111TH CONGRESS
1ST SESSION

S. 330

To amend title XVIII of the Social Security Act to deliver a meaningful benefit and lower prescription drug prices under the Medicare Program.

IN THE SENATE OF THE UNITED STATES

JANUARY 27, 2009

Mr. DURBIN (for himself, Mr. WHITEHOUSE, Mr. AKAKA, Mr. BROWN, and Mr. SANDERS) introduced the following bill; which was read twice and referred to the Committee on Finance

---

A BILL

To amend title XVIII of the Social Security Act to deliver a meaningful benefit and lower prescription drug prices under the Medicare Program.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medicare Prescription Drug Savings and Choice Act of 2009''.

SEC. 2. ESTABLISHMENT OF MEDICARE OPERATED PRESCRIPTION DRUG PLAN OPTION.

(a) IN GENERAL.—Subpart 2 of part D of the Social Security Act is amended by inserting after section 1860D–11 (42 U.S.C. 1395w–111) the following new section:

''MEDICARE OPERATED PRESCRIPTION DRUG PLAN OPTION

''SEC. 1860D–11A. (a) IN GENERAL.—Notwithstanding any other provision of this part, for each year (beginning with 2010), in addition to any plans offered under section 1860D–11, the Secretary shall offer one or more medicare operated prescription drug plans (as defined in subsection (c)) with a service area that consists of the entire United States and shall enter into negotiations in accordance with subsection (b) with pharmaceutical manufacturers to reduce the purchase cost of covered part D drugs for eligible part D individuals who enroll in such a plan.

''(b) NEGOTIATIONS.—Notwithstanding section 1860D–11(i), for purposes of offering a medicare operated prescription drug plan under this section, the Secretary shall negotiate with pharmaceutical manufacturers with respect to the purchase price of covered part D drugs in a Medicare operated prescription drug plan and shall encourage the use of more affordable therapeutic equivalents to the extent such practices do not override medical neces-

sity as determined by the prescribing physician. To the extent practicable and consistent with the previous sentence, the Secretary shall implement strategies similar to those used by other Federal purchasers of prescription drugs, and other strategies, including the use of a formulary and formulary incentives in subsection (e), to reduce the purchase cost of covered part D drugs.

''(c) MEDICARE OPERATED PRESCRIPTION DRUG PLAN DEFINED.—For purposes of this part, the term 'medicare operated prescription drug plan' means a prescription drug plan that offers qualified prescription drug coverage and access to negotiated prices described in section 1860D–2(a)(1)(A). Such a plan may offer supplemental prescription drug coverage in the same manner as other qualified prescription drug coverage offered by other prescription drug plans.

''(d) MONTHLY BENEFICIARY PREMIUM.—

''(1) QUALIFIED PRESCRIPTION DRUG COVERAGE.—The monthly beneficiary premium for qualified prescription drug coverage and access to negotiated prices described in section 1860D–2(a)(1)(A) to be charged under a medicare operated prescription drug plan shall be uniform nationally. Such premium for months in 2010 and each succeeding year shall be based on the average monthly

per capita actuarial cost of offering the medicare operated prescription drug plan for the year involved, including administrative expenses.

''(2) SUPPLEMENTAL PRESCRIPTION DRUG COVERAGE.—Insofar as a medicare operated prescription drug plan offers supplemental prescription drug coverage, the Secretary may adjust the amount of the premium charged under paragraph (1).

''(e) USE OF A FORMULARY AND FORMULARY INCENTIVES.—

''(1) IN GENERAL.—With respect to the operation of a medicare operated prescription drug plan, the Secretary shall establish and apply a formulary (and may include formulary incentives described in paragraph (2)(C)(ii)) in accordance with this subsection in order to—

''(A) increase patient safety;

''(B) increase appropriate use and reduce inappropriate use of drugs; and

''(C) reward value.

''(2) DEVELOPMENT OF INITIAL FORMULARY.—

''(A) IN GENERAL.—In selecting covered part D drugs for inclusion in a formulary. the Secretary shall consider clinical benefit and price.

