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42 U.S. Code § 1395m-1

Improving policies for clinical diagnostic laboratory tests

(a) Reporting of private sector payment rates for establishment of medicare payment rates

(1) In general

(A) General reporting requirements

Subject to subparagraph (B), beginning January 1, 2016, and every 3 years thereafter (or, annually, in the case of reporting with respect to an advanced diagnostic laboratory test, as defined in subsection (d)(5)), an applicable laboratory (as defined in paragraph (2)) shall report to the Secretary, at a time specified by the Secretary (referred to in this subsection as the "reporting period"), applicable information (as defined in paragraph (3)) for a data collection period (as defined in paragraph (4)) for each clinical diagnostic laboratory test that the laboratory furnishes during such period for which payment is made under this part.

(B) Revised reporting period

In the case of reporting with respect to clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests, the Secretary shall revise the reporting period under subparagraph (A) such that—

(i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2024;

(ii) reporting is required during the period beginning January 1, 2025, and ending March 31, 2025; and

(iii) reporting is required every three years after the period described in clause (ii).

(2) Definition of applicable laboratory

In this section, the term "applicable laboratory" means a laboratory that, with respect to its revenues under this subchapter, a majority of such revenues are from this section, section 1395*l*(h) of this title, or section 1395w–4 of this title. The Secretary may establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory under this paragraph, as the Secretary determines appropriate.

(3) Applicable information defined

(A) In general

In this section, subject to subparagraph (B), the term "applicable information" means, with respect to a laboratory test for a data collection period, the following:

(i) The payment rate (as determined in accordance with paragraph (5)) that was paid by each private payor for the test during the period.

(ii) The volume of such tests for each such payor for the period.

(B) Exception for certain contractual arrangements

Such term shall not include information with respect to a laboratory test for which payment is made on a capitated basis or other similar payment basis during the data collection period.

(4) Data collection period defined

(A) In general

Subject to subparagraph (B), in this section, the term "data collection period" means a period of time, such as a previous 12 month period, specified by the Secretary.

(B) Exception

In the case of the reporting period described in paragraph (1)(B)(ii) with respect to clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests, the term "data collection period" means the period beginning January 1, 2019, and ending June 30, 2019.

(5) Treatment of discounts

The payment rate reported by a laboratory under this subsection shall reflect all discounts, rebates, coupons, and other price concessions, including those described in section 1395w–3a(c)(3) of this title.

(6) Ensuring complete reporting

In the case where an applicable laboratory has more than one payment rate for the same payor for the same test or more than one payment rate for different payors for the same test, the applicable laboratory shall report each such payment rate and the volume for the test at each such rate under this subsection. Beginning with January 1, 2019, the Secretary may establish rules to aggregate reporting with respect to the situations described in the preceding sentence.

(7) Certification

An officer of the laboratory shall certify the accuracy and completeness of the information reported under this subsection.

(8) Private payor defined

In this section, the term "private payor" means the following:

(A) A health insurance issuer and a group health plan (as such terms are defined insection 300gg–91 of this title).

(B) A Medicare Advantage plan under part C.

(C) A medicaid managed care organization (as defined in section 1396b(m) of this title).