

118TH CONGRESS
1ST SESSION

S. 2085

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

JUNE 21, 2023

Mr. CRAPO (for himself, Mr. BENNET, Mr. SCOTT of South Carolina, and Mr. CARDIN) 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 “Medicare Multi-Cancer
5 Early Detection Screening Coverage Act”.

6 **SEC. 2. PURPOSE.**

7 The purpose of this Act is to create a covered benefit
8 for multi-cancer early detection screening tests to ensure
9 Medicare beneficiary access to these tests without unnece-

1 essary delay once approved under the Federal Food, Drug,
2 and Cosmetic Act.

3 **SEC. 3. MEDICARE COVERAGE OF MULTI-CANCER EARLY**
4 **DETECTION SCREENING TESTS.**

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

7 (1) in subsection (s)(2)—

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

10 (B) by adding at the end the following new
11 subparagraph:

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

14 (2) by adding at the end the following new sub-
15 section:

16 “(nnn) MULTI-CANCER EARLY DETECTION SCREEN-
17 ING TESTS.—The term ‘multi-cancer early detection
18 screening test’ means any of the following tests, approved
19 or cleared by the Food and Drug Administration, insofar
20 as the Secretary determines coverage of such tests is ap-
21 propriate, furnished to an individual for the purpose of
22 earlier detection of cancer across many cancer types (such
23 as described in the National Cancer Institute’s Annual Re-
24 port to the Nation on the Status of Cancer):

1 “(1) A genomic sequencing blood or blood prod-
2 uct test that includes the analysis of cell-free nucleic
3 acids.

4 “(2) Such other equivalent tests (which are
5 based on blood, blood products, urine, or other sam-
6 ple of biological material) as the Secretary deter-
7 mines appropriate in providing results comparable to
8 those obtained with a test described in paragraph
9 (1).”.

10 (b) PAYMENT AND FREQUENCY LIMIT.—

11 (1) PAYMENT UNDER FEE SCHEDULE.—Section
12 1833(h) of the Social Security Act (42 U.S.C.
13 1395l(h)) is amended—

14 (A) in paragraph (1)(A), by inserting after
15 “(including” the following: “multi-cancer early
16 detection screening tests under section
17 1861(nnn), and including”; and

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

20 “(10) No payment may be made under this
21 part for a multi-cancer early detection screening test
22 (as defined in section 1861(nnn)) for an individual
23 if such a test was furnished to the individual during
24 the previous 11 months.”.

1 (2) CONFORMING AMENDMENT.—Section
 2 1862(a) of the Social Security Act (42 U.S.C.
 3 1395y(a)) is amended—

4 (A) in paragraph (1)—

5 (i) in subparagraph (O), by striking
 6 “and” at the end;

7 (ii) in subparagraph (P), by striking
 8 the semicolon at the end and inserting “,
 9 and”; and

10 (iii) by adding at the end the fol-
 11 lowing new subparagraph:

12 “(Q) in the case of a multi-cancer early detec-
 13 tion screening test (as defined in section
 14 1861(nnn)), which is performed more frequently
 15 than is covered under section 1833(h)(10);” and

16 (B) in paragraph (7), by striking “or (P)”
 17 and inserting “(P), or (Q)”.

18 (c) RULE OF CONSTRUCTION RELATING TO OTHER
 19 CANCER SCREENING TESTS.—Nothing in this section, in-
 20 cluding the amendments made by this section, shall be
 21 construed—

22 (1) in the case of an individual who undergoes
 23 a multi-cancer early detection screening test, to af-
 24 fect coverage under part B of title XVIII of the So-
 25 cial Security Act for other cancer screening tests

1 covered under such title, such as screening tests for
2 breast, cervical, colorectal, lung, or prostate cancer;
3 or

4 (2) in the case of an individual who undergoes
5 another cancer screening test, to affect coverage
6 under such part for a multi-cancer early detection
7 screening test or the use of such a test as a diag-
8 nostic or confirmatory test for a result of the other
9 cancer screening test.

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