

116TH CONGRESS
2D SESSION

H. R. 1570

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Removing Barriers to
3 Colorectal Cancer Screening Act of 2020”.

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

6 (a) IN GENERAL.—Section 1833(a) of the Social Se-
7 curity Act (42 U.S.C. 1395l(a)) is amended—

8 (1) in the second sentence, by striking “section
9 1834(0)” and inserting “section 1834(o)”;

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

12 (3) by inserting the following third sentence fol-
13 lowing such second sentence: “For services furnished
14 on or after January 1, 2022, paragraph (1)(Y) shall
15 apply with respect to a colorectal cancer screening
16 test regardless of the code that is billed for the es-
17 tablishment of a diagnosis as a result of the test, or
18 for the removal of tissue or other matter or other
19 procedure that is furnished in connection with, as a
20 result of, and in the same clinical encounter as the
21 screening test.”.

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

1 (1) in subsection (a)(1)(Y), by inserting “sub-
2 ject to subsection (dd),” before “with respect to”;
3 and

4 (2) by adding at the end the following new sub-
5 section:

6 “(dd) SPECIAL COINSURANCE RULE FOR CERTAIN
7 COLORECTAL CANCER SCREENING TESTS.—

8 “(1) IN GENERAL.—In the case of a colorectal
9 cancer screening test to which paragraph (1)(Y) of
10 subsection (a) would not apply but for the third sen-
11 tence of such subsection that is furnished during a
12 year beginning on or after January 1, 2022, and be-
13 fore January 1, 2030, the amount paid shall be
14 equal to the specified percent (as defined in para-
15 graph (2)) for such year of the lesser of the actual
16 charge for the service or the amount determined
17 under the fee schedule that applies to such test
18 under this part (or, in the case such test is a cov-
19 ered OPD service (as defined in subsection
20 (t)(1)(B)), the amount determined under subsection
21 (t)).

22 “(2) SPECIFIED PERCENT DEFINED.—For pur-
23 poses of paragraph (1), the term ‘specified percent’
24 means—

25 “(A) for 2022 and 2023, 80 percent;

1 “(B) for 2024 and 2025, 85 percent;

2 “(C) for 2026 and 2027, 90 percent; and

3 “(D) for 2028 and 2029, 95 percent.”.

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

7 (1) in subparagraph (C)(ii), in the matter pre-
8 ceding subclause (I), by striking “Notwithstanding”
9 and inserting “Subject to section 1833(a)(1)(Y), but
10 notwithstanding”; and

11 (2) in subparagraph (D), by striking “If dur-
12 ing” and inserting “Subject to section
13 1833(a)(1)(Y), if during”.

14 **SEC. 3. REQUIRING CERTAIN MANUFACTURERS TO REPORT**
15 **DRUG PRICING INFORMATION WITH RE-**
16 **SPECT TO DRUGS UNDER THE MEDICARE**
17 **PROGRAM.**

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

20 (1) in subsection (b)—

21 (A) in paragraph (2)(A), by inserting “or
22 subsection (f)(2), as applicable” before the pe-
23 riod at the end;

24 (B) in paragraph (3), in the matter pre-
25 ceding subparagraph (A), by inserting “or sub-

1 section (f)(2), as applicable,” before “deter-
2 mined by”; and

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

7 (2) in subsection (f)—

8 (A) by striking “For requirements” and
9 inserting the following:

10 “(1) IN GENERAL.—For requirements”; and

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

13 “(2) MANUFACTURERS WITHOUT A REBATE
14 AGREEMENT UNDER TITLE XIX.—

15 “(A) IN GENERAL.—If the manufacturer
16 of a drug or biological described in subpara-
17 graph (C), (E), or (G) of section 1842(o)(1) or
18 in section 1881(b)(14)(B) that is payable under
19 this part has not entered into and does not
20 have in effect a rebate agreement described in
21 subsection (b) of section 1927, for calendar
22 quarters beginning with the second calendar
23 quarter beginning on or after the date of the
24 enactment of this paragraph, such manufac-
25 turer shall report to the Secretary the informa-

1 tion described in subsection (b)(3)(A)(iii) of
2 such section 1927 with respect to such drug or
3 biological in a time and manner specified by the
4 Secretary. For purposes of applying this para-
5 graph, a drug or biological described in the pre-
6 vious sentence includes items, services, supplies,
7 and products that are payable under this part
8 as a drug or biological.

