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108TH CONGRESS
1ST SESSION

H. R. 1199

To amend titles XVIII and XIX of the Social Security Act to provide for a voluntary Medicare prescription medicine benefit, to provide greater access to affordable pharmaceuticals, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 11, 2003

Mr. RANGEL (for himself, Mr. DINGELL, Mr. HOLDEN, Mr. BROWN of Ohio, Mr. STARK, Mr. WAXMAN, Mr. PALLONE, Mr. ABERCROMBIE, Mr. ACKERMAN, Mr. ALEXANDER, Mr. ALLEN, Mr. ANDREWS, Ms. BALDWIN, Mr. BECERRA, Mr. BELL, Ms. BERKLEY, Mr. BERMAN, Mr. BERRY, Mr. BISHOP of New York, Mr. BOSWELL, Mr. BOUCHER, Ms. CORRINE BROWN of Florida, Mrs. CAPPS, Mr. CAPUANO, Mr. CARDIN, Mr. CARDOZA, Mrs. CHRISTENSEN, Mr. CLAY, Mr. CONYERS, Mr. CROWLEY, Mr. CUMMINGS, Mr. DAVIS of Illinois, Mr. DELAHUNT, Ms. DELAURO, Mr. DEUTSCH, Mr. DICKS, Mr. DOYLE, Mr. ENGEL, Mr. EVANS, Mr. FARR, Mr. FILNER, Mr. FRANK of Massachusetts, Mr. FROST, Mr. GEPHARDT, Mr. GORDON, Mr. GREEN of Texas, Mr. GRIJALVA, Mr. HASTINGS of Florida, Mr. HINCHEY, Mr. HINOJOSA, Mr. HOEFFEL, Mr. HOYER, Ms. JACKSON-LEE of Texas, Mr. JEFFERSON, Ms. EDDIE BERNICE JOHNSON of Texas, Mr. KANJORSKI, Ms. KAPTUR, Mr. KENNEDY of Rhode Island, Mr. KILDEE, Ms. KILPATRICK, Mr. KLECZKA, Mr. LAMPSON, Mr. LANGEVIN, Mr. LANTOS, Mr. LARSON of Connecticut, Ms. LEE, Mr. LEVIN, Mr. LEWIS of Georgia, Mrs. LOWEY, Mr. LYNCH, Mrs. MALONEY, Mr. MARKEY, Mr. MATSUI, Ms. MCCARTHY of Missouri, Ms. MCCOLLUM, Mr. MCDERMOTT, Mr. MCGOVERN, Mr. MCNULTY, Mr. MEEHAN, Mr. MEEK of Florida, Mr. MEEKS of New York, Ms. MILLENDER-MCDONALD, Mr. GEORGE MILLER of California, Mr. MOLLOHAN, Mr. MURTHA, Mr. NADLER, Mrs. NAPOLITANO, Mr. NEAL of Massachusetts, Ms. NORTON, Mr. OBERSTAR, Mr. OLVER, Mr. ORTIZ, Mr. OWENS, Ms. PELOSI, Mr. RAHALL, Mr. REYES, Mr. RODRIGUEZ, Mr. ROSS, Ms. ROYBAL-ALLARD, Mr. RUSH, Ms. LINDA T. SÁNCHEZ of California, Mr. SANDERS, Mr. SANDLIN, Ms. SCHAKOWSKY, Mr. SCHIFF, Mr. SCOTT of Virginia, Mr. SERRANO, Ms. SLAUGHTER, Ms. SOLIS, Mr. STRICKLAND, Mr. THOMPSON of Mississippi, Mr. TIERNEY, Mr. TOWNS, Mrs. JONES of Ohio, Mr. UDALL of New Mexico, Mr. VAN HOLLEN, Mr. VISCLOSKY, Ms. WATSON, Mr. WEINER, Mr. WEXLER, Ms. WOOLSEY, and Mr. WYNN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee

on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend titles XVIII and XIX of the Social Security Act to provide for a voluntary Medicare prescription medicine benefit, 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; REFERENCES IN ACT; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Medicare Rx Drug Benefit and Discount Act of 2003''.

(b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as otherwise specifically provided, whenever in this Act an amendment is expressed in terms of an amendment to or repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Social Security Act.

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

TITLE I—MEDICARE PRESCRIPTION MEDICINE BENEFIT

SEC. 101. VOLUNTARY MEDICARE OUTPATIENT PRESCRIPTION MEDICINE PROGRAM.

(a) IN GENERAL.—Title XVIII (42 U.S.C. 1395 et seq.) is amended—

(1) by redesignating section 1859 and part D as section 1858 and part E, respectively; and

(2) by inserting after part C the following new part:

''PART D—VOLUNTARY PRESCRIPTION MEDICINE BENEFIT FOR THE AGED AND DISABLED

''MEDICARE OUTPATIENT PRESCRIPTION MEDICINE BENEFIT

''SEC. 1859. Subject to the succeeding provisions of this part, the voluntary prescription medicine benefit program under this part provides the following:

''(1) PREMIUM.—The monthly premium is $25.

''(2) DEDUCTIBLE.—The annual deductible is $100.

''(3) COINSURANCE.—The coinsurance is 20 percent.

''(4) OUT-OF-POCKET LIMIT.—The annual limit on out-of-pocket spending on covered medicines is $2,000.

''NEGOTIATING FAIR PRICES WITH PHARMACEUTICAL MANUFACTURERS

''SEC. 1859A. (a) AUTHORITY TO NEGOTIATE PRICES WITH MANUFACTURERS.—The Secretary shall, consistent with the requirements of this part and the goals of providing quality care and containing costs under this part, negotiate contracts with manufacturers of covered outpatient prescription medicines that provide for the maximum prices that may be charged to individuals enrolled under this part by participating pharmacies for dispensing such medicines to such individuals.

''(b) PROMOTION OF BREAKTHROUGH MEDICINES.—In conducting negotiations with manufacturers under this part, the Secretary shall take into account the goal of promoting the development of breakthrough medicines (as defined in section 1859H(b)).

''CONTRACT AUTHORITY

''SEC. 1859B. (a) CONTRACT AUTHORITY.—

''(1) IN GENERAL.—The Secretary is responsible for the administration of this part and shall enter into contracts with appropriate pharmacy contractors on a national or regional basis to administer the benefits under this part.

''(2) PROCEDURES.—The Secretary shall establish procedures under which the Secretary—

''(A) accepts bids submitted by entities to serve as pharmacy contractors under this part in a region or on a national basis;

''(B) awards contracts to such contractors to administer benefits under this part to eligible beneficiaries in the region or on a national basis; and

''(C) provides for the termination (and nonrenewal) of a contract in the case of a contractor's failure to meet the requirements of the contract and this part.

''(3) 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.

''(4) TERMS AND CONDITIONS.—Such contracts shall have such terms and conditions as the Secretary shall specify and shall be for such terms (of at least 2 years, but not to exceed 5 years) as the Secretary shall specify consistent with this part.

''(5) USE OF PHARMACY CONTRACTORS IN PRICE NEGOTIATIONS.—Such contracts shall require the contractor involved to negotiate contracts with manufacturers that provide for maximum prices for covered outpatient prescription medicines that are lower than the maximum prices negotiated under section 1859A(a), if applicable. The price reductions shall be passed on to eligible beneficiaries and the Secretary shall hold the contractor accountable for meeting performance requirements with respect to price reductions and limiting price increases.

''(6) AREA FOR CONTRACTS.—

''(A) REGIONAL BASIS.—

''(i) IN GENERAL.—Except as provided in clause (ii) and subject to subpara-

graph (B), the contract entered into between the Secretary and a pharmacy contractor shall require the contractor to administer the benefits under this part in a region determined by the Secretary under subparagraph (B) or on a national basis.

''(ii) PARTIAL REGIONAL BASIS.—

''(I) IN GENERAL.—If determined appropriate by the Secretary, the Secretary may permit the benefits to be administered in a partial region determined appropriate by the Secretary.

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

''(B) DETERMINATION.—

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

''(I) take into account the number of individuals enrolled under this part in an area in order to encourage participation by pharmacy contractors; and

''(II) ensure that there are at least 10 different regions in the United States.

''(ii) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—The determination of administrative areas under this paragraph shall not be subject to administrative or judicial review.

