enrollment); and

''(ii) coordinate enrollments, disenrollments, and terminations of enrollment under part C with enrollments, disenrollments, and terminations of enrollment under this part.

''(2) FIRST ENROLLMENT PERIOD FOR PLAN ENROLLMENT.—The process developed under paragraph (1) shall—

''(A) ensure—

''(i) that an individual who meets or will meet the definition of an eligible bene-

ficiary under section 1860(2) upon the date of implementation of the Prescription Drug Benefit and Cost Containment Act of 2003, as determined by the Secretary in accordance with section 1860A(a)(1), is permitted to enroll with an eligible entity prior to such date; and

''(ii) that coverage under this part for such an individual is effective as of such date; and

''(B) be coordinated with the open enrollment period under section 1860B(b)(2).

''(b) MEDICARE+CHOICE ENROLLEES.—

''(1) IN GENERAL.—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.

''(2) RULES.—Enrollment in a Medicare+Choice plan is subject to the rules for enrollment in such a plan under section 1851.

''PROVIDING INFORMATION TO BENEFICIARIES

''SEC. 1860D. (a) ACTIVITIES.—

''(1) IN GENERAL.—The Secretary shall conduct activities that are designed to broadly dissemi-

nate 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 individuals who meet or will meet the definition of an eligible beneficiary under section 1860(2) upon the date of implementation of the Prescription Drug Benefit and Cost Containment Act of 2003, as determined by the Secretary in accordance with section 1860A(a)(1), and other prospective eligible beneficiaries, are provided with such information at least 30 days prior to the open enrollment period described in section 1860B(b)(2).

''(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 plans offered by eligible

entities under this part that are available to eligible beneficiaries residing in an area.

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

''(A) BENEFITS.—The benefits provided under the plan, including the prices beneficiaries will be charged for covered outpatient drugs, any preferred pharmacy networks used by the eligible entity under the plan, and the formularies and appeals processes under the plan.

''(B) QUALITY AND PERFORMANCE.—To the extent available, the quality and performance of the eligible entity offering the plan.

''(C) BENEFICIARY COST-SHARING.—The cost-sharing required of eligible beneficiaries under the plan.

''(D) CONSUMER SATISFACTION SURVEYS.—To the extent available, the results of consumer satisfaction surveys regarding the plan and the eligible entity offering such plan.

''(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 under—

''(A) this section;

''(B) section 1851(d); and

''(C) 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, out of any moneys in the Treasury not otherwise 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. 1860E. (a) ANNUAL ESTABLISHMENT OF MONTHLY PART D PREMIUM RATES.—

''(1) ESTABLISHMENT OF RATE.—The Secretary shall determine and promulgate, during September of each year (beginning with the first September after the date that is 1 year after the imple-

mentation date of the Prescription Drug Benefit and Cost Containment Act of 2003, as determined by the Secretary in accordance with section 1860A(a)(1)) a monthly part D premium rate for the succeeding year.

''(2) AMOUNT.—The Secretary shall determine the monthly part D premium rate as follows:

''(A) PREMIUM FOR INITIAL PERIOD OF IMPLEMENTATION.—The monthly part D premium rate for any months occurring during the period that begins on the implementation date of the Prescription Drug Benefit and Cost Containment Act of 2003, as determined by the Secretary in accordance with section 1860A(a)(1) and ends on the first December 31 that occurs after the September described in paragraph (1), shall be $25.

''(B) INFLATION ADJUSTMENT OF PREMIUM FOR SUBSEQUENT YEARS.—

''(i) IN GENERAL.—Subject to clause (ii), in the case of any calendar year beginning after the period described in subparagraph (A), the monthly part D premium rate for the year shall be the amount de-

scribed in subparagraph (A) increased by an amount equal to—

"(I) such dollar amount, multiplied by

"(II) the percentage (if any) by which the amount of the average annual per capita aggregate expenditures payable from the Prescription Drug Account for the year (as estimated under section 1860J(c)(2)(C)) exceeds the amount of such expenditures in the period described in subparagraph (A).

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

"(b) COLLECTION OF PART D PREMIUM.—The monthly part D premium applicable to an eligible beneficiary under this part (after application of any increase under section 1860B(b)(1)) shall be collected and credited to the Prescription Drug Account in the same manner as the monthly premium determined under section 1839 is collected and credited to the Federal Supplementary Medical Insurance Trust Fund under section 1840.

''OUTPATIENT PRESCRIPTION DRUG BENEFITS

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

''(1) coverage of covered outpatient drugs—

''(A) without the application of any deductible; and

''(B) with the cost-sharing described in subsection (b); and

''(2) access to negotiated prices for such drugs under subsection (c).

''(b) COST-SHARING.—

''(1) ESTABLISHMENT.—

''(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, an eligible beneficiary shall be responsible for making a payment for a covered outpatient drug furnished to the beneficiary in a year in an amount equal to the applicable percentage of the cost of the drug.

''(B) APPLICABLE PERCENTAGE DEFINED.—For purposes of subparagraph (A), the term '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 costs of the beneficiary for such drug, when added to the out-of-pocket costs of the beneficiary for covered outpatient drugs previously provided in the year, do not exceed $3,700; and

"(ii) 0 percent to the extent such expenses, when so added, would exceed $3,700.

"(C) APPLICATION OF OUT-OF-POCKET COSTS.—For purposes of subparagraph (B)—

"(i) out-of-pocket costs shall only include costs incurred for the cost-sharing described in this subsection; but

"(ii) such costs shall be treated as incurred without regard to whether the individual or another person, including a State program or other third-party coverage, has paid for such costs.

"(2) REDUCTION OR SUBSTITUTION BY ELIGIBLE ENTITY.—An eligible entity may reduce the applicable cost-sharing amount that an eligible beneficiary is subject to under paragraph (1) or substitute a copayment amount if the Secretary determines that such reduction or substitution—

"(A) is tied to the performance requirements described in section 1860I(b)(1)(C); and

"(B) will not result in an increase in the expenditures made from the Prescription Drug Account.

"(3) TREATMENT OF MEDICALLY NECESSARY NONFORMULARY DRUGS.—The eligible entity shall treat a covered outpatient drug that is not included on the formulary established by the eligible entity (pursuant to section 1860H(c)) for the plan as a drug so included if the nonformulary drug is determined (pursuant to subparagraph (D) or (E) of section 1860H(a)(4)) to be medically necessary.

"(4) BENEFICIARY RESPONSIBLE FOR NEGOTIATED PRICE OF NONFORMULARY DRUGS.—In the case of a covered outpatient drug that is dispensed to an eligible beneficiary and that is not included on the formulary established by the eligible entity (pursuant to section 1860H(c)) for the plan (and not treated as a drug on the formulary under paragraph (3)), the beneficiary shall be responsible for the negotiated price for the drug (as reported to the Secretary pursuant to section 1860H(a)(6)(A)).

"(5) COST-SHARING MAY NOT EXCEED NEGOTIATED PRICE.—If the amount of cost-sharing for a

covered outpatient drug that would otherwise be required under this subsection (but for this paragraph) is greater than the negotiated price for the drug (as reported to the Secretary pursuant to section 1860H(a)(6)(A)), then the amount of such cost-sharing shall be reduced to an amount equal to such negotiated price.

''(6) INFLATION ADJUSTMENT FOR ANNUAL OUT-OF-POCKET LIMIT FOR SUBSEQUENT YEARS.—

''(A) IN GENERAL.—For any year after the period described in section 1860E(a)(2)(A), the dollar amounts specified in clauses (i) and (ii) of paragraph (1)(B) are equal to the dollar amounts determined under such clauses (or this paragraph) for the previous year increased by the annual percentage increase specified in subparagraph (B).

''(B) ANNUAL PERCENTAGE INCREASE SPECIFIED IN SUBPARAGRAPH (B).—The annual percentage increase specified in this subparagraph for a year is equal to the annual percentage increase in average per capita aggregate expenditures for covered outpatient drugs in the United States for medicare beneficiaries, as de-

termined by the Secretary for the 12-month period ending in July of the previous year.

''(C) ROUNDING.—If any amount determined under subparagraph (A) is not a multiple of $1, such amount shall be rounded to the nearest multiple of $1.

''(c) ACCESS TO NEGOTIATED PRICES.—

''(1) ACCESS.—Under a plan offered by an eligible entity with a contract under this part, the eligible entity offering such plan shall provide eligible beneficiaries enrolled in such plan with access to negotiated prices (including applicable discounts) used for payment for covered outpatient drugs, regardless of the fact that only partial benefits may be payable under the coverage with respect to such drugs because of the application of the cost-sharing under subsection (b).

''(2) MEDICAID RELATED PROVISIONS.—Insofar as a State elects to provide medical assistance under title XIX for a drug based on the prices negotiated under a plan under this part, the requirements of section 1927 shall not apply to such drugs. The prices negotiated under a plan under this part with respect to covered outpatient drugs, under a Medicare+Choice plan with respect to such drugs,

or under a qualified retiree prescription drug plan (as defined in section 1860J(e)(3)) with respect to such drugs, on behalf of eligible beneficiaries, shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).

''ENTITIES ELIGIBLE TO PROVIDE OUTPATIENT DRUG BENEFIT

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

''(1) IN GENERAL.—The Secretary shall establish procedures under which the Secretary—

''(A) accepts bids submitted by eligible entities for the plans which such entities intend to offer in an area established under subsection (b); and

''(B) awards contracts to such entities to provide such plans to eligible beneficiaries in the 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 with respect to a plan shall require the eligible entity to provide coverage of covered outpatient drugs under the plan in a region established by the Secretary under paragraph (2).

''(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 in a partial region determined appropriate by the Secretary.

''(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) ESTABLISHMENT OF REGIONS.—

''(A) IN GENERAL.—In establishing regions for contracts 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 regions in the United States.

''(B) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—The establishment of regions and partial regions under this section shall not be subject to administrative or judicial review.

''(c) SUBMISSION OF BIDS.—

''(1) SUBMISSION.—

''(A) IN GENERAL.—Subject to subparagraph (B), each eligible entity desiring to offer a plan under this part in an area shall submit a bid with respect to such plan to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

''(B) BID THAT COVERS MULTIPLE AREAS.—The Secretary shall permit an eligible

entity to submit a single bid for multiple areas if the bid is applicable to all such areas.

''(2) REQUIRED INFORMATION.—A bid 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) a statement regarding the amount that the entity will charge the Secretary for managing, administering, and delivering the benefits under the contract;

''(C) a statement regarding whether the entity will reduce the applicable cost-sharing amount or substitute a copayment amount pursuant to section 1860F(b)(2) and if so, the amount of such reduction or copayments and how such reduction or substitution is tied to the performance requirements described in section 1860I(b)(1)(C);

''(D) a detailed description of the performance requirements for which the payments to the entity will be subject to risk pursuant to section 1860I(b)(1)(C);

''(E) a detailed description of access to pharmacy services provided under the plan, including proposed contracts with local pharmacy providers designed to ensure access and proposed compensation for local pharmacists' services;

''(F) with respect to the formulary used by the entity, a detailed description of the procedures and standards the entity will use for—

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

''(ii) determining when and how often the formulary should be modified;

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

''(H) a detailed description of the entity's estimated marketing and advertising expenditures related to enrolling eligible beneficiaries under the plan and retaining such enrollment; 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 TO BENEFITS IN CERTAIN AREAS.—

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

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

''(3) 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 Prescription Drug Benefit and Cost Containment Act of 2003, 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 eligible 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 to offer a plan in an area, unless only 1 bidding entity (and the plan offered by the 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 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 (and the plan offered by the entity) meet such minimum standards;

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

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

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

''(E) the factors described in section 1860D(b)(2);

''(F) prior experience of the entity in managing, administering, and delivering a prescription drug benefit program;

''(G) effectiveness of the entity and plan 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 beneficiaries enrolled under this part; 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 with respect to a plan 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 awarded under this part shall be for a term of at least 2 years but not more than 5 years, as determined by the Secretary.

