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# CMS Releases Proposed Plan to Overhaul Medicare Laboratory Payment

+Insights

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The long-awaited proposed rule offers some insights into how CMS will implement the reforms of the Protecting Access to Medicare Act of 2014, but leaves many key questions unanswered. Laboratories and other stakeholders should review the proposed rule and consider submitting comments to CMS by November 24, 2015.

On September 25, 2015, the Centers for Medicare and Medicaid Services (CMS) released a long-awaited and much-delayed proposed rule to implement Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), legislation that requires the agency to substantially overhaul how and how much Medicare pays for clinical laboratory services.

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On April 1, 2014, Congress enacted the Protecting Access to Medicare Act of 2014 (PAMA), legislation that overhauled the statutory framework and instructions that guided Medicare coverage and payment for clinical laboratory services for more than three decades. Generally, PAMA replaced the historical processes of "cross-walking" and "gap-filling" to determine Medicare payment amounts for lab services in favor of a market-based and driven payment system that will peg Medicare payments to payments made by private payers for lab services.

CMS was **required** by statute **to complete** this **rulemaking**, including issuing a final rule, by **June 30, 2015**, but is just now issuing a proposed rule.

As in most legislation, Congress provided a broad framework, but left it to the regulatory agency to fill in specific details. CMS was required by statute to complete this rulemaking, including issuing a *final* rule, by June 30, 2015, but is just now issuing a *proposed* rule, well behind schedule. The laboratory community and other affected stakeholders therefore have been anxiously awaiting the release of this proposed rulemaking to see how CMS interprets and intends to implement the various reporting, rate-setting and other requirements established by PAMA. The proposed rule provides considerably more details about the

agency's plans, but also defers on a wide variety of important details until future rulemaking.

CMS states in the rule that it intends to implement new payment rates derived from market prices by the statutory implementation date of January 1, 2017, and begin requiring affected laboratories to report that market information by January 1, 2016. Both dates, however, are called into question by the agency's tardiness in issuing this rulemaking, as well as by the many concerns about the draft already being voiced by the affected community.

**Reporting**

*"Applicable Laboratory": Laboratories Subject to the Reporting Requirement*

Under PAMA, "applicable laboratories" must report payment rates to CMS for diagnostic laboratory tests beginning in 2016. How CMS would define the term "applicable laboratories" and which laboratories would be required to report payment rate data pursuant to this requirement has been the focus of much speculation, concern and lobbying.

CMS opted to apply the reporting obligation to entities that derive more than 50 percent of their Medicare revenues from payments under Medicare's Clinical Laboratory Fee Schedule (CLFS) or Physician Fee Schedule (PFS) during a defined collection period, but that also realize at least $50,000 in Medicare revenues for CLFS services in that same period. CMS proposes to use a full 12-month reporting period once fully implemented, but to use only a six-month collection period (July 1, 2015, through December 31, 2015) during the first year of implementation.

Consistent with this truncated collection period, CMS proposes to prorate the minimum Medicare revenue threshold such that laboratories with less than $25,000 in Medicare revenues for CLFS services in this six-month period would be excluded.

Using these parameters, CMS expects that only independent laboratories and a small number of physician offices will be considered "applicable laboratories" and required to report, and that hospital based laboratories will not be included. CMS proposes that entities that fall outside of these parameters would not only be exempt, but in fact would be barred from reporting. Consequently, the $50,000 minimum annual Medicare revenue threshold may block some start-up laboratories without significant Medicare revenue from reporting and having a Medicare payment amount determined using exclusively private payer rate data.

**Applicable Laboratory**:
- ⇨ Meets the CLIA definition of lab
- ⇨ Is a lab itself or has at least one component that is a lab
- ⇨ 50% of Medicare revenues from CLFS and PFS during data reporting period
- ⇨ $50,000 threshold in CLFS revenues during data collection period

*"Applicable Information": Data Subject to the Reporting Requirement*

Under the statute, applicable laboratories must report information on rates paid by private payers for their laboratory services ("applicable information"). The statute was fairly prescriptive and broad, seeking to cover the waterfront of private payers, including

Medicare Advantage and Medicaid managed care organizations. CMS chose to largely reflect the statutory definition of applicable information without much elaboration.

*Reporting Process*

PAMA also gave CMS broad authority to define the form and manner in which laboratories would report private payer rates. CMS is not disclosing its reporting format or plan at this time, instead indicating that guidance regarding the mechanism for reporting will be forthcoming. Nonetheless, the proposed rule is clear that CMS expects laboratories subject to the reporting requirement to report detailed and comprehensive information on rates and volume for all covered lab services, including each payment amount received from a payer throughout a year, and the volume of claims paid at each rate by each payer.

