

116TH CONGRESS
1ST SESSION

H. R. 4769

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

OCTOBER 21, 2019

Ms. SCHAKOWSKY 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 2019”.

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 2021), 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 (d)) with a service area that consists
15 of the entire United States and shall enter into negotia-
16 tions in accordance with subsection (c) 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) ENROLLMENT.—Notwithstanding subpara-
21 graphs (C) and (D) of section 1860D–1(b)(1), a Medicare
22 operated prescription drug plan offered under this section
23 shall serve as the default prescription drug plan for all
24 part D enrollees unless another prescription drug plan is
25 selected.

1 “(c) NEGOTIATIONS.—Notwithstanding section
2 1860D–11(i), for purposes of offering a Medicare operated
3 prescription drug plan under this section, the Secretary
4 shall negotiate with pharmaceutical manufacturers with
5 respect to the purchase price of covered part D drugs in
6 a Medicare operated prescription drug plan and shall en-
7 courage the use of more affordable therapeutic equivalents
8 to the extent such practices do not override medical neces-
9 sity as determined by the prescribing physician. To the
10 extent practicable and consistent with the previous sen-
11 tence, the Secretary shall implement negotiation and in-
12 centive strategies similar to those used by other Federal
13 purchasers of prescription drugs to reduce the purchase
14 cost of covered Part D drugs, and other strategies, as de-
15 scribed in subsection (f), which may include the use of a
16 pricing scale based on an international price index.

17 “(d) MEDICARE OPERATED PRESCRIPTION DRUG
18 PLAN DEFINED.—For purposes of this part, the term
19 ‘Medicare operated prescription drug plan’ means a com-
20 prehensive prescription drug plan that offers qualified pre-
21 scription drug coverage and access to negotiated prices de-
22 scribed in section 1860D–2(a)(1)(A). Such a plan may
23 offer supplemental prescription drug coverage in the same
24 manner as other qualified prescription drug coverage of-
25 fered by other prescription drug plans.

1 “(e) MONTHLY BENEFICIARY PREMIUM.—

2 “(1) QUALIFIED PRESCRIPTION DRUG COV-
3 ERAGE.—The monthly beneficiary premium for
4 qualified prescription drug coverage and access to
5 negotiated prices described in section 1860D–
6 2(a)(1)(A) to be charged under a Medicare operated
7 prescription drug plan shall be uniform nationally.
8 Such premium for months in 2021 and each suc-
9 ceeding year shall be based on the average monthly
10 per capita actuarial cost of offering the Medicare op-
11 erated prescription drug plan for the year involved,
12 including administrative expenses.

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

18 “(f) USE OF NEGOTIATION AND BENEFIT DESIGN
19 INCENTIVES.—

20 “(1) IN GENERAL.—With respect to the oper-
21 ation of a Medicare operated prescription drug plan
22 and in negotiating with respect to the purchase price
23 of covered part D drugs in such plan, the Secretary
24 shall reward value, increase appropriate use of

1 drugs, and ensure patient safety and access to medi-
2 cations.

3 “(2) ROLE OF AHRQ.—The Director of the
4 Agency for Healthcare Research and Quality, in co-
5 ordination with the Administrator of the Centers for
6 Medicare & Medicaid Services, shall be responsible
7 for assessing the clinical benefit of covered part D
8 drugs and making recommendations to the Secretary
9 regarding the negotiated prices of covered drugs and
10 any appropriate tiering or incentive strategies under
11 the plan. In conducting such assessments and mak-
12 ing such recommendations, the Director shall carry
13 out the following activities:

14 “(A) Consider the comparable inter-
15 national price of such drugs based upon the me-
16 dian retail list price of such drug (which shall
17 be, as practicable, the volume-weighted price for
18 comparable units and dosage forms) among a
19 category of at least the following peer reference
20 countries: Canada, the United Kingdom,
21 France, Japan, Australia, and Germany.

22 “(B) Consider safety concerns and post-
23 market data, including those identified by the
24 Food and Drug Administration and from na-
25 tional health registries.

1 “(C) Use available data and evaluations,
2 including from research supported by the Na-
3 tional Institutes of Health, with priority given
4 to randomized controlled trials, to examine clin-
5 ical effectiveness, comparative effectiveness,
6 safety, and enhanced compliance with a drug
7 regimen.

8 “(D) Use the same classes of drugs devel-
9 oped by United States Pharmacopeia for this
10 part.

11 “(E) Consider evaluations made by—

12 “(i) the Director under section 1013
13 of the Medicare Prescription Drug, Im-
14 provement, and Modernization Act of
15 2003;

16 “(ii) other Federal entities, such as
17 the Secretary of Veterans Affairs; and

18 “(iii) other private and public entities,
19 which may include the Drug Effectiveness
20 Review Project and Medicaid programs.

21 “(F) Consider recommendations made by
22 the advisory committee pursuant to paragraph
23 (3)(F).

24 “(G) Recommend to the Secretary those
25 drugs in a class that provide a greater clinical

1 benefit, including fewer safety concerns or less
2 risk of side-effects, than another drug in the
3 same class.

4 “(3) USE OF ADVISORY COMMITTEE.—

5 “(A) IN GENERAL.—The Secretary shall
6 establish and appoint an advisory committee (in
7 this paragraph referred to as the ‘advisory com-
8 mittee’)—

9 “(i) to review petitions from drug
10 manufacturers, health care provider orga-
11 nizations, patient groups, and other enti-
12 ties regarding negotiated prices; and

13 “(ii) to recommend any changes in
14 order to further negotiations with respect
15 to such prices.

