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At Long Last, CMS Issues Final Rule for Lab Fee Schedule Changes

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Last Friday afternoon ***CMS*** released its eagerly anticipated final rule (the Final Rule) implementing the ***Protecting Access to Medicare Act of 2014*** ***(PAMA)***, which, together with the Final Rule, will make sweeping changes to the rate-setting process under the ***Medicare Clinical Laboratory Fee Schedule*** ***(MCLFS)***. According to CMS estimates, Medicare Part B payments for clinical diagnostic laboratory tests (CDLTs) will decrease by $390 million in fiscal year 2018 when the repricing will take effect. The Final Rule comes nearly nine months after CMS issued its proposed rule (the Proposed Rule) and long after PAMA's statutory deadline.

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In brief, PAMA requires CMS to update the MCLFS based on private payor rates for laboratory tests reported by "applicable laboratories." CMS will set MCLFS rates based on the weighted median of the reported private payor rates, with limits on the amount that the rate for a particular test can be decreased each year. As the first data collection period is already underway, affected laboratories should ensure that they have systems in place for gathering the requisite data and reporting to CMS in the first quarter of 2017. Virtually every laboratory will need a system for collecting the required data because many laboratories are unlikely to know in advance whether they must submit a report to CMS.

The most important differences between the Final Rule and the Proposed Rule include:

- revised dates for data collection and submission and a shorter data collection period of six months;
- a delayed effective date for new reimbursement rates of January 1, 2018;
- a revised definition of "applicable laboratory" that is based on a lab's national provider identifier (NPI) rather than its taxpayer identification number (TIN), which should extend reporting obligations to many hospital outreach laboratories; and
- expansion of the definition of advanced diagnostic laboratory test (ADLT) to include protein-only tests and elimination of the requirement that an ADLT must be performed only at a single laboratory facility.

New Dates

Due to CMS's lengthy delay in issuing the Final Rule – and strong pressure from Congress – CMS pushed out the effective date of the rate adjustments from January 1, 2017 to January 1, 2018. The Final Rule made corresponding changes to the initial data collection and reporting periods. The first data collection period will run from January 1, 2016 to June 30, 2016, with data submission occurring between January 1, 2017 to March 31, 2017.

Under the Proposed Rule, the initial data collection period was to run for six months, with subsequent collection periods to span a full year. The Final Rule instead makes each data collection period six months long, running from January 1 to June 30. Data submission will still occur between January 1 and March 31 in the year following the

data collection. CMS believes that the additional six months between the end of data collection and the beginning of data submission will give laboratories sufficient time to collect and organize data. In some instances, laboratories will also need to use this six-month window to determine if they are exempt from reporting under the low expenditure threshold established by CMS, as further described below. Given that the initial 2016 data collection period is nearly over, laboratories must immediately begin working through this process.

Because data related to CDLTs will be reported to CMS every three years, the next reporting period will run from January through June 2019 with revisions to the CLFS made beginning January 1, 2021. Laboratories must report data related to ADLTs annually.

New Definition of "Applicable Laboratory"

The Final Rule made significant changes to the definition of "applicable laboratory" and the incorporated the concept of a "reporting entity." PAMA defines an "applicable laboratory" as a laboratory that receives a majority of its Medicare revenues under the MCLFS or the Medicare Physician Fee Schedule (MPFS). Multiple commenters, including the American Clinical Laboratory Association (ACLA) (comments) and the American Hospital Association (AHA) (comments), expressed concerned that CMS's proposal to define "applicable laboratory" based on an entity's TIN would exclude hospital outreach laboratories from reporting, which the organizations felt would skew pricing considering the volume of Medicare Part B testing performed by those laboratories. As noted by AHA, excluding hospital outreach laboratories would distort the payment data collected and lead to lower reimbursement rates.

Based on these concerns, CMS revised the definition of "applicable laboratory" in the Final Rule to mean an entity that bills Medicare Part B under its own NPI and receives more than 50% of its Medicare revenues during the applicable data collection period under the MCLFS or the MPFS. However, entities will still report at the TIN level. That is, each single corporate entity (with a single TIN) that operates a facility meeting the definition of an "applicable laboratory" must aggregate the reports of any applicable laboratories that it owns and make one consolidated report.

CMS also revised the low expenditure threshold for defining an "applicable laboratory." Under that threshold, a laboratory need not report if its MCLFS revenues received during the data collection period are less than $12,500, as opposed to the $50,000 threshold set by the Proposed Rule. As further described below, this threshold does not apply to reporting related to ADLTs.

Additional Guidance on Information to Report

The Final Rule provides much-needed additional guidance to laboratories on how to categorize private payor rates for reporting purposes. As laboratories prepare for reporting beginning on January 1, 2017, they should review the Final Rule's guidance carefully. The chart below summarizes a few key points regarding what should and should not be reflected in the data reported to CMS:

INCLUDED	**EXCLUDED**
Tests performed and paid for during the data collection period	Claims subject to appeal
Non-contracted, out-of-network payments	Denials
Medicare Advantage payments	Tests paid for on a capitated basis
Medicaid managed care plan payments	
Patient cost-sharing obligations (e.g., copayments, deductibles, coinsurance)	
Price concessions (but not financial hardship waivers)	

CMS will publish a list of HCPCS codes for which laboratories must report private payor rates. Reporting will not cover "not otherwise classified" or unlisted CPT codes.

Revised Definition for ADLTs

Based on feedback on the Proposed Rule's definition of an ADLT, which included only molecular pathology analyses of DNA or RNA, the Final Rule amended the definition to include tests involving the analysis of proteins. Additionally, CMS responded to comments that the Proposed Rule's definition of "single laboratory" for purposes of defining an ADLT was too limited because it did not reflect the corporate and operational structures of many laboratory companies. The definition of a "single laboratory" thus includes entities that own, or are owned by, the laboratory that furnishes the test.

The Final Rule also provides that the initial period for a new ADLT (i.e., the three quarters during which it is paid for by Medicare based on actual list charge amount) begins on the later of the date on which a Medicare Part B coverage determination for the test is made or the date on which CMS grants the test ADLT status.

What's Next?

In a press release issued not long after CMS released the Final Rule, ACLA sounded cautiously optimistic but made clear that its review is ongoing. We agree that the Final Rule seems to have made a bad situation a little better given that the Final Rule included significant concessions consistent with comments submitted by ACLA and other interested groups.

CMS has promised that additional sub-regulatory guidance will be forthcoming. Laboratories should track this additional guidance carefully as CMS is notorious for using this venue – which doesn't subject CMS to notice-and-comment requirements –to make under-the-radar policy decisions. With only a little more than nine months until the reporting deadline of March 31, 2017, laboratories have limited time to digest this entirely new data collection and reporting system, which will profoundly affect the laboratory industry for years to come.

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