

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

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.

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 Negotiation
5 and Competitive Licensing Act of 2019”.

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

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

8 “(i) NEGOTIATION OF LOWER DRUG PRICES.—

9 “(1) IN GENERAL.—Notwithstanding any other
10 provision of law, the Secretary shall, for plan years
11 beginning on or after the date of the enactment of
12 this subsection, negotiate with pharmaceutical man-
13 ufacturers the prices (including discounts, rebates,
14 and other price concessions) that may be charged to
15 PDP sponsors and MA organizations during a nego-
16 tiated price period (as specified by the Secretary) for
17 covered part D drugs for part D eligible individuals
18 who are enrolled under a prescription drug plan or
19 under an MA–PD plan. In negotiating such prices
20 under this section, the Secretary shall take into ac-
21 count the following factors:

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

25 “(B) The budgetary impact of providing
26 coverage of such drug.

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

4 “(D) The associated financial burden on
5 patients that utilize such drug.

6 “(E) The associated unmet patient need
7 for such drug.

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

12 “(2) FINALIZATION OF NEGOTIATED PRICE.—
13 The negotiated price of each covered part D drug for
14 a negotiated price period shall be finalized not later
15 than 30 days before a PDP sponsor is required to
16 submit information described in subsection (b)(2)
17 for the first plan year in such negotiated price pe-
18 riod.

19 “(3) COMPETITIVE LICENSING AUTHORITY.—

20 “(A) IN GENERAL.—Notwithstanding any
21 exclusivity under clause (iii) or (iv) of section
22 505(j)(5)(F) of the Federal Food, Drug, and
23 Cosmetic Act, clause (iii) or (iv) of section
24 505(c)(3)(E) of such Act, section 351(k)(7)(A)
25 of the Public Health Service Act, or section

1 527(a) of the Federal Food, Drug, and Cos-
2 metic Act, or by an extension of such exclusivity
3 under section 505A of such Act or section 505E
4 of such Act, and any other provision of law that
5 provides for market exclusivity (or extension of
6 market exclusivity) with respect to a drug, in
7 the case that the Secretary is unable to success-
8 fully negotiate an appropriate price for a cov-
9 ered part D drug for a negotiated price period,
10 the Secretary shall authorize the use of any
11 patent, clinical trial data, or other exclusivity
12 granted by the Federal Government with re-
13 spect to such drug as the Secretary determines
14 appropriate for purposes of manufacturing such
15 drug for sale under a prescription drug plan or
16 MA-PD plan. Any entity making use of a com-
17 petitive license to use patent, clinical trial data,
18 or other exclusivity under this section shall pro-
19 vide to the manufacturer holding such exclu-
20 sivity reasonable compensation, as determined
21 by the Secretary based on the following factors:

22 “(i) The risk-adjusted value of any
23 Federal Government subsidies and invest-
24 ments in research and development used to
25 support the development of such drug.

1 “(ii) The risk-adjusted value of any
2 investment made by such manufacturer in
3 the research and development of such
4 drug.

5 “(iii) The impact of the price, includ-
6 ing license compensation payments, on
7 meeting the medical need of all patients.

8 “(iv) The relationship between the
9 price of such drug, including compensation
10 payments, and the health benefits of such
11 drug.

12 “(v) Other relevant factors determined
13 appropriate by the Secretary to provide
14 reasonable compensation.

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

19 “(C) INTERIM PERIOD.—

20 “(i) IN GENERAL.—Until 1 year after
21 a drug described in subparagraph (A) is
22 approved under section 505(j) of the Fed-
23 eral Food, Drug, and Cosmetic Act or sec-
24 tion 351(k) of the Public Health Service
25 Act and is provided under license issued by

1 the Secretary under such subparagraph,
2 PDP plans and MA–PD plans shall not
3 pay more for such drug than the average
4 of the prices available, during the most re-
5 cent 12-month period for which data is
6 available prior to the beginning of such ne-
7 gotiated price period, from the manufac-
8 turer to any wholesaler, retailer, provider,
9 health maintenance organization, nonprofit
10 entity, or governmental entity in the ten
11 OECD (Organization for Economic Co-
12 operation and Development) countries that
13 have the largest gross domestic product
14 with a per capita income that is not less
15 than half the per capita income of the
16 United States, as reported by the manufac-
17 turer to the Secretary.

18 “(ii) FEDERAL PROGRAM LICENS-
19 ING.—If such drug is not made available
20 at the price determined, the Secretary shall
21 authorize such entities to use any patent,
22 clinical trial data, or other exclusivity
23 granted by the Federal Government with
24 respect to such drug as the Secretary de-
25 termines appropriate for purposes of man-

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

6 “(D) AUTHORIZATION FOR SECRETARY TO
7 PROCURE DRUGS DIRECTLY.—

8 “(i) IN GENERAL.—The Secretary
9 may procure a drug manufactured pursu-
10 ant to a competitive license under subpara-
11 graph (A) for purposes of this part or pur-
12 suant to a Federal program license under
13 subparagraph (C)(ii) for purposes of a
14 Federal program directly from the entity
15 manufacturing the drug pursuant to such
16 a license.

17 “(ii) CLARIFICATION REGARDING AP-
18 PLICATION OF BUY AMERICAN ACT.—In
19 the case where the Secretary procures a
20 drug under this subparagraph, the provi-
21 sions of chapter 83 of title 41, United
22 States Code (commonly referred to as the
23 ‘Buy American Act’) shall apply.

24 “(E) PRIORITY FOR U.S. MANUFACTURERS
25 IN AUTHORIZING COMPETITIVE LICENSES.—In

1 authorizing a competitive license under this
2 paragraph, the Secretary—

3 “(i) shall give preference to entities
4 that the Secretary determines have the
5 highest safety and security standards; and

6 “(ii) may give priority to entities that
7 will manufacture such drug in the United
8 States.

9 “(4) FDA REVIEW OF LICENSED DRUG APPLI-
10 CATIONS.—The Secretary shall prioritize review of
11 applications under section 505(j) of the Federal
12 Food, Drug, and Cosmetic Act for drugs licensed
13 under paragraph (3)(A).

14 “(5) PROHIBITION OF ANTICOMPETITIVE BE-
15 HAVIOR.—No drug manufacturer may engage in
16 anticompetitive behavior with another manufacturer
17 that may interfere with the issuance and implemen-
18 tation of a competitive license or run contrary to
19 public policy.

20 “(6) REQUIRED REPORTING.—The Secretary
21 may require drug manufacturers to disclose to the
22 Secretary such information that the Secretary deter-
23 mines necessary for purposes of carrying out this
24 subsection.

1 “(7) CLARIFICATION.—Nothing in this sub-
2 section shall be construed as preventing the sponsor
3 of a prescription drug plan or an organization offer-
4 ing an MA–PD plan from obtaining a discount or
5 reduction of the price for a covered part D drug
6 below the price negotiated by the Secretary.”.

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