

114TH CONGRESS
1ST SESSION

H. R. 3261

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

IN THE HOUSE OF REPRESENTATIVES

JULY 28, 2015

Ms. SCHAKOWSKY (for herself, Mr. GRIJALVA, Mr. FARR, Ms. PINGREE, Ms. CLARKE of New York, Ms. DEGETTE, and Mr. McDERMOTT) 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

A BILL

To amend part D of 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 2015”.

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

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

7 “MEDICARE OPERATED PRESCRIPTION DRUG PLAN
 8 OPTION

9 “SEC. 1860D–11A. (a) IN GENERAL.—Notwith-
 10 standing any other provision of this part, for each year
 11 (beginning with 2016), in addition to any plans offered
 12 under section 1860D–11, the Secretary shall offer one or
 13 more Medicare operated prescription drug plans (as de-
 14 fined in subsection (c)) with a service area that consists
 15 of the entire United States and shall enter into negotia-
 16 tions in accordance with subsection (b) with pharma-
 17 ceutical manufacturers to reduce the purchase cost of cov-
 18 ered part D drugs for eligible part D individuals who en-
 19 roll in such a plan.

20 “(b) NEGOTIATIONS.—Notwithstanding section
 21 1860D–11(i), for purposes of offering a Medicare operated
 22 prescription drug plan under this section, the Secretary
 23 shall negotiate with pharmaceutical manufacturers with
 24 respect to the purchase price of covered part D drugs in
 25 a Medicare operated prescription drug plan and shall en-
 26 courage the use of more affordable therapeutic equivalents

1 to the extent such practices do not override medical neces-
2 sity as determined by the prescribing physician. To the
3 extent practicable and consistent with the previous sen-
4 tence, the Secretary shall implement strategies similar to
5 those used by other Federal purchasers of prescription
6 drugs, and other strategies, including the use of a for-
7 mulary and formulary incentives in subsection (e), to re-
8 duce the purchase cost of covered part D drugs.

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

18 “(d) MONTHLY BENEFICIARY PREMIUM.—

19 “(1) QUALIFIED PRESCRIPTION DRUG COV-
20 ERAGE.—The monthly beneficiary premium for
21 qualified prescription drug coverage and access to
22 negotiated prices described in section 1860D–
23 2(a)(1)(A) to be charged under a Medicare operated
24 prescription drug plan shall be uniform nationally.
25 Such premium for months in 2016 and each suc-

ceeding 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

1 Secretary shall consider clinical benefit and
2 price.

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

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

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

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

24 “(iv) consider evaluations made by—

1 “(I) the Director under section
2 1013 of the Medicare Prescription
3 Drug, Improvement, and Moderniza-
4 tion Act of 2003;

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

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

12 “(v) recommend to the Secretary—

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

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

1 “(III) drugs in a class with same
2 or similar clinical benefit for which it
3 would be appropriate for the Sec-
4 retary to competitively bid (or nego-
5 tiate) for placement on the formulary.

6 “(C) CONSIDERATION OF AHRQ REC-
7 OMMENDATIONS.—

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

14 “(I) have a lower cost and pro-
15 vide a greater clinical benefit than
16 other drugs;

17 “(II) have a lower cost than
18 other drugs with same or similar clin-
19 ical benefit; and

20 “(III) have the same cost but
21 provide greater clinical benefit than
22 other drugs.

23 “(ii) FORMULARY INCENTIVES.—The
24 formulary incentives under clause (i) may

1 be in the form of one or more of the fol-
 2 lowing:

3 “(I) Tiered copayments.

4 “(II) Reference pricing.

5 “(III) Prior authorization.

6 “(IV) Step therapy.

7 “(V) Medication therapy manage-
 8 ment.

9 “(VI) Generic drug substitution.

10 “(iii) FLEXIBILITY.—In applying such
 11 formulary incentives the Secretary may de-
 12 cide not to impose any cost-sharing for a
 13 covered part D drug for which—

14 “(I) the elimination of cost shar-
 15 ing would be expected to increase
 16 compliance with a drug regimen; and

17 “(II) compliance would be ex-
 18 pected to produce savings under part
 19 A or B or both.

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

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

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

3 “(C) to add a drug that the Secretary
4 identifies as a drug which treats a condition for
5 which there has not previously been a treatment
6 option or for which a clear and significant ben-
7 efit has been demonstrated over other covered
8 part D drugs.

