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CMS Proposes Overhaul of Clinical Lab Payment Methodology: What You Need To Know

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In this Issue:

On Friday, CMS issued a long-awaited proposed rule that would drastically change the payment rates for clinical laboratory services beginning January 1, 2017 (the "Proposed Rule"). As mandated by Congress under the Protecting Access to Medicare Act of 2014 ("PAMA"), the Proposed Rule would require "applicable laboratories" to report payment rates received from private insurers and would base the new Medicare payment amounts on a weighted median of those rates. CMS expects this to result in a $360 million pay cut for laboratories in 2017 alone and potential savings for Medicare of over $2.94 billion over the next five years.

What You Need to Know

In establishing an entirely new basis for payment under the clinical lab fee schedule ("CLFS"), the Proposed Rule envisions a key role for laboratories as the primary source of data regarding private payer rates. Below we explore the highlights of the Proposed Rule, including the reporting requirements and the nuances of the potential rate reductions.

Who Must Report

The private payer rates that will serve as the basis for the revised Medicare CLFS will ultimately be determined by aggregating data from "applicable laboratories." Under PAMA, an "applicable laboratory" must report private payer rate information for each clinical lab test that it furnishes during a relevant data collection period. Building on the definition within PAMA, CMS proposed to define an "applicable laboratory" by the following features:

- The entity: (i) is itself a laboratory as defined by CLIA (at 42 C.F.R. § 493.2); ***or*** (ii) is an entity that includes a laboratory (*e.g.,* a health care system that is comprised of multiple hospitals, clinics, and labs). CMS proposes to define an "applicable laboratory" at the Tax Identification

Number ("TIN")-level rather than the NPI-level. This means that a health system with multiple laboratories operating under the same TIN would be considered a single "applicable laboratory" for purposes of reporting.

- The entity – as a whole – receives a majority of its Medicare revenues from payments under the CLFS and the Physician Fee Schedule ("PFS") during the applicable reporting period. CMS proposes to define "majority" as 50%, and it proposes to define the universe of "Medicare revenues" to include all fee-for-service payments under Medicare Parts A and B as well as all payments under Medicare Advantage and Part D plans. If more than 50% of all Medicare revenues are attributable to the CLFS or PFS, then the laboratory qualifies as an "applicable laboratory." Based on this provision, CMS expects most hospital-based laboratories to be exempt from reporting.

- The entity receives at least $50,000 in revenue for laboratory tests paid under the CLFS. Any entity below that threshold is exempt from reporting.

Although not explicit in the Proposed Rule, CMS appears to expect each laboratory to determine independently whether it qualifies as an "applicable laboratory" for purposes of reporting.

What Information Must Be Reported

Under the Proposed Rule, applicable laboratories would be required to report "applicable information." For each test furnished during the data collection period, this includes: (1) the payment rate paid by each private payer; (2) the volume; and (3) the HCPCS code. The payment rate as reported must include patient copayment and deductible amounts, and it must take into account all rebates, discounts, coupons, and other price concessions. Notably, however, laboratories would not be required to report any payment made on a capitated basis or under a similar payment methodology. Also, as proposed, "private payers" include all health insurance issuers and group health plans (as defined in § 2791 of the Public Health Service Act), all Medicare Advantage plans, and all Medicaid managed care organizations.

In addition, as authorized by PAMA, CMS has proposed to impose civil monetary penalties ("CMPs") of up to $10,000 per day for each failure to report, misrepresentation, or omission in reporting the necessary data.

Reporting Periods

As a general rule, every three years laboratories will be expected to report private payer rate information for a full calendar year (referred to by CMS as a "data collection period") by no later than three months following the end of the data collection period. CMS has proposed an exception for 2015, the first year in which data must be reported, for which laboratories would only be required to report data for the collection period spanning from July 1, 2015 through December 31, 2015. CMS provides the following chart to illustrate its proposal more clearly:

Data Collection Period	Data Reporting Period	Used for CLFS Rate Years
07/01/2015 – 12/31/2015	01/01/2016 – 03/31/2016	2017 – 2019
01/01/2018	01/01/2019 – 03/31/2019	2020 – 2022

Under the Proposed Rule, the first deadline for applicable laboratories would be March 31, 2016.

Calculation of Payment Rates & Important Limits on Payment Reductions

Using the information supplied by the applicable laboratories, CMS proposes to develop a uniform CLFS payment rate for each HCPCS code that is based upon the weighted median of the reported private payer rates. The term "weighted" means that CMS will not simply identify all individual rates represented and calculate the median from there, but instead it will consider the volume of tests paid at

a particular rate. Simplifying greatly, if Laboratory A performs four lipid panels for $10 each and Laboratory B performs three lipid panels for $12 each, the weighted median will be calculated as the fourth entry (the middle of seven total amounts): $10, $10, $10, **$10**, $12, $12, $12. By contrast to the current CLFS, CMS proposes not to make any geographic adjustments to these uniform payment rates.

Per PAMA, the rate for a particular lab test under the new CLFS payment methodology may not be reduced by more than 10% from the preceding year for CY 2017 through 2019 or by more than 15% for CY 2020 through 2022. For example, if a lab receives $20 for a particular test in CY 2016, the maximum reduction for CY 2017 is $2 (10%) to $18, even if the private payer data would otherwise require a payment rate of $15. CMS would incorporate this statutory phase-in, proposing to use the National Limitation Amount as the baseline rate for purposes of comparing CY 2016 rates to new CY 2017 rates.

Special Rules for New Clinical Lab Tests and Advanced Diagnostic Laboratory Tests

The Proposed Rule also provides significant detail regarding payment for *new* clinical lab tests as well as *new* and *existing* advanced diagnostic laboratory tests ("ADLTs") for which laboratories may not yet have consistent data from private payers or for which special payment status is warranted. New clinical lab tests are defined as those assigned a new or substantially revised HCPCS code on or after April 1, 2014. An ADLT is, generally, a test that is unique and performed only by the laboratory that developed the test (or a subsequent owner of that laboratory). As specified in PAMA and proposed by CMS, these tests will be subject to separate phase-in payment methodologies that are further described on pages 77-93 of the display copy of the Proposed Rule.

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As a final observation, under the proposed definition of "applicable laboratory" and the proposed calculation of the "weighted median" of the reported rates, the new CLFS rates would be driven by the rates high-volume independent labs have negotiated with private payers. This may work to the advantage of CMS/Congress seeking to pay lower rates and to the detriment of smaller laboratories, which do not benefit from the same economies of scale as the high-volume labs. Smaller, independent and community labs may struggle to continue to serve Medicare beneficiaries at reduced rates.

Comments to the Proposed Rule are due by November 24, 2015. The rule will be published in the Federal Register on October 1; until then, it is accessible in display copy here.

For More Information

For more information regarding this alert, please contact one of the authors, a member of the Polsinelli's Health Care practice, or your Polsinelli attorney.

- Sara V. Iams | 202.626.8361 | siams@polsinelli.com
- Jennifer L. Evans | 303.583.8211 | jevans@polsinelli.com

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[1] *U.S. News & World Report, November 2014*
[2] *Modern Healthcare, June 2015*
[3] *Chambers USA: America's Leading Lawyers for Business, May 2015*

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