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

Mr. ARRINGTON 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 “Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Cov-
5 erage Act”.
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 4 times greater survival rate compared to 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 early stage cancer is half the cost of metastatic cancer.

(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 have been limited to five cancers. According to the National Cancer Institute’s Surveillance, Epidemiology, and End Results program, 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. About 1,000,000 Medicare beneficiaries will be diagnosed with cancer this year, as the median age for cancer diagnosis is 66 years of age.

(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 the semicolon at the end of subparagraph (JJ) and inserting “; and”;

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

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

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

“(nnn) 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, insofar as the Secretary determines coverage of such tests is appropriate, furnished to an individual for the purpose of earlier detection of cancer across many cancer types (such as described in the National Cancer Institute’s Annual Report to the Nation on the Status of Cancer):
“(2) A genomic sequencing blood or blood product test that includes the analysis of cell-free nucleic acids.

“(3) Such other equivalent tests (which are based on blood, blood products, urine or other sample of biological material) as the Secretary determines appropriate in providing results comparable to those obtained with a test described in paragraph (1).”

(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(nnn), 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(nnn)) 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”;

(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 So-
social Security Act 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 under such part 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.