

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medicare Prescription
5 Drug Savings and Choice Act of 2009”.

1 **SEC. 2. ESTABLISHMENT OF MEDICARE OPERATED PRE-**
2 **SCRIPTION DRUG PLAN OPTION.**

3 (a) IN GENERAL.—Subpart 2 of part D of the Social
4 Security Act is amended by inserting after section 1860D–
5 11 (42 U.S.C. 1395w–111) the following new section:

6 “MEDICARE OPERATED PRESCRIPTION DRUG PLAN
7 OPTION

8 “SEC. 1860D–11A. (a) IN GENERAL.—Notwith-
9 standing any other provision of this part, for each year
10 (beginning with 2010), in addition to any plans offered
11 under section 1860D–11, the Secretary shall offer one or
12 more medicare operated prescription drug plans (as de-
13 fined in subsection (c)) with a service area that consists
14 of the entire United States and shall enter into negotia-
15 tions in accordance with subsection (b) with pharma-
16 ceutical manufacturers to reduce the purchase cost of cov-
17 ered part D drugs for eligible part D individuals who en-
18 roll in such a plan.

19 “(b) NEGOTIATIONS.—Notwithstanding section
20 1860D–11(i), for purposes of offering a medicare operated
21 prescription drug plan under this section, the Secretary
22 shall negotiate with pharmaceutical manufacturers with
23 respect to the purchase price of covered part D drugs in
24 a Medicare operated prescription drug plan and shall en-
25 courage the use of more affordable therapeutic equivalents
26 to the extent such practices do not override medical neces-

1 sity as determined by the prescribing physician. To the
 2 extent practicable and consistent with the previous sen-
 3 tence, the Secretary shall implement strategies similar to
 4 those used by other Federal purchasers of prescription
 5 drugs, and other strategies, including the use of a for-
 6 mulary and formulary incentives in subsection (e), to re-
 7 duce the purchase cost of covered part D drugs.

8 “(c) MEDICARE OPERATED PRESCRIPTION DRUG
 9 PLAN DEFINED.—For purposes of this part, the term
 10 ‘medicare operated prescription drug plan’ means a pre-
 11 scription drug plan that offers qualified prescription drug
 12 coverage and access to negotiated prices described in sec-
 13 tion 1860D–2(a)(1)(A). Such a plan may offer supple-
 14 mental prescription drug coverage in the same manner as
 15 other qualified prescription drug coverage offered by other
 16 prescription drug plans.

17 “(d) MONTHLY BENEFICIARY PREMIUM.—

18 “(1) QUALIFIED PRESCRIPTION DRUG COV-
 19 ERAGE.—The monthly beneficiary premium for
 20 qualified prescription drug coverage and access to
 21 negotiated prices described in section 1860D–
 22 2(a)(1)(A) to be charged under a medicare operated
 23 prescription drug plan shall be uniform nationally.
 24 Such premium for months in 2010 and each suc-
 25 ceeding year shall be based on the average monthly

1 per capita actuarial cost of offering the medicare op-
 2 erated prescription drug plan for the year involved,
 3 including administrative expenses.

4 “(2) SUPPLEMENTAL PRESCRIPTION DRUG COV-
 5 ERAGE.—Insofar as a medicare operated prescrip-
 6 tion drug plan offers supplemental prescription drug
 7 coverage, the Secretary may adjust the amount of
 8 the premium charged under paragraph (1).

9 “(e) USE OF A FORMULARY AND FORMULARY INCEN-
 10 TIVES.—

11 “(1) IN GENERAL.—With respect to the oper-
 12 ation of a medicare operated prescription drug plan,
 13 the Secretary shall establish and apply a formulary
 14 (and may include formulary incentives described in
 15 paragraph (2)(C)(ii)) in accordance with this sub-
 16 section in order to—

17 “(A) increase patient safety;

18 “(B) increase appropriate use and reduce
 19 inappropriate use of drugs; and

20 “(C) reward value.

21 “(2) DEVELOPMENT OF INITIAL FORMULARY.—

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

1 “(B) ROLE OF AHRQ.—The Director of the
2 Agency for Healthcare Research and Quality
3 shall be responsible for assessing the clinical
4 benefit of covered part D drugs and making
5 recommendations to the Secretary regarding
6 which drugs should be included in the for-
7 mulary. In conducting such assessments and
8 making such recommendations, the Director
9 shall—

10 “(i) consider safety concerns including
11 those identified by the Federal Food and
12 Drug Administration;

13 “(ii) use available data and evalua-
14 tions, with priority given to randomized
15 controlled trials, to examine clinical effec-
16 tiveness, comparative effectiveness, safety,
17 and enhanced compliance with a drug regi-
18 men;

19 “(iii) use the same classes of drugs
20 developed by United States Pharmacopeia
21 for this part;

