117TH CONGRESS 1ST SESSION  

H. R. _____

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

IN THE HOUSE OF REPRESENTATIVES

Ms. SEWELL introduced the following bill; which was 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. FINDINGS; PURPOSE.
7 (a) FINDINGS.—Congress finds the following:
(1) Detecting cancer early, before it has spread throughout the body, saves lives. Cancers detected when still localized can be treated more effectively and have a 5-year cancer specific survival of approximately 90 percent compared with approximately 20 percent for cancers found after metastasis has occurred. Existing Medicare-covered early detection tests such as mammograms and colonoscopies, have led to a substantial reduction in age-adjusted mortality.

(2) Diagnosing and treating cancer earlier often results in less invasive treatments for patients, which are also less expensive. According to peer reviewed literature, treatment of metastatic cancer is two times more costly than treatment of cancer before it metastasizes.

(3) Driving national strategies to broadly detect cancer earlier will help reduce pervasive health disparities since racial, ethnic, and geographic groups experience later stages of diagnosis, along with higher cancer incidence and mortality.

(4) The benefits of early cancer detection to Medicare beneficiaries has been limited to five cancers. According to the National Cancer Institute’s Surveillance, Epidemiology, and End Results pro-
gram, 71 percent of the 600,000 cancer deaths each year are from types of cancer without a Medicare-
covered early detection test.

(5) Age is the leading risk factor for cancer, placing Medicare beneficiaries at elevated risk. Americans who are 65 years of age and older are more than 7 times as likely as Americans who are under 65 years of age to be diagnosed with cancer.

(6) Several innovative private and academic efforts are engaged in research, including advanced clinical trials to develop multi-cancer early detection blood-based tests. Published data indicate that these tests can screen for many cancers at the same time, including rare cancers, with one example currently able to screen for more than 50 cancers.

(7) Multi-cancer early detection tests can complement the covered early detection tests enacted by Congress and extend the benefits of early detection to more cancers and more Americans. Medicare coverage of comprehensive multi-cancer early detection screening tests could substantially transform cancer care for Americans, and the Medicare law needs modernizing to provide timely coverage and keep pace with medical innovation.
(b) 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 unnecessary 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”;

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

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

(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 prod-
uct 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 mate-
rial) 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.”.
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 for other cancer screen-
ing tests covered under this 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.