

Key Takeaways on CMS Final Rule on PAMA's Reimbursement Policies for Clinical Diagnostic Laboratory Tests

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Health Care

On June 23, the Centers for Medicare & Medicaid Services (“CMS”) published its [final rule](#) to implement Medicare laboratory policy changes made under Section 216(a) of the Protecting Access to Medicare Act of 2014 (“PAMA”).¹ Responding to public comments it received on last year’s proposed rule²—our client alert on the proposed rule is available [here](#)—CMS made a number of significant changes and postponed the PAMA effective date by one year, to January 1, 2018.

Under PAMA, subject to certain exceptions, Medicare will pay for affected clinical diagnostic laboratory tests (“CDLTs”) at amounts equal to the weighted median of private payor rates determined for the test. These private payor rates must be reported to CMS by “applicable laboratories” for a specified collection period. The new payment system would replace the current clinical laboratory fee schedule (“CLFS”) payment methodology. In its final rule, CMS addresses public comments and how the agency will define applicable laboratories and determine payment, coding and coverage for the laboratory tests, including those CDLTs that are classified as advanced clinical diagnostic laboratory tests (“ADLTs”). We offer in this client alert some of the final rule’s key takeaways, including related changes from the proposed rule.

What is an “Applicable Laboratory”?

An applicable laboratory is an entity that reports private payor rates and other applicable information to CMS. In its final rule, CMS adopted a multi-prong definition, and only laboratories meeting all the prongs report information used for Medicare rate-setting.³

First, the laboratory must meet the definition of laboratory in the existing CMS Clinical Laboratory Improvements Amendments (“CLIA”) regulations.⁴

Second, the laboratory must meet a minimum revenue threshold—over fifty percent of its Medicare revenues during a single data collection period must come from services paid under

¹ 81 Fed. Reg. 41036 (June 23, 2016). See Pub. L. 113-93, adding §1834A to the Social Security Act.

² 80 Fed. Reg. 59386 (Oct. 1, 2015).

³ 42 C.F.R. § 414.502; 81 Fed. Reg. at 41098.

⁴ The current CLIA definition of laboratory is found at 42 C.F.R. § 493.2.

the clinical laboratory fee schedule (“CLFS”) and/or the physician fee schedule.⁵

Third, the laboratory must bill for Medicare Part B testing services under its National Provider Identifier (“NPI”)—the unique identifier healthcare providers and suppliers report on reimbursement claims. This criterion is a departure from the proposed rule, where CMS considered identifying applicable laboratories using the entity’s tax identification number (“TIN”). Changes were prompted by commenters’ concerns that a classification at the TIN level would, among other things, exclude hospital laboratories from the definition because the TIN-level entity (*i.e.*, the hospital) would not derive more than fifty percent of Medicare revenues from laboratory services. With this change, certain private-payor rates charged by hospital outreach laboratories—which often are higher than non-provider-based laboratories—would be considered in developing payment rates. Private payor data must be collected at the NPI level, therefore. Notwithstanding this change to an NPI-level classification, however, to reduce the burden on applicable laboratories, including those laboratories owned by a single entity that also owns other laboratories, reporting by applicable laboratories will be the responsibility of the TIN-level organization.⁶

Fourth, the laboratory must receive a minimum Medicare revenue threshold. Because applicable laboratory is now defined at the NPI level, CMS also adjusted its low-expenditure threshold, and will exclude laboratories that receive less than \$12,500 (instead of \$25,000) in Medicare CLFS revenues in a given 6-month collection period.

CMS projects that its low-expenditure threshold would relieve 95 percent of physician office laboratories and 55 percent of independent laboratories from reporting obligations. CMS believes it will nonetheless capture a high percentage of Medicare utilization, which would include approximately 92 percent of CLFS spending on physician office laboratories and 99 percent of CLFS spending on independent laboratories.

CMS finalized its proposal to exclude single laboratories offering and furnishing an ADLT from the \$12,000 threshold. This means that applicable information for an ADLT would need to be reported, regardless of whether the laboratory falls within the low-expenditure threshold. A laboratory that has less than \$12,000 in Medicare revenues, but offers both ADLTs and CDLTs, must still report private payor data for the ADLT (and is prohibited from reporting data on its CDLTs).⁷

What is “Applicable Information”?