*Reporting Frequency*

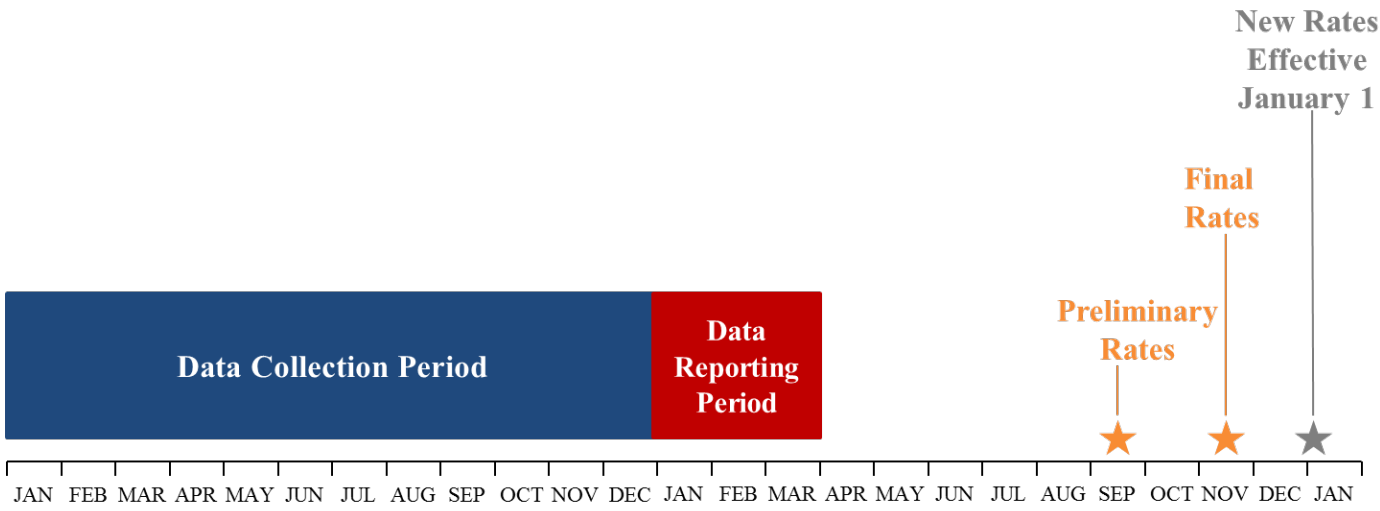
PAMA distinguishes between two types of tests: Clinical Diagnostic Laboratory Tests (CDLTs) and Advanced Diagnostic Laboratory Tests (ADLTs). The statute prescribes different reporting intervals for each type of test. The law requires labs to report payment data for CDLTs every three years, but to report annually for tests that are ADLTs. CMS's proposed rule would clarify that payment rates and the reporting period will coincide with a calendar year, as opposed to a 12-month rolling period, and that the PAMA rate-setting process will follow the current timeline for CLFS rate-setting.

CMS proposes a truncated six-month collection period for 2015 beginning July 1, 2015, and ending December 31, 2015. Beginning in 2016, CMS would allow laboratories a full calendar year to collect data to be reported. This data collection period would be immediately followed by a 90-day period during which laboratories may verify and validate their private payer rate data before data would be due to CMS by the final day of the 90-day reporting period. All laboratories subject to the law would be required to make a first report by March 31, 2016. The data reported by this date would be used to determine rates for 2017.

**Rate-Setting**

*Rate-Setting for Existing Tests*

Beginning in January 2017, Medicare payment for existing diagnostic laboratory tests will be based on the weighted median of the payment rates from private payers for the test. CMS proposes to further define the rate-setting methodology by proposing to array every payment rate, by payer, submitted by laboratories and to determine the median of the entire array. CMS will list each distinct private payer rate the same number of times in the array as its volume. In its example, CMS states that if a private payer rate of $5 is reported 5,000 times (that is, by 5,000 different payers or laboratories), the value $5 will be given 5,000 entries in the array. CMS proposes to repeat this process for each reported rate and determine the median of the entire array. This volume-weighted median will be the CLFS payment amount for the lab test.




CMS will update the payment for CDLTs every three years, and for ADLTs annually, following the reporting periods described above.

CMS proposes to publish preliminary rates in September with final rates published in November to become effective the next January following the applicable reporting period.

PAMA protected laboratories from potentially dramatic reimbursement cuts by limiting payment reductions between 2017 and 2019 to 10 percent each year. Cuts to payment rates between 2020 and 2022 are limited to 15 percent each year. CMS again chose to mirror the statute in the regulations; however, the agency clarified that each year's reduction would be based on the payment rate for the immediately prior year, as opposed to basing cuts on a base year. This has the effect of limiting payment reductions between 2017 and 2019 to a maximum of 27.1 percent. Under the CMS proposal, however, payment reductions over the six-year period of 2017 to 2022 could be as high as 55.2 percent.

