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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

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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.

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 2019''.

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

(a) IN GENERAL.—Subpart 2 of part D of title XVIII 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 2021), 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 (d)) with a service area that consists of the entire United States and shall enter into negotiations in accordance with subsection (c) 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) ENROLLMENT.—Notwithstanding subparagraphs (C) and (D) of section 1860D–1(b)(1), a Medicare operated prescription drug plan offered under this section shall serve as the default prescription drug plan for all part D enrollees unless another prescription drug plan is selected.

''(c) 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 necessity as determined by the prescribing physician. To the extent practicable and consistent with the previous sentence, the Secretary shall implement negotiation and incentive strategies similar to those used by other Federal purchasers of prescription drugs to reduce the purchase cost of covered Part D drugs, and other strategies, as described in subsection (f), which may include the use of a pricing scale based on an international price index.

''(d) MEDICARE OPERATED PRESCRIPTION DRUG PLAN DEFINED.—For purposes of this part, the term 'Medicare operated prescription drug plan' means a comprehensive 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.

''(e) 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 2021 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).

''(f) USE OF NEGOTIATION AND BENEFIT DESIGN INCENTIVES.—

''(1) IN GENERAL.—With respect to the operation of a Medicare operated prescription drug plan and in negotiating with respect to the purchase price of covered part D drugs in such plan, the Secretary shall reward value, increase appropriate use of

drugs, and ensure patient safety and access to medications.

"(2) ROLE OF AHRQ.—The Director of the Agency for Healthcare Research and Quality, in coordination with the Administrator of the Centers for Medicare & Medicaid Services, shall be responsible for assessing the clinical benefit of covered part D drugs and making recommendations to the Secretary regarding the negotiated prices of covered drugs and any appropriate tiering or incentive strategies under the plan. In conducting such assessments and making such recommendations, the Director shall carry out the following activities:

"(A) Consider the comparable international price of such drugs based upon the median retail list price of such drug (which shall be, as practicable, the volume-weighted price for comparable units and dosage forms) among a category of at least the following peer reference countries: Canada, the United Kingdom, France, Japan, Australia, and Germany.

"(B) Consider safety concerns and post-market data, including those identified by the Food and Drug Administration and from national health registries.

''(C) Use available data and evaluations, including from research supported by the National Institutes of Health, with priority given to randomized controlled trials, to examine clinical effectiveness, comparative effectiveness, safety, and enhanced compliance with a drug regimen.

''(D) Use the same classes of drugs developed by United States Pharmacopeia for this part.

''(E) Consider evaluations made by—

''(i) the Director under section 1013 of the 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, which may include the Drug Effectiveness Review Project and Medicaid programs.

''(F) Consider recommendations made by the advisory committee pursuant to paragraph (3)(F).

''(G) Recommend to the Secretary 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.

''(3) USE OF ADVISORY COMMITTEE.—

''(A) IN GENERAL.—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 regarding negotiated prices; and

''(ii) to recommend any changes in order to further negotiations with respect to such prices.

''(B) COMPOSITION.—Subject to subparagraph (C), the advisory committee shall be composed of 9 members and shall include representatives of physicians, pharmacists, 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 special Government employees for purposes of applying the conflict of interest pro-

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

''(C) BANNED INDIVIDUALS.—

''(i) DRUG COMPANY LOBBYISTS.—No former registered drug manufacturer lobbyist—

''(I) may be appointed to the advisory committee; or

''(II) may be employed by the advisory committee during the 6-year period beginning on the date on which the registered lobbyist terminates its registration in accordance with section 4(d) of the Lobbying Disclosure Act of 1995 (2 U.S.C. 1603(d)) or the agent terminates its status, as applicable.

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

''(I) may be appointed to the Advisory Committee; or

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

''(aa) the date of the settlement described in item (aa) of clause (iii)(II); or

''(bb) the date on which the enforcement action described in item (bb) of such clause has concluded.

''(iii) COVERED ENTITY.—The term 'covered entity' means any entity that is—

''(I) a drug manufacturer; and

''(II)(aa) operating under Federal settlement including a Federal consent decree; or

''(bb) the subject of an enforcement action in a court of the United States or by an agency.

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

''(E) 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)(i) in order to assess cost-effectiveness, clinical effectiveness, comparative effectiveness, safety, and compliance with a drug regimen.

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

''(G) LIMITATIONS ON REVIEW OF MANUFACTURER PETITIONS.—The advisory committee shall not review a petition of a drug manufacturer under subparagraph (A)(i) 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) INFORMING BENEFICIARIES.—The Secretary shall take steps to inform part D eligible individuals not previously enrolled in a Medicare operated drug plan (including such individuals who are newly eligible to enroll under this part) regarding the enrollment of such individual in a Medicare operated drug plan in accordance with this section, including providing information in the annual handbook and adding information to the official public Medicare website related to prescription drug coverage available through this part.

"(h) 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(d)) 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 THROUGH 2020.—The provisions of this section shall only apply with respect to 2006 through 2020.''.

(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 2020.—A fallback prescription drug plan shall not be available after December 31, 2020.''.

(3) Section 1860D–13(c)(3) of the Social Security 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 the Social Security 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 the Social Security 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(d).''.

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

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

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 (as defined in section 1860D–11A(d)). Such process shall be efficient, impose minimal administrative burdens, and ensure the timely procurement of medications. Medical necessity shall be based on professional medical judgment, the medical condition of the beneficiary, and other medical evidence.

''(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.''.

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