

118TH CONGRESS
1ST SESSION

H. R. 5391

To amend title XVIII of the Social Security Act to provide for a rebate by manufacturers for selected drugs and biological products subject to maximum fair price negotiation.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 12, 2023

Mr. BURGESS (for himself and Mr. MURPHY) 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 provide for a rebate by manufacturers for selected drugs and biological products subject to maximum fair price negotiation.

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 “Protecting Patient Ac-
5 cess to Cancer and Complex Therapies Act”.

1 **SEC. 2. REBATE BY MANUFACTURERS FOR SELECTED**
 2 **DRUGS AND BIOLOGICAL PRODUCTS SUB-**
 3 **JECT TO MAXIMUM FAIR PRICE NEGOTIA-**
 4 **TION.**

5 (a) MAINTAINING PAYMENTS UNDER PART B BASED
 6 ON ASP+6.—Section 1847A(b)(1)(B) of the Social Secu-
 7 rity Act (42 U.S.C. 1395w–3a(b)(1)(B)) is amended by
 8 striking “or in the case of such a drug or biological prod-
 9 uct that is a selected drug” and all that follows through
 10 the semicolon and inserting a semicolon.

11 (b) REBATE BY MANUFACTURERS FOR SELECTED
 12 DRUGS AND BIOLOGICAL PRODUCTS SUBJECT TO MAX-
 13 IMUM FAIR PRICE NEGOTIATION.—

14 (1) IN GENERAL.—Section 1847A of the Social
 15 Security Act (42 U.S.C. 1395w–3a) is amended—

16 (A) by redesignating subsection (j) as sub-
 17 section (k); and

18 (B) by inserting after subsection (i) the
 19 following new subsection:

20 “(j) REBATE BY MANUFACTURERS FOR SELECTED
 21 DRUGS AND BIOLOGICAL PRODUCTS SUBJECT TO MAX-
 22 IMUM FAIR PRICE NEGOTIATION.—

23 “(1) REQUIREMENTS.—

24 “(A) SECRETARIAL PROVISION OF INFOR-
 25 MATION.—Not later than 6 months after the
 26 end of each calendar quarter beginning on or

1 after the first day of the initial price applica-
2 bility period (as defined in section 1191(b)(2)),
3 the Secretary shall, for each selected drug (as
4 defined in section 1192(c)) of each manufac-
5 turer with an agreement under section 1193 for
6 which a maximum fair price is in effect and for
7 which payment may be made under this part,
8 report to each manufacturer of such selected
9 drug the following for such calendar quarter
10 during such price applicability period:

11 “(i) Information on the total number
12 of units of the billing and payment code
13 for such selected drug furnished under this
14 part during such calendar quarter.

15 “(ii) Information on the sum of—

16 “(I) the amount (if any) by
17 which—

18 “(aa) the ASP+6 payment
19 amount (as defined in paragraph
20 (5)) for such drug and calendar
21 quarter, less the ASP+6 coinsur-
22 ance amount for such drug and
23 calendar quarter; exceeds

24 “(bb) the MFP+6 payment
25 amount (as so defined) for such

1 drug and calendar quarter, less
2 the MFP+6 coinsurance amount
3 for such drug and calendar quar-
4 ter; and

5 “(II) the amount (if any) by
6 which—

7 “(aa) the ASP+6 coinsur-
8 ance amount (as defined in para-
9 graph (5)) for such drug and cal-
10 endar quarter; exceeds

11 “(bb) the MFP+6 coinsur-
12 ance amount (as so defined) for
13 such drug and calendar quarter.

14 “(iii) The rebate amount specified
15 under subparagraph (B) for such drug and
16 calendar quarter.

17 “(B) MANUFACTURER REQUIREMENT.—

18 For each calendar quarter beginning on or after
19 the first day of the initial price applicability pe-
20 riod (as defined in section 1191(b)(2)), the
21 manufacturer of a selected drug shall, for such
22 drug, not later than 30 days after the date of
23 receipt from the Secretary of the information
24 described in subparagraph (A) for such cal-
25 endar quarter, provide to the Secretary a rebate

1 that is equal to the amount specified in sub-
2 paragraph (A)(ii) multiplied by the number of
3 units specified in subparagraph (A)(i) for such
4 drug for such calendar quarter. The rebate re-
5 quired under this subparagraph shall be in ad-
6 dition to any other rebates required under this
7 title or title XIX, including the payments re-
8 quired under subsections (h) and (i).