"MINIMUM STANDARDS FOR ELIGIBLE ENTITIES

"SEC. 1860H. (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.—

''(A) IN GENERAL.—The eligible entity has in place drug utilization review procedures to ensure—

''(i) the appropriate utilization by eligible beneficiaries enrolled in the plan covered by the contract of the benefits to be provided under the plan;

''(ii) the avoidance of adverse drug reactions among such beneficiaries, 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; and

"(iii) the reasonable application of peer-reviewed medical literature pertaining to improvements in pharmaceutical safety and appropriate use of drugs.

"(B) AUTHORITY TO USE CERTAIN COMPENDIA AND LITERATURE.—The eligible entity may use the compendia and literature referred to in clauses (i) and (ii), respectively, of section 1927(g)(1)(B) as a source for the utilization review under subparagraph (A).

"(3) ELECTRONIC PRESCRIPTION PROGRAM.—

"(A) IN GENERAL.—The eligible entity has in place, as soon as practicable, an electronic prescription drug program that includes at least the following components, consistent with national standards established under subparagraph (B):

"(i) ELECTRONIC TRANSMITTAL OF PRESCRIPTIONS.—Prescriptions are only received electronically, except in emergency cases and other exceptional circumstances recognized by the Secretary.

"(ii) PROVISION OF INFORMATION TO PRESCRIBING HEALTH CARE PROFESSIONAL.—The program provides, upon

transmittal of a prescription by a prescribing health care professional, for transmittal by the pharmacist to the professional of information that includes—

"(I) information (to the extent available and feasible) on the drugs being prescribed for that patient and other information relating to the medical history or condition of the patient that may be relevant to the appropriate prescription for that patient;

"(II) cost-effective alternatives (if any) for the use of the drug prescribed; and

"(III) information on the drugs included in the applicable formulary.

To the extent feasible, such program shall permit the prescribing health care professional to provide (and be provided) related information on an interactive, real-time basis.

"(B) STANDARDS.—

"(i) DEVELOPMENT.—The Secretary shall provide for the development of national standards relating to the electronic

prescription drug program described in subparagraph (A). Such standards shall be compatible with standards established under part C of title XI.

''(ii) ADVISORY TASK FORCE.—In developing such standards, the Secretary shall establish a task force that includes representatives of physicians, hospitals, pharmacists, and technology experts and representatives of the Departments of Veterans Affairs and Defense and other appropriate Federal agencies to provide recommendations to the Secretary on such standards, including recommendations relating to the following:

''(I) The range of available computerized prescribing software and hardware and their costs to develop and implement.

''(II) The extent to which such systems reduce medication errors and can be readily implemented by physicians and hospitals.

''(III) Efforts to develop a common software platform for computerized prescribing.

''(IV) The cost of implementing such systems in the range of hospital and physician office settings, including hardware, software, and training costs.

''(V) Implementation issues as they relate to part C of title XI, and current Federal and State prescribing laws and regulations and their impact on implementation of computerized prescribing.

''(iii) DEADLINES.—

''(I) The Secretary shall establish the task force under clause (ii) as soon as possible after the date of enactment of the Prescription Drug Benefit and Cost Containment Act of 2003.

''(II) The task force shall submit recommendations to the Secretary by not later than 9 months after the date

the task force is first established under clause (i).

"(III) The Secretary shall develop and promulgate the national standards referred to in clause (ii) by not later than 1 year after the date the task force submits recommendations to the Secretary.

"(C) DELAY IN IMPLEMENTATION NOT TO DELAY IMPLEMENTATION OF DRUG BENEFIT.—Any delay in the development and implementation of the national standards referred to in subparagraph (B)(ii) or in the implementation of an electronic prescription drug program in accordance with such standards by an eligible entity shall not delay the implementation of the outpatient prescription drug benefit program established under this part. In accordance with section 1860A(a)(1), the Secretary shall implement the outpatient prescription drug benefit program as soon as possible after the date of enactment of the Prescription Drug Benefit and Cost Containment Act of 2003 and shall waive compliance with any requirements related to the electronic prescription drug program required

under this paragraph to the extent necessary until such time as the requirements for the program are established.

''(D) WAIVER OF APPLICATION FOR CERTAIN RURAL PROVIDERS.—If the Secretary determines that it is unduly burdensome on providers in rural areas to comply with the requirements under this paragraph, the Secretary may waive such requirements for such providers.

''(E) GRANT PROGRAM TO PROVIDE ASSISTANCE IN IMPLEMENTING ELECTRONIC PRESCRIPTION DRUG PROGRAMS.—

''(i) IN GENERAL.—The Secretary is authorized to establish a grant program to provide assistance to health care providers in implementing electronic prescription drug programs pursuant to this paragraph.

''(ii) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out clause (i), there are authorized to be appropriated such sums as may be necessary.

''(4) PATIENT PROTECTIONS.—

''(A) ACCESS.—

''(i) IN GENERAL.—The eligible entity ensures that the covered outpatient drugs

are accessible and convenient to eligible beneficiaries enrolled in the plan covered by the contract, including by offering the services 24 hours a day and 7 days a week for emergencies.

''(ii) AGREEMENTS WITH PHARMACIES.—

''(I) IN GENERAL.—The eligible entity shall enter into a participation agreement with any pharmacy that meets the requirements of subsection (d) to dispense covered prescription drugs to eligible beneficiaries under this part.

''(II) REQUIREMENT REGARDING PARTICIPATION.—The eligible entity shall include terms in such agreements that secure the participation of sufficient numbers of pharmacies to ensure convenient access (including adequate emergency access).

''(III) DISPENSING FEE.—Such agreements shall include the payment of a reasonable dispensing fee for cov-

ered outpatient drugs dispensed to a beneficiary under the agreement.

''(iii) PREFERRED PHARMACY NETWORKS.—If the eligible entity utilizes a preferred pharmacy network, the network complies with the standards under subsection (e).

''(B) ENSURING THAT BENEFICIARIES ARE NOT OVERCHARGED.—The eligible entity has procedures in place to ensure that each pharmacy with a participation agreement under this part with the entity complies with the requirements under subsection (d)(1)(C) (relating to adherence to negotiated prices).

''(C) 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 1860C(a)(1)), 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 or, if eligible, with a Medicare+Choice organization.

''(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.

''(D) PROCEDURES REGARDING THE DETERMINATION OF DRUGS THAT ARE MEDICALLY NECESSARY.—

''(i) IN GENERAL.—The eligible entity has in place procedures on a case-by-case basis to treat a drug not included on the formulary of the plan as a drug on the formulary under this part if the formulary drug for the treatment of the same condition is determined—

''(I) to be not as effective for the enrollee in preventing or slowing the deterioration of, or improving or maintaining, the health of the enrollee; or

''(II) to have a significant adverse effect on the enrollee.

''(ii) REQUIREMENT.—The procedures under clause (i) shall require that determinations under such clause are based on professional medical judgment, the medical condition of the enrollee, and other medical evidence.

''(E) PROCEDURES REGARDING APPEAL RIGHTS WITH RESPECT TO DENIALS OF CARE.—The eligible entity has in place procedures to ensure—

''(i) a timely internal review for resolution of denials of coverage (in whole or in part and including those regarding the coverage of drugs not included on the formulary of the plan as drugs so included) in accordance with the medical exigencies of the case and a timely resolution of complaints, by enrollees in the plan, or by providers, pharmacists, and other individuals acting on behalf of each such enrollee (with the enrollee's consent) in accordance with requirements (as established by the Secretary) that are comparable to such requirements for Medicare+Choice organizations under part C (and are not less favor-

able to the enrollee than such requirements under such part as in effect on the date of enactment of the Prescription Drug Benefit and Cost Containment Act of 2003);

''(ii) that the entity complies in a timely manner with requirements established by the Secretary that (I) provide for an external review by an independent entity selected by the Secretary of denials of coverage described in clause (i) not resolved in the favor of the beneficiary (or other complainant) under the process described in such clause, and (II) are comparable to the external review requirements established for Medicare+Choice organizations under part C (and are not less favorable to the enrollee than such requirements under such part as in effect on the date of enactment of the Prescription Drug Benefit and Cost Containment Act of 2003); and

''(iii) that enrollees are provided with information regarding the appeals procedures under this part at the time of enroll-

ment with the entity and upon request thereafter.

''(F) PROCEDURES REGARDING PATIENT CONFIDENTIALITY.—Insofar as an eligible entity maintains individually identifiable medical records or other health information regarding eligible beneficiaries enrolled in the plan that is covered by the contract, 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.

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

''(i) IN GENERAL.—The eligible entity has in place procedures for the timely transfer of records and information de-

scribed in subparagraph (F) (with respect to a beneficiary who loses coverage under this part with the entity and enrolls with another entity (including a Medicare+Choice organization) 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 (F).

''(H) PROCEDURES REGARDING MEDICAL ERRORS.—The eligible entity has in place procedures for—

''(i) working with the Secretary to deter medical errors related to the provision of covered outpatient drugs; and

''(ii) ensuring that pharmacies with a contract with the entity have in place procedures to deter medical errors related to the provision of covered outpatient drugs.

''(5) PROCEDURES TO CONTROL FRAUD, ABUSE, AND WASTE.—

''(A) IN GENERAL.—The eligible entity has in place procedures to control fraud, abuse, and waste.

"(B) APPLICABILITY OF FRAUD AND ABUSE PROVISIONS.—The provisions of section 1128 through 1128C (relating to fraud and abuse) apply to eligible entities with contracts under this part.

"(6) REPORTING REQUIREMENTS.—

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

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

"(ii) The prices that eligible beneficiaries enrolled in the plan that is covered by the contract will be charged for covered outpatient drugs.

"(iii) The management 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 part, 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)

(except for information described in clause (ii) of such subparagraph) 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 complies with the requirements described in section 1860G(f).

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

''(b) SPECIAL RULES REGARDING COST-EFFECTIVE PROVISION OF BENEFITS.—

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

''(A) employ mechanisms to provide the benefits economically, that may include the use of—

''(i) alternative methods of distribution;

''(ii) preferred pharmacy networks (pursuant to subsection (e)); and

''(iii) generic drug substitution;

''(B) use mechanisms to encourage eligible beneficiaries to select cost-effective drugs or less costly means of receiving drugs, that may include the use of—

''(i) pharmacy incentive programs;

''(ii) therapeutic interchange programs; and

''(iii) disease management programs;

''(C) encourage pharmacy providers to—

''(i) inform beneficiaries of the differentials in price between generic and brand name 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 adverse events associated with medications; and

''(D) develop and implement a formulary in accordance with subsection (c).

''(2) RESTRICTION.—If an eligible entity uses alternative methods of distribution pursuant to paragraph (1)(A)(i), the entity may not require that a beneficiary use such methods in order to obtain covered outpatient drugs.

''(c) REQUIREMENTS FOR FORMULARIES.—

''(1) STANDARDS.—

''(A) IN GENERAL.—The formulary developed and implemented by the eligible entity shall comply with standards established by the Secretary in consultation with the Medicare Prescription Drug Advisory Committee established under section 1860L.

''(B) NO NATIONAL FORMULARY OR REQUIREMENT TO EXCLUDE SPECIFIC DRUGS.—

''(i) SECRETARY MAY NOT ESTABLISH A NATIONAL FORMULARY.—The Secretary may not establish a national formulary.

"(ii) NO REQUIREMENT TO EXCLUDE SPECIFIC DRUGS.—The standards established by the Secretary pursuant to subparagraph (A) may not require that an eligible entity exclude a specific covered outpatient drug from the formulary developed and implemented by the entity.