''(7) SUBMISSION OF BIDS.—

''(A) SUBMISSION.—

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

''(ii) BID THAT COVERS MULTIPLE AREAS.—The Secretary shall permit an en-

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

"(B) REQUIRED INFORMATION.—The bids described in subparagraph (A) shall include—

"(i) a proposal for the estimated prices of covered outpatient prescription medicines and the projected annual increases in such prices, including the additional reduction in price negotiated below the Secretary's maximum price and differentials between preferred and nonpreferred prices, if applicable;

"(ii) a statement regarding the amount that the entity will charge the Secretary for administering the benefits under the contract;

"(iii) a statement regarding whether the entity will reduce the applicable coinsurance percentage pursuant to section 1859E(a)(1)(A)(ii) and if so, the amount of such reduction and how such reduction is tied to the performance requirements described in subsection (c)(4)(A)(ii);

''(iv) a detailed description of the performance requirements for which the administrative fee of the entity will be subject to risk pursuant to subsection (c)(4)(A)(ii);

''(v) a detailed description of access to pharmacy services provided by the entity, including information regarding whether the pharmacy contractor will use a preferred pharmacy network, and, if so, how the pharmacy contractor will ensure access to pharmacies that choose to be outside of that network, and whether there will be increased cost-sharing for beneficiaries if they obtain medicines at such pharmacies;

''(vi) a detailed description of the procedures and standards the entity will use for—

''(I) selecting preferred prescription medicines; and

''(II) determining when and how often the list of preferred prescription medicines should be modified;

''(vii) a detailed description of any ownership or shared financial interests with pharmaceutical manufacturers, phar-

macies, and other entities involved in the administration or delivery of benefits under this part as proposed in the bid;

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

''(ix) 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.

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

''(8) AWARDING OF CONTRACTS.—

''(A) NUMBER OF CONTRACTS.—The Secretary shall, consistent with the requirements of this part and the goals of providing quality care and of containing costs under this part, award in a competitive manner at least 2 contracts to administer benefits under this part in each area specified under paragraph (6), unless only 1 pharmacy contractor submitting a bid meets the

minimum standards specified under this part and by the Secretary.

''(B) DETERMINATION.—In determining which of the pharmacy contractors 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 relevant factors, with respect to—

''(i) how well the contractor meets such minimum standards;

''(ii) the amount that the contractor will charge the Secretary for administering the benefits under the contract;

''(iii) the performance standards established under subsection (c)(2) and performance requirements for which the administrative fee of the entity will be subject to risk pursuant to subsection (c)(4)(A)(ii);

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

''(v) factors relating to benefits, quality and performance, beneficiary cost-sharing, and consumer satisfaction;

''(vi) past performance and prior experience of the contractor in administering a prescription medicine benefit program;

''(vii) effectiveness of the contractor in containing costs through pricing incentives and utilization management; and

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

''(C) EXCEPTION TO CONFLICT OF INTEREST RULES.—In awarding contracts with pharmacy contractors 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—

''(i) is not inconsistent with the—

''(I) purposes of the programs under this part; or

''(II) best interests of beneficiaries enrolled under this part; and

"(ii) 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.

"(D) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—The determination of the Secretary to award or not award a contract to a pharmacy contractor under this part shall not be subject to administrative or judicial review.

"(9) ACCESS TO BENEFITS IN CERTAIN AREAS.—

"(A) AREAS NOT COVERED BY CONTRACTS.—The Secretary shall develop procedures for the provision of covered outpatient prescription medicines 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.

"(B) 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.

''(b) QUALITY, FINANCIAL, AND OTHER STANDARDS AND PROGRAMS.—In consultation with appropriate pharmacy contractors, pharmacists, and health care professionals with expertise in prescribing, dispensing, and the appropriate use of prescription medicines, the Secretary shall establish standards and programs for the administration of this part to ensure appropriate prescribing, dispensing, and utilization of outpatient medicines under this part, to avoid adverse medicine reactions, and to continually reduce errors in the delivery of medically appropriate covered benefits. The Secretary shall not award a contract to a pharmacy contractor under this part unless the Secretary finds that the contractor agrees to comply with such standards and programs and other terms and conditions as the Secretary shall specify. The standards and programs under this subsection shall be applied to any administrative agreements described in subsection (a) the Secretary enters into. Such standards and programs shall include the following:

''(1) ACCESS.—

''(A) IN GENERAL.—The pharmacy contractor shall ensure that covered outpatient prescription medicines are accessible and convenient to eligible beneficiaries enrolled under this part for whom benefits are administered by the

pharmacy contractor, including by offering the services 24 hours a day and 7 days a week for emergencies.

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

''(C) GUARANTEED ACCESS TO MEDICINES IN RURAL AND HARD-TO-SERVE AREAS.—The Secretary shall ensure that all beneficiaries have guaranteed access to the full range of pharmaceuticals under this part, and shall give special attention to access, pharmacist counseling, and delivery in rural and hard-to-serve areas, including through the use of incentives such as bonus payments to retail pharmacists in rural areas and extra payments to the pharmacy contractor for the cost of rapid delivery of pharmaceuticals and any other actions necessary.

''(D) PREFERRED PHARMACY NETWORKS.—

"(i) IN GENERAL.—If a pharmacy contractor uses a preferred pharmacy network to deliver benefits under this part, such network shall meet minimum access standards established by the Secretary.

"(ii) STANDARDS.—In establishing standards under clause (i), the Secretary shall take into account reasonable distances to pharmacy services in both urban and rural areas.

"(E) ADHERENCE TO NEGOTIATED PRICES.—The pharmacy contractor shall have in place procedures to assure compliance of pharmacies with the requirements of subsection (d)(3)(C) (relating to adherence to negotiated prices).

"(F) CONTINUITY OF CARE.—

"(i) IN GENERAL.—The pharmacy contractor shall ensure 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 1859C(b)(3)), the contractor will continue to provide cov-

erage under this part to such beneficiary until the beneficiary enrolls and receives such coverage with another pharmacy contractor under this part or, if eligible, with a Medicare+Choice organization.

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

''(2) ENROLLEE GUIDELINES.—The pharmacy contractor shall, consistent with State law, apply guidelines for counseling enrollees regarding—

''(A) the proper use of covered outpatient prescription medicine; and

''(B) interactions and contra-indications.

''(3) EDUCATION.—The pharmacy contractor shall apply methods to identify and educate providers, pharmacists, and enrollees regarding—

''(A) instances or patterns concerning the unnecessary or inappropriate prescribing or dispensing of covered outpatient prescription medicines;

''(B) instances or patterns of substandard care;

''(C) potential adverse reactions to covered outpatient prescription medicines;

''(D) inappropriate use of antibiotics;

''(E) appropriate use of generic products; and

''(F) the importance of using covered outpatient prescription medicines in accordance with the instruction of prescribing providers.

''(4) COORDINATION.—The pharmacy contractor shall coordinate with State prescription medicine programs, other pharmacy contractors, pharmacies, and other relevant entities as necessary to ensure appropriate coordination of benefits with respect to enrolled individuals when such individual is traveling outside the home service area, and under such other circumstances as the Secretary may specify.

''(5) COST DATA.—

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

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

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

''(ii) make such prescription medicine cost data available for review and audit by the Secretary; and

''(iii) certify that the prescription medicine cost data are current, accurate, and complete, and reflect all discounts obtained by the pharmacist or physician in the purchasing of covered outpatient prescription medicines.

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

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

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

''(B) utilization of benefits under this part;

''(C) marketing and advertising expenditures related to enrolling and retaining individuals under this part; and

''(D) grievances and appeals.

''(7) RECORDS AND AUDITS.—The pharmacy contractor shall maintain adequate records related to the administration of benefits under this part and afford the Secretary access to such records for auditing purposes.

''(8) APPROVAL OF MARKETING MATERIAL AND APPLICATION FORMS.—The pharmacy contractor shall comply with requirements of section 1851(h) (relating to marketing material and application forms) with respect to this part in the same manner as such requirements apply under part C, except that the provisions of paragraph (4)(A) of such section shall not apply with respect to discounts or rebates provided in accordance with this part.

''(c) INCENTIVES FOR COST AND UTILIZATION MANAGEMENT AND QUALITY IMPROVEMENT.—

''(1) IN GENERAL.—The Secretary shall include in a contract awarded under subsection (b) with a pharmacy contractor such incentives for cost and utilization management and quality improvement as the Secretary may deem appropriate. The contract may provide financial or other incentives to encourage greater savings to the program under this part.

''(2) PERFORMANCE STANDARDS.—The Secretary shall provide for performance standards (which may include monetary bonuses if the standards are met and penalties if the standards are not met), including standards relating to the time taken to answer member and pharmacy inquiries (written or by telephone), the accuracy of responses, claims processing accuracy, online system availability, appeal procedure turnaround time, system availability, the accuracy and timeliness of reports, and level of beneficiary satisfaction.

''(3) OTHER INCENTIVES.—Such incentives under this subsection may also include—

''(A) financial incentives under which savings derived from the substitution of generic and other preferred multi-source medicines in

lieu of nongeneric and nonpreferred medicines are made available to pharmacy contractors, pharmacies, beneficiaries, and the Federal Medicare Prescription Medicine Trust Fund; and

''(B) any other incentive that the Secretary deems appropriate and likely to be effective in managing costs or utilization or improving quality that does not reduce the access of beneficiaries to medically necessary covered outpatient medicines.

''(4) REQUIREMENTS FOR PROCEDURES.—

''(A) IN GENERAL.—The Secretary shall establish procedures for making payments to each pharmacy contractor with a contract under this part for the administration of the benefits under this part. The procedures shall provide for the following:

''(i) ADMINISTRATIVE PAYMENT.—Payment of administrative fees for such administration.

