

117TH CONGRESS
2D SESSION

S. 4449

To amend title XVIII of the Social Security Act to improve the accuracy of market-based Medicare payment for clinical diagnostic laboratory services, to reduce administrative burdens in the collection of data, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 22, 2022

Mr. BURR (for himself and Mr. BROWN) 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 improve the accuracy of market-based Medicare payment for clinical diagnostic laboratory services, to reduce administrative burdens in the collection of data, and for other purposes.

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 “Saving Access to Lab-
5 oratory Services Act”.

1 **SEC. 2. MODIFICATION OF REQUIREMENTS FOR MEDICARE**
2 **CLINICAL DIAGNOSTIC LABORATORY TESTS.**

3 (a) USE OF STATISTICAL SAMPLING FOR WIDELY
4 AVAILABLE CLINICAL DIAGNOSTIC LABORATORY
5 TESTS.—

6 (1) IN GENERAL.—Section 1834A(a)(1) of the
7 Social Security Act (42 U.S.C. 1395m–1(a)(1)) is
8 amended—

9 (A) in subparagraph (A), by striking “Sub-
10 ject to subparagraph (B)” and inserting “Sub-
11 ject to subparagraphs (B) and (C)”; and

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

14 “(C) USE OF STATISTICAL SAMPLING FOR
15 WIDELY AVAILABLE CLINICAL DIAGNOSTIC LAB-
16 ORATORY TESTS.—

17 “(i) IN GENERAL.—Subject to clause
18 (ii), with respect to data collection periods
19 for reporting periods beginning on or after
20 January 1, 2026, in the case of a widely
21 available clinical diagnostic laboratory test
22 (as defined in clause (iii)), in lieu of re-
23 quiring the reporting of applicable infor-
24 mation from each applicable laboratory,
25 the Secretary shall require the collection
26 and reporting of applicable information

1 from a statistically valid sample of applica-
2 ble laboratories for each such widely avail-
3 able clinical diagnostic laboratory test.

4 “(ii) REQUIREMENTS FOR STATIS-
5 TICAL SAMPLING.—

6 “(I) IN GENERAL.—The Sec-
7 retary, in consultation with stake-
8 holders, shall develop a methodology
9 for a statistically valid sample under
10 clause (i), using the maximal brewer
11 selection method, as described in the
12 June 2021 Medicare Payment Access
13 Commission Report to the Congress,
14 to establish the payment amount for a
15 widely available clinical diagnostic lab-
16 oratory test under paragraph (2) of
17 subsection (b) for each applicable
18 HCPCS code for a widely available
19 clinical diagnostic laboratory test.

20 “(II) REPRESENTATIVE SAM-
21 PLING.—The methodology under sub-
22 clause (I) for a statistically valid sam-
23 ple under clause (i) shall, for each ap-
24 plicable HCPCS code for a widely

1 available clinical diagnostic laboratory
2 test—

3 “(aa) provide for a sample
4 that allows for the payment
5 amounts established under para-
6 graph (2) of subsection (b) for
7 such a test to be representative
8 of rates paid by private payors to
9 applicable laboratories receiving
10 payment under this section, in-
11 cluding independent laboratories,
12 hospital laboratories, hospital
13 outreach laboratories, and physi-
14 cian office laboratories that fur-
15 nish the widely available clinical
16 diagnostic laboratory test;

17 “(bb) include applicable in-
18 formation (as defined in para-
19 graph (3)) with respect to such
20 widely available clinical diag-
21 nostic laboratory test from such
22 different types of applicable lab-
23 oratories; and

24 “(cc) be of sufficient size to
25 accurately and proportionally

1 represent the range of private
2 payor payment rates received by
3 each such type of applicable lab-
4 oratory weighted according to the
5 utilization rates of each type of
6 applicable laboratory for the
7 widely available clinical diag-
8 nostic laboratory test during the
9 first 6 months of the calendar
10 year immediately preceding the
11 data collection period applicable
12 to the sample to be collected.

13 “(III) LEAST BURDENSOME DATA
14 COLLECTION AND REPORTING PROC-
15 ESSES.—The methodology developed
16 by the Secretary shall be designed to
17 reduce administrative burdens of data
18 collection and reporting on applicable
19 laboratories and the Centers for Medi-
20 care & Medicaid Services to the great-
21 est extent practicable.