22 “(iv) consider evaluations made by—

23 “(I) the Director under section
24 1013 of Medicare Prescription Drug,

1 Improvement, and Modernization Act
2 of 2003;

3 “(II) other Federal entities, such
4 as the Secretary of Veterans Affairs;
5 and

6 “(III) other private and public
7 entities, such as the Drug Effective-
8 ness Review Project and Medicaid
9 programs; and

10 “(v) recommend to the Secretary—

11 “(I) those drugs in a class that
12 provide a greater clinical benefit, in-
13 cluding fewer safety concerns or less
14 risk of side-effects, than another drug
15 in the same class that should be in-
16 cluded in the formulary;

17 “(II) those drugs in a class that
18 provide less clinical benefit, including
19 greater safety concerns or a greater
20 risk of side-effects, than another drug
21 in the same class that should be ex-
22 cluded from the formulary; and

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

1 retary to competitively bid (or nego-
2 tiate) for placement on the formulary.

3 “(C) CONSIDERATION OF AHRQ REC-
4 COMMENDATIONS.—

5 “(i) IN GENERAL.—The Secretary,
6 after taking into consideration the rec-
7 ommendations under subparagraph (B)(v),
8 shall establish a formulary, and formulary
9 incentives, to encourage use of covered
10 part D drugs that—

11 “(I) have a lower cost and pro-
12 vide a greater clinical benefit than
13 other drugs;

14 “(II) have a lower cost than
15 other drugs with same or similar clin-
16 ical benefit; and

17 “(III) drugs that have the same
18 cost but provide greater clinical ben-
19 efit than other drugs.

20 “(ii) FORMULARY INCENTIVES.—The
21 formulary incentives under clause (i) may
22 be in the form of one or more of the fol-
23 lowing:

24 “(I) Tiered copayments.

25 “(II) Reference pricing.

1 “(III) Prior authorization.

2 “(IV) Step therapy.

3 “(V) Medication therapy manage-
4 ment.

5 “(VI) Generic drug substitution.

6 “(iii) FLEXIBILITY.—In applying such
7 formulary incentives the Secretary may de-
8 cide not to impose any cost-sharing for a
9 covered part D drug for which—

10 “(I) the elimination of cost shar-
11 ing would be expected to increase
12 compliance with a drug regimen; and

13 “(II) compliance would be ex-
14 pected to produce savings under part
15 A or B or both.

16 “(3) LIMITATIONS ON FORMULARY.—In any
17 formulary established under this subsection, the for-
18 mulary may not be changed during a year, except—

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

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

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

1 option or for which a clear and significant ben-
2 efit has been demonstrated over other covered
3 part D drugs.

4 “(4) ADDING DRUGS TO THE INITIAL FOR-
5 MULARY.—

6 “(A) USE OF ADVISORY COMMITTEE.—The
7 Secretary shall establish and appoint an advi-
8 sory committee (in this paragraph referred to
9 as the ‘advisory committee’)—

10 “(i) to review petitions from drug
11 manufacturers, health care provider orga-
12 nizations, patient groups, and other enti-
13 ties for inclusion of a drug in, or other
14 changes to, such formulary; and

15 “(ii) to recommend any changes to the
16 formulary established under this sub-
17 section.

18 “(B) COMPOSITION.—The advisory com-
19 mittee shall be composed of 9 members and
20 shall include representatives of physicians,
21 pharmacists, and consumers and others with ex-
22 pertise in evaluating prescription drugs. The
23 Secretary shall select members based on their
24 knowledge of pharmaceuticals and the Medicare
25 population. Members shall be deemed to be spe-

1 cial Government employees for purposes of ap-
2 plying the conflict of interest provisions under
3 section 208 of title 18, United States Code, and
4 no waiver of such provisions for such a member
5 shall be permitted.

6 “(C) CONSULTATION.—The advisory com-
7 mittee shall consult, as necessary, with physi-
8 cians who are specialists in treating the disease
9 for which a drug is being considered.

10 “(D) REQUEST FOR STUDIES.—The advi-
11 sory committee may request the Agency for
12 Healthcare Research and Quality or an aca-
13 demic or research institution to study and make
14 a report on a petition described in subpara-
15 graph (A)(ii) in order to assess—

16 “(i) clinical effectiveness;

17 “(ii) comparative effectiveness;

18 “(iii) safety; and

19 “(iv) enhanced compliance with a
20 drug regimen.

