116TH CONGRESS
2D SESSION

H. R. 1570

IN THE SENATE OF THE UNITED STATES

DECEMBER 10, 2020

Received; read twice and referred to the Committee on Health, Education, Labor, and Pensions

AN ACT

To amend title XVIII of the Social Security Act to waive coinsurance under Medicare for colorectal cancer screening tests, regardless of whether therapeutic intervention is required during the screening, and for other purposes.

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 ''Removing Barriers to Colorectal Cancer Screening Act of 2020''.

SEC. 2. WAIVING MEDICARE COINSURANCE FOR CERTAIN COLORECTAL CANCER SCREENING TESTS.

(a) IN GENERAL.—Section 1833(a) of the Social Security Act (42 U.S.C. 1395l(a)) is amended—

(1) in the second sentence, by striking ''section 1834(0)'' and inserting ''section 1834(o)'';

(2) by moving such second sentence 2 ems to the left; and

(3) by inserting the following third sentence following such second sentence: ''For services furnished on or after January 1, 2022, paragraph (1)(Y) shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test.''.

(b) SPECIAL COINSURANCE RULE FOR CERTAIN TESTS.—Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended—

(1) in subsection (a)(1)(Y), by inserting ''subject to subsection (dd),'' before ''with respect to''; and

(2) by adding at the end the following new subsection:

''(dd) SPECIAL COINSURANCE RULE FOR CERTAIN COLORECTAL CANCER SCREENING TESTS.—

''(1) IN GENERAL.—In the case of a colorectal cancer screening test to which paragraph (1)(Y) of subsection (a) would not apply but for the third sentence of such subsection that is furnished during a year beginning on or after January 1, 2022, and before January 1, 2030, the amount paid shall be equal to the specified percent (as defined in paragraph (2)) for such year of the lesser of the actual charge for the service or the amount determined under the fee schedule that applies to such test under this part (or, in the case such test is a covered OPD service (as defined in subsection (t)(1)(B)), the amount determined under subsection (t)).

''(2) SPECIFIED PERCENT DEFINED.—For purposes of paragraph (1), the term 'specified percent' means—

''(A) for 2022 and 2023, 80 percent;

''(B) for 2024 and 2025, 85 percent;

''(C) for 2026 and 2027, 90 percent; and

''(D) for 2028 and 2029, 95 percent.''.

(c) CONFORMING AMENDMENTS.—Paragraphs (2) and (3) of section 1834(d) of the Social Security Act (42 U.S.C. 1395m(d)) are each amended—

(1) in subparagraph (C)(ii), in the matter preceding subclause (I), by striking ''Notwithstanding'' and inserting ''Subject to section 1833(a)(1)(Y), but notwithstanding''; and

(2) in subparagraph (D), by striking ''If during'' and inserting ''Subject to section 1833(a)(1)(Y), if during''.

SEC. 3. REQUIRING CERTAIN MANUFACTURERS TO REPORT DRUG PRICING INFORMATION WITH RESPECT TO DRUGS UNDER THE MEDICARE PROGRAM.

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

(1) in subsection (b)—

(A) in paragraph (2)(A), by inserting ''or subsection (f)(2), as applicable'' before the period at the end;

(B) in paragraph (3), in the matter preceding subparagraph (A), by inserting ''or sub-

section (f)(2), as applicable,'' before ''determined by''; and

(C) in paragraph (6)(A), in the matter preceding clause (i), by inserting ''or subsection (f)(2), as applicable,'' before ''determined by''; and

(2) in subsection (f)—

(A) by striking ''For requirements'' and inserting the following:

''(1) IN GENERAL.—For requirements''; and

(B) by adding at the end the following new paragraph:

''(2) MANUFACTURERS WITHOUT A REBATE AGREEMENT UNDER TITLE XIX.—

''(A) IN GENERAL.—If the manufacturer of a drug or biological described in subparagraph (C), (E), or (G) of section 1842(o)(1) or in section 1881(b)(14)(B) that is payable under this part has not entered into and does not have in effect a rebate agreement described in subsection (b) of section 1927, for calendar quarters beginning with the second calendar quarter beginning on or after the date of the enactment of this paragraph, such manufacturer shall report to the Secretary the informa-

tion described in subsection (b)(3)(A)(iii) of such section 1927 with respect to such drug or biological in a time and manner specified by the Secretary. For purposes of applying this paragraph, a drug or biological described in the previous sentence includes items, services, supplies, and products that are payable under this part as a drug or biological.

