

116TH CONGRESS
2D SESSION

S. 5051

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

DECEMBER 17, 2020

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 of 2020”.

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 “and” at the end of sub-
9 paragraph (GG);

10 (B) by striking the period at the end of
11 subparagraph (HH) and inserting “; and”; and

12 (C) by adding at the end the following new
13 subparagraph:

14 “(II) multi-cancer early detection screening
15 tests (as defined in subsection (kkk));”; and

16 (2) by adding at the end the following new sub-
17 section:

18 “(kkk) MULTI-CANCER EARLY DETECTION SCREEN-
19 ING TESTS.—The term ‘multi-cancer early detection
20 screening test’ means any of the following tests, approved
21 or cleared by the Food and Drug Administration, fur-
22 nished to an individual for the purpose of early detection
23 of cancer across many cancer types (as categorized in the
24 Annual Report to the Nation on the Status of Cancer
25 issued by the National Cancer Institute):

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 urine or other sample of biological mate-
6 rial) as the Secretary determines appropriate.”.

7 (b) PAYMENT AND FREQUENCY LIMIT.—

8 (1) PAYMENT UNDER FEE SCHEDULE.—Section
9 1833(h) of the Social Security Act (42 U.S.C.
10 1395l(h)) is amended—

11 (A) in paragraph (1)(A), by inserting after
12 “(including” the following: “multi-cancer early
13 detection screening tests under section
14 1861(kkk) and including”; and

15 (B) by adding at the end the following new
16 paragraph:

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

22 (2) CONFORMING AMENDMENT.—Section
23 1862(a) of the Social Security Act (42 U.S.C.
24 1395y(a)) is amended—

25 (A) in paragraph (1)—

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

3 (ii) in subparagraph (P), by striking
4 the semicolon at the end and inserting “,
5 and”; and

6 (iii) by adding at the end the fol-
7 lowing new subparagraph:

8 “(Q) in the case of multi-cancer early de-
9 tection screening tests (as defined in section
10 1861(kkk)), which are performed more fre-
11 quently than is covered under section
12 1833(h)(10);”; and

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

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

19 (1) in the case of an individual who undergoes
20 a multi-cancer early detection screening test, to af-
21 fect coverage under part B for other cancer screen-
22 ing tests covered under this title, such as screening
23 tests for breast, cervical, colorectal, lung, or prostate
24 cancer; or

1 (2) in the case of an individual who undergoes
2 another cancer screening test, to affect coverage for
3 a multi-cancer early detection screening test or the
4 use of such a test as a diagnostic or confirmatory
5 test for a result of the other cancer screening test.

○