''(ii) RISK REQUIREMENT.—An adjustment of a percentage (determined under subparagraph (B)) of the administrative fee payments made to a pharmacy

contractor to ensure that the contractor, in administering the benefits under this part, pursues performance requirements established by the Secretary, including the following:

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

"(II) QUALITY CLINICAL CARE.—The contractor provides such beneficiaries with quality clinical care, as measured by such factors as providing notification to such beneficiaries and to providers in order to prevent adverse drug reactions and reduce medication errors and specific clinical sug-

gestions to improve health and patient and prescriber education as appropriate.

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

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

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

"(ii) 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 paragraph at a level that jeopardizes the ability of a pharmacy contractor to administer the benefits under this part or administer such benefits in a quality manner.

''(C) RISK ADJUSTMENT OF PAYMENTS BASED ON ENROLLEES IN PLAN.—To the extent that a pharmacy contractor is at risk under this paragraph, the procedures established under this paragraph may include a methodology for risk adjusting the payments made to such contractor based on the differences in actuarial risk of different enrollees being served if the Secretary determines such adjustments to be necessary and appropriate.

''(d) AUTHORITY RELATING TO PHARMACY PARTICIPATION.—

''(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, a pharmacy contractor may establish consistent with this part conditions for the participation of pharmacies, including conditions relating to quality (including reduction of medical errors) and technology.

''(2) AGREEMENTS WITH PHARMACIES.—Each pharmacy contractor shall enter into a participation agreement with any pharmacy that meets the requirements of this subsection and section 1859E to furnish covered outpatient prescription medicines to individuals enrolled under this part.

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

''(A) APPLICABLE REQUIREMENTS.—The pharmacy shall meet (and throughout the contract 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 such a pharmacy contractor) shall establish concerning the quality of, and enrolled individuals' access to, pharmacy services under this part. Such standards shall require the pharmacy—

''(i) not to refuse to dispense covered outpatient prescription medicines to any individual enrolled under this part;

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

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

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

''(C) ADHERENCE TO NEGOTIATED PRICES.—(i) The total charge for each medicine dispensed by the pharmacy to an enrolled individual under this part, without regard to whether the individual is financially responsible for any or all of such charge, shall not exceed the price negotiated under section 1859A(a) or, if lower, negotiated under subsection (a)(5) (or, if less, the retail price for the medicine involved) with respect to such medicine plus a reasonable dispensing fee determined contractually with the pharmacy contractor.

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

''(D) ADDITIONAL REQUIREMENTS.—The pharmacy shall meet such additional contract requirements as the applicable pharmacy contractor specifies under this section.

''(4) 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.

''ELIGIBILITY; VOLUNTARY ENROLLMENT; COVERAGE

''SEC. 1859C. (a) ELIGIBILITY.—Each individual who is entitled to hospital insurance benefits under part A or is eligible to be enrolled in the medical insurance program under part B is eligible to enroll in accordance with this section for outpatient prescription medicine benefits under this part.

''(b) VOLUNTARY ENROLLMENT.—

''(1) IN GENERAL.—An individual may enroll under this part only in such manner and form as may be prescribed by regulations, and only during

an enrollment period prescribed in or under this subsection.

"(2) INITIAL ENROLLMENT PERIOD.—

"(A) INDIVIDUALS CURRENTLY COVERED.—In the case of an individual who satisfies subsection (a) as of November 1, 2005, the initial general enrollment period shall begin on August 1, 2005, and shall end on March 1, 2006.

"(B) INDIVIDUAL COVERED IN FUTURE.—In the case of an individual who first satisfies subsection (a) on or after November 1, 2005, the individual's initial enrollment period shall begin on the first day of the third month before the month in which such individual first satisfies such paragraph and shall end seven months later. The Secretary shall apply rules similar to the rule described in the second sentence of section 1837(d).

"(3) SPECIAL ENROLLMENT PERIODS (WITHOUT PREMIUM PENALTY).—

"(A) EMPLOYER COVERAGE AT TIME OF INITIAL GENERAL ENROLLMENT PERIOD.—In the case of an individual who—

"(i) at the time the individual first satisfies subsection (a) is enrolled in a group health plan (including continuation coverage) that provides outpatient prescription medicine coverage by reason of the individual's (or the individual's spouse's) current (or, in the case of continuation coverage, former) employment status, and

"(ii) has elected not to enroll (or to be deemed enrolled) under this subsection during the individual's initial enrollment period,

there shall be a special enrollment period of 6 months beginning with the first month that includes the date of the individual's (or individual's spouse's) retirement from or termination of current employment status with the employer that sponsors the plan, or, in the case of continuation coverage, that includes the date of termination of such coverage, or that includes the date the plan substantially terminates outpatient prescription medicine coverage.

"(B) DROPPING OF RETIREE PRESCRIPTION MEDICINE COVERAGE.—In the case of an individual who—

"(i) at the time the individual first satisfies subsection (a) is enrolled in a group health plan that provides outpatient prescription medicine coverage other than by reason of the individual's (or the individual's spouse's) current employment; and

"(ii) has elected not to enroll (or to be deemed enrolled) under this subsection during the individual's initial enrollment period,

there shall be a special enrollment period of 6 months beginning with the first month that includes the date that the plan substantially terminates outpatient prescription medicine coverage and ending 6 months later.

"(C) LOSS OF MEDICARE+CHOICE PRESCRIPTION MEDICINE COVERAGE.—In the case of an individual who is enrolled under part C in a Medicare+Choice plan that provides prescription medicine benefits, if such enrollment is terminated because of the termination or reduction in service area of the plan, there shall be a spe-

cial enrollment period of 6 months beginning with the first month that includes the date that such plan is terminated or such reduction occurs and ending 6 months later.

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

''(i) satisfies subsection (a);

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

''(iii) is not otherwise enrolled under this subsection at the time of such loss of eligibility,

there shall be a special enrollment period specified by the Secretary of not less than 6 months beginning with the first month that includes the date that the individual loses such eligibility.

''(4) LATE ENROLLMENT WITH PREMIUM PENALTY.—The Secretary shall permit an individual who satisfies subsection (a) to enroll other than during the initial enrollment period under paragraph (2) or a special enrollment period under paragraph (3).

But, in the case of such an enrollment, the amount of the monthly premium of the individual is subject to an increase under section 1859C(e)(1).

''(5) INFORMATION.—

''(A) IN GENERAL.—The Secretary shall broadly distribute information to individuals who satisfy subsection (a) on the benefits provided under this part. The Secretary shall periodically make available information on the cost differentials to enrollees for the use of generic medicines and other medicines.

''(B) TOLL-FREE HOTLINE.—The Secretary shall maintain a toll-free telephone hotline (which may be a hotline already used by the Secretary under this title) for purposes of providing assistance to beneficiaries in the program under this part, including responding to questions concerning coverage, enrollment, benefits, grievances and appeals procedures, and other aspects of such program.

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

''(c) COVERAGE PERIOD.—

''(1) IN GENERAL.—The period during which an individual is entitled to benefits under this part (in this subsection referred to as the individual's 'coverage period') shall begin on such a date as the Secretary shall establish consistent with the type of coverage rules described in subsections (a) and (e) of section 1838, except that in no case shall a coverage period begin before January 1, 2006. No payments may be made under this part with respect to the expenses of an individual unless such expenses were incurred by such individual during a period which, with respect to the individual, is a coverage period.

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

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

''(e) LATE ENROLLMENT PENALTIES; PAYMENT OF PREMIUMS.—

''(1) LATE ENROLLMENT PENALTY.—

"(A) IN GENERAL.—In the case of a late enrollment described in subsection (b)(4), subject to the succeeding provisions of this paragraph, the Secretary shall establish procedures for increasing the amount of the monthly premium under this part applicable to such enrollee by an amount that the Secretary determines is actuarially sound for each such period.

"(B) PERIODS TAKEN INTO ACCOUNT.—For purposes of calculating any 12-month period under subparagraph (A), there shall be taken into account months of lapsed coverage in a manner comparable to that applicable under the second sentence of section 1839(b).

"(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 enrollee can demonstrate that the enrollee was covered under a group health plan that provides coverage of the cost of prescription medicines whose actuarial value (as defined by

the Secretary) to the enrollee equals or exceeds the actuarial value of the benefits provided to an individual enrolled in the outpatient prescription medicine benefit program under this part.

''(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 the date on which the plan terminates or reduces its service area (in a manner that results in termination of enrollment), ceases to provide, or reduces the value of the prescription medicine coverage under such plan to below the value of the coverage provided under the program under this part.

''(2) INCORPORATION OF PREMIUM PAYMENT AND GOVERNMENT CONTRIBUTIONS PROVISIONS.—The provisions of sections 1840 and 1844(a)(1) shall apply to enrollees under this part in the same manner as they apply to individuals 65 years of age or older enrolled under part B. For purposes of this subsection, any reference in a section referred to in

a previous subsection to the Federal Supplementary Medical Insurance Trust Fund is deemed a reference to the Federal Medicare Prescription Medicine Trust Fund.

