II

108TH CONGRESS
2D SESSION

S. 2487

To amend part D of title XVIII of the Social Security Act to ensure that every medicare beneficiary has access to a medicare administered prescription drug plan option, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 2, 2004

Mr. DAYTON introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend part D of title XVIII of the Social Security Act to ensure that every medicare beneficiary has access to a medicare administered prescription drug plan option, and for other purposes.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Right Prescription for Seniors Act of 2004''.

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

SEC. 2. ESTABLISHMENT OF MEDICARE OPERATED PLAN OPTION.

(a) IN GENERAL.—Section 1860D–11(g) of the Social Security Act, as added by section 101(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173), is amended to read as follows:

''(g) MEDICARE OPERATED PLAN OPTION.—

''(1) IN GENERAL.—Separate from the bidding process under subsection (b), the Secretary shall provide for the offering in each PDP region of a medicare operated plan option (as defined in paragraph (4)) and shall enter into negotiations with pharmaceutical manufacturers to reduce the purchase cost of covered part D drugs for eligible part D individuals in accordance with paragraph (2).

''(2) NEGOTIATIONS.—The Secretary shall negotiate with pharmaceutical manufacturers with respect to the purchase price of covered part D drugs and shall encourage the use of more affordable therapeutic equivalents to the extent such practices do not override medical necessity as determined by the prescribing physician. To the extent practicable and consistent with the previous sentence, the Sec-

retary shall implement strategies similar to those used by other Federal purchasers of prescription drugs, and other strategies, to reduce the purchase cost of covered part D drugs.

''(3) MEDICARE OPERATED PLAN OPTION.—For purposes of this part, the term 'medicare operated plan option' means a prescription drug plan that offers coverage similar to the standard prescription drug coverage and access to negotiated prices described in section 1860D–2(a)(1)(A) and does not include any supplemental prescription drug coverage, except that such plan shall provide continuous coverage and shall not have a coverage gap.

''(4) MONTHLY BENEFICIARY PREMIUM.—

''(A) IN GENERAL.—Except as provided in section 1860D–13(b) (relating to late enrollment penalty) and subject to section 1860D–14 (relating to low-income assistance), the monthly beneficiary premium to be charged under the medicare operated plan option shall be—

''(i) for months in 2006, $35; and

''(ii) for months in a subsequent year, the lesser of—

''(I) the amount determined under this paragraph for months in

the previous year, increased by the annual percentage increase described in subparagraph (B) for the year involved; or

"(II) in the case of months in years prior to 2014, the specified amount (as defined in subparagraph (C)).

"(B) ANNUAL PERCENTAGE INCREASE.—The annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in average per capita aggregate expenditures for covered drugs in the United States for beneficiaries under this title, as determined by the Administrator for the 12-month period ending in July of the previous year.

"(C) SPECIFIED AMOUNT.—For purposes of the paragraph, the term 'specified amount' means—

"(i) for months in 2007, $37;

"(ii) for months in 2008, $40;

"(iii) for months in 2009, $43;

"(iv) for months in 2010, $46;

"(v) for months in 2011, $51;

''(vi) for months in 2012, $54; and

''(vii) for months in 2013, $59.

''(5) NO AFFECT ON ACCESS REQUIREMENTS.—The medicare operated plan option shall be in addition to the plans required under subsection (d)(1)''.

(b) CONFORMING AMENDMENTS.—

(1) Section 1860D–3 of the Social Security Act, as added by section 101(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173), is repealed.

(2) Section 1860D–11(f) of the Social Security Act, as added by section 101(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173), is amended—

(A) by striking paragraph (1) and inserting the following:

''(1) CONDITIONS FOR APPROVAL OF LIMITED RISK PLANS.—

''(A) IN GENERAL.—The Secretary may only approve a limited risk plan (as defined in paragraph (4)(A)) for a PDP region if the access requirements under subparagraph (B) would not be met for the region but for the approval of such a plan.

''(B) ENSURING ACCESS TO A CHOICE OF COVERAGE.—

''(i) CHOICE OF AT LEAST TWO PLANS IN EACH AREA.—The Secretary shall ensure that each part D eligible individual has available, consistent with clause (ii), a choice of enrollment in at least 2 qualifying plans (as defined in clause (iii)) in the area in which the individual resides, at least one of which is a prescription drug plan.

''(ii) REQUIREMENT FOR DIFFERENT PLAN SPONSORS.—The requirement in clause (i) is not satisfied with respect to an area if only one entity offers all the qualifying plans in the area.

''(iii) QUALIFYING PLAN DEFINED.—For purposes of this section, the term 'qualifying plan' means—

''(I) a prescription drug plan; or

''(II) an MA–PD plan described in section 1851(a)(2)(A)(i) that provides basic prescription drug coverage or qualified prescription drug coverage that provides supplemental prescrip-

tion drug coverage so long as there is no MA monthly supplemental beneficiary premium applied under the plan, due to the application of a credit against such premium of a rebate under section 1854(b)(1)(C).'';

(B) in paragraph (2)(A), by striking ''section 1860D–3(a)'' and inserting ''paragraph (1)(B)''; and

(C) in subparagraphs (A) and (B) of paragraph (4), by striking ''fallback prescription drug plan'' each place it appears and inserting ''medicare operated plan option''.

(3) Section 1860D–11(h) is amended—

(A) in the heading, by striking ''AND FALLBACK PLANS''; and

(B) by striking the first sentence and inserting the following: ''The Secretary shall submit to Congress an annual report that describes instances in which limited risk plans were offered under subsection (f).''.