9 “(2) CALCULATION OF BENEFICIARY COINSUR-
10 ANCE BASED ON MFP+6.—

11 “(A) IN GENERAL.—Subject to subpara-
12 graph (B), in the case of a selected drug with
13 respect to which a rebate is paid under this
14 subsection—

15 “(i) the amount of any coinsurance
16 applicable under this part to an individual
17 to whom such drug is furnished during a
18 calendar quarter shall be equal to the
19 MFP+6 coinsurance amount; and

20 “(ii) the amount of such coinsurance
21 for such calendar quarter shall be applied
22 as a percent, as determined by the Sec-
23 retary, to the payment amount that would
24 otherwise apply under subsection
25 (b)(1)(B).

1 “(B) CLARIFICATION REGARDING APPLICA-
2 TION OF INFLATION REBATE.—If a rebate is re-
3 quired under subsection (i) with respect to a se-
4 lected drug for a calendar quarter, the lesser of
5 the amount of coinsurance computed under sub-
6 paragraph (A) or the coinsurance computed
7 under subsection (i)(5) shall apply for such
8 drug and calendar quarter.

9 “(3) REBATE DEPOSITS.—Amounts paid as re-
10 bates under paragraph (1)(B) shall be deposited into
11 the Federal Supplementary Medical Insurance Trust
12 Fund established under section 1841.

13 “(4) CIVIL MONEY PENALTY.—The civil money
14 penalty established under paragraph (7) of sub-
15 section (i) shall apply to the failure to comply with
16 this subsection in the same manner as such penalty
17 applies to failures to comply with the requirements
18 under paragraph (1)(B) of subsection (i).

19 “(5) DEFINITIONS.—In this subsection, with re-
20 spect to a selected drug for a calendar quarter dur-
21 ing a price applicability period:

22 “(A) ASP+6 COINSURANCE AMOUNT.—
23 The ‘ASP+6 coinsurance amount’ is equal to
24 20 percent of the ASP+6 payment amount.

1 “(B) ASP+6 PAYMENT AMOUNT.—The
 2 ‘ASP+6 payment amount’ is equal to 106 per-
 3 cent of the amount determined under para-
 4 graph (4) of subsection (b) for such drug dur-
 5 ing such calendar quarter.

6 “(C) MFP+6 COINSURANCE AMOUNT.—
 7 The ‘MFP+6 coinsurance amount’ is equal to
 8 20 percent of the MFP+6 payment amount.

9 “(D) MFP+6 PAYMENT AMOUNT.—The
 10 ‘MFP+6 payment amount’ is equal to 106 per-
 11 cent of the maximum fair price (as defined in
 12 section 1191(c)(2)) applicable for such drug
 13 during such calendar quarter.

14 “(6) CLARIFICATION.—Nothing in part E of
 15 title XI or this subsection shall be construed to re-
 16 quire a manufacturer to provide selected drugs at
 17 maximum fair prices other than through the rebate
 18 required under this subsection.”.

19 (2) AMOUNTS PAYABLE; COST-SHARING.—Sec-
 20 tion 1833(a)(1) of the Social Security Act (42
 21 U.S.C. 1395l(a)(1)) is amended—

22 (A) in subparagraph (G), by striking “sub-
 23 section (i)(9)” and inserting “paragraphs (9)
 24 and (10) of subsection (i)”;

1 (B) in subparagraph (S), by striking “sub-
 2 paragraph (EE)” and inserting “subparagraphs
 3 (EE) and (II)”;

4 (C) by striking “and (HH)” and inserting
 5 “(HH)”; and

6 (D) by inserting before the semicolon at
 7 the end the following: “, and (II) with respect
 8 to a selected drug (as defined in section
 9 1192(c)) that is subject to a rebate under sec-
 10 tion 1847A(j), the amounts paid shall be equal
 11 to the percent of the payment amount otherwise
 12 determined under section 1847A(b)(1)(B) that
 13 equals the difference between (i) 100 percent,
 14 and (ii) the percent applied under section
 15 1847A(j)(2)(A)(ii)”.