"(2) REQUIREMENTS FOR STANDARDS.—The standards established under paragraph (1) shall require that the eligible entity—

"(A) use a pharmacy and therapeutic committee (that meets the standards for a pharmacy and therapeutic committee established by the Secretary in consultation with such Medicare Prescription Drug Advisory Committee) to develop and implement the formulary;

"(B) include—

"(i) all generic covered outpatient drugs on the formulary;

"(ii) at least 1 brand name 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 Pharmacy and Therapeutics

Advisory Committee) on the formulary; and

''(iii) if there is more than 1 brand name drug available in a therapeutic class, at least 2 brand name drugs from such class on the formulary; and

''(C) develop procedures for the modification of the formulary, including for the addition of new drugs to an existing therapeutic class;

''(D) pursuant to section 1860F(b)(3), provide for coverage of nonformulary drugs at the formulary drug rate when determined under subparagraph (D) or (E) of subsection (a)(3) to be medically necessary;

''(E) 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 on the formulary and any difference in the cost-sharing for—

''(i) drugs included on the formulary; and

''(ii) for drugs not included on the formulary; and

''(F) provide a reasonable amount of notice to beneficiaries enrolled in the plan that is covered by the contract under this part of any change on the formulary.

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

''(A) educating prescribing providers, pharmacists, and beneficiaries about the medical and cost benefits of drugs included on the formulary for the plan (including generic drugs); or

''(B) requesting prescribing providers to consider a drug included on the formulary prior to dispensing of a drug not so included, as long as such a request does not unduly delay the provision of the drug.

''(d) TERMS OF PARTICIPATION AGREEMENT WITH PHARMACIES.—

''(1) IN GENERAL.—A participation agreement between an eligible entity and a pharmacy under this part (pursuant to subsection (a)(3)(A)(ii)) shall include the following terms and conditions:

''(A) APPLICABLE REQUIREMENTS.—The pharmacy shall meet (and throughout the con-

tract period continue to meet) all applicable Federal requirements and State and local licensing requirements.

''(B) ACCESS AND QUALITY STANDARDS.—The pharmacy shall comply with such standards as the Secretary (and the eligible entity) shall establish concerning the quality of, and enrolled beneficiaries' access to, pharmacy services under this part. Such standards shall require the pharmacy—

''(i) not to refuse to dispense covered outpatient drugs to any eligible beneficiary enrolled under this part;

''(ii) to keep patient records (including records on expenses) for all covered outpatient drugs dispensed to such enrolled beneficiaries;

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

''(iv) to comply with periodic audits to assure compliance with the requirements of

this part and the accuracy of information submitted.

''(C) ENSURING THAT BENEFICIARIES ARE NOT OVERCHARGED.—

''(i) ADHERENCE TO NEGOTIATED PRICES.—The total charge for each covered outpatient drug dispensed by the pharmacy to a beneficiary enrolled in the plan, without regard to whether the individual is financially responsible for any or all of such charge, shall not exceed the negotiated price for the drug (as reported to the Secretary pursuant to subsection (a)(6)(A)).

''(ii) ADHERENCE TO BENEFICIARY OBLIGATION.—The pharmacy may not charge (or collect from) such beneficiary an amount that exceeds the cost-sharing that the beneficiary is responsible for under this part (as determined under section 1860F(b) using the negotiated price of the drug).

''(D) ADDITIONAL REQUIREMENTS.—The pharmacy shall meet such additional contract

requirements as the eligible entity specifies under this section.

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

''(e) PREFERRED PHARMACY NETWORKS.—

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

''(2) STANDARDS.—In establishing standards under paragraph (1), the Secretary shall take into account reasonable distances to pharmacy services in both urban and rural areas. Such standards shall be consistent with the requirements of this part.

''PAYMENTS

''SEC. 1860I. (a) PROCEDURES FOR PAYMENTS TO ELIGIBLE ENTITIES.—The Secretary shall establish procedures for making payments to each eligible entity with a contract to offer a plan under this part for the management, administration, and delivery of the benefits under the plan.

''(b) REQUIREMENTS FOR PROCEDURES.—

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

''(A) MANAGEMENT PAYMENT.—Payment for the management, administration, and delivery of the benefits under the plan.

''(B) REIMBURSEMENT FOR NEGOTIATED COSTS OF DRUGS PROVIDED.—Payments for the negotiated costs of covered outpatient drugs provided to eligible beneficiaries enrolled under this part and in the plan, reduced by any applicable cost-sharing under section 1860F(b).

''(C) RISK REQUIREMENT TO ENSURE PURSUIT OF PERFORMANCE REQUIREMENTS.—An adjustment of a percentage (as determined under paragraph (2)) of the payments made to an entity under subparagraph (A) to ensure that the entity, in managing, administering, and delivering the benefits under this part, pursues performance requirements established by the Secretary, including the following:

''(i) CONTROL OF MEDICARE AND BENEFICIARY COSTS.—The entity contains costs to the Prescription Drug Account and to eligible beneficiaries enrolled under this part and in the plan offered by the en-

tity, as measured by generic substitution rates, price discounts, and other factors determined appropriate by the Secretary that do not reduce the access of such beneficiaries to medically necessary covered outpatient drugs.

''(ii) QUALITY CLINICAL CARE.—The entity provides such beneficiaries with quality clinical care, as measured by such factors as—

''(I) the level of adverse drug reactions and medical errors among such beneficiaries; and

''(II) providing specific clinical suggestions to improve health and patient and prescriber education as appropriate.

''(iii) QUALITY SERVICE.—The entity provides such beneficiaries with quality services, as measured by such factors as sustained pharmacy network access, timeliness and accuracy of service delivery in claims processing and card production, pharmacy and member service support access, response time in mail delivery service,

and timely action with regard to appeals and current beneficiary service surveys.

''(2) PERCENTAGE OF PAYMENT TIED TO RISK.—

''(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall determine the percentage (which may be up to 100 percent) of the payments made to an entity under paragraph (1)(A) that will be tied to the performance requirements described in paragraph (1)(C).

''(B) LIMITATION ON RISK TO ENSURE PROGRAM STABILITY.—In order to provide for program stability, the Secretary may not establish a percentage to be adjusted under this subsection at a level that jeopardizes the ability of an eligible entity to administer and deliver the benefits under this part or administer and deliver such benefits in a quality manner.

''(3) RISK ADJUSTMENT OF PAYMENTS BASED ON ENROLLEES IN PLAN.—To the extent that an eligible entity is at risk under this subsection, the procedures established under subsection (a) may include a methodology for risk adjusting the payments made to such entity based on the differences in actuarial

risk of different enrollees being served if the Secretary determines such adjustments to be necessary and appropriate.

''(4) PASS-THROUGH OF REBATES, DISCOUNTS, AND PRICE CONCESSIONS OBTAINED BY THE ELIGIBLE ENTITY.—The Secretary shall establish procedures for reducing the amount of payments to an eligible entity under paragraph (1) to take into account any rebates, discounts, or price concessions obtained by the entity from manufacturers of covered outpatient drugs, unless the Secretary determines that such procedures are not in the best interests of the medicare program or eligible beneficiaries.

''(c) PAYMENTS TO MEDICARE+CHOICE ORGANIZATIONS.—For provisions related to payments to Medicare+Choice organizations for the management, administration, and delivery of benefits under this part to eligible beneficiaries enrolled in a Medicare+Choice plan offered by the organization, see section 1853(c)(8).

''(d) 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. 1860J. (a) PROGRAM AUTHORITY.—The Secretary is authorized to develop and implement a program under this section to be known as 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 (e)(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 or dependent) 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 PAYMENT.—

''(A) IN GENERAL.—The amount of the payment for a quarter shall be, for each individual described in paragraph (1), ⅔ of the

sum of the monthly Government contribution amounts (computed under subparagraph (B)) for each of the 3 months in the quarter.

''(B) COMPUTATION OF MONTHLY GOVERNMENT CONTRIBUTION AMOUNT.—For purposes of subparagraph (A), the monthly Government contribution amount for a month in a year is equal to the amount by which—

''(i) 1/12 of the amount estimated under subparagraph (C) for the year involved; exceeds

''(ii) the monthly Part D premium under section 1860E(a) (determined without regard to any increase under section 1860B(b)(1)) for the month involved.

''(C) ESTIMATE OF AVERAGE ANNUAL PER CAPITA AGGREGATE EXPENDITURES.—

''(i) IN GENERAL.—The Secretary shall for each year after the period described in section 1860E(a)(2)(A), estimate for that year an amount equal to the average annual per capita aggregate expenditures payable from the Prescription Drug Account for that year.

"(ii) TIMEFRAME FOR ESTIMATION.—The Secretary shall make the estimate described in clause (i) for a year before the beginning of that year.

"(3) PAYMENT DATE.—The payment 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, whether provided by voluntary insurance coverage or pursuant to statutory or contractual obligation, 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 with an actuarial value (as defined by the Secretary) to each retired beneficiary that 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.

''PRESCRIPTION DRUG ACCOUNT IN THE FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND

''SEC. 1860K. (a) ESTABLISHMENT.—

''(1) IN GENERAL.—There is created within the Federal Supplementary Medical Insurance Trust Fund established by section 1841 an account to be known as the 'Prescription Drug Account' (in this section referred to as the 'Account').

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

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

''(b) PAYMENTS FROM ACCOUNT.—

''(1) IN GENERAL.—The Managing Trustee shall pay from time to time from the Account such amounts as the Secretary certifies are necessary to make payments to operate the program under this part, including payments to eligible entities under section 1860I, payments to Medicare+Choice organizations under section 1853(c)(8), and payments with respect to administrative expenses under this part in accordance with section 201(g).

''(2) TREATMENT IN RELATION TO PART B PREMIUM.—Amounts payable from the Account shall not be taken into account in computing actuarial rates or premium amounts under section 1839.

''(c) APPROPRIATIONS TO COVER BENEFITS AND ADMINISTRATIVE COSTS.—There are appropriated to the Account in a fiscal year, out of any moneys in the Treasury not otherwise appropriated, an amount equal to the amount by which the benefits and administrative costs of providing the benefits under this part in the year exceed the premiums collected under section 1860E(b) for the year.

''MEDICARE PRESCRIPTION DRUG ADVISORY COMMITTEE

''SEC. 1860L. (a) ESTABLISHMENT OF COMMITTEE.—There is established a Medicare Prescription Drug Advisory Committee (in this section referred to as the 'Committee').

''(b) FUNCTIONS OF COMMITTEE.—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 1860H(c)(2)(A);

''(B) standards required under subparagraphs (D) and (E) of section 1860H(a)(4) for determining if a drug is medically necessary;

''(C) standards for—

''(i) establishing therapeutic classes; and

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

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

''(E) 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 as soon as possible after the date of enactment of the Prescription Drug Benefit and Cost Containment Act of 2003.

''(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, attainments, and understanding of pharmaceutical cost control and quality enhancement, exceptionally qualified to perform the duties of members of the Committee.

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

''(i) five shall be chosen to represent physicians, 2 of whom shall be geriatricians;

''(ii) two shall be chosen to represent nurse practitioners;

"(iii) four shall be chosen to represent pharmacists;

"(iv) one shall be chosen to represent the Centers for Medicare & Medicaid Services;

"(v) four shall be chosen to represent actuaries, pharmacoeconomists, researchers, and other appropriate experts;

"(vi) one shall be chosen to represent emerging drug technologies;

"(vii) one shall be chosen to represent the Food and Drug Administration; and

"(viii) one shall be chosen to represent individuals enrolled under this part.

"(d) CHAIRPERSON.—The Secretary shall designate a member of the Committee as Chairperson. The term as Chairperson shall be for a 1-year period.

