

119TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

To amend title XVIII of the Social Security Act to provide for Medicare coverage of multi-cancer early detection screening tests.

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IN THE SENATE OF THE UNITED STATES

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Mr. CRAPO (for himself, Mr. BENNET, Mr. SCOTT of South Carolina, and Mr. WYDEN) introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

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## A BILL

To amend title XVIII of the Social Security Act to provide for Medicare coverage of multi-cancer early detection screening tests.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Nancy Gardner Sewell  
5 Medicare Multi-Cancer Early Detection Screening Cov-  
6 erage Act”.

1 **SEC. 2. MEDICARE COVERAGE OF MULTI-CANCER EARLY**  
2 **DETECTION SCREENING TESTS.**

3 (a) **COVERAGE.**—Section 1861 of the Social Security  
4 Act (42 U.S.C. 1395x) is amended—

5 (1) in subsection (s)(2)—

6 (A) by striking the semicolon at the end of  
7 subparagraph (JJ) and inserting “; and”; and

8 (B) by adding at the end the following new  
9 subparagraph:

10 “(KK) multi-cancer early detection screening  
11 tests (as defined in subsection (nnn));”; and

12 (2) by adding at the end the following new sub-  
13 section:

14 “(nnn) **MULTI-CANCER EARLY DETECTION SCREEN-**  
15 **ING TESTS.**—

16 “(1) **IN GENERAL.**—The term ‘multi-cancer  
17 early detection screening test’ means a test fur-  
18 nished to an individual for the concurrent detection  
19 of multiple cancer types across multiple organ sites  
20 on or after January 1, 2028, that—

21 “(A) is cleared under section 510(k), clas-  
22 sified under section 513(f)(2), or approved  
23 under section 515 of the Federal Food, Drug,  
24 and Cosmetic Act;

25 “(B) is—

1                   “(i) a genomic sequencing blood or  
2                   blood product test that includes the anal-  
3                   ysis of cell-free nucleic acids; or

4                   “(ii) a test based on samples of bio-  
5                   logical material that provides results com-  
6                   parable to those obtained with a test de-  
7                   scribed in clause (i), as determined by the  
8                   Secretary; and

9                   “(C) the Secretary determines is—

10                   “(i) reasonable and necessary for the  
11                   prevention or early detection of an illness  
12                   or disability; and

13                   “(ii) appropriate for individuals enti-  
14                   tled to benefits under part A or enrolled  
15                   under part B.

16                   “(2) NCD PROCESS.—In making determina-  
17                   tions under paragraph (1)(C) regarding the coverage  
18                   of a new test, the Secretary shall use the process for  
19                   making national coverage determinations (as defined  
20                   in section 1869(f)(1)(B)) under this title.”.

21                   (b) PAYMENT AND STANDARDS FOR MULTI-CANCER  
22                   EARLY DETECTION SCREENING TESTS.—

23                   (1) IN GENERAL.—Section 1834 of the Social  
24                   Security Act (42 U.S.C. 1395m) is amended by add-  
25                   ing at the end the following new subsection:

1           “(aa) PAYMENT AND STANDARDS FOR MULTI-CAN-  
2 CER EARLY DETECTION SCREENING TESTS.—

3           “(1) PAYMENT AMOUNT.—The payment  
4 amount for a multi-cancer early detection screening  
5 test (as defined in section 1861(nnn)) is—

6           “(A) with respect to such a test furnished  
7 before January 1, 2031, equal to the payment  
8 amount in effect on the date of the enactment  
9 of this subsection for a multi-target stool  
10 screening DNA test covered pursuant to section  
11 1861(pp)(1)(D); and

12           “(B) with respect to such a test furnished  
13 on or after January 1, 2031, equal to the lesser  
14 of—

15           “(i) the amount described in subpara-  
16 graph (A); or

17           “(ii) the payment amount determined  
18 for such test under section 1834A.

19           “(2) LIMITATIONS.—

20           “(A) IN GENERAL.—No payment may be  
21 made under this part for a multi-cancer early  
22 detection screening test furnished during a year  
23 to an individual if—

1                   “(i) as of January 1 of such year,  
2                   such individual has attained the age speci-  
3                   fied in subparagraph (B) for such year; or

4                   “(ii) such a test was furnished to the  
5                   individual during the previous 11 months.

6                   “(B) AGE SPECIFIED.—For purposes of  
7                   subparagraph (A)(i), the age specified in this  
8                   subparagraph is—

9                   “(i) for 2028, 68 years of age; and

10                   “(ii) for a succeeding year, the age  
11                   specified in this subparagraph for the pre-  
12                   ceding year, increased by 1 year.

13                   “(3) STANDARDS FOLLOWING USPSTF RAT-  
14                   ING.—In the case of a multi-cancer early detection  
15                   screening test that is recommended with a grade of  
16                   A or B by the United States Preventive Services  
17                   Task Force, beginning on the date on which cov-  
18                   erage for such test is provided pursuant to section  
19                   1861(ddd)(1), the preceding provisions of this sub-  
20                   section shall not apply.”.

21                   (2) CONFORMING AMENDMENTS.—

22                   (A) Section 1833 of the Social Security  
23                   Act (42 U.S.C. 1395l) is amended—

24                   (i) in subsection (a)—

## 6

1 (I) in paragraph (1)(D)(i)(I), by  
2 striking “section 1834(d)(1)” and in-  
3 sserting “subsection (d)(1) or (aa) of  
4 section 1834”; and

5 (II) in paragraph (2)(D)(i)(I), by  
6 striking “section 1834(d)(1)” and in-  
7 sserting “subsection (d)(1) or (aa) of  
8 section 1834”; and

9 (ii) in subsection (h), by striking “sec-  
10 tion 1834(d)(1)” and inserting “sub-  
11 sections (d)(1) and (aa) of section 1834”.

12 (B) Section 1862(a) of the Social Security  
13 Act (42 U.S.C. 1395y(a)) is amended—

14 (i) in paragraph (1)—

15 (I) in subparagraph (O), by  
16 striking “and” at the end;

17 (II) in subparagraph (P), by  
18 striking the semicolon at the end and  
19 inserting “, and”; and

20 (III) by adding at the end the  
21 following new subparagraph:

22 “(Q) in the case of multi-cancer early detection  
23 screening tests (as defined in section 1861(nnn)),  
24 which are not reasonable and necessary for the con-

1 current detection of multiple cancer types across  
2 multiple organ sites;” and

3 (ii) in paragraph (7), by striking “or  
4 (P)” and inserting “(P), or (Q)”.

5 (c) RULE OF CONSTRUCTION RELATING TO OTHER  
6 CANCER SCREENING TESTS.—Nothing in this section, in-  
7 cluding the amendments made by this section, shall be  
8 construed—

9 (1) in the case of an individual who undergoes  
10 a multi-cancer early detection screening test, to af-  
11 fect coverage under part B of title XVIII of the So-  
12 cial Security Act for other cancer screening tests  
13 covered under such title, such as screening tests for  
14 breast, cervical, colorectal, lung, or prostate cancer;  
15 or

16 (2) in the case of an individual who undergoes  
17 another cancer screening test, to affect coverage  
18 under such part for a multi-cancer early detection  
19 screening test or the use of such a test as a diag-  
20 nostic or confirmatory test for a result of the other  
21 cancer screening test.