

116TH CONGRESS
1ST SESSION

H. R. 1046

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 HOUSE OF REPRESENTATIVES

FEBRUARY 7, 2019

Mr. DOGGETT (for himself, Mr. WELCH, Mr. CUMMINGS, Ms. ADAMS, Ms. BASS, Mrs. BEATTY, Mr. BLUMENAUER, Ms. BONAMICI, Mr. CARTWRIGHT, Mr. CASE, Mr. CASTEN of Illinois, Ms. CASTOR of Florida, Mr. CASTRO of Texas, Ms. JUDY CHU of California, Mr. CICILLINE, Mr. CISNEROS, Mr. CLAY, Mr. CLEAVER, Mr. COHEN, Mr. COURTNEY, Mr. CRIST, Mr. CROW, Mr. DANNY K. DAVIS of Illinois, Mr. DEFazio, Ms. DELAURO, Mr. DESAULNIER, Mrs. DINGELL, Mr. MICHAEL F. DOYLE of Pennsylvania, Ms. ESCOBAR, Mr. ESPAILLAT, Mr. EVANS, Ms. FRANKEL, Mr. GALLEGO, Mr. GARAMENDI, Mr. GOLDEN, Mr. GONZALEZ of Texas, Mr. GREEN of Texas, Mr. GRIJALVA, Ms. HAALAND, Mr. HARDER of California, Mr. HASTINGS, Mr. HIGGINS of New York, Ms. HILL of California, Ms. JACKSON LEE, Ms. JAYAPAL, Ms. JOHNSON of Texas, Ms. KAPTUR, Mr. KHANNA, Mr. KIM, Mrs. KIRKPATRICK, Mr. KRISHNAMOORTHY, Mr. LANGEVIN, Mr. LARSON of Connecticut, Mr. LAWSON of Florida, Ms. LEE of California, Mrs. LEE of Nevada, Mr. LEVIN of Michigan, Mr. LEWIS, Mr. LIPINSKI, Mr. LOEBSACK, Ms. LOFGREN, Mr. LOWENTHAL, Mr. LYNCH, Mrs. CAROLYN B. MALONEY of New York, Mr. SEAN PATRICK MALONEY of New York, Ms. MCCOLLUM, Mr. MCNERNEY, Ms. MOORE, Mr. NADLER, Mrs. NAPOLITANO, Mr. NEGUSE, Ms. NORTON, Ms. OCASIO-CORTEZ, Ms. OMAR, Mr. PERLMUTTER, Mr. PETERSON, Mr. PHILLIPS, Ms. PINGREE, Mr. POCAN, Ms. PORTER, Ms. PRESSLEY, Mr. RASKIN, Mr. RICHMOND, Mr. ROSE of New York, Ms. ROYBAL-ALLARD, Mr. RUPPERSBERGER, Mr. RUSH, Mr. RYAN, Mr. SARBANES, Ms. SCHAKOWSKY, Mr. SCHIFF, Mr. SCOTT of Virginia, Mr. SERRANO, Mr. SHERMAN, Ms. SLOTKIN, Ms. SPANBERGER, Mr. SUOZZI, Mr. TAKANO, Mr. THOMPSON of Mississippi, Ms. TITUS, Ms. TLAIB, Mrs. TORRES of California, Ms. VELÁZQUEZ, Mr. VISCLOSKY, Ms. WASSERMAN SCHULTZ, Ms. WATERS, Ms. WILD, Mr. YARMUTH, and Mr. MALINOWSKI) 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 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”.

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

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

13 “(i) **NEGOTIATION OF LOWER DRUG PRICES.**—

14 “(1) **IN GENERAL.**—Notwithstanding any other
 15 provision of law, the Secretary shall, for plan years
 16 beginning on or after the date of the enactment of
 17 this subsection, negotiate with pharmaceutical man-
 18 ufacturers the prices (including discounts, rebates,

1 and other price concessions) that may be charged to
2 PDP sponsors and MA organizations during a nego-
3 tiated price period (as specified by the Secretary) for
4 covered part D drugs for part D eligible individuals
5 who are enrolled under a prescription drug plan or
6 under an MA–PD plan. In negotiating such prices
7 under this section, the Secretary shall take into ac-
8 count the following factors:

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

12 “(B) The budgetary impact of providing
13 coverage of such drug.

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

17 “(D) The associated financial burden on
18 patients that utilize such drug.

19 “(E) The associated unmet patient need
20 for such drug.

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

1 “(2) FINALIZATION OF NEGOTIATED PRICE.—

2 The negotiated price of each covered part D drug for
3 a negotiated price period shall be finalized not later
4 than 30 days before a PDP sponsor is required to
5 submit information described in subsection (b)(2)
6 for the first plan year in such negotiated price pe-
7 riod.