As noted above, TIN-level entities must report information on the rates paid by each private payor for each test “offered and furnished” by an applicable laboratory during the data collection period. Applicable information includes the volume of tests and the associated HCPCS codes, but does not include information about a test for which payment is made on a capitated basis.⁸

⁵ The two fee schedules at issue are defined at 42 C.F.R. Part 414, Subparts B & G.

⁶ 81 Fed. Reg. at 41037.

⁷ *Id.*

⁸ See 42 C.F.R. § 414.502; 81 Fed. Reg. at 41098.

Applicable information must reflect discounts, rebates, coupons, free goods and other price concessions. CMS clarified that laboratories should only consider those price concessions that are applied by the private payor, and should not consider concessions applied by the laboratory.

A laboratory would not report, for example, concessions extended to patients, such as the waiver of patient coinsurance, copayments, or deductibles due to a patient's financial hardship.⁹

CMS further clarified that a private payor rate is subject to reporting only when the laboratory receives final payment for the test. The payment must be final during the data collection period at issue. Payment is not final if subsequent post-payment activities might change the initial payment amount, such as an ongoing appeal. In addition, denied payments are not considered in determining private payor rates.¹⁰ Payments that cannot be correlated to a specific HCPCS code, including grouped test-level payments that are not paid according to individual HCPCS code, also would be excluded from the definition of "applicable information" and are not to be reported.¹¹

How Does an ADLT Differ From a CDLT?

Definition of ADLT

PAMA defines an ADLT as a CDLT that is both covered under Medicare Part B and is:

1. "Offered and furnished" only by a "single laboratory";
2. Not sold for use by a laboratory other than the original developing laboratory; and
3. Meets one of the following criteria:
 - A. The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result; or
 - B. The test is cleared or approved by the FDA; or
 - C. The test meets other similar criteria established by the Secretary.¹²

The proposed rule had departed from the statutory definition in a number of significant ways. CMS proposed to define "single laboratory" as a laboratory that has only one CLIA certificate. This would have required every aspect of the test (*i.e.*, offering, furnishing, developing and selling) to be accomplished at one physical location. In its final rule, CMS acknowledged that the proposed definition did not reflect how laboratories are structured or how they operate. CMS defined a single laboratory as one that furnishes the test, and that *may* also design, offer, or sell the test. The definition permits entities that own the laboratory or entities that are owned by the laboratory to design, offer, or sell the test.¹³

⁹ 81 Fed. Reg. at 41055.

¹⁰ 81 Fed. Reg. at 41054.

¹¹ *Id.*

¹² See 42 U.S.C. § 1395m-1(d)(5); § 1834A(d)(5) of the Social Security Act.

¹³ See 42 C.F.R. § 414.502; 81 Fed. Reg. at 41059, 41098.

CMS's proposed rule defined ADLTs as molecular pathology tests and excluded all protein-only tests from the definition. This sparked considerable criticism. Addressing commenter concerns and the recommendations of its Advisory Panel on Clinical Diagnostic Laboratory Tests, CMS modified its proposed definition to align with the statutory criteria. CMS added protein-only tests to its final ADLT definition, but also expressed an expectation that only complex protein-only tests would qualify. As with biomarkers of DNA and RNA, the test's complexity is evaluated through the application of the unique algorithm requirement.

CMS did not accept commenters' suggestions to rely solely on the statutory language regarding the algorithm requirement. CMS concluded that an ADLT must yield a patient-specific result *and* provide new clinical diagnostic information that cannot be provided by any other test or combination of tests. The agency finalized its proposal to require that when the test is combined with an empirically-derived algorithm, the test must "yield a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies)." CMS also finalized the requirement that the new diagnostic information could not be acquired from other tests.¹⁴

Initial Period Payments for New ADLTs

Before they are subject to the final rule's rate-setting, CDLTs are to be paid under current crosswalking or gapfilling processes.¹⁵ Payment for ADLTs furnished between April 1, 2014 and December 31, 2017 likewise are based on these processes.¹⁶

"New ADLTs" are defined as ADLTs for which payment has not been made under the CLFS before January 1, 2018.¹⁷ Payment for these tests during an initial period of three quarters is based on the actual list charge. CMS's proposed approach was to begin the ADLT initial period in reference to the date the test is first performed. In its final rule, CMS acknowledged that it can take up to a year or longer to obtain Medicare coverage and during this time, an ADLT's opportunity to be paid the actual list charge rate could expire before Medicare pays at that rate. The initial period was revised to begin the first day of the first full quarter following the later of the following dates: when ADLT status is granted by CMS or when the test has received a Medicare Part B coverage determination.¹⁸

CMS also modified its proposed recoupment policy for ADLTs. If the actual list charge during the initial payment period is more than 130 percent of the later-determined market-based rates, then CMS will recoup the amount in excess of 130 percent, rather than the full amount in excess of actual list charge.¹⁹

¹⁴ See 42 C.F.R. § 414.502; 81 Fed. Reg. at 41060-61, 41098.