''(f) ELECTION OF PHARMACY CONTRACTOR TO ADMINISTER BENEFITS.—The Secretary shall establish a process whereby each individual enrolled under this part and residing in a region may elect the pharmacy contractor that will administer the benefits under this part with respect to the individual. Such process shall permit the individual to make an initial election and to change such an election on at least an annual basis and under such other circumstances as the Secretary shall specify.

''PROVISION OF, AND ENTITLEMENT TO, BENEFITS

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

''(1) COVERED OUTPATIENT PRESCRIPTION MEDICINE BENEFITS.—Entitlement to have payment made on the individual's behalf for covered outpatient prescription medicines.

''(2) LIMITATION ON COST-SHARING FOR PART B OUTPATIENT PRESCRIPTION MEDICINES.—

''(A) IN GENERAL.—Once an enrollee has incurred aggregate countable cost-sharing (as

defined in subparagraph (B)) equal to the stop-loss limit specified in subsection (c)(4) for expenses in a year, entitlement to the elimination of cost-sharing otherwise applicable under part B for additional expenses incurred in the year for outpatient prescription medicines or biologicals for which payment is made under part B.

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

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

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

"(b) COVERED OUTPATIENT PRESCRIPTION MEDICINE DEFINED.—

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

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

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

"(ii)(I) 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 medicine, and

(II) 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)(I) 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, simi-

lar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a medicine, and

(II) 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 medicine under such section because the Secretary has determined that the medicine is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling.

''(B) 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.

''(C) Insulin approved under appropriate Federal law, and needles, syringes, and dispos-

able pumps for the administration of such insulin.

''(D) A prescribed medicine or biological product that would meet the requirements of subparagraph (A) or (B) but that is available over-the-counter in addition to being available upon prescription, but only if the particular dosage form or strength prescribed and required for the individual is not available over-the-counter.

''(E) Smoking cessation agents (as specified by the Secretary).

''(2) EXCLUSION.—The term 'covered outpatient prescription medicine' does not include—

''(A) medicines or classes of medicines, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2), other than subparagraph (E) thereof (relating to smoking cessation agents), as the Secretary may specify and does not include such other medicines, classes, and uses as the Secretary may specify consistent with the goals of providing quality care and containing costs under this part;

"(B) except as provided in paragraphs (1)(D) and (1)(E), any product which may be distributed to individuals without a prescription;

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

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

"(c) PAYMENT OF BENEFITS.—

"(1) COVERED OUTPATIENT PRESCRIPTION MEDICINES.—There shall be paid from the Federal Medicare Prescription Medicine Trust Fund, in the case of each enrollee who incurs expenses for medicines with respect to which benefits are payable under this part under subsection (a)(1), amounts equal to the sum of—

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

"(B) a reasonable dispensing fee.

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

''(2) DEDUCTIBLE.—The amount of payment under paragraph (1) for expenses incurred in a year, beginning with 2006, shall be reduced by an annual deductible equal to the amount specified in section 1859(2) (subject to adjustment under paragraph (8)). Only expenses for countable cost-sharing (as defined in subsection (a)(2)(B)) shall be taken into account in applying this paragraph.

''(3) COINSURANCE.—

''(A) IN GENERAL.—The amount of payment under paragraph (1) for expenses incurred in a year shall be further reduced (subject to the stop-loss limit under paragraph (4)) by coinsurance as provided under this paragraph.

''(B) PREFERRED MEDICINES.—The coinsurance under this paragraph in the case of a preferred medicine (including a medicine treated as a preferred medicine under paragraph (5)), is equal to 20 percent of the price applicable under paragraph (1)(A) (or such lower percentage as may be provided for under section 1859E(a)(1)(A)(ii)). In this part, the term 'pre-

ferred medicine' means, with respect to medicines classified within a therapeutic class, those medicines which have been designated as a preferred medicine by the Secretary or the pharmacy contractor involved with respect to that class and (in the case of a nongeneric medicine) with respect to which a contract has been negotiated under this part.

''(C) NONPREFERRED MEDICINES.—The coinsurance under this paragraph in the case of a nonpreferred medicine that is not treated as a preferred medicine under paragraph (5) is equal to the sum of—

''(i) 20 percent of the price for lowest price preferred medicine that is within the same therapeutic class; and

''(ii) the amount by which—

''(I) the price at which the nonpreferred medicine is made available to the enrollee; exceeds

''(II) the price of such lowest price preferred medicine.

''(4) NO COINSURANCE ONCE OUT-OF-POCKET EXPENDITURES EQUAL STOP-LOSS LIMIT.—Once an enrollee has incurred aggregate countable cost-shar-

ing under paragraph (3) (including cost-sharing under part B attributable to outpatient prescription drugs or biologicals) equal to the amount specified in section 1859(4) (subject to adjustment under paragraph (8)) for expenses in a year—

"(A) there shall be no coinsurance under paragraph (3) for additional expenses incurred in the year involved; and

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

"(5) APPEALS RIGHTS RELATING TO COVERAGE OF NONPREFERRED MEDICINES.—

"(A) PROCEDURES REGARDING THE DETERMINATION OF MEDICINES THAT ARE MEDICALLY NECESSARY.—Each pharmacy contractor shall have in place procedures on a case-by-case basis to treat a nonpreferred medicine as a preferred medicine under this part if the preferred medicine is determined to be not as effective for the enrollee or to have significant adverse effect on the enrollee. Such procedures shall require that such determinations are based on profes-

sional medical judgment, the medical condition of the enrollee, and other medical evidence.

"(B) PROCEDURES REGARDING DENIALS OF CARE.—Such contractor shall have 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 nonpreferred medicines) 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;

"(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 re-

solved 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

''(iii) that enrollees are provided with information regarding the appeals procedures under this part at the time of enrollment with a pharmacy contractor under this part and upon request thereafter.

''(6) TRANSFER OF FUNDS TO COVER COSTS OF PART B PRESCRIPTION MEDICINE CATASTROPHIC BENEFIT.—With respect to benefits described in subsection (a)(2), there shall be transferred from the Federal Medicare Prescription Medicine Trust Fund to the Federal Supplementary Medical Insurance Trust Fund amounts equivalent to the elimination of cost-sharing described in such subsection.

''(7) PERMITTING APPLICATION UNDER PART B OF NEGOTIATED PRICES.—For purposes of making payment under part B for medicines that would be covered outpatient prescription medicines but for the exclusion under subparagraph (B) or (C) of subsection (b)(2), the Secretary may elect to apply the

payment basis used for payment of covered outpatient prescription medicines under this part instead of the payment basis otherwise used under such part, if it results in a lower cost to the program.

''(8) INFLATION ADJUSTMENT.—

''(A) IN GENERAL.—With respect to expenses incurred in a year after 2006—

''(i) the deductible under paragraph (2) is equal to the deductible determined under such paragraph (or this subparagraph) for the previous year increased by the percentage increase in per capita program expenditures (as estimated in advance for the year involved under subparagraph (B)); and

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

The Secretary shall adjust such percentage increase in subsequent years to take into account misestimations made of the per capita program expenditures under clauses (i) and (ii) in pre-

vious years. Any increase under this subparagraph that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

''(B) ESTIMATION OF INCREASE IN PER CAPITA PROGRAM EXPENDITURES.—The Secretary shall before the beginning of each year (beginning with 2007) estimate the percentage increase in average per capita aggregate expenditures from the Federal Medicare Prescription Medicine Trust Fund for the year involved compared to the previous year.

''(C) RECONCILIATION.—The Secretary shall also compute (beginning with 2008) the actual percentage increase in such aggregate expenditures in order to provide for reconciliation of deductibles, stop-loss limits, and premiums under the second sentence of subparagraph (A) and under section 1859D(d)(2).

''(d) AMOUNT OF PREMIUMS.—

''(1) MONTHLY PREMIUM RATE IN 2006.—The monthly premium rate in 2006 for prescription medicine benefits under this part is the amount specified in section 1859(1).

''(2) INFLATION ADJUSTMENT FOR SUBSEQUENT YEARS.—The monthly premium rate for a

year after 2006 for prescription medicine benefits under this part is equal to the monthly premium rate for the previous year under this subsection increased by the percentage increase in per capita program expenditures (as estimated in advance for the year involved under subsection (c)(8)(B)). The Secretary shall adjust such percentage in subsequent years to take into account misestimations made of the per capita program expenditures under the previous sentence in previous years. Any increase under this paragraph that is not a multiple of $1 shall be rounded to the nearest multiple of $1.

''ADMINISTRATION; QUALITY ASSURANCE

''SEC. 1859E. (a) RULES RELATING TO PROVISION OF BENEFITS.—

''(1) PROVISION OF BENEFITS.—

''(A) IN GENERAL.—In providing benefits under this part, the Secretary (directly or through the contracts with pharmacy contractors) shall employ mechanisms to provide benefits appropriately and efficiently, and those mechanisms may include—

''(i) the use of—

''(I) price negotiations (consistent with subsection (b));

''(II) reduced coinsurance (below 20 percent) to encourage the utilization of appropriate preferred medicines; and

''(III) methods to reduce medication errors and encourage appropriate use of medications; and

''(ii) permitting pharmacy contractors, as approved by the Secretary, to make exceptions to section 1859D(c)(3)(C) (relating to cost-sharing for non-preferred medicines) to secure best prices for enrollees so long as the payment amount under section 1859D(c)(1) does not equal zero.