22 “(IV) PUBLICATION OF LIST OF
23 WIDELY AVAILABLE CLINICAL DIAG-
24 NOSTIC LABORATORY TESTS AND NO-
25 TIFICATION TO APPLICABLE LABORA-

1 TORIES REQUIRED TO REPORT APPLI-
 2 CABLE INFORMATION.—Not later than
 3 September 30 of the year immediately
 4 preceding each data collection period
 5 (as defined in paragraph (4)), the
 6 Secretary shall publish in the Federal
 7 Register a list of widely available clin-
 8 ical diagnostic laboratory tests and
 9 shall directly notify applicable labora-
 10 tories required to report applicable in-
 11 formation under this subsection.

12 “(iii) DEFINITION OF WIDELY AVAIL-
 13 ABLE CLINICAL DIAGNOSTIC LABORATORY
 14 TEST.—In this subparagraph, the term
 15 ‘widely available clinical diagnostic labora-
 16 tory test’ means a clinical diagnostic lab-
 17 oratory test that meets both of the fol-
 18 lowing criteria during the first 6 months of
 19 the calendar year immediately preceding
 20 the data collection period applicable to the
 21 sample to be collected:

22 “(I) PAYMENT RATE.—The pay-
 23 ment amount determined for the clin-
 24 ical diagnostic laboratory test under

1 this section is less than \$1,000 per
2 test.

3 “(II) NUMBER OF LABORATORIES
4 PERFORMING THE TEST.—The num-
5 ber of applicable laboratories receiving
6 payments under this section for the
7 clinical diagnostic laboratory test (as
8 determined by the Secretary using the
9 national provider identifier of the pro-
10 vider of services or supplier on the
11 claim submitted for payment under
12 this part for such test) exceeds 100.”.

13 (2) DELAYS TO REVISED REPORTING PERIODS
14 AND REPORTING PERIOD FREQUENCY.—

15 (A) IN GENERAL.—Section
16 1834A(a)(1)(B) of the Social Security Act (42
17 U.S.C. 1395m–1(a)(1)(B)) is amended—

18 (i) in clause (i), by striking “Decem-
19 ber 31, 2022” and inserting “December
20 31, 2024”;

21 (ii) in clause (ii), by striking “begin-
22 ning January 1, 2023, and ending March
23 31, 2023” and inserting “beginning Janu-
24 ary 1, 2026, and ending March 31, 2026”;
25 and

1 (iii) in clause (iii) by striking “every
 2 three years” and inserting “every four
 3 years”.

4 (B) CONFORMING CHANGE TO DEFINITION
 5 OF DATA COLLECTION PERIOD.—Section
 6 1834A(a)(4)(B) of the Social Security Act (42
 7 U.S.C. 1395m–1(a)(4)(B)) is amended by strik-
 8 ing “January 1, 2019, and ending June 30,
 9 2019” and inserting “January 1, 2025, and
 10 ending June 30, 2025”.

11 (b) ELIMINATION OF MAJORITY OF MEDICARE REVE-
 12 NUES TEST.—The first sentence of section 1834A(a)(2)
 13 of the Social Security Act (42 U.S.C. 1395m–1(a)(2)) is
 14 amended by striking “In this section” and all that follows
 15 through the period and inserting the following: “Notwith-
 16 standing determinations of applicable laboratories made
 17 prior to January 1, 2024, the term ‘applicable laboratory’
 18 means a laboratory that receives at least \$12,500 in pay-
 19 ments under this section during the first 6 months of the
 20 calendar year immediately preceding the applicable data
 21 collection period.”.

22 (c) MODIFICATIONS TO APPLICABLE INFORMATION
 23 REPORTED.—

24 (1) MEDICAID MANAGED CARE RATES.—Section
 25 1834A(a)(8)(C) of the Social Security Act (42

1 U.S.C. 1395m–1(a)(8)(C)) is amended by striking
 2 “A medicaid managed care organization” and insert-
 3 ing “With respect to data collection periods for re-
 4 porting periods beginning before January 1, 2026, a
 5 medicaid managed care organization (as defined in
 6 section 1903(m))”.