8 “(3) COMPETITIVE LICENSING AUTHORITY.—

9 “(A) IN GENERAL.—Notwithstanding any
10 exclusivity under clause (iii) or (iv) of section
11 505(j)(5)(F) of the Federal Food, Drug, and
12 Cosmetic Act, clause (iii) or (iv) of section
13 505(c)(3)(E) of such Act, section 351(k)(7)(A)
14 of the Public Health Service Act, or section
15 527(a) of the Federal Food, Drug, and Cos-
16 metic Act, or by an extension of such exclusivity
17 under section 505A of such Act or section 505E
18 of such Act, and any other provision of law that
19 provides for market exclusivity (or extension of
20 market exclusivity) with respect to a drug, in
21 the case that the Secretary is unable to success-
22 fully negotiate an appropriate price for a cov-
23 ered part D drug for a negotiated price period,
24 the Secretary shall authorize the use of any
25 patent, clinical trial data, or other exclusivity

1 granted by the Federal government with respect
2 to such drug as the Secretary determines ap-
3 propriate for purposes of manufacturing such
4 drug for sale under a prescription drug plan or
5 MA–PD plan. Any entity making use of a com-
6 petitive license to use patent, clinical trial data,
7 or other exclusivity under this section shall pro-
8 vide to the manufacturer holding such exclu-
9 sivity reasonable compensation, as determined
10 by the Secretary based on the following factors:

11 “(i) The risk-adjusted value of any
12 Federal government subsidies and invest-
13 ments in research and development used to
14 support the development of such drug.

15 “(ii) The risk-adjusted value of any
16 investment made by such manufacturer in
17 the research and development of such
18 drug.

19 “(iii) The impact of the price, includ-
20 ing license compensation payments, on
21 meeting the medical need of all patients.

22 “(iv) The relationship between the
23 price of such drug, including compensation
24 payments, and the health benefits of such
25 drug.

1 “(v) Other relevant factors determined
2 appropriate by the Secretary to provide
3 reasonable compensation.

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

8 “(C) INTERIM PERIOD.—

9 “(i) IN GENERAL.—Until 1 year after
10 a drug described in subparagraph (A) is
11 approved under section 505(j) of the Fed-
12 eral Food, Drug, and Cosmetic Act or sec-
13 tion 351(k) of the Public Health Service
14 Act and is provided under license issued by
15 the Secretary under such subparagraph,
16 PDP plans and MA–PD plans shall not
17 pay more for such drug than the average
18 of the prices available, during the most re-
19 cent 12-month period for which data is
20 available prior to the beginning of such ne-
21 gotiated price period, from the manufac-
22 turer to any wholesaler, retailer, provider,
23 health maintenance organization, nonprofit
24 entity, or governmental entity in the ten
25 OECD (Organization for Economic Co-

1 operation and Development) countries that
2 have the largest gross domestic product
3 with a per capita income that is not less
4 than half the per capita income of the
5 United States.

6 “(ii) FEDERAL PROGRAM LICENS-
7 ING.—If such drug is not made available
8 at the price determined, the Secretary shall
9 authorize such entities to use any patent,
10 clinical trial data, or other exclusivity
11 granted by the Federal government with
12 respect to such drug as the Secretary de-
13 termines appropriate for purposes of man-
14 ufacturing such drug for sale under any
15 Federal program, including those provided
16 by Medicare, Medicaid, Veterans Affairs,
17 the Department of Defense, and the Coast
18 Guard.

19 “(D) AUTHORIZATION FOR SECRETARY TO
20 PROCURE DRUGS DIRECTLY.—

21 “(i) IN GENERAL.—The Secretary
22 may procure a drug manufactured pursu-
23 ant to a competitive license under subpara-
24 graph (A) for purposes of this part or pur-
25 suant to a Federal program license under

1 subparagraph (C)(ii) for purposes of a
2 Federal program directly from the entity
3 manufacturing the drug pursuant to such
4 a license.

5 “(ii) CLARIFICATION REGARDING AP-
6 PLICATION OF BUY AMERICAN ACT.—In
7 the case where the Secretary procures a
8 drug under this subparagraph, the provi-
9 sions of chapter 83 of title 41, United
10 States Code (commonly referred to as the
11 ‘Buy American Act’) shall apply.

12 “(E) PRIORITY FOR U.S. MANUFACTURERS
13 IN AUTHORIZING COMPETITIVE LICENSES.—In
14 authorizing a competitive license under this
15 paragraph, the Secretary—

16 “(i) shall give preference to entities
17 that the Secretary determines have the
18 highest safety and security standards; and

19 “(ii) may give priority to entities that
20 will manufacture such drug in the United
21 States.

22 “(4) FDA REVIEW OF LICENSED DRUG APPLI-
23 CATIONS.—The Secretary shall prioritize review of
24 applications under section 505(j) of the Federal

1 Food, Drug, and Cosmetic Act for drugs licensed
2 under paragraph (3)(A).

3 “(5) PROHIBITION OF ANTICOMPETITIVE BE-
4 HAVIOR.—No drug manufacturer may engage in
5 anticompetitive behavior with another manufacturer
6 that may interfere with the issuance and implemen-
7 tation of a competitive license or run contrary to
8 public policy.

9 “(6) REQUIRED REPORTING.—The Secretary
10 may require pharmaceutical manufacturers to dis-
11 close to the Secretary such information that the Sec-
12 retary determines necessary for purposes of carrying
13 out this subsection.

14 “(7) CLARIFICATION.—Nothing in this sub-
15 section shall be construed as preventing the sponsor
16 of a prescription drug plan or an organization offer-
17 ing an MA–PD plan from obtaining a discount or
18 reduction of the price for a covered part D drug
19 below the price negotiated by the Secretary.”.

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