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:

SEC. 11005. REBATE BY MANUFACTURERS FOR SELECTED
DRUGS AND BIOLOGICAL SUBJECT TO MAXIMUM FAIR PRICE NEGOTIATION.

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

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

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

(A) by redesignating subsection (j) as subsection (k); and

(B) by inserting after subsection (i) the following new subsection:
“(j) Rebate by Manufacturers for Selected Drugs and Biologicals Subject to Maximum Fair Price Negotiation.—

“(1) Requirements.—

“(A) Secretarial provision of information.—Not later than 6 months after the end of each calendar quarter beginning on or after the first day of the initial price applicability period (as defined in section 1191(b)(2)), the Secretary shall, for each selected drug (as defined in section 1192(c)) of each manufacturer with an agreement under section 1193 for which a maximum fair price is in effect and for which payment may be made under this part, report to each manufacturer of such selected drug the following for such calendar quarter during such price applicability period:

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

“(ii) Information on the sum of—

“(I) the amount (if any) by which—
“(aa) the ASP+6 payment amount (as defined in paragraph (5)) for such drug and calendar quarter, less the ASP+6 coinsurance amount for such drug and calendar quarter; exceeds

“(bb) the MFP+6 payment amount (as so defined) for such drug and calendar quarter, less the MFP+6 coinsurance amount for such drug and calendar quarter; and

“(II) the amount (if any) by which—

“(aa) the ASP+6 coinsurance amount (as defined in paragraph (5)) for such drug and calendar quarter; exceeds

“(bb) the MFP+6 coinsurance amount (as so defined) for such drug and calendar quarter.

“(iii) The rebate amount specified under subparagraph (B) for such drug and calendar quarter.
“(B) MANUFACTURER REQUIREMENT.—

For each calendar quarter beginning on or after the first day of the price applicability period, the manufacturer of a selected drug shall, for such drug, not later than 30 days after the date of receipt from the Secretary of the information described in subparagraph (A) for such calendar quarter, provide to the Secretary a rebate that is equal to the amount specified in subparagraph (A)(ii) multiplied by the number of units specified in subparagraph (A)(i) for such drug for such calendar quarter. The rebate required under this subparagraph shall be in addition to any other rebates required under this title or title XIX, including the payments required under subsections (h) and (i).

“(2) CALCULATION OF BENEFICIARY COINSURANCE BASED ON MFP+6.—

“(A) IN GENERAL.—Subject to subparagraph (B), in the case of a selected drug with respect to which a rebate is paid under this subsection—

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

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

“(B) Clarification regarding application
of inflation rebate.—If a rebate is re-
quired under subsection (i) with respect to a se-
lected drug for a calendar quarter, the lesser of
the amount of coinsurance computed under sub-
paragraph (A) or the coinsurance computed
under subsection (i)(5) shall apply for such
drug and calendar quarter.

“(3) Rebate deposits.—Amounts paid as re-
bates under paragraph (1)(B) shall be deposited into
the Federal Supplementary Medical Insurance Trust
Fund established under section 1841.

“(4) Civil money penalty.—The civil money
penalty established under paragraph (7) of sub-
section (i) shall apply to the failure to comply with
this subsection in the same manner as such penalty
applies to failures to comply with the requirements under paragraph (1)(B) of subsection (i).

“(5) DEFINITIONS.—In this subsection, with respect to a selected drug for a calendar quarter during a price applicability period:

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

“(B) ASP+6 PAYMENT AMOUNT.—The ‘ASP+6 payment amount’ is equal to 106 percent of the amount determined under paragraph (4) of subsection (b) for such drug during such calendar quarter.

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

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

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

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

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

(B) in subparagraph (S), by striking “subparagraph (EE)” and inserting “subparagraphs (EE) and (FF)”;

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

(D) by inserting before the semicolon at the end the following: “, and (FF) with respect to a selected drug (as defined in section 1192(c)) that is subject to a rebate under section 1847A(j), the amounts paid shall be equal to the percent of the payment amount otherwise determined under section 1847A(b)(1)(B) that equals the difference between (i) 100 percent, and (ii) the percent applied under section 1847A(j)(2)(A)(ii)”.
(3) ASC CONFORMING AMENDMENTS.—Section 1833(i) of the Social Security Act (42 U.S.C. 1395l(i)) is amended by adding at the end the following new paragraph:

“(10) In the case of a selected drug (as defined in section 1192(c)), subject to a rebate under section 1847A(j) for which payment under this subsection is not packaged into a payment for a service furnished on or after the initial price applicability year for the selected drug under the revised payment system under this subsection, in lieu of calculation of coinsurance and the amount of payment otherwise applicable under this subsection, the provisions of section 1847(j)(2) and paragraph (1)(FF) of subsection (a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of section 1847A(j)(2) and subsection (a) apply under such section and subsection.”.

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

“(G) SELECTED DRUGS SUBJECT TO REBATE.—In the case of a selected drug (as de-
fined in section 1192(e), subject to a rebate
under section 1847A(j) for which payment
under this subsection is not packaged into a
payment for a covered OPD service (or group
of services) furnished on or after the initial
price applicability year for the selected drug,
and the payment for such drug is the same as
the amount for a calendar quarter under sec-
tion 1847A(b)(1)(B), under the system under
this subsection, in lieu of the calculation of the
copayment amount and the amount otherwise
applicable under this subsection (other than the
application of the limitation described in sub-
paragraph (C)), the provisions of section
1847A(j)(2) and paragraph (1)(FF) of sub-
section (a), shall, as determined by the Sec-
retary apply under this section in the same
manner as such provisions of section
1847A(j)(2) and subsection (a) apply under
such section and subsection.”.

(5) EXCLUSION OF SELECTED DRUG MFP RE-
BATES FROM ASP CALCULATION.—Section
1847A(c)(3) of the Social Security Act (42 U.S.C.
1395w–3a(c)(3)), as amended by section
11101(e)(1) and 11102(b)(1), is amended by strik-
ing “subsection (i)” and inserting “subsection (i), subsection (j)”.

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

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

(A) in paragraph (1), by striking subpara-
graph (B) and inserting the following:
“(B) by paying rebates in accordance with
section 1847A(j);”.

(B) in paragraph (2), by striking subpara-
graph (B) and inserting the following:
“(B) by paying rebates in accordance with
section 1847A(j);”.

(C) in paragraph (3), by striking subpara-
graph (B) and inserting the following:
“(B) by paying rebates in accordance with
section 1847A(j);”.

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

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

(B) by striking “(or, in the case of a part B rebatable drug that is a selected drug (as defined in section 1192(c)), the payment amount described in subsection (b)(1)(B) for such drug)”;

(2) Section 1833(a)(1)(EE) of the Social Security Act, as added by section 11101, is amended—

(A) by striking “(or, in the case of a part B rebatable drug that is a selected drug (as defined in section 1192(e) for which, the payment amount described in section 1847A(b)(1)(B))”;

and

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