

112TH CONGRESS
1ST SESSION

S. 560

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

MARCH 10, 2011

Mr. DURBIN (for himself, Mr. BROWN of Ohio, and Mr. AKAKA) 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 2011”.

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

8 (a) IN GENERAL.—Subpart 2 of part D of title XVIII
9 of the Social Security Act is amended by inserting after

1 section 1860D–11 (42 U.S.C. 1395w–111) the following
2 new section:

3 “MEDICARE OPERATED PRESCRIPTION DRUG PLAN

4 OPTION

5 “SEC. 1860D–11A. (a) IN GENERAL.—Notwith-
6 standing any other provision of this part, for each year
7 (beginning with 2012), in addition to any plans offered
8 under section 1860D–11, the Secretary shall offer one or
9 more Medicare operated prescription drug plans (as de-
10 fined in subsection (c)) with a service area that consists
11 of the entire United States and shall enter into negotia-
12 tions in accordance with subsection (b) with pharma-
13 ceutical manufacturers to reduce the purchase cost of cov-
14 ered part D drugs for eligible part D individuals who en-
15 roll in such a plan.

16 “(b) NEGOTIATIONS.—Notwithstanding section
17 1860D–11(i), for purposes of offering a Medicare operated
18 prescription drug plan under this section, the Secretary
19 shall negotiate with pharmaceutical manufacturers with
20 respect to the purchase price of covered part D drugs in
21 a Medicare operated prescription drug plan and shall en-
22 courage the use of more affordable therapeutic equivalents
23 to the extent such practices do not override medical neces-
24 sity as determined by the prescribing physician. To the
25 extent practicable and consistent with the previous sen-
26 tence, the Secretary shall implement strategies similar to

1 those used by other Federal purchasers of prescription
2 drugs, and other strategies, including the use of a for-
3 mulary and formulary incentives in subsection (e), to re-
4 duce the purchase cost of covered part D drugs.

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

14 “(d) MONTHLY BENEFICIARY PREMIUM.—

15 “(1) QUALIFIED PRESCRIPTION DRUG COV-
16 ERAGE.—The monthly beneficiary premium for
17 qualified prescription drug coverage and access to
18 negotiated prices described in section 1860D–
19 2(a)(1)(A) to be charged under a Medicare operated
20 prescription drug plan shall be uniform nationally.
21 Such premium for months in 2012 and each suc-
22 ceeding year shall be based on the average monthly
23 per capita actuarial cost of offering the Medicare op-
24 erated prescription drug plan for the year involved,
25 including administrative expenses.

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

6 “(e) USE OF A FORMULARY AND FORMULARY INCEN-
7 TIVES.—

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

14 “(A) increase patient safety;

15 “(B) increase appropriate use and reduce
16 inappropriate use of drugs; and

17 “(C) reward value.

18 “(2) DEVELOPMENT OF INITIAL FORMULARY.—

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

23 “(B) ROLE OF AHRQ.—The Director of the
24 Agency for Healthcare Research and Quality
25 shall be responsible for assessing the clinical

1 benefit of covered part D drugs and making
2 recommendations to the Secretary regarding
3 which drugs should be included in the for-
4 mulary. In conducting such assessments and
5 making such recommendations, the Director
6 shall—

7 “(i) consider safety concerns including
8 those identified by the Federal Food and
9 Drug Administration;

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

16 “(iii) use the same classes of drugs
17 developed by the United States Pharma-
18 copeia for this part;

19 “(iv) consider evaluations made by—

20 “(I) the Director under section
21 1013 of the Medicare Prescription
22 Drug, Improvement, and Moderniza-
23 tion Act of 2003;

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

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

8 “(v) recommend to the Secretary—

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

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

21 “(III) drugs in a class with same
22 or similar clinical benefit for which it
23 would be appropriate for the Sec-
24 retary to competitively bid (or nego-
25 tiate) for placement on the formulary.

1 “(C) CONSIDERATION OF AHRQ REC-
2 COMMENDATIONS.—

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

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

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

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

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

22 “(I) Tiered copayments.

23 “(II) Reference pricing.

24 “(III) Prior authorization.

25 “(IV) Step therapy.

1 “(V) Medication therapy manage-
2 ment.

3 “(VI) Generic drug substitution.

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

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

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

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

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

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

21 “(C) to add a drug that the Secretary
22 identifies as a drug which treats a condition for
23 which there has not previously been a treatment
24 option or for which a clear and significant ben-

1 efit has been demonstrated over other covered
2 part D drugs.

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

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

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

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

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

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

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

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

15 “(i) clinical effectiveness;

16 “(ii) comparative effectiveness;

17 “(iii) safety; and

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

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

23 “(i) whether a covered part D drug is
24 found to provide a greater clinical benefit,
25 including fewer safety concerns or less risk

1 of side-effects, than another drug in the
2 same class that is currently included in the
3 formulary and should be included in the
4 formulary;

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

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

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

23 “(i) Raw data from clinical trials on
24 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 op-
21 erated 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
5 THROUGH 2011.—The provisions of this section shall only
6 apply with respect to 2006 through 2011.”.

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 2011.—A fallback prescription drug plan shall
12 not be available after December 31, 2011.”.

13 (3) Section 1860D–13(c)(3) of the Social Secu-
14 rity Act (42 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 the Social Secu-
22 rity Act (42 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 the Social Security
10 Act (42 U.S.C. 1395w–151(a)) is amended by add-
11 ing at the 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 **SEC. 3. IMPROVED APPEALS PROCESS UNDER THE MEDI-
17 CARE OPERATED PRESCRIPTION DRUG PLAN.**

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

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

23 “(A) IN GENERAL.—The Secretary shall
24 develop a well-defined process for appeals for
25 denials of benefits under this part under the

1 Medicare operated prescription drug plan. Such
2 process shall be efficient, impose minimal ad-
3 ministrative burdens, and ensure the timely
4 procurement of non-formulary drugs or exemp-
5 tion from formulary incentives when medically
6 necessary. Medical necessity shall be based on
7 professional medical judgment, the medical con-
8 dition of the beneficiary, and other medical evi-
9 dence. Such appeals process shall include—

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

12 “(ii) for appeals denied during the ini-
13 tial review and determination, the option of
14 an external review and determination by
15 an independent entity selected by the Sec-
16 retary.

17 “(B) CONSULTATION IN DEVELOPMENT OF
18 PROCESS.—In developing the appeals process
19 under subparagraph (A), the Secretary shall
20 consult with consumer and patient groups, as
21 well as other key stakeholders to ensure the
22 goals described in subparagraph (A) are
23 achieved.”.

○