

118TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

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.

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IN THE SENATE OF THE UNITED STATES

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Mr. BARRASSO introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

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## 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 of 2023”.

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(e)) 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 (11) 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(e)), 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,”.