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

''(i) such incentives are designed not to result in any increase in the aggregate expenditures under the Federal Medicare Prescription Medicine Trust Fund; and

"(ii) a beneficiary's coinsurance shall be no greater than 20 percent in the case of a preferred medicine (including a non-preferred medicine treated as a preferred medicine under section 1859D(c)(5)).

"(2) CONSTRUCTION.—Nothing in this part shall preclude the Secretary or a pharmacy contractor from—

"(A) educating prescribing providers, pharmacists, and enrollees about medical and cost benefits of preferred medicines;

"(B) requesting prescribing providers to consider a preferred medicine prior to dispensing of a nonpreferred medicine, as long as such request does not unduly delay the provision of the medicine;

"(C) using mechanisms to encourage enrollees under this part to select cost-effective medicines or less costly means of receiving or administering medicines, including the use of therapeutic interchange programs, disease management programs, and notification to the beneficiary that a more affordable generic medicine equivalent was not selected by the prescribing

provider and a statement of the lost cost savings to the beneficiary;

''(D) using price negotiations to achieve reduced prices on covered outpatient prescription medicines, including new medicines, medicines for which there are few therapeutic alternatives, and medicines of particular clinical importance to individuals enrolled under this part; and

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

''(b) PRICE NEGOTIATIONS PROCESS.—

''(1) REQUIREMENTS WITH RESPECT TO PREFERRED MEDICINES.—Negotiations of contracts with manufacturers with respect to covered outpatient prescription medicines under this part shall be conducted in a manner so that—

''(A) there is at least a contract for a medicine within each therapeutic class (as defined by the Secretary in consultation with such Medicare Prescription Medicine Advisory Committee);

''(B) if there is more than 1 medicine available in a therapeutic class, there are con-

tracts for at least 2 medicines within such class unless determined clinically inappropriate in accordance with standards established by the Secretary; and

''(C) if there are more than 2 medicines available in a therapeutic class, there is a contract for at least 2 medicines within such class and a contract for generic medicine substitute if available unless determined clinically inappropriate in accordance with standards established by the Secretary.

''(2) ESTABLISHMENT OF THERAPEUTIC CLASSES.—The Secretary, in consultation with the Medicare Prescription Medicine Advisory Committee (established under section 1859H), shall establish for purposes of this part therapeutic classes and assign to such classes covered outpatient prescription medicines.

''(3) DISCLOSURE CONCERNING PREFERRED MEDICINES.—The Secretary shall provide, through pharmacy contractors or otherwise, for—

''(A) disclosure to current and prospective enrollees and to participating providers and pharmacies in each service area a list of the preferred medicines and differences in applica-

ble cost-sharing between such medicines and nonpreferred medicines; and

''(B) advance disclosure to current enrollees and to participating providers and pharmacies in each service area of changes to any such list of preferred medicines and differences in applicable cost-sharing.

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

''(c) CONFIDENTIALITY.—The Secretary shall ensure that the confidentiality of individually identifiable health information relating to the provision of benefits under this part is protected, consistent with the standards for the privacy of such information promulgated by the Secretary under the Health Insurance Portability and Accountability Act of 1996, or any subsequent comprehensive and more protective set of confidentiality standards enacted into law or promulgated by the Secretary. Nothing in this subsection shall be construed as preventing the coordination of data with a State prescription medicine program so long as such program has in place confidentiality standards

that are equal to or exceed the standards used by the Secretary.

''(d) FRAUD AND ABUSE SAFEGUARDS.—The Secretary, through the Office of the Inspector General, is authorized and directed to issue regulations establishing appropriate safeguards to prevent fraud and abuse under this part. Such safeguards, at a minimum, should include compliance programs, certification data, audits, and recordkeeping practices. In developing such regulations, the Secretary shall consult with the Attorney General and other law enforcement and regulatory agencies.

''FEDERAL MEDICARE PRESCRIPTION MEDICINE TRUST FUND

''SEC. 1859F. (a) ESTABLISHMENT.—There is hereby created on the books of the Treasury of the United States a trust fund to be known as the 'Federal Medicare Prescription Medicine Trust Fund' (in this section referred to as the 'Trust Fund'). The Trust Fund 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, such fund as provided in this part.

''(b) APPLICATION OF SMI TRUST FUND PROVISIONS.—The provisions of subsections (b) through (i) of section 1841 shall apply to this part and the Trust Fund in the same manner as they apply to part B and the Fed-

eral Supplementary Medical Insurance Trust Fund, respectively.

''COMPENSATION FOR EMPLOYERS COVERING RETIREE MEDICINE COSTS

''SEC. 1859G. (a) IN GENERAL.—In the case of an individual who is eligible to be enrolled under this part and is a participant or beneficiary under a group health plan that provides outpatient prescription medicine coverage to retirees the actuarial value of which is not less than the actuarial value of the coverage provided under this part, the Secretary shall make payments to such plan subject to the provisions of this section. Such payments shall be treated as payments under this part for purposes of sections 1859F and 1859C(e)(2). In applying the previous sentence with respect to section 1859C(e)(2), the amount of the Government contribution referred to in section 1844(a)(1)(A) is deemed to be equal to the aggregate amount of the payments made under this section.

''(b) REQUIREMENTS.—To receive payment under this section, a group health plan shall comply with the following requirements:

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

''(2) ANNUAL ASSURANCES AND NOTICE BEFORE TERMINATION.—The sponsor of the plan shall—

''(A) annually attest, and provide such assurances as the Secretary may require, that the coverage offered under the group health plan meets the requirements of this section and will continue to meet such requirements 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 enrollees—

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

''(ii) immediately upon determining that the actuarial value of the prescription medicine benefit under the plan falls below the actuarial value required under subsection (a).

''(3) BENEFICIARY INFORMATION.—The sponsor of the plan shall report to the Secretary, for each calendar quarter for which it seeks a payment under this section, the names and social security numbers of all enrollees described in subsection (a) covered under such plan during such quarter and

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

''(4) AUDITS.—The sponsor or plan seeking payment 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 medicine coverage, the accuracy of payments made, and such other matters as may be appropriate.

''(c) PAYMENT.—

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

''(2) AMOUNT OF PAYMENT.—

''(A) IN GENERAL.—The amount of the payment for a quarter shall approximate, for each such covered individual, 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 average per capita aggregate expenditures, as estimated under section 1859D(c)(8) for the year involved; exceeds

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

''MEDICARE PRESCRIPTION MEDICINE ADVISORY COMMITTEE

''SEC. 1859H. (a) ESTABLISHMENT OF COMMITTEE.—There is established a Medicare Prescription Medicine 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 medicine benefit program under this part; and

''(2) the development of—

''(A) standards required of pharmacy contractors under section 1859D(c)(5) for determining if a medicine is as effective for an enrollee or has a significant adverse effect on an enrollee under this part;

''(B) standards for—

''(i) defining therapeutic classes;

''(ii) adding new therapeutic classes;

''(iii) assigning to such classes covered outpatient prescription medicines; and

''(iv) identifying breakthrough medicines;

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

''(D) procedures for negotiations, and standards for entering into contracts, with manufacturers, including identifying medicines or classes of medicines where Secretarial negotiation is most likely to yield savings under this part significantly above those that which could be achieved by a pharmacy contractor; and

''(E) procedures to ensure that pharmacy contractors with a contract under this part are

in compliance with the requirements under this part.

For purposes of this part, a medicine is a 'breakthrough medicine' if the Secretary, in consultation with the Committee, determines it is a new product that will make a significant and major improvement by reducing physical or mental illness, reducing mortality, or reducing disability, and that no other product is available to beneficiaries that achieves similar results for the same condition. The Committee may consider cost-effectiveness in establishing standards for defining therapeutic classes and assigning drugs to such classes under subparagraph (B).

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

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

''(2) MEMBERSHIP.—

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

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

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

''(ii) 2 shall be chosen to represent practicing nurse practitioners;

''(iii) 4 shall be chosen to represent practicing pharmacists;

''(iv) 1 shall be chosen to represent the Centers for Medicare & Medicaid Services;

''(v) 4 shall be chosen to represent actuaries, pharmacoeconomists, researchers, and other appropriate experts;

''(vi) 1 shall be chosen to represent emerging medicine technologies;

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

''(viii) 1 shall be chosen to represent individuals enrolled under this part.

''(d) TERMS OF APPOINTMENT.—Each member of the Committee shall serve for a term determined appropriate by the Secretary. The terms of service of the members initially appointed shall begin on January 1, 2005.

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

''(f) 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.

''(g) 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.