"(B) ROLE OF AHRQ.—The Director of the Agency for Healthcare Research and Quality shall be responsible for assessing the clinical benefit of covered part D drugs and making recommendations to the Secretary regarding which drugs should be included in the formulary. In conducting such assessments and making such recommendations, the Director shall—

"(i) consider safety concerns including those identified by the Federal Food and Drug Administration;

"(ii) use available data and evaluations, with priority given to randomized controlled trials, to examine clinical effectiveness, comparative effectiveness, safety, and enhanced compliance with a drug regimen;

"(iii) use the same classes of drugs developed by United States Pharmacopeia for this part;

"(iv) consider evaluations made by—

"(I) the Director under section 1013 of Medicare Prescription Drug,

Improvement, and Modernization Act of 2003;

''(II) other Federal entities, such as the Secretary of Veterans Affairs; and

''(III) other private and public entities, such as the Drug Effectiveness Review Project and Medicaid programs; and

''(v) recommend to the Secretary—

''(I) those drugs in a class that provide a greater clinical benefit, including fewer safety concerns or less risk of side-effects, than another drug in the same class that should be included in the formulary;

''(II) those drugs in a class that provide less clinical benefit, including greater safety concerns or a greater risk of side-effects, than another drug in the same class that should be excluded from the formulary; and

''(III) drugs in a class with same or similar clinical benefit for which it would be appropriate for the Sec-

retary to competitively bid (or negotiate) for placement on the formulary.

"(C) CONSIDERATION OF AHRQ RECOMMENDATIONS.—

"(i) IN GENERAL.—The Secretary, after taking into consideration the recommendations under subparagraph (B)(v), shall establish a formulary, and formulary incentives, to encourage use of covered part D drugs that—

"(I) have a lower cost and provide a greater clinical benefit than other drugs;

"(II) have a lower cost than other drugs with same or similar clinical benefit; and

"(III) drugs that have the same cost but provide greater clinical benefit than other drugs.

"(ii) FORMULARY INCENTIVES.—The formulary incentives under clause (i) may be in the form of one or more of the following:

"(I) Tiered copayments.

"(II) Reference pricing.

"(III) Prior authorization.

"(IV) Step therapy.

"(V) Medication therapy management.

"(VI) Generic drug substitution.

"(iii) FLEXIBILITY.—In applying such formulary incentives the Secretary may decide not to impose any cost-sharing for a covered part D drug for which—

"(I) the elimination of cost sharing would be expected to increase compliance with a drug regimen; and

"(II) compliance would be expected to produce savings under part A or B or both.

"(3) LIMITATIONS ON FORMULARY.—In any formulary established under this subsection, the formulary may not be changed during a year, except—

"(A) to add a generic version of a covered part D drug that entered the market;

"(B) to remove such a drug for which a safety problem is found; and

"(C) to add a drug that the Secretary identifies as a drug which treats a condition for which there has not previously been a treatment

option or for which a clear and significant benefit has been demonstrated over other covered part D drugs.

''(4) ADDING DRUGS TO THE INITIAL FORMULARY.—

''(A) USE OF ADVISORY COMMITTEE.—The Secretary shall establish and appoint an advisory committee (in this paragraph referred to as the 'advisory committee')—

''(i) to review petitions from drug manufacturers, health care provider organizations, patient groups, and other entities for inclusion of a drug in, or other changes to, such formulary; and

''(ii) to recommend any changes to the formulary established under this subsection.

''(B) COMPOSITION.—The advisory committee shall be composed of 9 members and shall include representatives of physicians, pharmacists, and consumers and others with expertise in evaluating prescription drugs. The Secretary shall select members based on their knowledge of pharmaceuticals and the Medicare population. Members shall be deemed to be spe-

cial Government employees for purposes of applying the conflict of interest provisions under section 208 of title 18, United States Code, and no waiver of such provisions for such a member shall be permitted.

''(C) CONSULTATION.—The advisory committee shall consult, as necessary, with physicians who are specialists in treating the disease for which a drug is being considered.

''(D) REQUEST FOR STUDIES.—The advisory committee may request the Agency for Healthcare Research and Quality or an academic or research institution to study and make a report on a petition described in subparagraph (A)(ii) in order to assess—

''(i) clinical effectiveness;

''(ii) comparative effectiveness;

''(iii) safety; and

''(iv) enhanced compliance with a drug regimen.

''(E) RECOMMENDATIONS.—The advisory committee shall make recommendations to the Secretary regarding—

''(i) whether a covered part D drug is found to provide a greater clinical benefit,

including fewer safety concerns or less risk of side-effects, than another drug in the same class that is currently included in the formulary and should be included in the formulary;

''(ii) whether a covered part D drug is found to provide less clinical benefit, including greater safety concerns or a greater risk of side-effects, than another drug in the same class that is currently included in the formulary and should not be included in the formulary; and

''(iii) whether a covered part D drug has the same or similar clinical benefit to a drug in the same class that is currently included in the formulary and whether the drug should be included in the formulary.

''(F) LIMITATIONS ON REVIEW OF MANUFACTURER PETITIONS.—The advisory committee shall not review a petition of a drug manufacturer under subparagraph (A)(ii) with respect to a covered part D drug unless the petition is accompanied by the following:

''(i) Raw data from clinical trials on the safety and effectiveness of the drug.