7 (2) AUTHORITY TO EXCLUDE MANUAL REMIT-
 8 TANCES.—Section 1834A(a)(3) of the Social Secu-
 9 rity Act (42 U.S.C. 1395m–1(a)(3)) is amended—

10 (A) in subparagraph (A), by striking “sub-
 11 ject to subparagraph (B),” and inserting “sub-
 12 ject to subparagraphs (B) and (C)”; and

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

15 “(C) EXCLUSION OF MANUAL REMIT-
 16 TANCES.—An applicable laboratory for which
 17 less than 10 percent of its total paid claims
 18 during a data collection period are paid by pri-
 19 vate payors by means other than an electronic
 20 standard transaction (as defined in section
 21 162.103 of title 45, Code of Federal Regula-
 22 tions (or any successor regulation)) may exclude
 23 from the definition of applicable information
 24 under this paragraph payments made by private

1 payors that are not made through an electronic
2 standard transaction.”.

3 (d) MODIFICATION TO LIMITS ON PAYMENT REDUC-
4 TIONS; IMPOSITION OF ANNUAL CAP ON PAYMENT IN-
5 CREASES.—

6 (1) PAYMENT REDUCTION LIMITS.—Section
7 1834A(b)(3) of the Social Security Act (42 U.S.C.
8 1395m–1(b)(3)) is amended—

9 (A) in subparagraph (A), by striking “for
10 each of 2017 through 2025” and inserting “for
11 2017 and each succeeding year”; and

12 (B) in subparagraph (B)—

13 (i) in clause (ii), by striking “and” at
14 the end; and

15 (ii) by striking clause (iii) and insert-
16 ing the following:

17 “(iii) for 2023, 0 percent;

18 “(iv) for 2024, 2.5 percent; and

19 “(v) for 2025 and each subsequent
20 year, 5 percent.”.

21 (2) ANNUAL CAP ON PAYMENT RATE IN-
22 CREASES.—Section 1834A(b)(3) of the Social Secu-
23 rity Act (42 U.S.C. 1395m–1(b)(3)), as amended by
24 paragraph (1), is amended—

25 (A) in subparagraph (A)—

1 (i) by striking “test for 2017 and
2 each succeeding year—” and inserting
3 “test—

4 “(i) for 2017 and each succeeding
5 year”;

6 (ii) in clause (i), as added by clause
7 (i) of this subparagraph, by striking the
8 period and inserting “; and”; and

9 (iii) by adding at the end the fol-
10 lowing new clause:

11 “(ii) for 2023 and each succeeding
12 year, shall not result in an increase in pay-
13 ments for a clinical diagnostic laboratory
14 test for the year of greater than the appli-
15 cable percent (as defined in subparagraph
16 (D)) of the amount of payment for the test
17 for the preceding year.”;

18 (B) in subparagraph (B), in the matter
19 preceding clause (i), by striking “In this para-
20 graph” and inserting “In clause (i) of subpara-
21 graph (A)”;

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

24 “(D) DEFINITION OF APPLICABLE PER-
25 CENT FOR PURPOSES OF ANNUAL CAP ON PAY-

MENT INCREASES.—In clause (ii) of subparagraph (A), the term ‘applicable percent’ means the following:

“(i) WIDELY AVAILABLE CLINICAL DIAGNOSTIC LABORATORY TESTS.—With respect to a widely available clinical diagnostic laboratory test—

“(I) for 2023, 2.5 percent;

“(II) for 2024, 2.5 percent;

“(III) for 2025, 3.75 percent;

“(IV) for 2026, 3.75 percent;

and

“(V) for 2027 and each subsequent year, 5 percent.

“(ii) OTHER CLINICAL DIAGNOSTIC LABORATORY TESTS.—With respect to a clinical diagnostic laboratory test not described in clause (i), 5 percent.”.

(3) CONFORMING AMENDMENT.—Section 1834A(b)(3) of the Social Security Act (42 U.S.C. 1395m–1(b)(3)) is amended in the heading by striking “REDUCTIONS” and inserting “MEDICARE PAYMENT CHANGES”.

(e) REGULATIONS.—(1) Not later than December 31, 2023, the Secretary of Health and Human Services shall

1 implement the amendments made by this section (other
2 than subsection (d)) through notice and comment rule-
3 making.

4 (2) The Secretary of Health and Human Services
5 may implement the amendments made by subsection (d)
6 through interim final rulemaking, program instruction, or
7 otherwise.

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