21 “(E) RECOMMENDATIONS.—The advisory
22 committee shall make recommendations to the
23 Secretary regarding—

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

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

6 “(ii) whether a covered part D drug is
7 found to provide less clinical benefit, in-
8 cluding greater safety concerns or a great-
9 er risk of side-effects, than another drug in
10 the same class that is currently included in
11 the formulary and should not be included
12 in the formulary; and

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

18 “(F) LIMITATIONS ON REVIEW OF MANU-
19 FACTURER PETITIONS.—The advisory com-
20 mittee shall not review a petition of a drug
21 manufacturer under subparagraph (A)(ii) with
22 respect to a covered part D drug unless the pe-
23 tition is accompanied by the following:

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

1 “(ii) Any data from clinical trials con-
2 ducted using active controls on the drug or
3 drugs that are the current standard of
4 care.

5 “(iii) Any available data on compara-
6 tive effectiveness of the drug.

7 “(iv) Any other information the Sec-
8 retary requires for the advisory committee
9 to complete its review.

10 “(G) RESPONSE TO RECOMMENDATIONS.—

11 The Secretary shall review the recommenda-
12 tions of the advisory committee and if the Sec-
13 retary accepts such recommendations the Sec-
14 retary shall modify the formulary established
15 under this subsection accordingly. Nothing in
16 this section shall preclude the Secretary from
17 adding to the formulary a drug for which the
18 Director of the Agency for Healthcare Research
19 and Quality or the advisory committee has not
20 made a recommendation.

21 “(H) NOTICE OF CHANGES.—The Sec-
22 retary shall provide timely notice to bene-
23 ficiaries and health professionals about changes
24 to the formulary or formulary incentives.

1 “(f) INFORMING BENEFICIARIES.—The Secretary
2 shall take steps to inform beneficiaries about the avail-
3 ability of a Medicare operated drug plan or plans including
4 providing information in the annual handbook distributed
5 to all beneficiaries and adding information to the official
6 public Medicare website related to prescription drug cov-
7 erage available through this part.

8 “(g) APPLICATION OF ALL OTHER REQUIREMENTS
9 FOR PRESCRIPTION DRUG PLANS.—Except as specifically
10 provided in this section, any Medicare operated drug plan
11 shall meet the same requirements as apply to any other
12 prescription drug plan, including the requirements of sec-
13 tion 1860D–4(b)(1) relating to assuring pharmacy ac-
14 cess.”.

15 (b) CONFORMING AMENDMENTS.—

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

19 “(4) AVAILABILITY OF THE MEDICARE OPER-
20 ATED PRESCRIPTION DRUG PLAN.—A medicare oper-
21 ated prescription drug plan (as defined in section
22 1860D–11A(c)) shall be offered nationally in accord-
23 ance with section 1860D–11A.”.

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

4 “(c) PROVISIONS ONLY APPLICABLE IN 2006, 2007,
5 2008, AND 2009.—The provisions of this section shall only
6 apply with respect to 2006, 2007, 2008, and 2009.”.

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

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

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

15 (A) in the heading, by inserting “AND
16 MEDICARE OPERATED PRESCRIPTION DRUG
17 PLANS” after “FALLBACK PLANS”; and

18 (B) by inserting “or a medicare operated
19 prescription drug plan” after “a fallback pre-
20 scription drug plan”.

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

23 (A) in subparagraph (C), by striking
24 “and” after the semicolon at the end;

1 (B) in subparagraph (D), by striking the
2 period at the end and inserting “; and”; and

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

5 “(E) payments for expenses incurred with
6 respect to the operation of medicare operated
7 prescription drug plans under section 1860D–
8 11A.”.

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

12 “(19) MEDICARE OPERATED PRESCRIPTION
13 DRUG PLAN.—The term ‘medicare operated prescrip-
14 tion drug plan’ has the meaning given such term in
15 section 1860D–11A(c).”.

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

20 **SEC. 3. IMPROVED APPEALS PROCESS UNDER THE MEDI-
21 CARE OPERATED PRESCRIPTION DRUG PLAN.**

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

1 “(4) APPEALS PROCESS FOR MEDICARE OPER-
2 ATED PRESCRIPTION DRUG PLAN.—

3 “(A) IN GENERAL.—The Secretary shall
4 develop a well-defined process for appeals for
5 denials of benefits under this part under the
6 medicare operated prescription drug plan. Such
7 process shall be efficient, impose minimal ad-
8 ministrative burdens, and ensure the timely
9 procurement of non-formulary drugs or exemp-
10 tion from formulary incentives when medically
11 necessary. Medical necessity shall be based on
12 professional medical judgment, the medical con-
13 dition of the beneficiary, and other medical evi-
14 dence. Such appeals process shall include—

15 “(i) an initial review and determina-
16 tion made by the Secretary; and

17 “(ii) for appeals denied during the ini-
18 tial review and determination, the option of
19 an external review and determination by
20 an independent entity selected by the Sec-
21 retary.

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

1 well as other key stakeholders to ensure the
2 goals described in subparagraph (A) are
3 achieved.”.

○