"(e) COMMITTEE PERSONNEL MATTERS.—

"(1) MEMBERS.—

"(A) COMPENSATION.—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.

''(B) 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.

''(2) STAFF.—The Committee may appoint such personnel as the Committee considers appropriate.

''(f) OPERATION OF THE COMMITTEE.—

''(1) MEETINGS.—The Committee shall meet at the call of the Chairperson (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 Chairperson after such consultation.

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

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

''(h) 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 (including the Centers for Medicare & Medicaid Services), and such resources and assets of the Department used in carrying out this title, as the Committee requires.

''(i) 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 REASONABLE AND NECESSARY.—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 reasonable and necessary to prevent or slow the deterioration of, or improve or maintain, the health of eligible beneficiaries;''.

(c) CONFORMING AMENDMENTS TO FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND.—Section 1841 of the Social Security Act (42 U.S.C. 1395t) is amended—

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

(A) by striking ''and'' before ''such amounts''; and

(B) by inserting before the period the following: '', and such amounts as may be depos-

ited in, or appropriated to, the Prescription Drug Account established by section 1860K'';

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

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

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

(d) 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 Congress a legislative proposal providing for such technical and conforming amendments in the law as are required by the provisions of this title.

SEC. 102. 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 the Social Security 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 the Social Security 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 (as defined in section 1860(1)) provided to individuals enrolled under part D, the organization complies with the access requirements applicable under part D.''.

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

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

(A) 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)'';

(B) 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

(C) by inserting before the last sentence the following: ''In the case of the payments under subsection (c)(8) for the provision of coverage of covered outpatient drugs to individuals enrolled under part D, such payment shall be adjusted for the risk factors of each enrollee as the Secretary determines to be feasible and appropriate to ensure actuarial equivalence.''.

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

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

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

''(8) CAPITATION RATE FOR PART D BENEFITS.—

''(A) IN GENERAL.—In the case of a Medicare+Choice plan that provides coverage of covered outpatient drugs to an individual enrolled under part D, the capitation rate for such coverage shall be the amount described in subparagraph (B). Such payments shall be made in the same manner and at the same time

as the payments to the Medicare+Choice organization offering the plan for benefits under parts A and B are otherwise made, but such payments shall be payable from the Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund under section 1841.

''(B) AMOUNT.—The amount described in this paragraph is an amount equal to 1/12 of the average annual per capita aggregate expenditures payable from the Prescription Drug Account for the year (as estimated under section 1860J(c)(2)(C)).''.

(e) LIMITATION ON ENROLLEE LIABILITY.—Section 1854(e) of the Social Security 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 any deductible or pay a cost-sharing amount that exceeds the amount of cost-sharing applicable for such benefits for an eligible beneficiary under part D.''.

(f) REQUIREMENT FOR ADDITIONAL BENEFITS.—Section 1854(f)(1) of the Social Security 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.''.

(g) EFFECTIVE DATE.—The amendments made by this section shall apply to items and services provided under a Medicare+Choice plan on or after the implementation date of the Prescription Drug Benefit and Cost Containment Act of 2003, as determined by the Secretary of Health and Human Services in accordance with section 1860A(a)(1) of the Social Security Act (as added by section 101).

SEC. 103. 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 1860E(a).''; and

(2) in subparagraph (B)—

(A) by inserting ''(i)'' after ''(B)''; and

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

''(ii) Cost-sharing described in section 1860F(b).''.

(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) and for medicare cost-sharing described in section 1905(p)(3)(B)(ii),''; 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) and for medicare cost-

sharing described in section 1905(p)(3)(B)(ii) 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 described in section 1905(p)(3)(A)(iii) or for medicare cost-sharing described in section 1905(p)(3)(B)(ii).''.

(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 the cost-sharing described in section 1860F(b).''.

(e) INCREASE IN FEDERAL MEDICAL ASSISTANCE PERCENTAGES FOR ADDITIONAL ASSISTANCE FOR LOW-INCOME BENEFICIARIES.—

(1) IN GENERAL.—The first sentence of section 1905(b) of the Social Security Act (42 U.S.C. 1396d(b)) is amended—

(A) by striking ''and'' before ''(4)''; and

(B) by inserting before the period at the end the following: '', and (5) the Federal medical assistance percentage shall be equal to the Medicare Drug Benefit Low-Income Assistance percentage (as defined in subsection (x)) with respect to medical assistance provided for medicare cost-sharing described in subparagraph (A)(iii) or (B)(ii) of subsection (p)(3) and for administrative expenditures incurred by the

State that are attributable to providing such medicare cost-sharing''.

(2) DEFINITION OF MEDICARE DRUG BENEFIT LOW-INCOME ASSISTANCE PERCENTAGE.—Section 1905 of the Social Security Act (42 U.S.C. 1396d) is amended by adding at the end the following new subsection:

''(x)(1) For purposes of clause (5) of subsection (b), and except as provided in paragraph (2), the Medicare Drug Benefit Low-Income Assistance percentage is 100 percent.

''(2) With respect to medicare cost-sharing described in subparagraph (A)(iii) or (B)(ii) of subsection (p)(3) provided to individuals eligible for medical assistance under section 1902(a)(10)(A)(i)(I), 1902(a)(10)(A)(i)(II) or 1902(f) and administrative expenditures incurred by the State that are attributable to providing such medicare cost-sharing to such individuals, the Medicare Drug Benefit Low-Income Assistance percentage for purposes of clause (5) of subsection (b) shall be equal to the lesser of—

''(A) in the case of fiscal year 2005—

''(i) 100 percent; or

''(ii) the Federal medical assistance percentage determined for the State for fiscal year

2005 increased by the number of percentage points equal to 10 percent of the number of percentage points by which (I) such Federal medical assistance percentage for the State is less than (II) 100 percent; and

''(B) in the case of fiscal year 2006 and any subsequent fiscal year—

''(i) 100 percent; or

''(ii) the percentage determined under subparagraph (A)(ii) for the previous fiscal year increased by the number of percentage points equal to 10 percent of the number of percentage points by which (I) the Federal medical assistance percentage for the State for fiscal year 2005 is less than (II) 100 percent.''.

(f) TREATMENT OF TERRITORIES.—Section 1108(g) of the Social Security 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 fiscal year 2005 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 described in section 1905(p)(3)(A)(iii) and for medicare cost-sharing described in section 1905(p)(3)(B)(ii); to

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

(g) AMENDMENT TO BEST PRICE.—Section 1927(c)(1)(C)(i) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)(i)) is amended—

(1) by striking ''and'' at the end of subclause (III);

(2) by striking the period at the end of subclause (IV) and inserting ''; and''; and

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

''(V) any prices charged which are negotiated under a plan under part D of title XVIII with respect to covered outpatient drugs, under a

Medicare+Choice plan under part C of such title with respect to such drugs, or by a qualified retiree prescription drug plan (as defined in section 1860J(e)(3)) with respect to such drugs, on behalf of eligible beneficiaries (as defined in section 1860(2).''.

(h) 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)''.

(i) 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 implementation date of the Prescription Drug Benefit and Cost Containment Act of 2003, as determined by the Secretary of Health and Human Services in accordance with section 1860A(a)(1) of the Social Security Act (as added by section 101).

(j) RULE OF CONSTRUCTION.—Nothing in the amendments made by this section shall be construed as precluding a State from using State funds to provide coverage of outpatient prescription drugs that is in addition to the coverage of such drugs required under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), as amended by this section.

(k) SENSE OF THE SENATE.—It is the sense of the Senate that during consideration of any conference report for this legislation, conferees should explore ways to provide incentives to States (and in particular to those States that, as of the date of enactment of this Act, offer some form of prescription drug assistance to the elderly and the

disabled) to maintain existing State commitments to provide prescription drug assistance to the elderly and disabled or to supplement the drug benefit established by the conference report.

SEC. 104. 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) REVISION OF BENEFIT PACKAGES.—

''(A) IN GENERAL.—Notwithstanding subsection (p), 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)) shall be revised so that—

''(i) the coverage of outpatient prescription drugs available under such benefit packages is replaced with coverage of outpatient prescription drugs that complements but does not duplicate the coverage of outpatient prescription drugs that is otherwise available 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 more than 90 percent of the cost-sharing amount applicable to an individual under section 1860F(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;

''(v) such revised standards meet any additional requirements imposed by the amendments made by the Prescription Drug Benefit and Cost Containment Act of 2003; and

''(vi) except as revised under the preceding clauses or as provided under subsection (p)(1)(E), the benefit packages are identical to the benefit packages that were available on the date of enactment of the Prescription Drug Benefit and Cost Containment Act of 2003.

''(B) MANNER OF REVISION.—The benefit packages revised under this section shall be revised in the manner described in subparagraph (E) of subsection (p)(1), except that for purposes of subparagraph (C) of such subsection, the standards established under this subsection shall take effect not later than the implementation date of the Prescription Drug Benefit and Cost Containment Act of 2003, as determined by the Secretary of Health and Human Services in accordance with section 1860A(a)(1).

''(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) GUARANTEED ISSUANCE AND RENEWAL OF REVISED POLICIES.—The provisions of subsections (q) and (s), including provisions of subsection (s)(3) (relating to special enrollment periods in cases of termination or disenrollment), shall apply

to medicare supplemental policies revised under this subsection in the same manner as such provisions apply to medicare supplemental policies issued under the standards established under subsection (p).

''(4) OPPORTUNITY OF CURRENT POLICYHOLDERS TO PURCHASE REVISED POLICIES.—

''(A) IN GENERAL.—No medicare supplemental policy of an issuer with a benefit package that is revised under paragraph (1) shall be deemed to meet the standards in subsection (c) unless the issuer—

''(i) provides written notice during the 60-day period immediately preceding the period established for the open enrollment period established under section 1860B(b)(2), to each individual who is a policyholder or certificate holder of a medicare supplemental policy issued by that issuer (at the most recent available address of that individual) of the offer described in clause (ii) and of the fact that such individual will no longer be covered under such policy as of the implementation date of the Prescription Drug Benefit and Cost Containment Act of 2003, as determined by

the Secretary of Health and Human Services in accordance with section 1860A(a)(1); and

''(ii) offers the policyholder or certificate holder under the terms described in subparagraph (B), during at least the period established under section 1860B(b)(2), a medicare supplemental policy with the benefit package that the Secretary determines is most comparable to the policy in which the individual is enrolled with coverage effective as of the date on which the individual is first entitled to benefits under part D.

''(B) TERMS OF OFFER DESCRIBED.—The terms described in this subparagraph are terms which do not—

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

''(ii) discriminate in the pricing of such policy because of health status, claims

experience, receipt of health care, or medical condition; or

"(iii) impose an exclusion of benefits based on a preexisting condition under such policy.

"(5) PENALTIES.—Each penalty under this section shall apply with respect to policies revised under this subsection as if such policies were issued under the standards established under subsection (p), including the penalties under subsections (a), (d), (p)(8), (p)(9), (q)(5), (r)(6)(A), (s)(4), and (t)(2)(D).".

SEC. 105. COVERAGE OF IMMUNOSUPPRESSIVE DRUGS FOR ALL MEDICARE BENEFICIARIES UNDER PART B.

(a) COVERAGE REGARDLESS OF WHETHER MEDICARE PAID FOR TRANSPLANT.—Section 1861(s)(2)(J) of the Social Security Act (42 U.S.C. 1395x(s)(2)(J)) 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) CONTINUED ENTITLEMENT TO IMMUNOSUPPRESSIVE DRUGS.—

(1) KIDNEY TRANSPLANT RECIPIENTS.—Section 226A(b)(2) of the Social Security Act (42 U.S.C. 426–1(b)(2)) is amended by inserting ''(except for coverage of immunosuppressive drugs under section 1861(s)(2)(J))'' after ''shall end''.