9 “(B) AUDIT.—Information reported under
10 subparagraph (A) is subject to audit by the In-
11 spector General of the Department of Health
12 and Human Services.

13 “(C) VERIFICATION.—The Secretary may
14 survey wholesalers and manufacturers that di-
15 rectly distribute drugs described in subpara-
16 graph (A), when necessary, to verify manufac-
17 turer prices and manufacturer’s average sales
18 prices (including wholesale acquisition cost) if
19 required to make payment reported under sub-
20 paragraph (A). The Secretary may impose a
21 civil monetary penalty in an amount not to ex-
22 ceed \$100,000 on a wholesaler, manufacturer,
23 or direct seller, if the wholesaler, manufacturer,
24 or direct seller of such a drug refuses a request
25 for information about charges or prices by the

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

10 “(D) CONFIDENTIALITY.—Notwith-
11 standing any other provision of law, information
12 disclosed by manufacturers or wholesalers
13 under this paragraph (other than the wholesale
14 acquisition cost for purposes of carrying out
15 this section) is confidential and shall not be dis-
16 closed by the Secretary in a form which dis-
17 closes the identity of a specific manufacturer or
18 wholesaler or prices charged for drugs by such
19 manufacturer or wholesaler, except—

20 “(i) as the Secretary determines to be
21 necessary to carry out this section (includ-
22 ing the determination and implementation
23 of the payment amount), or to carry out
24 section 1847B;

1 “(ii) to permit the Comptroller Gen-
2 eral of the United States to review the in-
3 formation provided; and

4 “(iii) to permit the Director of the
5 Congressional Budget Office to review the
6 information provided.”.

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

9 (1) in subsection (d)(4)—

10 (A) in subparagraph (A), by striking “IN
11 GENERAL” and inserting “MISREPRESENTA-
12 TION”;

13 (B) in subparagraph (B), by striking “sub-
14 subparagraph (B)” and inserting “subparagraph
15 (A), (B), or (C)”;

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

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

20 “(B) FAILURE TO PROVIDE TIMELY INFOR-
21 MATION.—If the Secretary determines that a
22 manufacturer described in subsection (f)(2) has
23 failed to report on information described in sec-
24 tion 1927(b)(3)(A)(iii) with respect to a drug or
25 biological in accordance with such subsection,

1 the Secretary shall apply a civil money penalty
2 in an amount of \$10,000 for each day the man-
3 ufacturer has failed to report such information
4 and such amount shall be paid to the Treasury.

5 “(C) FALSE INFORMATION.—Any manu-
6 facturer required to submit information under
7 subsection (f)(2) that knowingly provides false
8 information is subject to a civil money penalty
9 in an amount not to exceed \$100,000 for each
10 item of false information. Such civil money pen-
11 alties are in addition to other penalties as may
12 be prescribed by law.”; and

13 (2) in subsection (c)(6)(A), by striking the pe-
14 riod at the end and inserting “, except that, for pur-
15 poses of subsection (f)(2), the Secretary may, if the
16 Secretary determines appropriate, exclude repack-
17 agers of a drug or biological from such term.”.

18 (c) MANUFACTURERS WITH A REBATE AGREE-
19 MENT.—

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

1 and products that are payable under this part as a
2 drug or biological.”.

3 (2) TECHNICAL AMENDMENT.—Section
4 1927(b)(3)(A)(iii) of the Social Security Act (42
5 U.S.C. 1396r-8(b)(3)(A)(iii)) is amended by striking
6 “section 1881(b)(13)(A)(ii)” and inserting “section
7 1881(b)(14)(B)”.

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

16 **SEC. 4. DETERMINATION OF BUDGETARY EFFECTS.**

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

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

Passed the House of Representatives December 9,
2020.

Attest:

Clerk.

116TH CONGRESS
2^D SESSION

H. R. 1570

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.