# PUBLICATION

## CMS Takes First Step to Reduce Payments for Clinical Laboratory Tests [Ober|Kaler]

**Authors: Robert E. Mazer**
**October 14, 2015**

## Introduction

CMS recently published a proposed rule that would substantially revise the methodology used to pay for clinical laboratory tests that continue to be compensated separately by Medicare. Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System, Proposed Rule, 80 Fed. Reg. 59386 (Oct. 1, 2015) [PDF]. This article will discuss two significant components of the proposed rule, as they apply to most clinical laboratory tests: (1) data reporting requirements related to the agency's collection of payment data to be used to assign new payment rates for clinical laboratory tests and (2) new payment rates that will be used by CMS to pay for clinical laboratory tests starting on January 1, 2017. Comments regarding the new rule will be accepted by CMS **through November 24, 2015**.

## Background

Since 1984, the Medicare statute has required Medicare to pay for clinical laboratory tests based on a special fee schedule that was based initially on prevailing charges from July 1, 1984 through June 30, 1985. The Protecting Access to Medicare Act of 2014 (PAMA), however, added statutory provisions that would substantially modify payments for clinical laboratory tests to reflect amounts paid by private payors for such services, effective January 1, 2017. As part of the process, PAMA requires certain laboratories to report payment rates used by private payors to pay for clinical laboratory tests. CMS would then use this data to establish new Medicare payment rates for such tests. The proposed rule reflects how the agency CMS proposes to implement the statutory requirements.

## Reporting Requirements

Under the proposed rule, an entity that is considered an "applicable laboratory" is required to report "applicable data" to CMS for the agency's use in computing new Medicare payment rates for clinical laboratory tests. An "applicable laboratory" must be a "laboratory" as that term is defined in regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), or be an entity that includes a "laboratory," such as a health system. The report must be submitted by the entity to which a tax identification number (TIN) has been assigned by the Internal Revenue Service. This could include an entity consisting of numerous providers each of which has its own national provider identification (NPI).

An "applicable laboratory" must receive a majority of its Medicare revenues (more than 50%) under Medicare regulatory provisions related to payments for clinical diagnostic laboratory tests and for services furnished by physicians and other practitioners. These revenues would include Medicare fee for service payments under Medicare Parts A and B, Medicare Advantage Payments under Medicare Part C, and prescription drug payments under Medicare Part D, including any applicable deductible and coinsurance payments. In determining whether at least 50% of Medicare revenues are from such services, data from each provider

operating under a single TIN is required to be combined. Medicare payments to hospitals for clinical laboratory tests furnished to hospital inpatients and registered outpatients would not be included among the revenues that could cause an entity to be considered an "applicable laboratory" because those payments are made as part of a prospective payments system provided for under different regulatory provisions.

The proposed rule includes a $50,000 threshold, i.e., entities that receive less than $50,000 in Medicare revenues under Medicare regulatory provisions for payment for clinical laboratory services during a one-year data collection period would not be an "applicable laboratory" required to report data to the agency. The threshold would be $25,000 for the initial six-month data reporting period, discussed below.

"Applicable information" required to be reported includes each private payor rate and the related test volume for each clinical laboratory test provided by the "applicable laboratory." A private payor, for this purpose, is a health insurance issuer or group health plan as defined under the Public Health Service Act, a Medicare Advantage plan, or a Medicaid managed care organization. The private payor rate required to be reported must reflect any discount or other price concession offered to the payor, and include any applicable coinsurance or deductible. Capitated payments, however, are not "applicable information" and need not be reported. In submitting data to CMS, the identity of each private payor need not (and cannot) be provided. CMS states that it will specify the form and manner for reporting information in guidance that it will issue prior to the first data reporting period.

Under the proposed rule, a calendar year is used as the basis for collection of data. The first such "data collection period" would be truncated, however, starting on July 1, 2015 and ending on December 31, 2015. Under the proposed rule, collected data must be reported within the three-month period starting after the end of the data collection period, which CMS refers to as the "data reporting period." For example, the data collected from the period between July 1, 2015 and December 31, 2015 would need to be reported between January 1, 2016 and March 31, 2016. The process would be repeated every three years.

A reporting laboratory will be required to certify that the data provided to the agency is accurate, complete, truthful and in accordance with CMS instructions. The certification will need to be signed by the laboratory's president, CEO, CFO, or a designated individual who reports to the person holding one of those positions. The proposed rule provides for civil monetary penalties of $10,000 per day if an "applicable laboratory" fails to report, or makes a misrepresentation or omission in reporting "applicable information."

Subject to specified exceptions, "applicable information" that would identify a specific payor or laboratory, or prices charged or payments made to a laboratory, is required to be kept confidential by the agency. CMS, however, can disclose information to the Office of Inspector General or Department of Justice for oversight and enforcement activities.

## Payment Rates

As provided for by the statute, the payment amount for each clinical laboratory test will be the weighted median of the private payor rates for the test. The data reported for the period from July 1, 2015 through December 31, 2015 will be used to compute new payment rates that will go into effect in 2017, and then remain in effect until 2020, without further adjustment.

The statute limits the *annual* reduction of payment amounts to 10% for *each* of 2017, 2018 and 2019, and 15% for *each* of 2020, 2021 and 2022. Although the proposed rule does not apply directly to Medicaid, CMS notes that Medicaid payments for clinical laboratory tests cannot exceed the amounts recognized by Medicare. Accordingly, Medicaid payment amounts are likely to be reduced as well.

## Ober|Kaler's Comments

CMS has estimated a cost savings of $360 million for fiscal year 2017 based on its assumption that generally private payor rates are approximately 20% less than rates under the Medicare clinical laboratory fee schedule. Assuming that the proposed rule is adopted as a final rule, hospitals and health systems operating under a single TIN should mostly avoid its impact. Generally, they should not be required to report data to CMS, and most of the clinical laboratory tests that they provide to Medicare beneficiaries are compensated based on the Medicare inpatient or outpatient prospective payment system that will not be affected by the new rule. Hospitals or health systems that operate significant "outreach programs" in which they furnish tests to individuals who are not registered hospital outpatients would suffer a reduction in Medicare revenues from these tests, similar to those that independent clinical laboratories will incur.

Independent laboratories and physician office laboratories (that exceed the applicable threshold) will need to prepare themselves for the process of reporting price data to CMS and the Medicare payment reductions that are anticipated to follow. Budgets and business plans may require review and revision. Laboratories that are able to reduce discounts to private payers may offset some of the anticipated loss in Medicare revenues – and theoretically help control future reductions in Medicare payments – but that may prove to be a strategy that is easier said than done.

In addition to the provisions described above, the proposed rule includes special provisions for any test that is considered a "new clinical diagnostic laboratory test" or an "advanced diagnostic laboratory test."

Laboratory organizations will undoubtedly submit comments addressing the proposed rule. To the extent that a clinical laboratory or other organization has concerns that it believes may not be adequately addressed by such organizations, it should consider submission of its own comments to CMS, on or before the November 24, 2015 deadline.