(2) OTHER TRANSPLANT RECIPIENTS.—The flush matter following paragraph (2)(C)(ii)(II) of section 226(b) of the Social Security Act (42 U.S.C. 426(b)) is amended by striking ''of this subsection)'' and inserting ''of this subsection and except for coverage of immunosuppressive drugs under section 1861(s)(2)(J))''.

(3) APPLICATION.—Section 1836 of the Social Security Act (42 U.S.C. 1395o) is amended—

(A) by striking ''Every individual who'' and inserting ''(a) IN GENERAL.—Every individual who''; and

(B) by adding at the end the following new subsection:

''(b) SPECIAL RULES APPLICABLE TO INDIVIDUALS ONLY ELIGIBLE FOR COVERAGE OF IMMUNOSUPPRESSIVE DRUGS.—

''(1) IN GENERAL.—In the case of an individual whose eligibility for benefits under this title has ended except for the coverage of immunosuppressive

drugs by reason of section 226(b) or 226A(b)(2), the following rules shall apply:

"(A) The individual shall be deemed to be enrolled under this part for purposes of receiving coverage of such drugs.

"(B) The individual shall be responsible for the full amount of the premium under section 1839 in order to receive such coverage.

"(C) The provision of such drugs shall be subject to the application of—

"(i) the deductible under section 1833(b); and

"(ii) the coinsurance amount applicable for such drugs (as determined under this part).

"(D) If the individual is an inpatient of a hospital or other entity, the individual is entitled to receive coverage of such drugs under this part.

"(2) ESTABLISHMENT OF PROCEDURES IN ORDER TO IMPLEMENT COVERAGE.—The Secretary shall establish procedures for—

"(A) identifying beneficiaries that are entitled to coverage of immunosuppressive drugs by reason of section 226(b) or 226A(b)(2); and

"(B) distinguishing such beneficiaries from beneficiaries that are enrolled under this part for the complete package of benefits under this part.".

(4) TECHNICAL AMENDMENT.—Subsection (c) of section 226A of the Social Security Act (42 U.S.C. 426–1), as added by section 201(a)(3)(D)(ii) of the Social Security Independence and Program Improvements Act of 1994 (Public Law 103–296; 108 Stat. 1497), is redesignated as subsection (d).

(c) EXTENSION OF SECONDARY PAYER REQUIREMENTS FOR ESRD BENEFICIARIES.—Section 1862(b)(1)(C) of the Social Security Act (42 U.S.C. 1395y(b)(1)(C)) is amended by adding at the end the following new sentence: "With regard to immunosuppressive drugs furnished on or after the date of enactment of this sentence, this subparagraph shall be applied without regard to any time limitation.".

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to drugs furnished on or after the date of enactment of this Act.

SEC. 106. HHS STUDY AND REPORT ON UNIFORM PHARMACY BENEFIT CARDS.

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

and advisability of establishing a uniform format for pharmacy benefit cards provided to beneficiaries by eligible entities under the outpatient prescription drug benefit program under part D of title XVIII of the Social Security Act (as added by section 101).

(b) REPORT.—Not later than 2 years 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 study conducted under subsection (a) together with any recommendations for legislation that the Secretary determines to be appropriate as a result of such study.

SEC. 107. EXPANSION OF MEMBERSHIP AND DUTIES OF MEDICARE PAYMENT ADVISORY COMMISSION (MEDPAC).

(a) EXPANSION OF MEMBERSHIP.—

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

(A) in paragraph (1), by striking ''17'' and inserting ''19''; and

(B) in paragraph (2)(B), by inserting ''experts in the area of pharmacology and prescription drug benefit programs,'' after ''other health professionals,''.

(2) INITIAL TERMS OF ADDITIONAL MEMBERS.—

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

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

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

(B) COMMENCEMENT OF TERMS.—Such terms shall begin on January 1, 2004.

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

''(D) PRESCRIPTION MEDICINE BENEFIT PROGRAM.—Specifically, the Commission shall review, with respect to the outpatient prescription drug benefit program under part D, the impact of such program on—

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

''(ii) franchise, independent, and rural pharmacies; and

''(iii) beneficiary access to outpatient prescription drugs, including an assessment of out-of-pocket spending, generic and brand name drug utilization, and pharmacists' services.''.

TITLE II—PRESCRIPTION DRUG COST CONTAINMENT AND QUALITY ASSURANCE

SEC. 201. FILING OF PATENT INFORMATION WITH THE FOOD AND DRUG ADMINISTRATION.

(a) FILING AFTER APPROVAL OF AN APPLICATION.—

(1) IN GENERAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) (as amended by section 210(a)(2)(B)(ii)) is amended in subsection (c) by striking paragraph (2) and inserting the following:

''(2) PATENT INFORMATION.—

"(A) IN GENERAL.—Not later than the date that is 30 days after the date of an order approving an application under subsection (b) (unless the Secretary extends the date because of extraordinary or unusual circumstances), the holder of the application shall file with the Secretary the patent information described in subparagraph (C) with respect to any patent—

"(i)(I) that claims the drug for which the application was approved; or

"(II) that claims an approved method of using the drug; and

"(ii) with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

"(B) SUBSEQUENTLY ISSUED PATENTS.—In a case in which a patent described in subparagraph (A) is issued after the date of an order approving an application under subsection (b), the holder of the application shall file with the Secretary the patent information described in subparagraph (C) not later than the date that is 30 days after the date on which the pat-

ent is issued (unless the Secretary extends the date because of extraordinary or unusual circumstances).

"(C) PATENT INFORMATION.—The patent information required to be filed under subparagraph (A) or (B) includes—

"(i) the patent number;

"(ii) the expiration date of the patent;

"(iii) with respect to each claim of the patent—

"(I) whether the patent claims the drug or claims a method of using the drug; and

"(II) whether the claim covers—

"(aa) a drug substance;

"(bb) a drug formulation;

"(cc) a drug composition; or

"(dd) a method of use;

"(iv) if the patent claims a method of use, the approved use covered by the claim;

"(v) the identity of the owner of the patent (including the identity of any agent of the patent owner); and

"(vi) a declaration that the applicant, as of the date of the filing, has provided

complete and accurate patent information for all patents described in subparagraph (A).

''(D) PUBLICATION.—On filing of patent information required under subparagraph (A) or (B), the Secretary shall—

''(i) immediately publish the information described in clauses (i) through (iv) of subparagraph (C); and

''(ii) make the information described in clauses (v) and (vi) of subparagraph (C) available to the public on request.

''(E) CIVIL ACTION FOR CORRECTION OR DELETION OF PATENT INFORMATION.—

''(i) IN GENERAL.—A person that has filed an application under subsection (b)(2) or (j) for a drug may bring a civil action against the holder of the approved application for the drug seeking an order requiring that the holder of the application amend the application—

''(I) to correct patent information filed under subparagraph (A); or

''(II) to delete the patent information in its entirety for the reason that—

''(aa) the patent does not claim the drug for which the application was approved; or

''(bb) the patent does not claim an approved method of using the drug.

''(ii) LIMITATIONS.—Clause (i) does not authorize—

''(I) a civil action to correct patent information filed under subparagraph (B); or

''(II) an award of damages in a civil action under clause (i).

''(F) NO CLAIM FOR PATENT INFRINGEMENT.—An owner of a patent with respect to which a holder of an application fails to file information on or before the date required under subparagraph (A) or (B) shall be barred from bringing a civil action for infringement of the patent against a person that—

''(i) has filed an application under subsection (b)(2) or (j); or

"(ii) manufactures, uses, offers to sell, or sells a drug approved under an application under subsection (b)(2) or (j).".

(2) TRANSITION PROVISION.—

(A) FILING OF PATENT INFORMATION.—Each holder of an application for approval of a new drug under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) that has been approved before the date of enactment of this Act shall amend the application to include the patent information required under the amendment made by paragraph (1) not later than the date that is 30 days after the date of enactment of this Act (unless the Secretary of Health and Human Services extends the date because of extraordinary or unusual circumstances).

(B) NO CLAIM FOR PATENT INFRINGEMENT.—An owner of a patent with respect to which a holder of an application under subsection (b) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) fails to file information on or before the date required under subparagraph (A) shall be barred

from bringing a civil action for infringement of the patent against a person that—

(i) has filed an application under subsection (b)(2) or (j) of that section; or

(ii) manufactures, uses, offers to sell, or sells a drug approved under an application under subsection (b)(2) or (j) of that section.

(b) FILING WITH AN APPLICATION.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (b)(2)—

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

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

(C) by adding at the end the following:

''(C) with respect to a patent that claims both the drug and a method of using the drug or claims more than 1 method of using the drug for which the application is filed—

''(i) a certification under subparagraph (A)(iv) on a claim-by-claim basis; and

''(ii) a statement under subparagraph (B) regarding the method of use claim.''; and

(2) in subsection (j)(2)(A), by inserting after clause (viii) the following:

''With respect to a patent that claims both the drug and a method of using the drug or claims more than 1 method of using the drug for which the application is filed, the application shall contain a certification under clause (vii)(IV) on a claim-by-claim basis and a statement under clause (viii) regarding the method of use claim.''.

SEC. 202. LIMITATION OF 30-MONTH STAY TO CERTAIN PATENTS.

(a) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is amended—

(1) in subparagraph (B)—

(A) in clause (iii)—

(i) by striking ''(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii),'' and inserting the following:

''(iii) SUBCLAUSE (IV) CERTIFICATION WITH RESPECT TO CERTAIN PATENTS.—If the applicant made a certification de-

scribed in paragraph (2)(A)(vii)(IV) with respect to a patent (other than a patent that claims a process for manufacturing the listed drug) for which patent information was filed with the Secretary under subsection (c)(2)(A),''; and

(ii) by adding at the end the following: ''The 30-month period provided under the second sentence of this clause shall not apply to a certification under paragraph (2)(A)(vii)(IV) made with respect to a patent for which patent information was filed with the Secretary under subsection (c)(2)(B).'';

(B) by redesignating clause (iv) as clause (v); and

(C) by inserting after clause (iii) the following:

''(iv) SUBCLAUSE (IV) CERTIFICATION WITH RESPECT TO OTHER PATENTS.—

''(I) IN GENERAL.—If the applicant made a certification described in paragraph (2)(A)(vii)(IV) with respect to a patent not described in clause (iii) for which patent information was

published by the Secretary under subsection (c)(2)(D), the approval shall be made effective on the date that is 45 days after the date on which the notice provided under paragraph (2)(B) was received, unless a civil action for infringement of the patent, accompanied by a motion for preliminary injunction to enjoin the applicant from engaging in the commercial manufacture or sale of the drug, was filed on or before the date that is 45 days after the date on which the notice was received, in which case the approval shall be made effective—

''(aa) on the date of a court action declining to grant a preliminary injunction; or

''(bb) if the court has granted a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug—

''(AA) on issuance by a court of a determination

that the patent is invalid or is not infringed;

"(BB) on issuance by a court of an order revoking the preliminary injunction or permitting the applicant to engage in the commercial manufacture or sale of the drug; or

"(CC) on the date specified in a court order under section 271(e)(4)(A) of title 35, United States Code, if the court determines that the patent is infringed.

"(II) COOPERATION.—Each of the parties shall reasonably cooperate in expediting a civil action under subclause (I).