16 (3) ASC CONFORMING AMENDMENTS.—Section
 17 1833(i) of the Social Security Act (42 U.S.C.
 18 1395l(i)) is amended by adding at the end the fol-
 19 lowing new paragraph:

20 “(11) In the case of a selected drug (as defined
 21 in section 1192(c)), subject to a rebate under section
 22 1847A(j) for which payment under this subsection is
 23 not packaged into a payment for a service furnished
 24 on or after the initial price applicability year for the
 25 selected drug under the revised payment system

1 under this subsection, in lieu of calculation of coin-
 2 surance and the amount of payment otherwise appli-
 3 cable under this subsection, the provisions of section
 4 1847(j)(2) and paragraph (1)(II) of subsection (a),
 5 shall, as determined appropriate by the Secretary,
 6 apply under this subsection in the same manner as
 7 such provisions of section 1847A(j)(2) and sub-
 8 section (a) apply under such section and sub-
 9 section.”.

10 (4) OPPS CONFORMING AMENDMENT.—Section
 11 1833(t)(8) of the Social Security Act (42 U.S.C.
 12 1395l(t)(8)) is amended by adding at the end the
 13 following new subparagraph:

14 “(G) SELECTED DRUGS SUBJECT TO RE-
 15 BATE.—In the case of a selected drug (as de-
 16 fined in section 1192(c)), subject to a rebate
 17 under section 1847A(j) for which payment
 18 under this subsection is not packaged into a
 19 payment for a covered OPD service (or group
 20 of services) furnished on or after the initial
 21 price applicability year for the selected drug,
 22 and the payment for such drug is the same as
 23 the amount for a calendar quarter under sec-
 24 tion 1847A(b)(1)(B), under the system under
 25 this subsection, in lieu of the calculation of the

1 copayment amount and the amount otherwise
 2 applicable under this subsection (other than the
 3 application of the limitation described in sub-
 4 paragraph (C)), the provisions of section
 5 1847A(j)(2) and paragraph (1)(II) of sub-
 6 section (a), shall, as determined by the Sec-
 7 retary apply under this section in the same
 8 manner as such provisions of section
 9 1847A(j)(2) and subsection (a) apply under
 10 such section and subsection.”.

11 (5) EXCLUSION OF SELECTED DRUG MFP RE-
 12 BATES FROM ASP CALCULATION.—Section
 13 1847A(c)(3) of the Social Security Act (42 U.S.C.
 14 1395w–3a(c)(3)) is amended by striking “subsection
 15 (i)” and inserting “subsection (i), subsection (j)”.

16 (6) COORDINATION WITH MEDICAID REBATE IN-
 17 FORMATION DISCLOSURES.—Section
 18 1927(b)(3)(D)(i) of the Social Security Act (42
 19 U.S.C. 1396r–8(b)(3)(D)(i)) is amended by striking
 20 “and the rebate” and inserting “and the rebates”.

21 (7) PROVISION OF REBATES.—Section 1193(a)
 22 of the Social Security Act (42 U.S.C. 1320f–2(a)) is
 23 amended—

24 (A) in paragraph (1), by striking subpara-
 25 graph (B) and inserting the following:

1 “(B) by paying rebates in accordance with
2 section 1847A(j);”;

3 (B) in paragraph (2), by striking subpara-
4 graph (B) and inserting the following:

5 “(B) by paying rebates in accordance with
6 section 1847A(j);”;

7 (C) in paragraph (3), by striking subpara-
8 graph (B) and inserting the following:

9 “(B) by paying rebates in accordance with
10 section 1847A(j);”.

11 (c) CONFORMING AMENDMENTS.—

12 (1) Section 1847A(i)(5) of the Social Security
13 Act (42 U.S.C. 1395w–3a(i)(5)) is amended, in the
14 matter preceding subparagraph (A)—

15 (A) by striking “In the case” and inserting
16 “Subsection to subsection (j)(2)(B), in the
17 case”; and

18 (B) by striking “(or, in the case of a part
19 B rebatable drug that is a selected drug (as de-
20 fined in section 1192(c)), the payment amount
21 described in subsection (b)(1)(B) for such
22 drug)”; and

23 (2) Section 1833(a)(1)(EE) of the Social Secu-
24 rity Act (42 U.S.C. 1395l(a)(1)(EE)) is amended—

1 (A) by striking “(or, in the case of a part
2 B rebatable drug that is a selected drug (as de-
3 fined in section 1192(c) for which, the payment
4 amount described in section 1847A(b)(1)(B))
5 for such drug for such quarter”; and

6 (B) by striking “or section
7 1847A(b)(1)(B), as applicable,”.

○