¹⁵ See 42 C.F.R. § 414.507 & .508; 81 Fed. Reg. at 41099-41100. Any CDLT for which CMS has no applicable information also will be paid under these current processes. 42 C.F.R. § 414.507(g).

¹⁶ See 42 C.F.R. § 414.507(h); 81 Fed. Reg. at 41062, 41100.

¹⁷ See 42 C.F.R. § 414.502; 81 Fed. Reg. at 41098.

¹⁸ See 42 C.F.R. § 414.502; 81 Fed. Reg. at 41067, 41098.

¹⁹ See 42 C.F.R. § 414.522(c); 81 Fed. Reg. at 41038, 41100-41101.

What Are the New Data Collection and Data Reporting Schedules?

Although there is an eighteen-month window until the January 1, 2018 effective date, considerable information will be gathered before that date. CMS has shortened the data collection to six months—with the first period to commence on January 1, 2016. The rates paid by private payors during the first six months of the year must be collected by the laboratory. The reporting period remains at three months—with the first period to commence on January 1, 2017. CMS will use the information to publish the first final rates in November 2017.

The data collection and reporting periods for CDLTs and ADLTs are illustrated in CMS's final rule, reproduced below.

Final Data Collection and Reporting Periods for CDLTs

Data Collection Period	Six Month Window	Data Reporting Period	Used for CLFS Rate Years
1/1/2016 – 6/30/2016	7/1/2016 – 12/31/2016	1/1/2017 – 3/31/2017	2018 – 2020
1/1/2019 – 6/30/2019	7/1/2019 – 12/31/2019	1/1/2020 – 3/31/2020	2021 – 2023
Continues every 3rd subsequent calendar year	Continues every 3rd subsequent calendar year	Continues every 3rd subsequent calendar year	New CLFS rate every 3rd year

Example of Final Data Collection and Reporting Period for New ADLTs

Test is Covered by Medicare Part B	ADLT Status is Granted	New ADLT Initial Period (Actual List Charge)	Data Collection Period	Data Reporting Period	Data Used for CLFS (Weighted Median Private Payor Rate)
4/6/2018	5/1/2018	7/1/2018 – 3/31/2019	7/1/2018 – 12/31/2018	By 12/31/2018	4/1/2019 – 12/31/2020

Example of Final Data Collection and Reporting Periods for New ADLTs (After New ADLT Initial Period)

Data Collection Period	Six Month Window	Data Reporting Period	Used for CLFS Rate Year
1/1/2019 – 6/30/2019	7/1/2019 – 12/31/2019	1/1/2020 – 3/31/2020	2021
1/1/2020 – 6/30/2020	7/1/2020 – 12/31/2020	1/1/2021 – 3/31/2021	2022
Continues every year	Continues every year	Continues every year	New CLFS rate every year

What Happens Next?

Although CMS has offered substantial insights into the new payment, coding and coverage policies under PAMA, many details are forthcoming and their interpretations are expected to evolve. Undisclosed to date are the details of the registration and reporting processes. No doubt, as with any new payment methodologies and reporting obligations, providers and suppliers will find they cannot anticipate all the issues they will face in the coming years. Laboratories and other interested parties, therefore, should monitor the developments in this area to evaluate their responsibilities and the full impact of the rule.

Some of the expected items to look out for when evaluating resources needed, are those CMS has deferred to subregulatory guidance. Examples include:

- A list of HCPCS codes for which applicable laboratories must report private payor rates.
- Instructions on how applicable information is to be reported to CMS, as well as a certification process for the submission of applicable information.
- The application process for requesting and approving ADLT status for a laboratory test.
- The process for submitting documentation on FDA clearance or approval to meet the ADLT definition.
- Details of the process CMS intends to follow for public review of the CLFS rates.

Given the complexities of the new payment methodology, its application to particular factual circumstances will require careful consideration. We will monitor and report on new developments, particularly as CMS releases its additional guidance in this area.

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