"(III) EXPEDITED NOTIFICATION.—If the notice under paragraph (2)(B) contains an address for the receipt of expedited notification of a civil action under subclause (I), the plaintiff shall, on the date on which

the complaint is filed, simultaneously cause a notification of the civil action to be delivered to that address by the next business day.''; and

(2) by inserting after subparagraph (B) the following:

''(C) FAILURE TO BRING INFRINGEMENT ACTION.—If, in connection with an application under this subsection, the applicant provides an owner of a patent notice under paragraph (2)(B) with respect to the patent, and the owner of the patent fails to bring a civil action against the applicant for infringement of the patent on or before the date that is 45 days after the date on which the notice is received, the owner of the patent shall be barred from bringing a civil action for infringement of the patent in connection with the development, manufacture, use, offer to sell, or sale of the drug for which the application was filed or approved under this subsection.''.

(b) OTHER APPLICATIONS.—Section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) (as amended by section 210(a)(3)(A)(iii)) is amended—

(1) in paragraph (3)—

(A) in subparagraph (C)—

(i) by striking ''(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A),'' and inserting the following:

''(C) CLAUSE (iv) CERTIFICATION WITH RESPECT TO CERTAIN PATENTS.—If the applicant made a certification described in subsection (b)(2)(A)(iv) with respect to a patent (other than a patent that claims a process for manufacturing the listed drug) for which patent information was filed with the Secretary under paragraph (2)(A),''; and

(ii) by adding at the end the following: ''The 30-month period provided under the second sentence of this subparagraph shall not apply to a certification under subsection (b)(2)(A)(iv) made with respect to a patent for which patent information was filed with the Secretary under paragraph (2)(B).''; and

(B) by inserting after subparagraph (C) the following:

''(D) CLAUSE (iv) CERTIFICATION WITH RESPECT TO OTHER PATENTS.—

"(i) IN GENERAL.—If the applicant made a certification described in subsection (b)(2)(A)(iv) with respect to a patent not described in subparagraph (C) for which patent information was published by the Secretary under paragraph (2)(D), the approval shall be made effective on the date that is 45 days after the date on which the notice provided under subsection (b)(3) was received, unless a civil action for infringement of the patent, accompanied by a motion for preliminary injunction to enjoin the applicant from engaging in the commercial manufacture or sale of the drug, was filed on or before the date that is 45 days after the date on which the notice was received, in which case the approval shall be made effective—

"(I) on the date of a court action declining to grant a preliminary injunction; or

"(II) if the court has granted a preliminary injunction prohibiting the applicant from engaging in the com-

mercial manufacture or sale of the drug—

"(aa) on issuance by a court of a determination that the patent is invalid or is not infringed;

"(bb) on issuance by a court of an order revoking the preliminary injunction or permitting the applicant to engage in the commercial manufacture or sale of the drug; or

"(cc) on the date specified in a court order under section 271(e)(4)(A) of title 35, United States Code, if the court determines that the patent is infringed.

"(ii) COOPERATION.—Each of the parties shall reasonably cooperate in expediting a civil action under clause (i).

"(iii) EXPEDITED NOTIFICATION.—If the notice under subsection (b)(3) contains an address for the receipt of expedited notification of a civil action under clause (i), the plaintiff shall, on the date on which the

complaint is filed, simultaneously cause a notification of the civil action to be delivered to that address by the next business day.''; and

(2) by inserting after paragraph (3) the following:

''(4) FAILURE TO BRING INFRINGEMENT ACTION.—If, in connection with an application under subsection (b)(2), the applicant provides an owner of a patent notice under subsection (b)(3) with respect to the patent, and the owner of the patent fails to bring a civil action against the applicant for infringement of the patent on or before the date that is 45 days after the date on which the notice is received, the owner of the patent shall be barred from bringing a civil action for infringement of the patent in connection with the development, manufacture, use, offer to sell, or sale of the drug for which the application was filed or approved under subsection (b)(2).''.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by subsections (a) and (b) shall be effective with respect to any certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of

the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) made after the date of enactment of this Act in an application filed under subsection (b)(2) or (j) of that section.

(2) TRANSITION PROVISION.—In the case of applications under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) filed before the date of enactment of this Act—

(A) a patent (other than a patent that claims a process for manufacturing a listed drug) for which information was submitted to the Secretary of Health and Human Services under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (as in effect on the day before the date of enactment of this Act) shall be subject to subsections (c)(3)(C) and (j)(5)(B)(iii) of section 505 of the Federal Food, Drug, and Cosmetic Act (as amended by this section); and

(B) any other patent (including a patent for which information was submitted to the Secretary under section 505(c)(2) of that Act (as in effect on the day before the date of enactment of this Act)) shall be subject to subsections (c)(3)(D) and (j)(5)(B)(iv) of section

505 of the Federal Food, Drug, and Cosmetic Act (as amended by this section).

SEC. 203. EXCLUSIVITY FOR ACCELERATED GENERIC DRUG APPLICANTS.

(a) IN GENERAL.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as amended by section 202(a)) is amended—

(1) in subparagraph (B)(v), by striking subclause (II) and inserting the following:

''(II) the earlier of—

''(aa) the date of a final decision of a court (from which no appeal has been or can be taken, other than a petition to the Supreme Court for a writ of certiorari) holding that the patent that is the subject of the certification is invalid or not infringed; or

''(bb) the date of a settlement order or consent decree signed by a Federal judge that enters a final judgment and includes a finding that the patent that is the subject of the certifi-

cation is invalid or not infringed;''; and

(2) by inserting after subparagraph (C) the following:

''(D) FORFEITURE OF 180-DAY PERIOD.—

''(i) DEFINITIONS.—In this subparagraph:

''(I) APPLICATION.—The term 'application' means an application for approval of a drug under this subsection containing a certification under paragraph (2)(A)(vii)(IV) with respect to a patent.

''(II) FIRST APPLICATION.—The term 'first application' means the first application to be filed for approval of the drug.

''(III) FORFEITURE EVENT.—The term 'forfeiture event', with respect to an application under this subsection, means the occurrence of any of the following:

''(aa) FAILURE TO MARKET.—The applicant fails to market the drug by the later of—

''(AA) the date that is 60 days after the date on which the approval of the application for the drug is made effective under clause (iii) or (iv) of subparagraph (B) (unless the Secretary extends the date because of extraordinary or unusual circumstances); or

''(BB) if 1 or more civil actions have been brought against the applicant for infringement of a patent subject to a certification under paragraph (2)(A)(vii)(IV) or 1 or more civil actions have been brought by the applicant for a declaratory judgment that such a patent is invalid or not infringed, the date that is 60 days after the date of a final decision (from which no appeal has been or can be taken, other

than a petition to the Supreme Court for a writ of certiorari) in the last of those civil actions to be decided (unless the Secretary extends the date because of extraordinary or unusual circumstances).

''(bb) WITHDRAWAL OF APPLICATION.—The applicant withdraws the application.

''(cc) AMENDMENT OF CERTIFICATION.—The applicant, voluntarily or as a result of a settlement or defeat in patent litigation, amends the certification from a certification under paragraph (2)(A)(vii)(IV) to a certification under paragraph (2)(A)(vii)(III).

''(dd) FAILURE TO OBTAIN APPROVAL.—The applicant fails to obtain tentative approval of an application within 30 months after the date on which the appli-

cation is filed, unless the failure is caused by—

"(AA) a change in the requirements for approval of the application imposed after the date on which the application is filed; or

"(BB) other extraordinary circumstances warranting an exception, as determined by the Secretary.

"(ee) FAILURE TO CHALLENGE PATENT.—In a case in which, after the date on which the applicant submitted the application, new patent information is submitted under subsection (c)(2) for the listed drug for a patent for which certification is required under paragraph (2)(A), the applicant fails to submit, not later than the date that is 60 days after the date on which the Secretary publishes the new patent information under paragraph

(7)(A)(iii) (unless the Secretary extends the date because of extraordinary or unusual circumstances)—

"(AA) a certification described in paragraph (2)(A)(vii)(IV) with respect to the patent to which the new patent information relates; or

"(BB) a statement that any method of use claim of that patent does not claim a use for which the applicant is seeking approval under this subsection in accordance with paragraph (2)(A)(viii).

"(ff) UNLAWFUL CONDUCT.—The Federal Trade Commission determines that the applicant engaged in unlawful conduct with respect to the application in violation of section 1 of the Sherman Act (15 U.S.C. 1).

"(IV) SUBSEQUENT APPLICATION.—The term 'subsequent application' means an application for approval of a drug that is filed subsequent to the filing of a first application for approval of that drug.

"(ii) FORFEITURE OF 180-DAY PERIOD.—

"(I) IN GENERAL.—Except as provided in subclause (II), if a forfeiture event occurs with respect to a first application—

"(aa) the 180-day period under subparagraph (B)(v) shall be forfeited by the first applicant; and

"(bb) any subsequent application shall become effective as provided under clause (i), (ii), (iii), or (iv) of subparagraph (B), and clause (v) of subparagraph (B) shall not apply to the subsequent application.

"(II) FORFEITURE TO FIRST SUBSEQUENT APPLICANT.—If the sub-

sequent application that is the first to be made effective under subclause (I) was the first among a number of subsequent applications to be filed—

"(aa) that first subsequent application shall be treated as the first application under this subparagraph (including subclause (I)) and as the previous application under subparagraph (B)(v); and

"(bb) any other subsequent applications shall become effective as provided under clause (i), (ii), (iii), or (iv) of subparagraph (B), but clause (v) of subparagraph (B) shall apply to any such subsequent application.

"(iii) AVAILABILITY.—The 180-day period under subparagraph (B)(v) shall be available to a first applicant submitting an application for a drug with respect to any patent without regard to whether an application has been submitted for the drug under this subsection containing such a

certification with respect to a different patent.

''(iv) APPLICABILITY.—The 180-day period described in subparagraph (B)(v) shall apply to an application only if a civil action is brought against the applicant for infringement of a patent that is the subject of the certification.''.

(b) APPLICABILITY.—The amendment made by subsection (a) shall be effective only with respect to an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the date of enactment of this Act for a listed drug for which no certification under section 505(j)(2)(A)(vii)(IV) of that Act was made before the date of enactment of this Act, except that if a forfeiture event described in section 505(j)(5)(D)(i)(III)(ff) of that Act occurs in the case of an applicant, the applicant shall forfeit the 180-day period under section 505(j)(5)(B)(v) of that Act without regard to when the applicant made a certification under section 505(j)(2)(A)(vii)(IV) of that Act.

SEC. 204. FAIR TREATMENT FOR INNOVATORS.

(a) BASIS FOR APPLICATION.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (b)(3)(B), by striking the second sentence and inserting ''The notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that, as of the date of the notice, the patent is not valid or is not infringed, and shall include, as appropriate for the relevant patent, a description of the applicant's proposed drug substance, drug formulation, drug composition, or method of use. All information disclosed under this subparagraph shall be treated as confidential and may be used only for purposes relating to patent adjudication. Nothing in this subparagraph precludes the applicant from amending the factual or legal basis on which the applicant relies in patent litigation.''; and

(2) in subsection (j)(2)(B)(ii), by striking the second sentence and inserting ''The notice shall include a detailed statement of the factual and legal basis of the opinion of the applicant that, as of the date of the notice, the patent is not valid or is not infringed, and shall include, as appropriate for the relevant patent, a description of the applicant's proposed drug substance, drug formulation, drug composition, or method of use. All information disclosed under this subparagraph shall be treated as con-

fidential and may be used only for purposes relating to patent adjudication. Nothing in this subparagraph precludes the applicant from amending the factual or legal basis on which the applicant relies in patent litigation.''.

(b) INJUNCTIVE RELIEF.—Section 505(j)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)) (as amended by section 202(a)(1)) is amended—

(1) in clause (iii), by adding at the end the following: ''A court shall not regard the extent of the ability of an applicant to pay monetary damages as a whole or partial basis on which to deny a preliminary or permanent injunction under this clause.''; and

(2) in clause (iv), by adding at the end the following:

''(IV) INJUNCTIVE RELIEF.—A court shall not regard the extent of the ability of an applicant to pay monetary damages as a whole or partial basis on which to deny a preliminary or permanent injunction under this clause.''.

