116TH CONGRESS
1ST SESSION

S. 377

To amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to negotiate prices of prescription drugs furnished under part D of the Medicare program.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 7, 2019

Mr. BROWN (for himself, Ms. BALDWIN, and Ms. KLOBUCHAR) introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to negotiate prices of prescription drugs furnished under part D of 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 Negotiation and Competitive Licensing Act of 2019''.

SEC. 2. REQUIRING THE SECRETARY OF HEALTH AND HUMAN SERVICES TO NEGOTIATE PRICES OF PRESCRIPTION DRUGS FURNISHED UNDER PART D OF THE MEDICARE PROGRAM.

Section 1860D–11 of the Social Security Act (42 U.S.C. 1395w–111) is amended by striking subsection (i) and inserting the following new subsection:

''(i) NEGOTIATION OF LOWER DRUG PRICES.—

''(1) IN GENERAL.—Notwithstanding any other provision of law, the Secretary shall, for plan years beginning on or after the date of the enactment of this subsection, negotiate with pharmaceutical manufacturers the prices (including discounts, rebates, and other price concessions) that may be charged to PDP sponsors and MA organizations during a negotiated price period (as specified by the Secretary) for covered part D drugs for part D eligible individuals who are enrolled under a prescription drug plan or under an MA–PD plan. In negotiating such prices under this section, the Secretary shall take into account the following factors:

''(A) The comparative clinical effectiveness and cost effectiveness, when available from an impartial source, of such drug.

''(B) The budgetary impact of providing coverage of such drug.

"(C) The number of similarly effective drugs or alternative treatment regimens for each approved use of such drug.

"(D) The associated financial burden on patients that utilize such drug.

"(E) The associated unmet patient need for such drug.

"(F) The total revenues from global sales obtained by the manufacturer for such drug and the associated investment in research and development of such drug by the manufacturer.

"(2) FINALIZATION OF NEGOTIATED PRICE.—The negotiated price of each covered part D drug for a negotiated price period shall be finalized not later than 30 days before a PDP sponsor is required to submit information described in subsection (b)(2) for the first plan year in such negotiated price period.

"(3) COMPETITIVE LICENSING AUTHORITY.—

"(A) IN GENERAL.—Notwithstanding any exclusivity under clause (iii) or (iv) of section 505(j)(5)(F) of the Federal Food, Drug, and Cosmetic Act, clause (iii) or (iv) of section 505(c)(3)(E) of such Act, section 351(k)(7)(A) of the Public Health Service Act, or section

527(a) of the Federal Food, Drug, and Cosmetic Act, or by an extension of such exclusivity under section 505A of such Act or section 505E of such Act, and any other provision of law that provides for market exclusivity (or extension of market exclusivity) with respect to a drug, in the case that the Secretary is unable to successfully negotiate an appropriate price for a covered part D drug for a negotiated price period, the Secretary shall authorize the use of any patent, clinical trial data, or other exclusivity granted by the Federal Government with respect to such drug as the Secretary determines appropriate for purposes of manufacturing such drug for sale under a prescription drug plan or MA–PD plan. Any entity making use of a competitive license to use patent, clinical trial data, or other exclusivity under this section shall provide to the manufacturer holding such exclusivity reasonable compensation, as determined by the Secretary based on the following factors:

"(i) The risk-adjusted value of any Federal Government subsidies and investments in research and development used to support the development of such drug.

"(ii) The risk-adjusted value of any investment made by such manufacturer in the research and development of such drug.

"(iii) The impact of the price, including license compensation payments, on meeting the medical need of all patients.

"(iv) The relationship between the price of such drug, including compensation payments, and the health benefits of such drug.

"(v) Other relevant factors determined appropriate by the Secretary to provide reasonable compensation.

"(B) REASONABLE COMPENSATION.—The manufacturer described in subparagraph (A) may seek recovery against the United States in the United States Court of Federal Claims.

"(C) INTERIM PERIOD.—

"(i) IN GENERAL.—Until 1 year after a drug described in subparagraph (A) is approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act or section 351(k) of the Public Health Service Act and is provided under license issued by

the Secretary under such subparagraph, PDP plans and MA–PD plans shall not pay more for such drug than the average of the prices available, during the most recent 12-month period for which data is available prior to the beginning of such negotiated price period, from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the ten OECD (Organization for Economic Cooperation and Development) countries that have the largest gross domestic product with a per capita income that is not less than half the per capita income of the United States, as reported by the manufacturer to the Secretary.

''(ii) FEDERAL PROGRAM LICENSING.—If such drug is not made available at the price determined, the Secretary shall authorize such entities to use any patent, clinical trial data, or other exclusivity granted by the Federal Government with respect to such drug as the Secretary determines appropriate for purposes of man-

ufacturing such drug for sale under any Federal program, including those provided by Medicare, Medicaid, Veterans Affairs, the Department of Defense, and the Coast Guard.

''(D) AUTHORIZATION FOR SECRETARY TO PROCURE DRUGS DIRECTLY.—

''(i) IN GENERAL.—The Secretary may procure a drug manufactured pursuant to a competitive license under subparagraph (A) for purposes of this part or pursuant to a Federal program license under subparagraph (C)(ii) for purposes of a Federal program directly from the entity manufacturing the drug pursuant to such a license.

''(ii) CLARIFICATION REGARDING APPLICATION OF BUY AMERICAN ACT.—In the case where the Secretary procures a drug under this subparagraph, the provisions of chapter 83 of title 41, United States Code (commonly referred to as the 'Buy American Act') shall apply.

''(E) PRIORITY FOR U.S. MANUFACTURERS IN AUTHORIZING COMPETITIVE LICENSES.—In

authorizing a competitive license under this paragraph, the Secretary—

"(i) shall give preference to entities that the Secretary determines have the highest safety and security standards; and

"(ii) may give priority to entities that will manufacture such drug in the United States.

"(4) FDA REVIEW OF LICENSED DRUG APPLICATIONS.—The Secretary shall prioritize review of applications under section 505(j) of the Federal Food, Drug, and Cosmetic Act for drugs licensed under paragraph (3)(A).

"(5) PROHIBITION OF ANTICOMPETITIVE BEHAVIOR.—No drug manufacturer may engage in anticompetitive behavior with another manufacturer that may interfere with the issuance and implementation of a competitive license or run contrary to public policy.

"(6) REQUIRED REPORTING.—The Secretary may require drug manufacturers to disclose to the Secretary such information that the Secretary determines necessary for purposes of carrying out this subsection.

''(7) CLARIFICATION.—Nothing in this subsection shall be construed as preventing the sponsor of a prescription drug plan or an organization offering an MA–PD plan from obtaining a discount or reduction of the price for a covered part D drug below the price negotiated by the Secretary.''.

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