

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 2407
OFFERED BY M. _____**

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE.

2 This Act may be cited as the “Nancy Gardner Sewell
3 Medicare Multi-Cancer Early Detection Screening Cov-
4 erage Act”.

**5 SEC. 2. MEDICARE COVERAGE OF MULTI-CANCER EARLY
6 DETECTION SCREENING TESTS.**

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

9 (1) in subsection (s)(2)—

10 (A) by striking the semicolon at the end of
11 subparagraph (JJ) and inserting “; and”; and

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

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

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

1 “(nnn) MULTI-CANCER EARLY DETECTION SCREEN-
2 ING TESTS.—

3 “(1) IN GENERAL.—The term ‘multi-cancer
4 early detection screening test’ means a test fur-
5 nished to an individual for the concurrent detection
6 of multiple cancer types across multiple organ sites
7 on or after January 1, 2028, that—

8 “(A) is cleared under section 510(k), clas-
9 sified under section 513(f)(2), or approved
10 under section 515 of the Federal Food, Drug,
11 and Cosmetic Act;

12 “(B) is—

13 “(i) a genomic sequencing blood or
14 blood product test that includes the anal-
15 ysis of cell-free nucleic acids; or

16 “(ii) a test based on samples of bio-
17 logical material that provide results com-
18 parable to those obtained with a test de-
19 scribed in clause (i), as determined by the
20 Secretary; and

21 “(C) the Secretary determines is—

22 “(i) reasonable and necessary for the
23 prevention or early detection of an illness
24 or disability; and

1 “(ii) appropriate for individuals enti-
2 tled to benefits under part A or enrolled
3 under part B.

4 “(2) NCD PROCESS.—In making determina-
5 tions under paragraph (1)(C) regarding the coverage
6 of a new test, the Secretary shall use the process for
7 making national coverage determinations (as defined
8 in section 1869(f)(1)(B)) under this title.”.

9 (b) PAYMENT AND STANDARDS FOR MULTI-CANCER
10 EARLY DETECTION SCREENING TESTS.—

11 (1) IN GENERAL.—Section 1834 of the Social
12 Security Act (42 U.S.C. 1395m) is amended by add-
13 ing at the end the following new subsection:

14 “(aa) PAYMENT AND STANDARDS FOR MULTI-CAN-
15 CER EARLY DETECTION SCREENING TESTS.—

16 “(1) PAYMENT AMOUNT.—The payment
17 amount for a multi-cancer early detection screening
18 test (as defined in section 1861(nnn)) is—

19 “(A) with respect to such a test furnished
20 before January 1, 2031, equal to the payment
21 amount in effect on the date of the enactment
22 of this subsection for a multi-target stool
23 screening DNA test covered pursuant to section
24 1861(pp)(1)(D); and

1 “(B) with respect to such a test furnished
2 on or after January 1, 2031, equal to—

3 “(i) the amount described in subpara-
4 graph (A); or

5 “(ii) the payment amount determined
6 for such test under section 1834A,
7 whichever is less.

8 “(2) LIMITATIONS.—

9 “(A) IN GENERAL.—No payment may be
10 made under this part for a multi-cancer early
11 detection screening test furnished during a year
12 to an individual if—

13 “(i) as of January 1 of such year,
14 such individual has attained the age speci-
15 fied in subparagraph (B) for such year; or

16 “(ii) such a test was furnished to the
17 individual during the previous 11 months.

18 “(B) AGE SPECIFIED.—For purposes of
19 subparagraph (A)(i), the age specified in this
20 subparagraph is—

21 “(i) for 2028, 68 years of age; and

22 “(ii) for a succeeding year, the age
23 specified in this subparagraph for the pre-
24 ceding year, increased by 1 year.

1 “(3) STANDARDS FOLLOWING USPSTF RAT-
2 ING.—In the case of a multi-cancer early detection
3 screening test that is recommended with a grade of
4 A or B by the United States Preventive Services
5 Task Force, beginning on the date on which cov-
6 erage for such test is provided pursuant to section
7 1861(ddd)(1), the preceding provisions of this sub-
8 section shall not apply.”.

9 (2) CONFORMING AMENDMENTS.—

10 (A) Section 1833 of the Social Security
11 Act (42 U.S.C. 1395l) is amended—

12 (i) in subsection (a)—

13 (I) in paragraph (1)(D)(i)(I), by
14 striking “section 1834(d)(1)” and in-
15 serting “subsection (d)(1) or (aa) of
16 section 1834”; and

17 (II) in paragraph (2)(D)(i)(I), by
18 striking “section 1834(d)(1)” and in-
19 serting “subsection (d)(1) or (aa) of
20 section 1834”; and

21 (ii) in subsection (h), by striking “sec-
22 tion 1834(d)(1)” and inserting “sub-
23 sections (d)(1) and (aa) of section 1834”.

24 (B) Section 1862(a) of the Social Security
25 Act (42 U.S.C. 1395y(a)) is amended—

1 (i) in paragraph (1)—

2 (I) in subparagraph (O), by
3 striking “and” at the end;

4 (II) in subparagraph (P), by
5 striking the semicolon at the end and
6 inserting “, and”; and

7 (III) by adding at the end the
8 following new subparagraph:

9 “(Q) in the case of multi-cancer early de-
10 tection screening tests (as defined in section
11 1861(nnn)), which are not reasonable and nec-
12 essary for the concurrent detection of multiple
13 cancer types across multiple organ sites;” and

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

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

20 (1) in the case of an individual who undergoes
21 a multi-cancer early detection screening test, to af-
22 fect coverage under part B of title XVIII of the So-
23 cial Security Act for other cancer screening tests
24 covered under such title, such as screening tests for

1 breast, cervical, colorectal, lung, or prostate cancer;
2 or

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

