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(Original Signature of Member)

118TH 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

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
5 Medicare Multi-Cancer Early Detection Screening Cov-
6 erage Act”.

7 **SEC. 2. FINDINGS; PURPOSE.**

8 (a) FINDINGS.—Congress finds the following:

1 (1) Detecting cancer early, before it has spread
2 throughout the body, saves lives. Cancers detected
3 when still localized can be treated more effectively
4 and have a 4 times greater survival rate compared
5 to cancers found after metastasis has occurred. Ex-
6 isting Medicare-covered early detection tests, such as
7 mammograms and colonoscopies, have led to a sub-
8 stantial reduction in age-adjusted mortality.

9 (2) Diagnosing and treating cancer earlier often
10 results in less invasive treatments for patients,
11 which are also less expensive. According to peer re-
12 viewed literature, treatment of early stage cancer is
13 half the cost of metastatic cancer.

14 (3) Driving national strategies to broadly detect
15 cancer earlier will help reduce pervasive health dis-
16 parities since racial, ethnic, and geographic groups
17 experience later stages of diagnosis, along with high-
18 er cancer incidence and mortality.

19 (4) The benefits of early cancer detection to
20 Medicare beneficiaries have been limited to five can-
21 cers. According to the National Cancer Institute's
22 Surveillance, Epidemiology, and End Results pro-
23 gram, 71 percent of the 600,000 cancer deaths each
24 year are from types of cancer without a Medicare-
25 covered early detection test.

1 (5) Age is the leading risk factor for cancer,
2 placing Medicare beneficiaries at elevated risk.
3 About 1,000,000 Medicare beneficiaries will be diag-
4 nosed with cancer this year, as the median age for
5 cancer diagnosis is 66 years of age.

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

13 (7) Multi-cancer early detection tests can com-
14 plement the covered early detection tests enacted by
15 Congress and extend the benefits of early detection
16 to more cancers and more Americans. Medicare cov-
17 erage of comprehensive multi-cancer early detection
18 screening tests could substantially transform cancer
19 care for Americans, and the Medicare law needs
20 modernizing to provide timely coverage and keep
21 pace with medical innovation.

22 (b) PURPOSE.—The purpose of this Act is to create
23 a covered benefit for multi-cancer early detection screen-
24 ing tests to ensure Medicare beneficiary access to these

1 tests without unnecessary delay once approved under the
2 Federal Food, Drug, 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 the semicolon at the end of
9 subparagraph (JJ) and inserting “; and”; and

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

12 “(KK) multi-cancer early detection screen-
13 ing tests (as defined in subsection (nnn));”; and

14 (2) by adding at the end the following new sub-
15 section:

16 “(nnn) MULTI-CANCER EARLY DETECTION SCREEN-
17 ING TESTS.—The term ‘multi-cancer early detection
18 screening test’ means any of the following tests, approved
19 or cleared by the Food and Drug Administration, insofar
20 as the Secretary determines coverage of such tests is ap-
21 propriate, furnished to an individual for the purpose of
22 earlier detection of cancer across many cancer types (such
23 as described in the National Cancer Institute’s Annual Re-
24 port to the Nation on the Status of Cancer):

1 “(2) A genomic sequencing blood or blood prod-
2 uct test that includes the analysis of cell-free nucleic
3 acids.

4 “(3) Such other equivalent tests (which are
5 based on blood, blood products, urine or other sam-
6 ple of biological material) as the Secretary deter-
7 mines appropriate in providing results comparable to
8 those obtained with a test described in paragraph
9 (1).”.

10 (b) PAYMENT AND FREQUENCY LIMIT.—

11 (1) PAYMENT UNDER FEE SCHEDULE.—Section
12 1833(h) of the Social Security Act (42 U.S.C.
13 1395l(h)) is amended—

14 (A) in paragraph (1)(A), by inserting after
15 “(including” the following: “multi-cancer early
16 detection screening tests under section
17 1861(nnn), and including”; and

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

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

1 (2) CONFORMING AMENDMENT.—Section
2 1862(a) of the Social Security Act (42 U.S.C.
3 1395y(a)) is amended—

4 (A) in paragraph (1)—

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

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

10 (iii) by adding at the end the fol-
11 lowing new subparagraph:

12 “(Q) in the case of multi-cancer early de-
13 tection screening tests (as defined in section
14 1861(III)), which are performed more frequently
15 than is covered under section 1833(h)(10);”;
16 and

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

19 (c) RULE OF CONSTRUCTION RELATING TO OTHER
20 CANCER SCREENING TESTS.—Nothing in this section, in-
21 cluding the amendments made by this section, shall be
22 construed—

23 (1) in the case of an individual who undergoes
24 a multi-cancer early detection screening test, to af-
25 fect coverage under part B of title XVIII of the So-

1 cial Security Act for other cancer screening tests
2 covered under such title, such as screening tests for
3 breast, cervical, colorectal, lung, or prostate cancer;
4 or

5 (2) in the case of an individual who undergoes
6 another cancer screening test, to affect coverage
7 under such part for a multi-cancer early detection
8 screening test or the use of such a test as a diag-
9 nostic or confirmatory test for a result of the other
10 cancer screening test.