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. CRAPÓ (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.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the “Medicare Multi-Cancer Early Detection Screening Coverage Act of 2021”.

SEC. 2. PURPOSE.

The purpose of this Act is to create a covered benefit for multi-cancer early detection screening tests to ensure Medicare beneficiary access to these tests without unnec-
necessary delay once approved under the Federal Food, Drug, and Cosmetic Act.

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

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

(1) in subsection (s)(2)—

(A) by striking “and” at the end of subparagraph (GG);

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

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

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

(2) by adding at the end the following new subsection:

“(lll) **MULTI-CANCER EARLY DETECTION SCREENING TESTS.**—The term ‘multi-cancer early detection screening test’ means any of the following tests, approved or cleared by the Food and Drug Administration, furnished to an individual for the purpose of early detection of cancer across many cancer types (as categorized in the Annual Report to the Nation on the Status of Cancer issued by the National Cancer Institute):
“(1) A genomic sequencing blood or blood product test that includes the analysis of cell-free nucleic acids.

“(2) Such other equivalent tests (which are based on urine or other sample of biological material) as the Secretary determines appropriate.”.

(b) Payment and Frequency Limit.—

(1) Payment under fee schedule.—Section 1833(h) of the Social Security Act (42 U.S.C. 1395l(h)) is amended—

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

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

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

(2) Conforming amendment.—Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)) is amended—

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

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

(iii) by adding at the end the following new subparagraph:

“(Q) in the case of multi-cancer early detection screening tests (as defined in section 1861(lll)), which are performed more frequently than is covered under section 1833(h)(10);”; and

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

(c) Rule of Construction Relating to Other Cancer Screening Tests.—Nothing in this section, including the amendments made by this section, shall be construed—

(1) in the case of an individual who undergoes a multi-cancer early detection screening test, to affect coverage under part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.) for other cancer screening tests covered under such title, such as screening tests for breast, cervical, colorectal, lung, or prostate cancer; or
(2) in the case of an individual who undergoes another cancer screening test, to affect coverage for a multi-cancer early detection screening test or the use of such a test as a diagnostic or confirmatory test for a result of the other cancer screening test.

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

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

(1) STUDY.—The Comptroller General of the United States shall conduct a study on the utilization of multi-cancer early detection tests under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.). Such study shall include an analysis of aggregate data on—

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

(B) the number of cancers detected through screening in Medicare beneficiaries and improvements in health outcomes.
(2) REPORT.—Not later than three years after the start of coverage of such tests under such title, the Comptroller General shall submit to Congress a report containing the results of the study conducted under paragraph (1), including recommendations for increasing access and utilization in underserved areas and other recommendations as the Comptroller General determines appropriate.