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

11 “(A) USE OF ADVISORY COMMITTEE.—The
12 Secretary shall establish and appoint an advi-
13 sory committee (in this paragraph referred to
14 as the ‘advisory committee’)—

15 “(i) to review petitions from drug
16 manufacturers, health care provider orga-
17 nizations, patient groups, and other enti-
18 ties for inclusion of a drug in, or other
19 changes to, such formulary; and

20 “(ii) to recommend any changes to the
21 formulary established under this sub-
22 section.

23 “(B) COMPOSITION.—The advisory com-
24 mittee shall be composed of 9 members and
25 shall include representatives of physicians,

1 pharmacists, and consumers and others with ex-
2 pertise in evaluating prescription drugs. The
3 Secretary shall select members based on their
4 knowledge of pharmaceuticals and the Medicare
5 population. Members shall be deemed to be spe-
6 cial Government employees for purposes of ap-
7 plying the conflict of interest provisions under
8 section 208 of title 18, United States Code, and
9 no waiver of such provisions for such a member
10 shall be permitted.

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

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

21 “(i) clinical effectiveness;

22 “(ii) comparative effectiveness;

23 “(iii) safety; and

24 “(iv) enhanced compliance with a
25 drug regimen.

1 “(E) RECOMMENDATIONS.—The advisory
2 committee shall make recommendations to the
3 Secretary regarding—

4 “(i) whether a covered part D drug is
5 found to provide a greater clinical benefit,
6 including fewer safety concerns or less risk
7 of side-effects, than another drug in the
8 same class that is currently included in the
9 formulary and should be included in the
10 formulary;

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

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

23 “(F) LIMITATIONS ON REVIEW OF MANU-
24 FACTURER PETITIONS.—The advisory com-
25 mittee shall not review a petition of a drug

1 manufacturer under subparagraph (A)(ii) with
2 respect to a covered part D drug unless the pe-
3 tition is accompanied by the following:

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

6 “(ii) Any data from clinical trials con-
7 ducted using active controls on the drug or
8 drugs that are the current standard of
9 care.

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

12 “(iv) Any other information the Sec-
13 retary requires for the advisory committee
14 to complete its review.

15 “(G) RESPONSE TO RECOMMENDATIONS.—

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

1 “(H) NOTICE OF CHANGES.—The Sec-
2 retary shall provide timely notice to bene-
3 ficiaries and health professionals about changes
4 to the formulary or formulary incentives.

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

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

19 (b) CONFORMING AMENDMENTS.—

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

23 “(4) AVAILABILITY OF THE MEDICARE OPER-
24 ATED PRESCRIPTION DRUG PLAN.—A Medicare op-
25 erated prescription drug plan (as defined in section

1 1860D–11A(c)) shall be offered nationally in accord-
2 ance with section 1860D–11A.”.

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

6 “(c) PROVISIONS ONLY APPLICABLE IN 2006
7 THROUGH 2015.—The provisions of this section shall only
8 apply with respect to 2006 through 2015.”.

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

12 “(8) NO AUTHORITY FOR FALLBACK PLANS
13 AFTER 2015.—A fallback prescription drug plan shall
14 not be available after December 31, 2015.”.

15 (3) Section 1860D–13(c)(3) of the Social Secu-
16 rity Act (42 U.S.C. 1395w–113(c)(3)) is amended—

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

20 (B) by inserting “or a Medicare operated
21 prescription drug plan” after “a fallback pre-
22 scription drug plan”.

23 (4) Section 1860D–16(b)(1) of the Social Secu-
24 rity Act (42 U.S.C. 1395w–116(b)(1)) is amended—

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

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

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

7 “(E) payments for expenses incurred with
8 respect to the operation of Medicare operated
9 prescription drug plans under section 1860D–
10 11A.”.

11 (5) Section 1860D–41(a) of the Social Security
12 Act (42 U.S.C. 1395w–151(a)) is amended by add-
13 ing at the end the following new paragraph:

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

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

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

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

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

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

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

20 “(B) CONSULTATION IN DEVELOPMENT OF
21 PROCESS.—In developing the appeals process
22 under subparagraph (A), the Secretary shall
23 consult with consumer and patient groups, as
24 well as other key stakeholders to ensure the

- 1 goals described in subparagraph (A) are
- 2 achieved.”.

○