

115TH CONGRESS
2D SESSION

H. R. 6505

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

JULY 25, 2018

Mr. DOGGETT (for himself, Mr. WELCH, Mr. CUMMINGS, Mr. KHANNA, Ms. DeLAURO, Ms. SCHAKOWSKY, Ms. KAPTUR, Mr. POCAN, Mr. GRIJALVA, Ms. ADAMS, Ms. BARRAGÁN, Ms. BASS, Mrs. BEATTY, Mr. BLUMENAUER, Ms. BONAMICI, Mr. CARTWRIGHT, Mr. CASTRO of Texas, Ms. JUDY CHU of California, Mr. CICILLINE, Ms. CLARKE of New York, Mr. CLEAVER, Mr. COHEN, Mr. CRIST, Mr. DEFazio, Mr. DESAULNIER, Mr. ELLISON, Mr. EVANS, Mr. GARAMENDI, Mr. GONZALEZ of Texas, Mr. AL GREEN of Texas, Mr. GUTIÉRREZ, Ms. HANABUSA, Mr. HASTINGS, Mr. HIGGINS of New York, Ms. JACKSON LEE, Ms. JAYAPAL, Ms. EDDIE BERNICE JOHNSON of Texas, Mr. JOHNSON of Georgia, Mr. KRISHNAMOORTHY, Mr. LANGEVIN, Mr. LAWSON of Florida, Ms. LEE, Mr. LEVIN, Mr. LEWIS of Georgia, Mr. LOWENTHAL, Ms. MICHELLE LUJAN GRISHAM of New Mexico, Mrs. CAROLYN B. MALONEY of New York, Ms. MCCOLLUM, Mr. MCNERNEY, Ms. MOORE, Mr. NADLER, Mrs. NAPOLITANO, Mr. NOLAN, Ms. NORTON, Mr. PERLMUTTER, Ms. PINGREE, Mr. RASKIN, Mr. RUPPERSBERGER, Mr. RYAN of Ohio, Mr. SARBANES, Mr. SCOTT of Virginia, Ms. SHEA-PORTER, Mr. SHERMAN, Mr. TAKANO, Mr. THOMPSON of Mississippi, Ms. TITUS, Mr. VARGAS, Mr. VEASEY, Ms. VELÁZQUEZ, Mr. VISCLOSKY, Ms. WASSERMAN SCHULTZ, Ms. MAXINE WATERS of California, Ms. WILSON of Florida, Mr. ESPAILLAT, Mr. PETERSON, Mr. DANNY K. DAVIS of Illinois, Mr. LARSON of Connecticut, Mr. SERRANO, Mr. JEFFRIES, and Ms. FRANKEL of Florida) 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.

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 2018”.

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

1 covered part D drugs for part D eligible individuals
2 who are enrolled under a prescription drug plan or
3 under an MA–PD plan. In negotiating such prices
4 under this section, the Secretary shall take into ac-
5 count the following factors:

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

9 “(B) The budgetary impact of providing
10 coverage of such drug.

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

14 “(D) The associated financial burden on
15 patients that utilize such drug.

16 “(E) The associated unmet patient need
17 for such drug.

18 “(F) The total revenues from global sales
19 obtained by the manufacturer for such drug.

20 “(2) FINALIZATION OF NEGOTIATED PRICE.—

21 The negotiated price of each covered part D drug for
22 a negotiated price period shall be finalized not later
23 than 30 days before a PDP sponsor is required to
24 submit information described in subsection (b)(2)

1 for the first plan year in such negotiated price pe-
2 riod.

3 “(3) COMPETITIVE LICENSING AUTHORITY.—

4 “(A) IN GENERAL.—Notwithstanding any
5 exclusivity under clause (iii) or (iv) of section
6 505(j)(5)(F) of the Federal Food, Drug, and
7 Cosmetic Act, clause (iii) or (iv) of section
8 505(c)(3)(E) of such Act, section 351(k)(7)(A)
9 of the Public Health Service Act, or section
10 527(a) of the Federal Food, Drug, and Cos-
11 metic Act, or by an extension of such exclusivity
12 under section 505A of such Act or section 505E
13 of such Act, and any other provision of law that
14 provides for market exclusivity (or extension of
15 market exclusivity) with respect to a drug, in
16 the case that the Secretary is unable to success-
17 fully negotiate an appropriate price for a cov-
18 ered part D drug for a negotiated price period,
19 the Secretary shall authorize the use of any
20 patent, clinical trial data, or other exclusivity
21 granted by the Federal government with respect
22 to such drug as the Secretary determines ap-
23 propriate for purposes of manufacturing such
24 drug for sale under a prescription drug plan or
25 MA–PD plan. Any entity making use of a com-

1 petitive license to use patent, clinical trial data,
2 or other exclusivity under this section shall pro-
3 vide to the manufacturer holding such exclu-
4 sivity reasonable compensation, as determined
5 by the Secretary based on the following factors:

6 “(i) The risk-adjusted value of any
7 Federal government subsidies and invest-
8 ments in research and development used to
9 support the development of such drug.

10 “(ii) The risk-adjusted value of any
11 investment made by such manufacturer in
12 the research and development of such
13 drug.

14 “(iii) The impact of the price, includ-
15 ing license compensation payments, on
16 meeting the medical need of all patients.

17 “(iv) The relationship between the
18 price of such drug, including compensation
19 payments, and the health benefits of such
20 drug.

21 “(v) Other relevant factors determined
22 appropriate by the Secretary to provide
23 reasonable compensation.

24 “(B) REASONABLE COMPENSATION.—The
25 manufacturer described in subparagraph (A)

1 may seek recovery against the United States in
2 the United States Court of Federal Claims.

3 “(C) INTERIM PERIOD.—

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

1 United States, as reported by the manufac-
2 turer to the Secretary.

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

16 “(4) FDA EXPEDITED REVIEW OF LICENSED
17 DRUG APPLICATIONS.—The Secretary shall prioritize
18 review of applications under section 505(j) of the
19 Federal Food, Drug, and Cosmetic Act for drugs li-
20 censed under paragraph (3)(A).

21 “(5) PROHIBITION OF ANTICOMPETITIVE BE-
22 HAVIOR.—No drug manufacturer may engage in
23 anticompetitive behavior with another manufacturer
24 that may interfere with the issuance and implemen-

1 tation of a competitive license or run contrary to
2 public policy.

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

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