(4) Section 1860D–12(b) of the Social Security Act, as added by section 101(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173), is amended—

(A) by striking paragraph (2); and

(B) by redesignating paragraph (3) as paragraph (2).

(5) Section 1860D–15 of the Social Security Act, as added by section 101(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173), is amended by striking subsection (g).

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect as if included in the enactment of section 101(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173).

SEC. 3. NEGOTIATING FAIR PRICES FOR MEDICARE PRESCRIPTION DRUGS.

Section 1860D–11 of the Social Security Act, as added by section 101(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173), is amended by striking subsection (i) (relating to noninterference) and by inserting the following:

''(i) NEGOTIATION OF PRICES WITH MANUFACTURERS.—In order to ensure that beneficiaries enrolled under prescription drug plans and MA–PD plans pay the lowest possible price, the Secretary shall—

''(1) have authority similar to that of other Federal entities that purchase prescription drugs in bulk to negotiate contracts with manufacturers of covered part D drugs, consistent with the requirements and in furtherance of the goals of providing quality care and containing costs under this part; and

''(2) use such authority to negotiate the prices of covered part D drugs furnished to part D eligible individuals under prescription drug plans offered by PDP sponsors under this part.''.

SEC. 4. IMPORTATION OF PRESCRIPTION DRUGS.

Section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384) is amended—

(1) in subsection (a)—

(A) by striking ''The Secretary'' and inserting ''Not later than 180 days after the date of enactment of the Pharmaceutical Market Access Act of 2003, the Secretary''; and

(B) by striking ''pharmacists and wholesalers'' and inserting ''pharmacists, wholesalers, and qualifying individuals'';

(2) in subsection (b)—

(A) by striking paragraph (1) and inserting the following:

''(1) require that each covered product imported under that subsection complies with sections 501, 502, and 505 and other applicable requirements of this Act; and'';

(B) in paragraph (2), by striking '', including subsection (d); and'' and inserting a period; and

(C) by striking paragraph (3);

(3) in subsection (c), by inserting ''by pharmacists and wholesalers (but not qualifying individuals)'' after ''importation of covered products'';

(4) in subsection (d)—

(A) by striking paragraphs (3) and (10);

(B) in paragraph (5), by striking '', including the professional license number of the importer, if any'';

(C) in paragraph (6)—

(i) in subparagraph (C), by inserting ''(if required under subsection (e))'' before the period;

(ii) in subparagraph (D), by inserting ''(if required under subsection (e))'' before the period; and

(iii) in subparagraph (E), by striking ''labeling'';

(D) in paragraph (7)—

(i) in subparagraph (A), by inserting ''(if required under subsection (e))'' before the period; and

(ii) by striking subparagraph (B) and inserting the following:

''(B) Certification from the importer or manufacturer of the product that the product meets all requirements of this Act.''; and

(E) by redesignating paragraphs (4) through (9) as paragraphs (3) through (8), respectively;

(5) by striking subsection (e) and inserting the following:

''(e) TESTING.—

''(1) IN GENERAL.—Subject to paragraph (2), regulations under subsection (a) shall require that testing referred to in paragraphs (5) through (7) of subsection (d) be conducted by the importer of the covered product, unless the covered product is a prescription drug subject to the requirements of section 505B for counterfeit-resistant technologies.

''(2) EXCEPTION.—The testing requirements of paragraphs (5) through (7) of subsection (d) shall

not apply to an importer unless the importer is a wholesaler.'';

(6) in subsection (f), by striking ''or designated by the Secretary, subject to such limitations as the Secretary determines to be appropriate to protect the public health'';

(7) in subsection (g)—

(A) by striking ''counterfeit or''; and

(B) by striking ''and the Secretary determines that the public is adequately protected from counterfeit and violative covered products being imported pursuant to subsection (a)'';

(8) in subsection (i)(1)—

(A) by striking subparagraph (A) and inserting the following:

''(A) STUDY.—

''(i) IN GENERAL.—The Secretary shall conduct, or contract with an entity to conduct, a study on the imports permitted under subsection (a), including consideration of the information received under subsection (d).

''(ii) EVALUATION.—In conducting the study, the Secretary or entity shall—

''(I) evaluate the compliance of importers with regulations under subsection (a), and the incidence of shipments under that subsection, if any, that have been determined to be misbranded or adulterated; and

''(II) determine how that compliance contrasts with the incidence of shipments of prescription drugs transported within the United States that have been determined to be misbranded or adulterated.''; and

(B) in subparagraph (B), by striking ''Not later than 2 years after the effective date of final regulations under subsection (a),'' and inserting ''Not later than 18 months after the date of enactment of the Pharmaceutical Market Access Act of 2003,'';

(9) in subsection (k)(2)—

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

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

"(D) QUALIFYING INDIVIDUAL.—The term 'qualifying individual' means an individual who is not a pharmacist or a wholesaler."; and

(10) by striking subsections (l) and (m).

SEC. 5. LIMITATION ON PRESCRIPTION DRUG BENEFITS OF MEMBERS OF CONGRESS.

(a) LIMITATION ON BENEFITS.—Notwithstanding any other provision of law, the actuarial value of the prescription drug benefits of any Member of Congress enrolled in a health benefits plan under chapter 89 of title 5, United States Code, may not exceed the actuarial value of basic prescription drug coverage (as defined in section 1860D–2(a)(3) of the Social Security Act, as added by section 101(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173)).

(b) REGULATIONS.—The Director of the Office of Personnel Management shall promulgate regulations to carry out this section.

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