

**AMENDMENT TO THE SENATE AMENDMENT TO  
H.R. 5376  
OFFERED BY MR. BURGESS OF TEXAS**

At the end of part 1 of subtitle B of title I, add the following:

1 **SEC. 11005. REBATE BY MANUFACTURERS FOR SELECTED**  
2 **DRUGS AND BIOLOGICAL SUBJECT TO MAX-**  
3 **IMUM FAIR PRICE NEGOTIATION.**

4 (a) MAINTAINING PAYMENTS UNDER PART B BASED  
5 ON ASP+6.—Section 11001(b)(1) of this Act is amended  
6 by striking subparagraph (A).

7 (b) REBATE BY MANUFACTURERS FOR SELECTED  
8 DRUGS AND BIOLOGICALS SUBJECT TO MAXIMUM FAIR  
9 PRICE NEGOTIATION.—

10 (1) IN GENERAL.—Section 1847A of the Social  
11 Security Act (42 U.S.C. 1395w-3a), as amended by  
12 section 11101, is amended—

13 (A) by redesignating subsection (j) as sub-  
14 section (k); and

15 (B) by inserting after subsection (i) the  
16 following new subsection:

1           “(j) REBATE BY MANUFACTURERS FOR SELECTED  
2 DRUGS AND BIOLOGICALS SUBJECT TO MAXIMUM FAIR  
3 PRICE NEGOTIATION.—

4           “(1) REQUIREMENTS.—

5           “(A) SECRETARIAL PROVISION OF INFOR-  
6 MATION.—Not later than 6 months after the  
7 end of each calendar quarter beginning on or  
8 after the first day of the initial price applica-  
9 bility period (as defined in section 1191(b)(2)),  
10 the Secretary shall, for each selected drug (as  
11 defined in section 1192(e)) of each manufac-  
12 turer with an agreement under section 1193 for  
13 which a maximum fair price is in effect and for  
14 which payment may be made under this part,  
15 report to each manufacturer of such selected  
16 drug the following for such calendar quarter  
17 during such price applicability period:

18           “(i) Information on the total number  
19 of units of the billing and payment code  
20 for such selected drug furnished under this  
21 part during such calendar quarter.

22           “(ii) Information on the sum of—

23                   “(I) the amount (if any) by  
24 which—

1                   “(aa) the ASP+6 payment  
2 amount (as defined in paragraph  
3 (5)) for such drug and calendar  
4 quarter, less the ASP+6 coinsur-  
5 ance amount for such drug and  
6 calendar quarter; exceeds

7                   “(bb) the MFP+6 payment  
8 amount (as so defined) for such  
9 drug and calendar quarter, less  
10 the MFP+6 coinsurance amount  
11 for such drug and calendar quar-  
12 ter; and

13                   “(II) the amount (if any) by  
14 which—

15                   “(aa) the ASP+6 coinsur-  
16 ance amount (as defined in para-  
17 graph (5)) for such drug and cal-  
18 endar quarter; exceeds

19                   “(bb) the MFP+6 coinsur-  
20 ance amount (as so defined) for  
21 such drug and calendar quarter.

22                   “(iii) The rebate amount specified  
23 under subparagraph (B) for such drug and  
24 calendar quarter.

1           “(B) MANUFACTURER REQUIREMENT.—

2           For each calendar quarter beginning on or after  
3           the first day of the price applicability period,  
4           the manufacturer of a selected drug shall, for  
5           such drug, not later than 30 days after the date  
6           of receipt from the Secretary of the information  
7           described in subparagraph (A) for such cal-  
8           endar quarter, provide to the Secretary a rebate  
9           that is equal to the amount specified in sub-  
10          paragraph (A)(ii) multiplied by the number of  
11          units specified in subparagraph (A)(i) for such  
12          drug for such calendar quarter. The rebate re-  
13          quired under this subparagraph shall be in ad-  
14          dition to any other rebates required under this  
15          title or title XIX, including the payments re-  
16          quired under subsections (h) and (i).

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

19                 “(A) IN GENERAL.—Subject to subpara-  
20                 graph (B), in the case of a selected drug with  
21                 respect to which a rebate is paid under this  
22                 subsection—

23                         “(i) the amount of any coinsurance  
24                         applicable under this part to an individual  
25                         to whom such drug is furnished during a

1 calendar quarter shall be equal to the  
2 MFP+6 coinsurance amount; and

3 “(ii) the amount of such coinsurance  
4 for such calendar quarter shall be applied  
5 as a percent, as determined by the Sec-  
6 retary, to the payment amount that would  
7 otherwise apply under subsection  
8 (b)(1)(B).

9 “(B) CLARIFICATION REGARDING APPLICA-  
10 TION OF INFLATION REBATE.—If a rebate is re-  
11 quired under subsection (i) with respect to a se-  
12 lected drug for a calendar quarter, the lesser of  
13 the amount of coinsurance computed under sub-  
14 paragraph (A) or the coinsurance computed  
15 under subsection (i)(5) shall apply for such  
16 drug and calendar quarter.

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

21 “(4) CIVIL MONEY PENALTY.—The civil money  
22 penalty established under paragraph (7) of sub-  
23 section (i) shall apply to the failure to comply with  
24 this subsection in the same manner as such penalty

1 applies to failures to comply with the requirements  
2 under paragraph (1)(B) of subsection (i).

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

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

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

14 “(C) MFP+6 COINSURANCE AMOUNT.—  
15 The ‘MFP+6 coinsurance amount’ is equal to  
16 20 percent of the MFP+6 payment amount.

