

117TH 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.

IN THE SENATE OF THE UNITED STATES

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 _____

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 2021”.

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 (lll));” and

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

18 “(lll) 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 1861(III)
14 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(III)) for an individual if
20 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 detection
9 screening tests (as defined in section 1861(III)),
10 which are performed more frequently than is covered
11 under section 1833(h)(10);”; and

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

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

18 (1) in the case of an individual who undergoes
19 a multi-cancer early detection screening test, to af-
20 fect coverage under part B of title XVIII of the So-
21 cial Security Act (42 U.S.C. 1395j et seq.) for other
22 cancer screening tests covered under such title, such
23 as screening tests for breast, cervical, colorectal,
24 lung, or prostate 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.

6 (d) IMPLEMENTATION.—The Secretary of Health and
7 Human Services shall provide for the implementation of
8 coverage of multi-cancer early detection screening tests
9 under the amendments made by this section through the
10 applicable Medicare coverage process under title XVIII of
11 the Social Security Act (42 U.S.C. 1395 et seq.).

12 (e) GAO STUDY AND REPORT ON MULTI-CANCER
13 EARLY DETECTION SCREENING TESTS.—

14 (1) STUDY.—The Comptroller General of the
15 United States shall conduct a study on the utiliza-
16 tion of multi-cancer early detection tests under title
17 XVIII of the Social Security Act (42 U.S.C. 1395 et
18 seq.). Such study shall include an analysis of aggre-
19 gate data on—

20 (A) the utilization of such tests by sex,
21 race, ethnicity, geography, and socioeconomic
22 status; and

23 (B) the number of cancers detected
24 through screening in Medicare beneficiaries and
25 improvements in health outcomes.

1 (2) REPORT.—Not later than three years after
2 the start of coverage of such tests under such title,
3 the Comptroller General shall submit to Congress a
4 report containing the results of the study conducted
5 under paragraph (1), including recommendations for
6 increasing access and utilization in underserved
7 areas and other recommendations as the Comptroller
8 General determines appropriate.