

119TH CONGRESS
1ST SESSION

S. 339

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

IN THE SENATE OF THE UNITED STATES

JANUARY 30, 2025

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 Finance

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)—

1 (I) in paragraph (1)(D)(i)(I), by
 2 striking “section 1834(d)(1)” and in-
 3 serting “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 serting “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.

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