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

22 “(6) CLARIFICATION.—Nothing in part E of  
23 title XI or this subsection shall be construed to re-  
24 quire a manufacturer to provide selected drugs at

1 maximum fair prices other than through the rebate  
2 required under this subsection.”.

3 (2) AMOUNTS PAYABLE; COST-SHARING.—Sec-  
4 tion 1833(a)(1) of the Social Security Act (42  
5 U.S.C. 1395l(a)(1)), as amended by section  
6 11101(b), is amended—

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

10 (B) in subparagraph (S), by striking “sub-  
11 paragraph (EE)” and inserting “subparagraphs  
12 (EE) and (FF)”;

13 (C) by striking “and (EE)” and inserting  
14 “(EE)”; and

15 (D) by inserting before the semicolon at  
16 the end the following: “, and (FF) with respect  
17 to a selected drug (as defined in section  
18 1192(c)) that is subject to a rebate under sec-  
19 tion 1847A(j), the amounts paid shall be equal  
20 to the percent of the payment amount otherwise  
21 determined under section 1847A(b)(1)(B) that  
22 equals the difference between (i) 100 percent,  
23 and (ii) the percent applied under section  
24 1847A(j)(2)(A)(ii)”.

1           (3) ASC CONFORMING AMENDMENTS.—Section  
2           1833(i) of the Social Security Act (42 U.S.C.  
3           1395l(i)) is amended by adding at the end the fol-  
4           lowing new paragraph:

5           “(10) In the case of a selected drug (as defined  
6           in section 1192(c)), subject to a rebate under section  
7           1847A(j) for which payment under this subsection is  
8           not packaged into a payment for a service furnished  
9           on or after the initial price applicability year for the  
10          selected drug under the revised payment system  
11          under this subsection, in lieu of calculation of coin-  
12          surance and the amount of payment otherwise appli-  
13          cable under this subsection, the provisions of section  
14          1847(j)(2) and paragraph (1)(FF) of subsection (a),  
15          shall, as determined appropriate by the Secretary,  
16          apply under this subsection in the same manner as  
17          such provisions of section 1847A(j)(2) and sub-  
18          section (a) apply under such section and sub-  
19          section.”.

20          (4) OPPTS CONFORMING AMENDMENT.—Section  
21          1833(t)(8) of the Social Security Act (42 U.S.C.  
22          1395l(t)(8)) is amended by adding at the end the  
23          following new subparagraph:

24                 “(G) SELECTED DRUGS SUBJECT TO RE-  
25                 BATE.—In the case of a selected drug (as de-



1            fined in section 1192(c)), subject to a rebate  
2            under section 1847A(j) for which payment  
3            under this subsection is not packaged into a  
4            payment for a covered OPD service (or group  
5            of services) furnished on or after the initial  
6            price applicability year for the selected drug,  
7            and the payment for such drug is the same as  
8            the amount for a calendar quarter under sec-  
9            tion 1847A(b)(1)(B), under the system under  
10           this subsection, in lieu of the calculation of the  
11           copayment amount and the amount otherwise  
12           applicable under this subsection (other than the  
13           application of the limitation described in sub-  
14           paragraph (C)), the provisions of section  
15           1847A(j)(2) and paragraph (1)(FF) of sub-  
16           section (a), shall, as determined by the Sec-  
17           retary apply under this section in the same  
18           manner as such provisions of section  
19           1847A(j)(2) and subsection (a) apply under  
20           such section and subsection.”.

21           (5) EXCLUSION OF SELECTED DRUG MFP RE-  
22           BATES FROM ASP CALCULATION.—Section  
23           1847A(c)(3) of the Social Security Act (42 U.S.C.  
24           1395w-3a(c)(3)), as amended by section  
25           11101(c)(1) and 11102(b)(1), is amended by strik-

1 ing “subsection (i)” and inserting “subsection (i),  
2 subsection (j)”.

3 (6) COORDINATION WITH MEDICAID REBATE IN-  
4 FORMATION DISCLOSURES.—Section  
5 1927(b)(3)(D)(i) of the Social Security Act (42  
6 U.S.C. 1396r–8(b)(3)(D)(i)), as amended by section  
7 11101(c)(3) and 11102(b)(3), is amended by strik-  
8 ing “and the rebate” and inserting “and the re-  
9 bates”.

10 (7) PROVISION OF REBATES.—Section 1193(a)  
11 of the Social Security Act, as added by section  
12 11001, is amended—

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

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

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

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

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

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

25 (c) CONFORMING AMENDMENTS.—

1           (1) Section 1847(i)(5) of the Social Security  
2 Act, as added by section 11101, is amended, in the  
3 matter preceding subparagraph (A)—

4           (A) by striking “In the case” and inserting  
5 “Subsection to subsection (j)(2)(B), in the  
6 case”; and

7           (B) by striking “(or, in the case of a part  
8 B rebatable drug that is a selected drug (as de-  
9 fined in section 1192(c)), the payment amount  
10 described in subsection (b)(1)(B) for such  
11 drug)”; and

12           (2) Section 1833(a)(1)(EE) of the Social Secu-  
13 rity Act, as added by section 11101, is amended—

14           (A) by striking “(or, in the case of a part  
15 B rebatable drug that is a selected drug (as de-  
16 fined in section 1192(c) for which, the payment  
17 amount described in section 1847A(b)(1)(B))”;  
18 and

19           (B) by striking “or section  
20 1847A(b)(1)(B), as applicable.”.