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

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

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

(b) APPLICATION OF GENERAL EXCLUSIONS FROM COVERAGE.—

(1) APPLICATION TO PART D.—Section 1862(a) (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 MEDICINES NOT EXCLUDED FROM COVERAGE IF APPROPRIATELY PRESCRIBED.—Section 1862(a)(1) (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 medicines covered under part D, which are not prescribed in accordance with such part;''.

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

(A) in section 1851(a)(2)(B) (42 U.S.C. 1395w–21(a)(2)(B)), by striking ''1859(b)(3)'' and inserting ''1858(b)(3)'';

(B) in section 1851(a)(2)(C) (42 U.S.C. 1395w–21(a)(2)(C)), by striking ''1859(b)(2)'' and inserting ''1858(b)(2)'';

(C) in section 1852(a)(1) (42 U.S.C. 1395w–22(a)(1)), by striking ''1859(b)(3)'' and inserting ''1858(b)(3)'';

(D) in section 1852(a)(3)(B)(ii) (42 U.S.C. 1395w–22(a)(3)(B)(ii)), by striking ''1859(b)(2)(B)'' and inserting ''1858(b)(2)(B)'';

(E) in section 1853(a)(1)(A) (42 U.S.C. 1395w–23(a)(1)(A)), by striking ''1859(e)(4)'' and inserting ''1858(e)(4)''; and

(F) in section 1853(a)(3)(D) (42 U.S.C. 1395w–23(a)(3)(D)), by striking ''1859(e)(4)'' and inserting ''1858(e)(4)''.

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

SEC. 102. PROVISION OF MEDICARE OUTPATIENT PRESCRIPTION MEDICINE COVERAGE UNDER THE MEDICARE+CHOICE PROGRAM.

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

''(j) AVAILABILITY OF PRESCRIPTION MEDICINE BENEFITS.—

''(1) IN GENERAL.—Notwithstanding any other provision of this part, each Medicare+Choice organization that makes available a Medicare+Choice plan described in section 1851(a)(2)(A) shall make available such a plan that offers coverage of covered outpatient prescription medicines that is at least actuarially equivalent to the benefits provided under part D. Information respecting such benefits shall be made available in the same manner as information on other benefits provided under this part is made available. Nothing in this paragraph shall be construed as requiring the offering of such coverage separate from coverage that includes benefits under parts A and B.

''(2) TREATMENT OF PRESCRIPTION MEDICINE ENROLLEES.—In the case of a Medicare+Choice eligible individual who is enrolled under part D, the

benefits described in paragraph (1) shall be treated in the same manner as benefits described in part B for purposes of coverage and payment and any reference in this part to the Federal Supplementary Medical Insurance Trust Fund shall be deemed, with respect to such benefits, to be a reference to the Federal Medicare Prescription Medicine Trust Fund.''.

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

(1) by striking ''and'' at the end of clause (xi);

(2) by striking the period at the end of clause (xii) and inserting '', and''; and

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

''(xiii) comply with the standards, and apply the programs, under section 1859B(b) for covered outpatient prescription medicines under the plan.''.

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

(1) in subsection (a)(1)(A), by striking ''and (i)'' and inserting ''(i), and (j)''; and

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

''(j) PAYMENT FOR PRESCRIPTION MEDICINE COVERAGE OPTION.—

''(1) IN GENERAL.—In the case of a Medicare+Choice plan that provides prescription medicine benefits described in section 1851(j)(1), the amount of payment otherwise made to the Medicare+Choice organization offering the plan shall be increased by the amount described in paragraph (2). Such payments shall be made in the same manner and time as the amount otherwise paid, but such amount shall be payable from the Federal Medicare Prescription Medicine Trust Fund.

''(2) AMOUNT.—The amount described in this paragraph is the monthly Government contribution amount computed under section 1859G(c)(2)(B), but subject to adjustment under paragraph (3). Such amount shall be uniform geographically and shall not vary based on the Medicare+Choice payment area involved.

''(3) RISK ADJUSTMENT.—The Secretary shall establish a methodology for the adjustment of the payment amount under this subsection in a manner that takes into account the relative risks for use of

outpatient prescription medicines by Medicare+Choice enrollees. Such methodology shall be designed in a manner so that the total payments under this title (including part D) are not changed as a result of the application of such methodology.''.

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

''(i) APPLICATION TO PRESCRIPTION MEDICINE COVERAGE.—The Secretary shall apply the previous provisions of this section (including the computation of the adjusted community rate) separately with respect to prescription medicine benefits described in section 1851(j)(1).''.

(e) CONFORMING AMENDMENTS.—

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

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

(B) in subsection (i) by inserting ''(and, if applicable, part D)'' after ''parts A and B''.

(2) Section 1852(a)(1)(A) (42 U.S.C. 1395w–22(a)(1)(A)) is amended by inserting ''(and under part D to individuals also enrolled under such part)'' after ''parts A and B''.

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

(A) by striking ''and'' at the end of subparagraph (D);

(B) by striking the period at the end of subparagraph (E) and inserting ''; and''; and

(C) by adding at the end the following:

''(F) the plan for part D benefits guarantees coverage of any specifically named prescription medicine for an enrollee to the extent that it would be required to be covered under part D.

In carrying out subparagraph (F), a Medicare+Choice organization has the same authority to enter into contracts with respect to coverage of preferred medicines as the Secretary has under part D, but subject to an independent contractor appeal or other appeal process that would be applicable to determinations by such a pharmacy contractor consistent with section 1859D(c)(5).''.

(f) LIMITATION ON COST-SHARING.—Section 1854(e) (42 U.S.C. 1395w–24(e)) is amended by adding at the end the following new paragraph:

''(5) LIMITATION ON COST-SHARING.—In no event may a Medicare+Choice organization include

a requirement that an enrollee pay cost-sharing in excess of the cost-sharing otherwise permitted under part D.''.

SEC. 103. MEDIGAP REVISIONS.

(a) REQUIRED COVERAGE OF COVERED OUTPATIENT PRESCRIPTION MEDICINES.—Section 1882(p)(2)(B) (42 U.S.C. 1395ss(p)(2)(B)) is amended by inserting before ''and'' at the end the following: ''including a requirement that an appropriate number of policies provide coverage of medicines which complements but does not duplicate the medicine benefits that beneficiaries are otherwise eligible for benefits under part D of this title (with the Secretary and the National Association of Insurance Commissioners determining the appropriate level of medicine benefits that each benefit package must provide and ensuring that policies providing such coverage are affordable for beneficiaries;''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on January 1, 2006.

(c) TRANSITION PROVISIONS.—

(1) IN GENERAL.—If the Secretary of Health and Human Services identifies a State as requiring a change to its statutes or regulations to conform its regulatory program to the amendments made by this section, the State regulatory program shall not be

considered to be out of compliance with the requirements of section 1882 of the Social Security Act due solely to failure to make such change until the date specified in paragraph (4).

(2) NAIC STANDARDS.—If, within 9 months after the date of enactment of this Act, the National Association of Insurance Commissioners (in this subsection referred to as the ''NAIC'') modifies its NAIC Model Regulation relating to section 1882 of the Social Security Act (referred to in such section as the 1991 NAIC Model Regulation, as subsequently modified) to conform to the amendments made by this section, such revised regulation incorporating the modifications shall be considered to be the applicable NAIC model regulation (including the revised NAIC model regulation and the 1991 NAIC Model Regulation) for the purposes of such section.

(3) SECRETARY STANDARDS.—If the NAIC does not make the modifications described in paragraph (2) within the period specified in such paragraph, the Secretary of Health and Human Services shall make the modifications described in such paragraph and such revised regulation incorporating the modifications shall be considered to be the appropriate regulation for the purposes of such section.

(4) DATE SPECIFIED.—

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

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

(ii) 1 year after the date the NAIC or the Secretary first makes the modifications under paragraph (2) or (3), respectively.

(B) ADDITIONAL LEGISLATIVE ACTION REQUIRED.—In the case of a State which the Secretary identifies as—

(i) requiring State legislation (other than legislation appropriating funds) to conform its regulatory program to the changes made in this section; but

(ii) having a legislature which is not scheduled to meet in 2004 in a legislative session in which such legislation may be considered;

the date specified in this paragraph is the first day of the first calendar quarter beginning after the close of the first legislative session of the

State legislature that begins on or after January 1, 2004. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

SEC. 104. TRANSITIONAL ASSISTANCE FOR LOW INCOME BENEFICIARIES.