SEC. 205. BIOEQUIVALENCE.

(a) IN GENERAL.—The amendments to part 320 of title 21, Code of Federal Regulations, promulgated by the

Commissioner of Food and Drugs on July 17, 1991 (57 Fed. Reg. 17997 (April 28, 1992)), shall continue in effect as an exercise of authorities under sections 501, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 355, 371).

(b) EFFECT.—Subsection (a) does not affect the authority of the Commissioner of Food and Drugs to amend part 320 of title 21, Code of Federal Regulations.

(c) EFFECT OF SECTION.—This section shall not be construed to alter the authority of the Secretary of Health and Human Services to regulate biological products under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). Any such authority shall be exercised under that Act as in effect on the day before the date of enactment of this Act.

SEC. 206. CLARIFICATION OF STATE AUTHORITY RELATING TO MEDICAID DRUG REBATE AGREEMENTS.

Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended by adding at the end the following:

''(l) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as prohibiting a State from—

''(1) directly entering into rebate agreements (on the State's own initiative or under a section 1115 waiver approved by the Secretary before, on, or after the date of enactment of this subsection)

that are similar to a rebate agreement described in subsection (b) with a manufacturer for purposes of ensuring the affordability of outpatient prescription drugs in order to provide access to such drugs by residents of a State who are not otherwise eligible for medical assistance under this title; or

''(2) making prior authorization (that satisfies the requirements of subsection (d) and that does not violate any requirements of this title that are designed to ensure access to medically necessary prescribed drugs for individuals enrolled in the State program under this title) a condition of not participating in such a similar rebate agreement.''.

SEC. 207. IMPORTATION OF PRESCRIPTION DRUGS.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804 and inserting the following:

''SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.

''(a) DEFINITIONS.—In this section:

''(1) IMPORTER.—The term 'importer' means a pharmacist or wholesaler.

''(2) PHARMACIST.—The term 'pharmacist' means a person licensed by a State to practice phar-

macy, including the dispensing and selling of prescription drugs.

''(3) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug subject to section 503(b), other than—

''(A) a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

''(B) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

''(C) an infused drug (including a peritoneal dialysis solution);

''(D) an intravenously injected drug; or

''(E) a drug that is inhaled during surgery.

''(4) QUALIFYING LABORATORY.—The term 'qualifying laboratory' means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

''(5) WHOLESALER.—

''(A) IN GENERAL.—The term 'wholesaler' means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A).

''(B) EXCLUSION.—The term 'wholesaler' does not include a person authorized to import drugs under section 801(d)(1).

''(b) REGULATIONS.—The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.

''(c) LIMITATION.—The regulations under subsection (b) shall—

''(1) require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with section 505 (including with respect to being safe and effective for the intended use of the prescription drug), with sections 501 and 502, and with other applicable requirements of this Act;

''(2) require that an importer of a prescription drug under the regulations comply with subsections (d)(1) and (e); and

''(3) contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs.

''(d) INFORMATION AND RECORDS.—

"(1) IN GENERAL.—The regulations under subsection (b) shall require an importer of a prescription drug under subsection (b) to submit to the Secretary the following information and documentation:

"(A) The name and quantity of the active ingredient of the prescription drug.

"(B) A description of the dosage form of the prescription drug.

"(C) The date on which the prescription drug is shipped.

"(D) The quantity of the prescription drug that is shipped.

"(E) The point of origin and destination of the prescription drug.

"(F) The price paid by the importer for the prescription drug.

"(G) Documentation from the foreign seller specifying—

"(i) the original source of the prescription drug; and

"(ii) the quantity of each lot of the prescription drug originally received by the seller from that source.

''(H) The lot or control number assigned to the prescription drug by the manufacturer of the prescription drug.

''(I) The name, address, telephone number, and professional license number (if any) of the importer.

''(J)(i) In the case of a prescription drug that is shipped directly from the first foreign recipient of the prescription drug from the manufacturer:

''(I) Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

''(II) Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient.

''(III)(aa) In the case of an initial imported shipment, documentation demonstrating that each batch of the prescrip-

tion drug in the shipment was statistically sampled and tested for authenticity and degradation.

''(bb) In the case of any subsequent shipment, documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation.

''(ii) In the case of a prescription drug that is not shipped directly from the first foreign recipient of the prescription drug from the manufacturer, documentation demonstrating that each batch in each shipment offered for importation into the United States was statistically sampled and tested for authenticity and degradation.

''(K) Certification from the importer or manufacturer of the prescription drug that the prescription drug—

''(i) is approved for marketing in the United States; and

''(ii) meets all labeling requirements under this Act.

''(L) Laboratory records, including complete data derived from all tests necessary to

ensure that the prescription drug is in compliance with established specifications and standards.

''(M) Documentation demonstrating that the testing required by subparagraphs (J) and (L) was conducted at a qualifying laboratory.

''(N) Any other information that the Secretary determines is necessary to ensure the protection of the public health.

''(2) MAINTENANCE BY THE SECRETARY.—The Secretary shall maintain information and documentation submitted under paragraph (1) for such period of time as the Secretary determines to be necessary.

''(e) TESTING.—The regulations under subsection (b) shall require—

''(1) that testing described in subparagraphs (J) and (L) of subsection (d)(1) be conducted by the importer or by the manufacturer of the prescription drug at a qualified laboratory;

''(2) if the tests are conducted by the importer—

''(A) that information needed to—

''(i) authenticate the prescription drug being tested; and

''(ii) confirm that the labeling of the prescription drug complies with labeling requirements under this Act;

be supplied by the manufacturer of the prescription drug to the pharmacist or wholesaler; and

''(B) that the information supplied under subparagraph (A) be kept in strict confidence and used only for purposes of testing or otherwise complying with this Act; and

''(3) may include such additional provisions as the Secretary determines to be appropriate to provide for the protection of trade secrets and commercial or financial information that is privileged or confidential.

''(f) REGISTRATION OF FOREIGN SELLERS.—Any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for importation into the United States shall register with the Secretary the name and place of business of the establishment.

''(g) SUSPENSION OF IMPORTATION.—The Secretary shall require that importations of a specific prescription drug or importations by a specific importer under subsection (b) be immediately suspended on discovery of a

pattern of importation of the prescription drugs or by the importer that is counterfeit or in violation of any requirement under this section, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b).

''(h) APPROVED LABELING.—The manufacturer of a prescription drug shall provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug.

''(i) PROHIBITION OF DISCRIMINATION.—

''(1) IN GENERAL.—It shall be unlawful for a manufacturer of a prescription drug to discriminate against, or cause any other person to discriminate against, a pharmacist or wholesaler that purchases or offers to purchase a prescription drug from the manufacturer or from any person that distributes a prescription drug manufactured by the drug manufacturer.

''(2) DISCRIMINATION.—For the purposes of paragraph (1), a manufacturer of a prescription drug shall be considered to discriminate against a pharmacist or wholesaler if the manufacturer enters into a contract for sale of a prescription drug, places

a limit on supply, or employs any other measure, that has the effect of—

''(A) providing pharmacists or wholesalers access to prescription drugs on terms or conditions that are less favorable than the terms or conditions provided to a foreign purchaser (other than a charitable or humanitarian organization) of the prescription drug; or

''(B) restricting the access of pharmacists or wholesalers to a prescription drug that is permitted to be imported into the United States under this section.

''(j) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, section 801(d)(1) continues to apply to a prescription drug that is donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian organization (including the United Nations and affiliates) or to a government of a foreign country.

''(k) WAIVER AUTHORITY FOR IMPORTATION BY INDIVIDUALS.—

''(1) DECLARATIONS.—Congress declares that in the enforcement against individuals of the prohibition of importation of prescription drugs and devices, the Secretary should—

"(A) focus enforcement on cases in which the importation by an individual poses a significant threat to public health; and

"(B) exercise discretion to permit individuals to make such importations in circumstances in which—

"(i) the importation is clearly for personal use; and

"(ii) the prescription drug or device imported does not appear to present an unreasonable risk to the individual.

"(2) WAIVER AUTHORITY.—

"(A) IN GENERAL.—The Secretary may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate.

"(B) GUIDANCE ON CASE-BY-CASE WAIVERS.—The Secretary shall publish, and update as necessary, guidance that accurately describes circumstances in which the Secretary will consistently grant waivers on a case-by-case basis under subparagraph (A), so that individuals

may know with the greatest practicable degree of certainty whether a particular importation for personal use will be permitted.

''(3) DRUGS IMPORTED FROM CANADA.—In particular, the Secretary shall by regulation grant individuals a waiver to permit individuals to import into the United States a prescription drug that—

''(A) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply;

''(B) is accompanied by a copy of a valid prescription;

''(C) is imported from Canada, from a seller registered with the Secretary;

''(D) is a prescription drug approved by the Secretary under chapter V;

''(E) is in the form of a final finished dosage that was manufactured in an establishment registered under section 510; and

''(F) is imported under such other conditions as the Secretary determines to be necessary to ensure public safety.

''(l) STUDIES; REPORTS.—

"(1) BY THE INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMY OF SCIENCES.—

"(A) STUDY.—

"(i) IN GENERAL.—The Secretary shall request that the Institute of Medicine of the National Academy of Sciences conduct a study of—

"(I) importations of prescription drugs made under the regulations under subsection (b); and

"(II) information and documentation submitted under subsection (d).

"(ii) REQUIREMENTS.—In conducting the study, the Institute of Medicine shall—

"(I) evaluate the compliance of importers with the regulations under subsection (b);

"(II) compare the number of shipments under the regulations under subsection (b) during the study period that are determined to be counterfeit, misbranded, or adulterated, and compare that number with the number of shipments made during

the study period within the United States that are determined to be counterfeit, misbranded, or adulterated; and

''(III) consult with the Secretary, the United States Trade Representative, and the Commissioner of Patents and Trademarks to evaluate the effect of importations under the regulations under subsection (b) on trade and patent rights under Federal law.

''(B) REPORT.—Not later than 2 years after the effective date of the regulations under subsection (b), the Institute of Medicine shall submit to Congress a report describing the findings of the study under subparagraph (A).

''(2) BY THE COMPTROLLER GENERAL.—

''(A) STUDY.—The Comptroller General of the United States shall conduct a study to determine the effect of this section on the price of prescription drugs sold to consumers at retail.

''(B) REPORT.—Not later than 18 months after the effective date of the regulations under subsection (b), the Comptroller General of the United States shall submit to Congress a report

describing the findings of the study under subparagraph (A).

''(m) CONSTRUCTION.—Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs, other than with respect to section 801(d)(1) as provided in this section.

''(n) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section.''.

(b) CONFORMING AMENDMENTS.—The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 301(aa) (21 U.S.C. 331(aa)), by striking ''covered product in violation of section 804'' and inserting ''prescription drug in violation of section 804''; and

(2) in section 303(a)(6) (21 U.S.C. 333(a)(6)), by striking ''covered product pursuant to section 804(a)'' and inserting ''prescription drug under section 804(b)''.

SEC. 208. PEDIATRIC LABELING OF DRUGS AND BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505A the following:

"SEC. 505B. PEDIATRIC LABELING OF DRUGS AND BIOLOGICAL PRODUCTS.

"(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

"(1) IN GENERAL.—A person that submits an application (or supplement to an application)—

"(A) under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration; or

"(B) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration;

shall submit with the application the assessments described in paragraph (2).

"(2) ASSESSMENTS.—

"(A) IN GENERAL.—The assessments referred to in paragraph (1) shall contain data, gathered using appropriate formulations, that are adequate—

"(i) to assess the safety and effectiveness of the drug, or the biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), for

the claimed indications in all relevant pediatric subpopulations; and

''(ii) to support dosing and administration for each pediatric subpopulation for which the drug, or the biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), is safe and effective.

