

117TH CONGRESS  
1ST SESSION

# S. 2149

To amend title XVIII of the Social Security Act to provide coverage under the Medicare program for FDA-approved qualifying colorectal cancer screening blood-based tests, to increase participation in colorectal cancer screening in under-screened communities of color, to offset the COVID–19 pandemic driven declines in colorectal cancer screening, and for other purposes.

---

IN THE SENATE OF THE UNITED STATES

JUNE 21, 2021

Mr. HEINRICH (for himself, Mr. WICKER, and Mr. PADILLA) introduced the following bill; which was read twice and referred to the Committee on Finance

---

## A BILL

To amend title XVIII of the Social Security Act to provide coverage under the Medicare program for FDA-approved qualifying colorectal cancer screening blood-based tests, to increase participation in colorectal cancer screening in under-screened communities of color, to offset the COVID–19 pandemic driven declines in colorectal cancer 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 “Donald Payne, Sr.,  
3 Colorectal Cancer Detection Act of 2021”.

4 **SEC. 2. MEDICARE COVERAGE FOR FDA-APPROVED QUALI-**  
5 **FYING COLORECTAL CANCER SCREENING**  
6 **BLOOD-BASED TESTS.**

7 (a) IN GENERAL.—Section 1861(pp) of the Social Se-  
8 curity Act (42 U.S.C. 1395x(pp)) is amended—

9 (1) in paragraph (1)—

10 (A) by redesignating subparagraph (D) as  
11 subparagraph (E); and

12 (B) by inserting after subparagraph (C)  
13 the following new subparagraph:

14 “(D) Qualifying colorectal cancer screening  
15 blood-based test.”; and

16 (2) by adding at the end the following new  
17 paragraph:

18 “(3) The term ‘qualifying colorectal cancer screening  
19 blood-based test’ means, with respect to a year, a screen-  
20 ing blood-based test for the early detection of colorectal  
21 cancer furnished in the year that was marketed or used,  
22 as applicable, in accordance with the relevant provisions  
23 of section 353 of the Public Health Service Act or the  
24 Federal Food, Drug, and Cosmetic Act more than 6  
25 months before the beginning of the year.”.

1 (b) FREQUENCY LIMITS FOR COLORECTAL CANCER  
2 SCREENING TESTS AND PAYMENT AMOUNT FOR QUALI-  
3 FYING COLORECTAL CANCER SCREENING BLOOD-BASED  
4 TESTS.—Section 1834(d) of the Social Security Act (42  
5 U.S.C. 1395m(d)) is amended—

6 (1) by amending clause (ii) of paragraph (1)(B)  
7 to read as follows:

8 “(ii) if the test is performed within—

9 “(I) the 11 months after a pre-  
10 vious screening fecal-occult blood test  
11 or a previous qualifying colorectal  
12 cancer screening blood-based test;

13 “(II) the 35 months after a pre-  
14 vious screening flexible sigmoidoscopy  
15 or a previous screening colonoscopy  
16 with adenoma findings;

17 “(III) the 59 months after a pre-  
18 vious screening colonoscopy with small  
19 polyp findings; or

20 “(IV) the 119 months after a  
21 previous screening colonoscopy with-  
22 out adenoma findings or small polyp  
23 findings.”;

24 (2) in paragraph (2)(E)(ii), by inserting “or  
25 within the 35 months after a previous screening

1 fecal-occult blood test or previous qualifying  
2 colorectal cancer screening blood-based test” after  
3 “sigmoidoscopy”;

4 (3) by amending subparagraph (E) of para-  
5 graph (3) to read as follows:

6 “(E) FREQUENCY LIMIT.—No payment  
7 may be made under this part for a colorectal  
8 cancer screening test consisting of a screening  
9 colonoscopy—

10 “(i) if the procedure is performed  
11 within the 11 months after a previous  
12 screening fecal-occult blood test or previous  
13 qualifying colorectal cancer screening  
14 blood-based test;

15 “(ii) for individuals at high risk for  
16 colorectal cancer if the procedure is per-  
17 formed within the 23 months after a pre-  
18 vious screening colonoscopy; or

19 “(iii) for individuals not at high risk  
20 for colorectal cancer if the procedure is  
21 performed within the 119 months after a  
22 previous screening colonoscopy or within  
23 the 47 months after a previous screening  
24 flexible sigmoidoscopy.”; and

1           (4) by adding at the end the following new  
2 paragraph:

3           “(4)    QUALIFYING    COLORECTAL    CANCER  
4 SCREENING BLOOD-BASED TESTS.—

5           “(A) PAYMENT AMOUNT.—The payment  
6 amount for colorectal cancer screening tests  
7 consisting of qualifying colorectal cancer screen-  
8 ing blood-based tests shall be established by the  
9 Secretary.

10          “(B) FREQUENCY LIMIT.—Paragraph  
11 (1)(B) shall apply to colorectal cancer screening  
12 tests consisting of qualifying colorectal cancer  
13 screening blood-based tests in the same manner  
14 as such paragraph applies to colorectal cancer  
15 screening tests consisting of fecal-occult blood  
16 tests.”.

17          (c) EFFECTIVE DATE.—The amendments made by  
18 this section shall apply to colorectal cancer screening tests  
19 furnished in a year beginning more than 6 months after  
20 the date of the enactment of this Act.

○