

115TH CONGRESS
1ST SESSION

S. 2067

To amend title XVIII of the Social Security Act to provide for coverage under the Medicare program of certain DNA Specimen Provenance Assay clinical diagnostic laboratory tests.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 2, 2017

Mr. CRAPO introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend title XVIII of the Social Security Act to provide for coverage under the Medicare program of certain DNA Specimen Provenance Assay clinical diagnostic laboratory 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 “Prostate Cancer Mis-
5 diagnosis Elimination Act of 2017”.

1 **SEC. 2. COVERAGE OF CERTAIN DNA SPECIMEN PROVE-**
2 **NANCE ASSAY CLINICAL DIAGNOSTIC LAB-**
3 **ORATORY TESTS UNDER MEDICARE.**

4 (a) **COVERAGE.**—Section 1862(a)(1) of the Social Se-
5 curity Act (42 U.S.C. 1395y(a)(1)) is amended—

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

8 (2) in subparagraph (P), by striking the semi-
9 colon at the end and inserting “, and”; and

10 (3) by adding at the end the following new sub-
11 paragraph:

12 “(Q) in the case of a DNA Specimen Prove-
13 nance Assay clinical diagnostic laboratory test
14 (DSPA test) furnished on or after the date specified
15 in section 1834A(j)(4), unless the DSPA test is fur-
16 nished to an individual enrolled under part B who
17 has had a prostate cancer biopsy the results of
18 which are positive, the DSPA test is furnished with
19 respect to such biopsy, and the DSPA test is or-
20 dered by the physician who furnished the prostate
21 cancer biopsy that obtained the specimen tested;”.

22 (b) **TEMPORARY PAYMENT AMOUNT FOR CERTAIN**
23 **TESTS FURNISHED BEFORE 2028 AND RELATED RE-**
24 **QUIREMENTS.**—Section 1834A of the Social Security Act
25 (42 U.S.C. 1395m–1) is amended—

1 (1) in subsection (b)(1)(A), by striking “and
2 (d)” and inserting “, (d), and (j)”; and

3 (2) by adding at the end the following new sub-
4 section:

5 “(j) DNA SPECIMEN PROVENANCE ASSAY CLINICAL
6 DIAGNOSTIC LABORATORY TESTS.—

7 “(1) TEMPORARY PAYMENT AMOUNT FOR CER-
8 TAIN TESTS FURNISHED BEFORE 2028.—With re-
9 spect to a DNA Specimen Provenance Assay clinical
10 diagnostic laboratory test furnished on or after the
11 date specified in paragraph (4) and before January
12 1, 2028, the payment amount under this section for
13 such test shall be equal to \$200.

14 “(2) HCPCS CODE AND MODIFIER ASSIGN-
15 MENT.—

16 “(A) IN GENERAL.—The Secretary shall
17 assign one or more HCPCS codes to the DNA
18 Specimen Provenance Assay clinical diagnostic
19 laboratory test and may use a modifier to facili-
20 tate making payment under this section with
21 respect to such test.

22 “(B) IDENTIFICATION OF DNA MATCH ON
23 CLAIM.—The Secretary shall require an indica-
24 tion on a claim for a DNA Specimen Prove-
25 nance Assay clinical diagnostic laboratory test

1 of whether the DNA of the prostate biopsy
2 specimen for such test matches the DNA of the
3 individual with respect to whom the test was or-
4 dered. Such indication may be made through
5 use of a HCPCS code, a modifier, or other
6 means, as determined appropriate by the Sec-
7 retary.

8 “(3) DNA MATCH REVIEW.—

9 “(A) IN GENERAL.—The Secretary shall
10 review at least three years of claims under part
11 B for DNA Specimen Provenance Assay clinical
12 diagnostic laboratory tests to identify whether
13 the DNA of the prostate biopsy specimens for
14 such tests matched the DNA of the individuals
15 with respect to whom such tests were ordered.

16 “(B) POSTING ON INTERNET WEBSITE.—
17 Not later than July 1, 2024, the Secretary shall
18 post on the Internet website of the Centers for
19 Medicare & Medicaid Services the findings of
20 the review conducted under subparagraph (A).

21 “(4) DATE SPECIFIED.—For purposes of para-
22 graph (1) and section 1862(a)(1)(Q), the date speci-
23 fied in this paragraph is the first day of the second

- 1 calendar quarter that begins at least 180 days after
- 2 the date of the enactment of this subsection.”.

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