''(B) AUDIT.—Information reported under subparagraph (A) is subject to audit by the Inspector General of the Department of Health and Human Services.

''(C) VERIFICATION.—The Secretary may survey wholesalers and manufacturers that directly distribute drugs described in subparagraph (A), when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of such a drug refuses a request for information about charges or prices by the

Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(D) CONFIDENTIALITY.—Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph (other than the wholesale acquisition cost for purposes of carrying out this section) is confidential and shall not be disclosed by the Secretary in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs by such manufacturer or wholesaler, except—

''(i) as the Secretary determines to be necessary to carry out this section (including the determination and implementation of the payment amount), or to carry out section 1847B;

"(ii) to permit the Comptroller General of the United States to review the information provided; and

"(iii) to permit the Director of the Congressional Budget Office to review the information provided.".

(b) ENFORCEMENT.—Section 1847A of such Act (42 U.S.C. 1395w–3a) is further amended—

(1) in subsection (d)(4)—

(A) in subparagraph (A), by striking "IN GENERAL" and inserting "MISREPRESENTATION";

(B) in subparagraph (B), by striking "subparagraph (B)" and inserting "subparagraph (A), (B), or (C)";

(C) by redesignating subparagraph (B) as subparagraph (D); and

(D) by inserting after subparagraph (A) the following new subparagraphs:

"(B) FAILURE TO PROVIDE TIMELY INFORMATION.—If the Secretary determines that a manufacturer described in subsection (f)(2) has failed to report on information described in section 1927(b)(3)(A)(iii) with respect to a drug or biological in accordance with such subsection,

the Secretary shall apply a civil money penalty in an amount of $10,000 for each day the manufacturer has failed to report such information and such amount shall be paid to the Treasury.

''(C) FALSE INFORMATION.—Any manufacturer required to submit information under subsection (f)(2) that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law.''; and

(2) in subsection (c)(6)(A), by striking the period at the end and inserting '', except that, for purposes of subsection (f)(2), the Secretary may, if the Secretary determines appropriate, exclude repackagers of a drug or biological from such term.''.

(c) MANUFACTURERS WITH A REBATE AGREEMENT.—

(1) IN GENERAL.—Section 1927(b)(3)(A) of the Social Security Act (42 U.S.C. 1396r-8(b)(3)(A)) is amended by adding at the end the following new sentence: ''For purposes of applying clause (iii), a drug or biological described in the flush matter following such clause includes items, services, supplies,

and products that are payable under this part as a drug or biological.''.

(2) TECHNICAL AMENDMENT.—Section 1927(b)(3)(A)(iii) of the Social Security Act (42 U.S.C. 1396r-8(b)(3)(A)(iii)) is amended by striking ''section 1881(b)(13)(A)(ii)'' and inserting ''section 1881(b)(14)(B)''.

(d) REPORT.—Not later than January 1, 2023, the Inspector General of the Department of Health and Human Services shall assess and submit to Congress a report on the accuracy of average sales price information submitted by manufacturers under section 1847A of the Social Security Act (42 U.S.C. 1395w–3a). Such report shall include any recommendations on how to improve the accuracy of such information.

SEC. 4. DETERMINATION OF BUDGETARY EFFECTS.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go Act of 2010, shall be determined by reference to the latest statement titled ''Budgetary Effects of PAYGO Legislation'' for this Act, submitted for printing in the Congressional Record by the Chairman of the House Budget Committee, pro-

vided that such statement has been submitted prior to the vote on passage.

Passed the House of Representatives December 9, 2020.

Attest: CHERYL L. JOHNSON,

Clerk.