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

(1) in subparagraph (A)—

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

(B) by adding ''and'' at the end of clause (ii), and

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

''(iii) premiums under section 1859D(d).'';

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

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

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

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

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

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

''(v)(I) for making medical assistance available for medicare cost-sharing described in section 1905(p)(3)(A)(iii) and medicare cost-sharing described in section 1905(p)(3)(B) and section 1905(p)(3)(C) but only insofar as it relates to benefits provided under part D of title XVIII, subject to section 1905(p)(4), for individuals (other than qualified medicare beneficiaries) who are enrolled under part D of title XVIII and are described in section 1905(p)(1)(B) or would be so described but for the fact that their income exceeds 100 percent, but is less than 150 percent, of the official poverty line (referred to in such section) for a family of the size involved;

''(II) subject to section 1905(p)(4), for individuals (other than qualified medicare bene-

ficiaries and individuals described in subclause (I)) who are enrolled under part D of title XVIII and would be described in section 1905(p)(1)(B) but for the fact that their income exceeds 150 percent, but is less than 175 percent, of the official poverty line (referred to in such section) for a family of the size involved, for making medical assistance available for medicare cost-sharing described in section 1905(p)(3)(A)(iii) and medicare cost-sharing described in section 1905(p)(3)(B) and section 1905(p)(3)(C) but only insofar as it relates to benefits provided under part D of title XVIII, and the assistance for medicare cost-sharing described in section 1905(p)(3)(A)(iii) is reduced (on a sliding scale based on income) from 100 percent to 0 percent as the income increases from 150 percent to 175 percent of such poverty line;''.

(c) FEDERAL FINANCING.—The third sentence of section 1905(b) (42 U.S.C. 1396d(b)) is amended by inserting before the period at the end the following: ''and with respect to amounts expended that are attributable to section 1902(a)(10)(E)(v) (other than for individuals described in section 1905(p)(1)(B))''.

(d) TREATMENT OF TERRITORIES.—

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

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

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

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

''(i) the provisions of paragraph (3) insofar as they relate to section 1859D and the provisions of section 1902(a)(10)(E)(v) shall not apply to residents of such State; and

''(ii) if the State establishes a plan described in subparagraph (B) (for providing medical assistance with respect to the provision of prescription medicines to medicare beneficiaries), the amount otherwise determined under section 1108(f) (as increased under section 1108(g)) for the State shall be increased by the amount specified in subparagraph (C).

''(B) The plan described in this subparagraph is a plan that—

''(i) provides medical assistance with respect to the provision of covered outpatient medicines (as de-

fined in section 1859D(b)) to low-income medicare beneficiaries; and

''(ii) assures that additional amounts received by the State that are attributable to the operation of this paragraph are used only for such assistance.

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

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

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

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

''(I) 2006, is equal to $25,000,000; or

''(II) a subsequent year, is equal to the aggregate amount specified in this clause for the previous year increased by annual percentage increase specified in section 1859D(c)(8)(B) for the year involved.

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

(2) CONFORMING AMENDMENT.—Section 1108(f) (42 U.S.C. 1308(f)) is amended by inserting

''and section 1905(p)(5)(A)(ii)'' after ''Subject to subsection (g)''.

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

(f) EFFECTIVE DATE.—The amendments made by this section apply to medical assistance for premiums and cost-sharing incurred on or after January 1, 2006, with regard to whether regulations to implement such amendments are promulgated by such date.

SEC. 105. EXPANSION OF MEMBERSHIP AND DUTIES OF MEDICARE PAYMENT ADVISORY COMMISSION (MEDPAC).

(a) EXPANSION OF MEMBERSHIP.—

(1) IN GENERAL.—Section 1805(c) (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 medicine 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) (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 prescription medicine benefit program under part D, the following:

''(i) The methodologies used for the management of costs and utilization of prescription medicines.

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

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

''(iv) The methodologies used to ensure access to covered outpatient prescription medicines and to ensure quality in the appropriate dispensing and utilization of such medicines.

''(v) The impact of the program on promoting the development of breakthrough medicines.''.

TITLE II—AFFORDABLE PHARMACEUTICALS

Subtitle A—Greater Access to Affordable Pharmaceuticals

SEC. 201. ACCELERATED GENERIC DRUG COMPETITION.

(a) IN GENERAL.—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)(iv), by striking subclause (II) and inserting the following:

''(II) the earlier of—

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

''(bb) the date of a settlement order or consent decree in such an action signed by a Federal judge that enters a final judgment and includes a finding that the patent that is the subject of the certification is invalid or not infringed;'';

(2) by redesignating subparagraphs (C) and (D) as subparagraphs (E) and (F), respectively; and

(3) by inserting before subparagraph (E) (as so redesignated) the following subparagraph:

''(D)(i) The 180-day period described in subparagraph (B)(iv) shall be forfeited by the previous applicant if—

''(I) the previous applicant fails to market the drug by the later of the date 60 days after the date on which the approval of the application for the drug is made effective under subparagraph (B)(iii) or, if such approval has been made effective, and if an action has been brought against the previous applicant for infringement of a patent subject to a certification under paragraph (2)(A)(vii)(IV), or an action has been brought by the previous applicant for a declaratory judgment that such a patent is invalid or not infringed, the date 60 days after the date of a final decision in such action, if there is no other such action pending by or against the previous applicant; except, however, that either of such dates may be extended due to extraordinary or unusual circumstances, as determined by the Secretary;

''(II) the previous applicant withdraws the application;

''(III) the previous applicant amends the certification from a certification under subclause (IV) of paragraph (2)(A)(vii) to a certification under subclause (III) of such paragraph, either voluntarily or as a result of a settlement or defeat in patent litigation;

''(IV) the previous applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by—

''(aa) a change in the requirements for tentative approval of the application imposed after the date on which the application was filed; or

''(bb) other extraordinary or unusual circumstances, as determined by the Secretary;

''(V) in a case in which, after the date on which the previous application was submitted under this subsection, new patent information is submitted under subsection (c)(2) for the listed drug for a patent for which certification or a method of use statement is required under paragraph (2)(A), the previous applicant fails to submit no later than 60 days from the date the applicant receives notice from the Secretary under paragraph (7)(A)(iii) of the submis-

sion of the new patent information either a certification described in paragraph (2)(A)(vii)(IV) or a statement that the method of use patent does not claim a use for which the applicant is seeking approval under this subsection in accordance with paragraph (2)(A)(viii); except, however, that such date may be extended due to extraordinary or unusual circumstances, as determined by the Secretary; or

''(VI) the previous applicant is determined by the Secretary, after a fair and sufficient hearing and in consultation with the Federal Trade Commission, to have engaged in anticompetitive or collusive conduct, or any other conduct intended to unfairly monopolize the commercial manufacturing of the drug of the application.

''(ii) If under clause (i) the previous applicant referred to in subparagraph (B)(iv) forfeits the 180-day period described in such subparagraph, such period shall become available to the next applicant submitting an application containing a certification under paragraph (2)(A)(vii)(IV) if—

''(I) no action described in subparagraph (B)(iii)(II) was brought against or by the previous applicant, or such an action was brought but did not

result in a final judgment that included a finding that the patent involved is invalid; and

''(II) an action described in subparagraph (B)(iii)(II) is brought against or by the next applicant, and such action results in a final judgment that includes a finding that the patent involved is invalid.

''(iii) The 180-day period described in subparagraph (B)(iv) shall be available only to—

''(I) the previous applicant submitting an application for a drug under this subsection containing a certification described in paragraph (2)(A)(vii)(IV) with respect to any patent; or

''(II) under clause (ii), the next applicant submitting an application for a drug under this subsection containing such a certification with respect to any patent;

even if an application has been submitted for the drug under this subsection containing such a certification with respect to a different patent.

''(iv) The 180-day period described in subparagraph (B)(iv) for an application containing a certification described in paragraph (2)(A)(vii)(IV) shall apply only if an action is brought for infringement of a patent that is the subject of the certification or the applicant brings an ac-

tion (not later than 60 days after the date on which the notice provided under paragraph (2)(B)(ii) was received) against the holder of the approved application for the listed drug.''.

(b) EFFECTIVE DATE.—The amendment made by this section 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)) 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 the enactment of this Act.

SEC. 202. PATENT CERTIFICATION.

(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), by striking clause (iii) and inserting the following:

''(iii)(I) If the applicant made a certification described in paragraph (2)(A)(vii)(IV) and—

''(aa) no action is brought for infringement of a patent that is the subject of the certification before the expiration of the 45-day period beginning on the date on which the notice provided under paragraph (2)(B)(ii) was received; and

''(bb) the applicant does not bring an action for declaratory judgment authorized in subclause (II) before the expiration of the 60-day period beginning on the date on which the notice provided under paragraph (2)(B)(ii) was received;

the approval shall be made effective on the expiration of 60 days after the date on which the notice provided under paragraph (2)(B)(ii) was received, provided none of the conditions for denial of approval in paragraph (4) apply.

''(II) With respect to an applicant who made a certification described in paragraph (2)(A)(vii)(IV), if an action referred to in item (aa) of subclause (I) is brought before the expiration of the period described in such item, or if the applicant brings an action for declaratory judgment of invalidity or noninfringement of such patent (which action is hereby authorized) before the expiration of the period described in item (bb) of such subclause, the approval shall, provided none of the conditions for denial of approval in paragraph (4) apply, be made effective in accordance with the following:

''(aa) If the action is an action referred to in subclause (I)(aa), and neither the holder of

the approved application nor the owner of the patent seek a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale (or both) of the drug, the approval shall be made effective on the expiration of 60 days after the date on which the notice provided under paragraph (2)(B)(ii) was received.

''(bb) If the action is an action referred to in subclause (I)(aa), and such a preliminary injunction is sought and the court denies the motion, the approval shall be made effective on the date on which the court denies the injunction.