''(B) SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DRUG OR BIOLOGICAL PRODUCT.—If the course of the disease and the effects of the drug are sufficiently similar in adults and pediatric patients, the Secretary may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies.

''(3) DEFERRAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until a specified date after approval of the drug or issuance of the license for a biological product if—

''(A) the Secretary finds that—

''(i) the drug or biological product is ready for approval for use in adults before pediatric studies are complete; or

''(ii) pediatric studies should be delayed until additional safety or effectiveness data have been collected; and

''(B) the applicant submits to the Secretary—

''(i) a certified description of the planned or ongoing studies; and

''(ii) evidence that the studies are being conducted or will be conducted with due diligence.

''(4) WAIVERS.—

''(A) FULL WAIVER.—At the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments under this subsection if—

''(i) necessary studies are impossible or highly impractical;

''(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups; or

''(iii) the drug or biological product—

''(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

''(II) is not likely to be used in a substantial number of pediatric patients.

''(B) PARTIAL WAIVER.—At the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments under this subsection with respect to a specific pediatric age group if—

''(i) necessary studies are impossible or highly impractical;

''(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

''(iii) the drug or biological product—

''(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

''(II) is not likely to be used in a substantial number of pediatric patients in that age group; or

''(iv) the applicant demonstrates that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

''(C) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

''(b) MARKETED DRUGS AND BIOLOGICAL PRODUCTS.—

''(1) IN GENERAL.—After providing notice and an opportunity for written response and a meeting, which may include an advisory committee meeting, the Secretary may by order require the holder of an approved application relating to a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262) to submit by a specified date the assessments described in subsection (a) if the Secretary finds that—

"(A)(i) the drug or biological product is used for a substantial number of pediatric patients for the labeled indications; and

"(ii) the absence of adequate labeling could pose significant risks to pediatric patients; or

"(B)(i) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; and

"(ii) the absence of adequate labeling could pose significant risks to pediatric patients.

"(2) WAIVERS.—

"(A) FULL WAIVER.—At the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments under this subsection if—

"(i) necessary studies are impossible or highly impractical; or

"(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups.

"(B) PARTIAL WAIVER.—At the request of an applicant, the Secretary shall grant a partial

waiver, as appropriate, of the requirement to submit assessments under this subsection with respect to a specific pediatric age group if—

"(i) necessary studies are impossible or highly impractical;

"(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

"(iii)(I) the drug or biological product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group;

"(II) the drug or biological product is not likely to be used in a substantial number of pediatric patients in that age group; and

"(III) the absence of adequate labeling could not pose significant risks to pediatric patients; or

"(iv) the applicant demonstrates that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

"(C) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

"(3) RELATIONSHIP TO OTHER PEDIATRIC PROVISIONS.—

"(A) NO ASSESSMENT WITHOUT WRITTEN REQUEST.—No assessment may be required under paragraph (1) for a drug subject to an approved application under section 505 unless—

"(i) the Secretary has issued a written request for related pediatric studies under section 505A(d) or section 409I of the Public Health Service Act; and

"(ii)(I) if the request was made under section 505A(d)—

"(aa) the recipient of the written request does not agree to the request; or

"(bb) the Secretary does not receive a response as specified under section 505A(d)(4)(A); or

"(II) if the request was made under section 409I of the Public Health Service Act—

"(aa) the recipient of the written request does not agree to the request; or

"(bb) the Secretary does not receive a response as specified under section 409I(c)(2) of that Act.

"(B) NO EFFECT ON OTHER AUTHORITY.—Nothing in this subsection shall be construed to alter any requirement under section 505A(d)(4) or section 409I of the Public Health Service Act. Subject to paragraph (2)(A), nothing in this subsection, section 505A(d)(4), or section 409I or 499 of the Public Health Service Act shall be construed to preclude the Secretary from exercising the authority of the Secretary under this subsection.

"(c) FAILURE TO SUBMIT ASSESSMENTS.—If a person fails to submit a supplemental application containing the information or request for approval of a pediatric for-

mulation described in subsection (a) or (b) within the time specified by the Secretary, the drug or biological product may be considered by the Secretary to be misbranded and subject to enforcement actions accordingly (except that the drug or biological product shall not be subject to action under section 303), and the failure shall not be the basis for a proceeding to withdraw approval for a drug under section 505(e) or revoke the license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262).

''(d) MEETINGS.—The Secretary shall meet at appropriate times in the investigational new drug process with the sponsor to discuss background information that the sponsor shall submit on plans and timelines for pediatric studies, or any planned request for waiver or deferral of pediatric studies.

(b) CONFORMING AMENDMENTS.—

(1) Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) is amended in the second sentence—

(A) by striking ''and (F)'' and inserting ''(F)''; and

(B) by striking the period at the end and inserting '', and (G) any assessments required under section 505B.''.

(2) Section 505A(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(h)) is amended—

(A) in the subsection heading, by striking ''REGULATIONS'' and inserting ''PEDIATRIC STUDY REQUIREMENTS''; and

(B) by striking ''pursuant to regulations promulgated by the Secretary'' and inserting ''by a provision of law (including a regulation) other than this section''.

(3) Section 351(a)(2) of the Public Health Service Act (42 U.S.C. 262(a)(2)) is amended—

(A) by redesignating subparagraph (B) as subparagraph (C); and

(B) by inserting after subparagraph (A) the following:

''(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act.''.

(c) FINAL RULE.—Except to the extent that the final rule is inconsistent with the amendment made by subsection (a), the final rule promulgating regulations requiring manufacturers to assess the safety and effectiveness

of new drugs and biological products in pediatric patients (63 Fed. Reg. 66632 (December 2, 1998)), shall be considered to implement the amendment made by subsection (a).

(d) NO EFFECT ON AUTHORITY.—Section 505B of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) does not affect whatever existing authority the Secretary of Health and Human Services has to require pediatric assessments regarding the safety and efficacy of drugs and biological products in addition to the assessments required under that section. The authority, if any, of the Secretary of Health and Human Services regarding specific populations other than the pediatric population shall be exercised in accordance with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) as in effect on the day before the date of enactment of this Act.

(e) TECHNICAL CORRECTION.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended in subparagraphs (A) and (B) of subsection (b)(2) and subparagraphs (A) and (B) of subsection (c)(2) by striking ''505(j)(4)(B)'' and inserting ''505(j)(5)(B)''.

SEC. 209. REPORT.

(a) IN GENERAL.—Not later than the date that is 5 years after the date of enactment of this Act, the Fed-

eral Trade Commission shall submit to Congress a report describing the extent to which implementation of the amendments made by this title—

(1) has enabled products to come to market in a fair and expeditious manner, consistent with the rights of patent owners under intellectual property law; and

(2) has promoted lower prices of drugs and greater access to drugs through price competition.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $5,000,000.

SEC. 210. CONFORMING AND TECHNICAL AMENDMENTS.

(a) SECTION 505.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (a), by striking ''(a) No person'' and inserting ''(a) IN GENERAL.—No person'';

(2) in subsection (b)—

(A) by striking ''(b)(1) Any person'' and inserting the following:

''(b) APPLICATIONS.—

''(1) REQUIREMENTS.—

''(A) IN GENERAL.—Any person'';

(B) in paragraph (1)—

(i) in the second sentence—

(I) by redesignating subparagraphs (A) through (F) as clauses (i) through (vi), respectively, and adjusting the margins appropriately;

(II) by striking ''Such persons'' and inserting the following:

''(B) INFORMATION TO BE SUBMITTED WITH APPLICATION.—A person that submits an application under subparagraph (A)''; and

(III) by striking ''application'' and inserting ''application—'';

(ii) by striking the third through fifth sentences; and

(iii) in the sixth sentence—

(I) by striking ''The Secretary'' and inserting the following:

''(C) GUIDANCE.—The Secretary''; and

(II) by striking ''clause (A)'' and inserting ''subparagraph (B)(i)''; and

(C) in paragraph (2)—

(i) by striking ''clause (A) of such paragraph'' and inserting ''paragraph (1)(B)(i)'';

(ii) in subparagraphs (A) and (B), by striking ''paragraph (1) or''; and

(iii) in subparagraph (B)—

(I) by striking ''paragraph (1)(A)'' and inserting ''paragraph (1)(B)(i)''; and

(II) by striking ''patent'' each place it appears and inserting ''claim'';

(3) in subsection (c)—

(A) in paragraph (3)—

(i) in subparagraph (A)—

(I) by striking ''(A) If the applicant'' and inserting the following:

''(A) CLAUSE (i) OR (ii) CERTIFICATION.—If the applicant''; and

(II) by striking ''may'' and inserting ''shall'';

(ii) in subparagraph (B)—

(I) by striking ''(B) If the applicant'' and inserting the following:

''(B) CLAUSE (iii) CERTIFICATION.—If the applicant''; and

(II) by striking ''may'' and inserting ''shall'';

(iii) by redesignating subparagraph (D) as subparagraph (E); and

(iv) in subparagraph (E) (as redesignated by clause (iii)), by striking ''clause (A) of subsection (b)(1)'' each place it appears and inserting ''subsection (b)(1)(B)(i)''; and

(B) by redesignating paragraph (4) as paragraph (5); and

(4) in subsection (j)—

(A) in paragraph (2)(A)—

(i) in clause (vi), by striking ''clauses (B) through ((F)'' and inserting ''subclauses (ii) through (vi) of subsection (b)(1)'';

(ii) in clause (vii), by striking ''(b) or''; and

(iii) in clause (viii)—

(I) by striking ''(b) or''; and

(II) by striking ''patent'' each place it appears and inserting ''claim''; and

(B) in paragraph (5)—

(i) in subparagraph (B)—

(I) in clause (i)—

(aa) by striking ''(i) If the applicant'' and inserting the following:

''(i) SUBCLAUSE (I) OR (II) CERTIFICATION.—If the applicant''; and

(bb) by striking ''may'' and inserting ''shall'';

(II) in clause (ii)—

(aa) by striking ''(ii) If the applicant'' and inserting the following:

''(i) SUBCLAUSE (III) CERTIFICATION.—If the applicant''; and

(bb) by striking ''may'' and inserting ''shall'';

(III) in clause (iii), by striking ''(2)(B)(i)'' each place it appears and inserting ''(2)(B)''; and

(IV) in clause (v) (as redesignated by section 4(a)(1)(B)), by striking ''continuing'' and inserting ''containing''; and

(ii) by redesignating subparagraphs (C) and (D) as subparagraphs (E) and (F), respectively.

(b) SECTION 505A.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i)—

(A) by striking ''(c)(3)(D)(ii)'' each place it appears and inserting ''(c)(3)(E)(ii)''; and

(B) by striking ''(j)(5)(D)(ii)'' each place it appears and inserting ''(j)(5)(F)(ii)'';

(2) in subsections (b)(1)(A)(ii) and (c)(1)(A)(ii)—

(A) by striking ''(c)(3)(D)'' each place it appears and inserting ''(c)(3)(E)''; and

(B) by striking ''(j)(5)(D)'' each place it appears and inserting ''(j)(5)(F)'';

(3) in subsections (e) and (l)—

(A) by striking ''505(c)(3)(D)'' each place it appears and inserting ''505(c)(3)(E)''; and

(B) by striking ''505(j)(5)(D)'' each place it appears and inserting ''505(j)(5)(F)''; and

(4) in subsection (k), by striking ''505(j)(5)(B)(iv)'' and inserting ''505(j)(5)(B)(v)''.

(c) SECTION 527.—Section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)) is

amended in the second sentence by striking ''505(c)(2)'' and inserting ''505(c)(1)(B)''.

○