16 “(B) COMPOSITION.—Subject to subpara-
17 graph (C), the advisory committee shall be com-
18 posed of 9 members and shall include represent-
19 atives of physicians, pharmacists, consumers,
20 and others with expertise in evaluating prescrip-
21 tion drugs. The Secretary shall select members
22 based on their knowledge of pharmaceuticals
23 and the Medicare population. Members shall be
24 deemed to be special Government employees for
25 purposes of applying the conflict of interest pro-

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

4 “(C) BANNED INDIVIDUALS.—

5 “(i) DRUG COMPANY LOBBYISTS.—No
6 former registered drug manufacturer lob-
7 byist—

8 “(I) may be appointed to the ad-
9 visory committee; or

10 “(II) may be employed by the ad-
11 visory committee during the 6-year
12 period beginning on the date on which
13 the registered lobbyist terminates its
14 registration in accordance with section
15 4(d) of the Lobbying Disclosure Act
16 of 1995 (2 U.S.C. 1603(d)) or the
17 agent terminates its status, as appli-
18 cable.

19 “(ii) SENIOR EXECUTIVES OF LAW-
20 BREAKING COMPANIES.—No former senior
21 executive of a covered entity (as defined in
22 clause (iii))—

23 “(I) may be appointed to the Ad-
24 visory Committee; or

1 “(II) may be employed by the
2 Advisory Committee during the 6-year
3 period beginning on the later of—

4 “(aa) the date of the settle-
5 ment described in item (aa) of
6 clause (iii)(II); or

7 “(bb) the date on which the
8 enforcement action described in
9 item (bb) of such clause has con-
10 cluded.

11 “(iii) COVERED ENTITY.—The term
12 ‘covered entity’ means any entity that is—

13 “(I) a drug manufacturer; and

14 “(II)(aa) operating under Fed-
15 eral settlement including a Federal
16 consent decree; or

17 “(bb) the subject of an enforce-
18 ment action in a court of the United
19 States or by an agency.

20 “(D) CONSULTATION.—The advisory com-
21 mittee shall consult, as necessary, with physi-
22 cians who are specialists in treating the disease
23 for which a drug is being considered.

24 “(E) REQUEST FOR STUDIES.—The advi-
25 sory committee may request the Agency for

1 Healthcare Research and Quality or an aca-
2 demic or research institution to study and make
3 a report on a petition described in subpara-
4 graph (A)(i) in order to assess cost-effective-
5 ness, clinical effectiveness, comparative effec-
6 tiveness, safety, and compliance with a drug
7 regimen.

8 “(F) RECOMMENDATIONS.—The advisory
9 committee shall make recommendations to the
10 Director of the Agency for Healthcare Research
11 and Quality regarding the appropriate price at
12 which to begin negotiations on a part D drug
13 pursuant to this section.

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

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

22 “(ii) Any data from clinical trials con-
23 ducted using active controls on the drug or
24 drugs that are the current standard of
25 care.

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

3 “(iv) Any other information the Sec-
4 retary requires for the advisory committee
5 to complete its review.

6 “(g) INFORMING BENEFICIARIES.—The Secretary
7 shall take steps to inform part D eligible individuals not
8 previously enrolled in a Medicare operated drug plan (in-
9 cluding such individuals who are newly eligible to enroll
10 under this part) regarding the enrollment of such indi-
11 vidual in a Medicare operated drug plan in accordance
12 with this section, including providing information in the
13 annual handbook and adding information to the official
14 public Medicare website related to prescription drug cov-
15 erage available through this part.

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

23 (b) CONFORMING AMENDMENTS.—

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

4 “(4) AVAILABILITY OF THE MEDICARE OPER-
5 ATED PRESCRIPTION DRUG PLAN.—A Medicare op-
6 erated prescription drug plan (as defined in section
7 1860D–11A(d)) shall be offered nationally in ac-
8 cordance with section 1860D–11A.”.

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

12 “(c) PROVISIONS ONLY APPLICABLE IN 2006
13 THROUGH 2020.—The provisions of this section shall only
14 apply with respect to 2006 through 2020.”.

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

18 “(8) NO AUTHORITY FOR FALLBACK PLANS
19 AFTER 2020.—A fallback prescription drug plan shall
20 not be available after December 31, 2020.”.

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

23 (A) in the heading, by inserting “AND
24 MEDICARE OPERATED PRESCRIPTION DRUG
25 PLANS” after “FALLBACK PLANS”; and

1 (B) by inserting “or a Medicare operated
2 prescription drug plan” after “a fallback pre-
3 scription drug plan”.

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

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

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

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

12 “(E) payments for expenses incurred with
13 respect to the operation of Medicare operated
14 prescription drug plans under section 1860D–
15 11A.”.

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

19 “(19) MEDICARE OPERATED PRESCRIPTION
20 DRUG PLAN.—The term ‘Medicare operated prescrip-
21 tion drug plan’ has the meaning given such term in
22 section 1860D–11A(d).”.

23 (c) RULE OF CONSTRUCTION.—Nothing in this sec-
24 tion shall be interpreted to supersede any other negotia-

1 tion authority granted to the Secretary under Federal law
2 with respect to prescription drug prices.

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

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

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

10 “(A) IN GENERAL.—The Secretary shall
11 develop a well-defined process for appeals for
12 denials of benefits under this part under the
13 Medicare operated prescription drug plan (as
14 defined in section 1860D–11A(d)). Such proc-
15 ess shall be efficient, impose minimal adminis-
16 trative burdens, and ensure the timely procure-
17 ment of medications. Medical necessity shall be
18 based on professional medical judgment, the
19 medical condition of the beneficiary, and other
20 medical evidence.

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

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

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