''(cc) If neither item (aa) nor (bb) applies, and the holding of the court in the decision in the action is that the patent is invalid or was not infringed, the approval shall be made effective on the date of the decision of the court.

''(dd) If neither item (aa) nor (bb) applies, and the holding of the court in the decision in the action is that the patent was infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code.''; and

(2) by inserting before subparagraph (D) (as added by section 201(a)(3)) the following subparagraph:

''(C) With respect to a civil action described in subparagraph (B)(iii)(II):

''(i) Each of the parties shall reasonably cooperate in expediting the action.

''(ii) If the notice under paragraph (2)(B)(ii) contains an address for the receipt of expedited notification of such an action, the plaintiff shall, on the date the complaint is filed in the court, simultaneously cause a notification of such action to be delivered to such address by the next business day.

''(iii) An action for a declaratory judgment authorized in such subparagraph may not be brought by the applicant until the expiration of 45 days after the date the notice provided under paragraph (2)(B)(ii) was received, except that if information on the patent involved has been published under subsection (c)(2) for at least one year after the date on which the application under this subsection was filed in relation to the listed drug involved, the applicant may immediately bring such an action for declaratory judgment.

''(iv) Any such action shall be brought in the judicial district in which the defendant has its principal place of business or a regular and established place of business.''.

(b) NEW DRUG APPLICATIONS.—Section 505(c)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)) is amended by striking subparagraph (C) and inserting the following:

''(C)(i)(I) If the applicant made a certification described in subsection (b)(2)(A)(iv) and—

''(aa) no action is brought for infringement of a patent that is the subject of the certification before the expiration of the 45-day period beginning on the date on which the notice provided under subsection (b)(3)(B) was received; and

''(bb) the applicant does not bring an action for declaratory judgment authorized in subclause (II) before the expiration of the 60-day period beginning on the date on which the notice provided under subsection (b)(3)(B) was received;

the approval shall be made effective on the expiration of 60 days after the date on which the notice provided under subsection (b)(3)(B) was received,

provided that none of the conditions for refusal of approval in subsection (d) apply.

''(II) With respect to an applicant who made a certification described in subsection (b)(2)(A)(iv), if an action referred to in item (aa) of subclause (I) is brought before the expiration of the period described in such item, or if the applicant brings an action for declaratory judgment of invalidity or noninfringement of such patent (which action is hereby authorized) before the expiration of the period described in item (bb) of such subclause, the approval shall, provided none of the conditions for refusal of approval in subsection (d) apply, be made effective in accordance with the following:

''(aa) If the action is an action referred to in subclause (I)(aa), and neither the holder of the approved application nor the owner of the patent seek a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale (or both) of the drug, the approval shall be made effective on the expiration of 60 days after the date on which the notice provided under subsection (b)(3)(B) was received.

''(bb) If the action is an action referred to in subclause (I)(aa), and such a preliminary injunction is sought and the court denies the motion, the approval shall be made effective on the date on which the court denies the injunction.

''(cc) If neither item (aa) nor (bb) applies, and the holding of the court in the decision in the action is that the patent is invalid or was not infringed, the approval shall be made effective on the date of the decision of the court.

''(dd) If neither item (aa) nor (bb) applies, and the holding of the court in the decision in the action is that the patent was infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code.

''(ii) With respect to a civil action described in clause (i)(II):

''(I) Each of the parties shall reasonably cooperate in expediting the action.

''(II) If the notice under subsection (b)(3)(B) contains an address for the receipt of expedited notification of such an action, the plaintiff shall, on the date the complaint is filed in the court, simultaneously cause a notification

of such action to be delivered to such address by the next business day.

''(III) An action for a declaratory judgment authorized in such clause may not be brought by the applicant until the expiration of 45 days after the date the notice provided under subsection (b)(3)(B) was received, except that if information on the patent involved has been published under paragraph (2) for at least one year after the date on which the application was filed in relation to the drug involved, the applicant may immediately bring such an action for declaratory judgment.

''(IV) Any such action shall be brought in the judicial district in which the defendant has its principal place of business or a regular and established place of business.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall not apply to an application submitted under section 505(b)(1) or 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) before the date of the enactment of this Act.

SEC. 203. ADDITIONAL USES.

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended by adding at the end the following paragraph:''

''(10)(A) A drug for which an application has been submitted or approved under this subsection shall not be considered ineligible for approval under this subsection or misbranded under section 502 on the basis that the labeling of the drug omits a use or any other aspect of labeling when the omitted use or other aspect is protected by patent or by exclusivity under clause (iii) or (iv) of paragraph (5)(D).

''(B) Notwithstanding clauses (iii) and (iv) of paragraph (5)(D), the Secretary may require that the labeling of a drug approved under this subsection that omits a use or other aspect of labeling as described in subparagraph (A) include—

''(i) any statement that the Secretary considers necessary for the safe use of the drug, such as appropriate contraindications, warnings, or precautions; and

''(ii) a statement that, because of marketing exclusivity for a manufacturer, the drug is not labeled for the use.''.

Subtitle B—Notification of Agreements Affecting the Sale or Marketing of Generic Drugs

SEC. 211. DEFINITIONS.

In this subtitle:

(1) AGREEMENT.—The term ''agreement'' means an agreement under section 1 of the Sherman Act (15 U.S.C. 1) or section 5 of the Federal Trade Commission Act (15 U.S.C. 45).

(2) ANTITRUST LAWS.—The term ''antitrust laws'' has the same meaning as in section 1 of the Clayton Act (15 U.S.C. 12), except that such term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section applies to unfair methods of competition.

(3) ANDA.—The term ''ANDA'' means an Abbreviated New Drug Application, as defined under section 505(j) of the Federal Food, Drug and Cosmetic Act.

(4) BRAND NAME DRUG COMPANY.—The term ''brand name drug company'' means a person engaged in the manufacture or marketing of a drug approved under section 505(b) of the Federal Food, Drug and Cosmetic Act.

(5) COMMISSION.—The term ''Commission'' means the Federal Trade Commission.

(6) FDA.—The term ''FDA'' means the United States Food and Drug Administration.

(7) GENERIC DRUG.—The term ''generic drug'' means a product that is the subject of an ANDA.

(8) GENERIC DRUG APPLICANT.—The term ''generic drug applicant'' means a person who has filed or received approval for an ANDA under section 505(j) of the Federal Food, Drug and Cosmetic Act.

(9) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

SEC. 212. NOTIFICATION OF AGREEMENTS AFFECTING THE SALE OR MARKETING OF GENERIC DRUGS.

A brand name drug company and a generic drug applicant that enter into an agreement regarding the sale or manufacture of a generic drug that the Secretary has determined is the therapeutic equivalent of a brand name drug that is manufactured or marketed by that brand name drug company, or for which the generic drug applicant seeks such a determination of therapeutic equivalence, and which agreement could have the effect of limiting the research, development, manufacture, marketing, or selling of a generic drug that has been or could be ap-

proved for sale by the FDA pursuant to an ANDA, shall file with the Commission and the Secretary the text of the agreement, an explanation of the purpose and scope of the agreement, and an explanation of whether the agreement could delay, restrain, limit, or in any way interfere with the production, manufacture, or sale of the generic version of the drug in question.

SEC. 213. FILING DEADLINES.

Any notice, agreement, or other material required to be filed under section 212 shall be filed with the Commission and the Secretary not later than 10 business days after the date the agreement is executed.

SEC. 214. ENFORCEMENT.

(a) CIVIL FINE.—Any person, or any officer, director, or partner thereof, who fails to comply with any provision of this subtitle shall be liable for a civil penalty of not more than $20,000 for each day during which such person is in violation of this subtitle. Such penalty may be recovered in a civil action brought by the United States, or brought by the Commission in accordance with the procedures established in section 16(a)(1) of the Federal Trade Commission Act (15 U.S.C. 56(a)).

(b) COMPLIANCE AND EQUITABLE RELIEF.—If any person, or any officer, director, partner, agent, or employee thereof, fails to comply with the notification re-

quirement under section 212 of this subtitle, the United States district court may order compliance, and may grant such other equitable relief as the court in its discretion determines necessary or appropriate, upon application of the Commission or the Assistant Attorney General.

SEC. 215. RULEMAKING.

The Commission, in consultation with the Secretary, and with the concurrence of the Assistant Attorney General and by rule in accordance with section 553 of title 5, United States Code, consistent with the purposes of this subtitle—

(1) may require that the notice described in section 212 of this subtitle be in such form and contain such documentary material and information relevant to the agreement as is necessary and appropriate to enable the Commission and the Assistant Attorney General to determine whether such agreement may violate the antitrust laws;

(2) may define the terms used in this subtitle;

(3) may exempt classes of persons or agreements from the requirements of this subtitle; and

(4) may prescribe such other rules as may be necessary and appropriate to carry out the purposes of this subtitle.

SEC. 216. EFFECTIVE DATES.

This subtitle shall take effect 90 days after the date of enactment of this Act.

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