

Medicare Clinical Diagnostic Laboratory Tests (CDLTs) Payment System Final Rule

OVERVIEW

On June 17th, the Centers for Medicare and Medicaid Services (CMS) released a final rule that will revise the payment methodology for CDLTs that are paid under the Clinical Laboratory Fee Schedule (CLFS). Under the final rule, applicable laboratories will be required to report private payer payment rates and volume for CDLTs. CMS will use these private payer payment rates to establish new CLFS payment rates for CY 2018. CMS will publish the preliminary CY 2018 CLFS rates in September 2017 and will accept comments on the preliminary rates, before finalizing new rates in November 2017. The final rule is available [here](#).

APPLICABLE LABORATORIES

Under the final rule, applicable laboratories include those that meet the following criteria:

- Have their own National Provider Identifier;
- Receive at least 50 percent of their total Medicare revenue under the CLFS or Physician Fee Schedule during the six-month data collection period; and
- Receive at least \$12,500 of their total Medicare revenue under the CLFS during the six-month data collection period.

The provisions of the final rule will apply to hospital and physician office laboratories that are independently enrolled in Medicare and meet the aforementioned criteria. This deviates from the proposed rule, which excluded hospital-based laboratories.

LABORATORY REPORTING REQUIREMENTS

Under the final rule, applicable laboratories will be required to collect and report data on private payer rates and volume for CDLTs every three years. For the first year, laboratories will collect data for CDLTs that were paid from January 1, 2016 to June 30, 2016 and report this data to CMS by March 31, 2017. Laboratories may be penalized up to \$10,000 per day for each failure to report, misrepresentation, or omission of private payer prices.

PAYMENT REDUCTIONS

Every three years, beginning with CY 2018, CMS will calculate new CLFS rates that are equal to the weighted median of private payer rates for each test. However, for the first six years CMS has established payment reduction limits for new CLFS rates. For CY 2018 through CY 2020, the payment amount for a test cannot decrease more than 10 percent from the previous year's payment amount. For CY 2021 through CY 2023, the payment amount for a test cannot decrease by more than 15 percent from the previous year's payment amount.