*Payment for New Tests*

Payment amounts for CDLTs that are assigned to a new or substantially revised HCPCS code after the date of enactment (April 1, 2014), and that therefore may not have private payer data to report to CMS, will first be determined using traditional cross-walking processes or, if no existing test is comparable to the new test, then by gap-filling processes.

Because of the unique nature of ADLTs, the legislation established an alternative rate-setting methodology for new ADLTs just emerging on the market. Specifically, the legislation provides that beginning in 2017, new ADLTs will be paid the Actual List Charge for an initial period before transitioning to the market-based payment system. CMS proposed that this initial period begin on the first day of the first full calendar quarter after the day the test is first performed. As an example, for a test that is first performed on February 4, the initial period during which payment will be at the Actual List Charge will begin April 1. During the period between February 4 and April 1,

the laboratory will work with its local contractor to determine appropriate pricing.

CMS proposed that the Actual List Charge be the lowest publicly available price at which the test is available according to sources such as websites, test registries or price listing for a patient without the benefit of negotiated prices. This rate is to be determined on the date the test is first available to be purchased and may be determined before the test is ever used.

Under the legislation, if CMS finds that the Actual List Charge for an ADLT is greater than 130 percent of the market-based payment amount ultimately determined for the test, CMS is required to recoup the difference between such payment amounts for tests furnished during such period. CMS proposes to recoup the full difference between the market-based amount and the Average List Charge.

*Defining Advanced Diagnostic Laboratory Tests*

The legislation defines ADLTs as tests that analyze multiple biomarkers of DNA, RNA or proteins using a unique algorithm and producing a single patient-specific result, or that are cleared or approved by the U.S. Food and Drug Administration (FDA). (A CDLT is a laboratory test that is not an ADLT). In this instance, CMS chose to deviate considerably from the statute, and to further clarify that ADLTs must evaluate the pathology of DNA or RNA, essentially excluding protein-based tests from being considered ADLTs unless those tests also include the "molecular pathology" of DNA or RNA. CMS further proposes that the algorithm associated with an ADLT must be empirically derived and that the test itself must provide new information that cannot be obtained from an existing test or combination of tests.

Notwithstanding the CMS proposal to allow laboratories to apply for ADLT status, CMS will be the arbiter of whether a test qualifies as an ADLT. Under this proposed rule, laboratories applying for ADLT status must show that the laboratory itself meets the criteria required as a single laboratory, that the laboratory is the only one that markets and performs the test, that the laboratory does not sell to or allow the test to be performed by a laboratory other than the laboratory that designed the test or its successors, and that the test itself meets the definition of an ADLT. Upon meeting these criteria, according to the regulations, the test would be designated as an ADLT.

**Coding**

In the proposed rule, CMS acknowledges that PAMA contemplated and intends to ensure that laboratory tests are identifiable by a unique code. CMS proposes to use its current coding process to meet its statutory obligation

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to assign codes to certain new tests. CMS believes that its current coding process is capable of creating codes in such a manner and with such timing as to satisfy the PAMA requirements.

Under the proposed rule, CMS would use its existing coding process to create and assign temporary G-codes for new ADLTs and new CDLTs that are FDA cleared or approved and that have not already been assigned either a CPT code or a Level II HCPCS code. These temporary G-codes would be effective until CPT or Level II HCPCS codes are assigned to the tests. CMS may choose, under its proposal, to extend the effective time of the temporary G-code beyond the two years contemplated in statute if by that time the test has not been assigned a CPT or Level II HCPCS code.

Because the statute requires CMS to assign unique codes to new and existing ADLTs and CDLTs that are FDA approved or cleared, CMS expects that each ADLT and each FDA-cleared or -approved CDLT will be assigned its own HCPCS code. However, CMS notes that it expects it would likely assign different codes to the FDA-approved and the non-FDA-approved variants of a CDLT.

**Contractor Consolidation**

While PAMA provided CMS with authority to implement changes to the structure of the contractors who process and pay claims for laboratory tests, CMS chose not to address those issues in this proposed rule. CMS claims that the level of administrative complexity associated with contractor reform necessitates careful review and consideration of the impact of any changes on both CMS claims systems and on contractor and stakeholder operations. CMS is soliciting comments on the issue of contractor consolidation.

**Conclusion**

PAMA established a framework for dramatic reforms to the way in which Medicare sets payment rates for laboratory services. CMS' proposed policy is a step toward implementing these reforms, but the proposed rule still leaves many questions unanswered and details unstated. Moreover, many of CMS's proposals are likely to concern and frustrate the affected community, and undoubtedly will lead to considerable discussion about the future course of this rulemaking. Stakeholders should review the proposed rule carefully to evaluate the potential impact of the proposed changes and to share views with CMS through comments. Comments on the proposed rule are due to CMS by November 24, 2015.

For more information, please contact Deb Godes, Paul Radensky, John Warren or Eric Zimmerman