"(ii) Any data from clinical trials conducted using active controls on the drug or drugs that are the current standard of care.

"(iii) Any available data on comparative effectiveness of the drug.

"(iv) Any other information the Secretary requires for the advisory committee to complete its review.

"(G) RESPONSE TO RECOMMENDATIONS.—The Secretary shall review the recommendations of the advisory committee and if the Secretary accepts such recommendations the Secretary shall modify the formulary established under this subsection accordingly. Nothing in this section shall preclude the Secretary from adding to the formulary a drug for which the Director of the Agency for Healthcare Research and Quality or the advisory committee has not made a recommendation.

"(H) NOTICE OF CHANGES.—The Secretary shall provide timely notice to beneficiaries and health professionals about changes to the formulary or formulary incentives.

''(f) INFORMING BENEFICIARIES.—The Secretary shall take steps to inform beneficiaries about the availability of a Medicare operated drug plan or plans including providing information in the annual handbook distributed to all beneficiaries and adding information to the official public Medicare website related to prescription drug coverage available through this part.

''(g) APPLICATION OF ALL OTHER REQUIREMENTS FOR PRESCRIPTION DRUG PLANS.—Except as specifically provided in this section, any Medicare operated drug plan shall meet the same requirements as apply to any other prescription drug plan, including the requirements of section 1860D–4(b)(1) relating to assuring pharmacy access.''.

(b) CONFORMING AMENDMENTS.—

(1) Section 1860D–3(a) of the Social Security Act (42 U.S.C. 1395w–103(a)) is amended by adding at the end the following new paragraph:

''(4) AVAILABILITY OF THE MEDICARE OPERATED PRESCRIPTION DRUG PLAN.—A medicare operated prescription drug plan (as defined in section 1860D–11A(c)) shall be offered nationally in accordance with section 1860D–11A.''.

(2)(A) Section 1860D–3 of the Social Security Act (42 U.S.C. 1395w–103) is amended by adding at the end the following new subsection:

''(c) PROVISIONS ONLY APPLICABLE IN 2006, 2007, 2008, AND 2009.—The provisions of this section shall only apply with respect to 2006, 2007, 2008, and 2009.''.

(B) Section 1860D–11(g) of such Act (42 U.S.C. 1395w–111(g)) is amended by adding at the end the following new paragraph:

''(8) NO AUTHORITY FOR FALLBACK PLANS AFTER 2009.—A fallback prescription drug plan shall not be available after December 31, 2009.''.

(3) Section 1860D–13(c)(3) of such Act (42 U.S.C. 1395w–113(c)(3)) is amended—

(A) in the heading, by inserting ''AND MEDICARE OPERATED PRESCRIPTION DRUG PLANS'' after ''FALLBACK PLANS''; and

(B) by inserting ''or a medicare operated prescription drug plan'' after ''a fallback prescription drug plan''.

(4) Section 1860D–16(b)(1) of such Act (42 U.S.C.1395w–116(b)(1)) is amended—

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

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

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

''(E) payments for expenses incurred with respect to the operation of medicare operated prescription drug plans under section 1860D–11A.''.

(5) Section 1860D–41(a) of such Act (42 U.S.C. 1395w–151(a)) is amended by adding at the end the following new paragraph:

''(19) MEDICARE OPERATED PRESCRIPTION DRUG PLAN.—The term 'medicare operated prescription drug plan' has the meaning given such term in section 1860D–11A(c).''.

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

SEC. 3. IMPROVED APPEALS PROCESS UNDER THE MEDICARE OPERATED PRESCRIPTION DRUG PLAN.

Section 1860D–4(h) of the Social Security Act (42 U.S.C. 1305w–104(h)) is amended by adding at the end the following new paragraph:

''(4) APPEALS PROCESS FOR MEDICARE OPERATED PRESCRIPTION DRUG PLAN.—

''(A) IN GENERAL.—The Secretary shall develop a well-defined process for appeals for denials of benefits under this part under the medicare operated prescription drug plan. Such process shall be efficient, impose minimal administrative burdens, and ensure the timely procurement of non-formulary drugs or exemption from formulary incentives when medically necessary. Medical necessity shall be based on professional medical judgment, the medical condition of the beneficiary, and other medical evidence. Such appeals process shall include—

''(i) an initial review and determination made by the Secretary; and

''(ii) for appeals denied during the initial review and determination, the option of an external review and determination by an independent entity selected by the Secretary.

''(B) CONSULTATION IN DEVELOPMENT OF PROCESS.—In developing the appeals process under subparagraph (A), the Secretary shall consult with consumer and patient groups, as

well as other key stakeholders to ensure the goals described in subparagraph (A) are achieved.''.

○