

CMS Issues Delayed Proposed Rule Implementing PAMA's New Clinical Laboratory Reimbursement Criteria

October 7, 2015

Health Care

On October 1, the Centers for Medicare & Medicaid Services ("CMS") published in the Federal Register its [proposed rule](#) on new Medicare payment, coding and coverage policies for certain clinical diagnostic laboratory tests ("CDLTs"), which would implement section 216(a) of the Protecting Access to Medicare Act of 2014 ("PAMA").¹ For affected CDLTs, PAMA requires Medicare payment amounts to equal the weighted median of private payor rates determined for the test. These private payor rates must be reported to CMS by applicable laboratories for specified collection periods. The new Medicare payment methodology goes into effect for CDLTs furnished beginning January 1, 2017.

The new framework would replace the current Clinical Laboratory Fee Schedule ("CLFS") payment methodology, under which annual payment adjustments are made only for inflation and multi-factor productivity adjustments. CMS expects significant reductions in Medicare payments as a result of this proposed rule, with estimated CLFS reductions of \$360 million for fiscal year 2017, \$2.94 billion in 5 years, and \$5.14 billion in 10 years. This is approximately a 6.4 percent reduction in payments over a 10-year period.²

Among other issues, the proposed rule addresses the following significant areas of change:

1. New definitions interpreting PAMA terms, in particular "applicable laboratory," "applicable information," "private payor" and "advanced diagnostic laboratory tests;"
2. Data collection and reporting obligations for applicable laboratories, including a schedule for reporting applicable information to CMS;
3. Data integrity and confidentiality of reported data;
4. Coding processes for CDLTs;
5. New payment methodologies for CDLTs; and

¹ 80 Fed. Reg. 59386 (Oct. 1, 2015). See Pub. L. 113-93, adding § 1834A to the Social Security Act ("the Act). PAMA required the final rule implementing these provisions to be completed by June 30, 2015, a deadline CMS has missed.

² 80 Fed. Reg. at 59416.

6. Procedures for local coverage determinations.

This client alert discusses some of these key changes and identifies issues for which CMS solicits input. Laboratories and other stakeholders should carefully review the potential impact of the CMS proposals, including the proposed definitions, and should consider taking advantage of the comment period. Comments on the proposed rule must be submitted by **November 24, 2015**.

New Definitions for “Applicable Laboratory,” “Applicable Information,” “Private Payor” and “Advanced Diagnostic Laboratory Test”

“Applicable Laboratory”

To define “applicable laboratories”³—that is, those entities that would be required to collect and report private payor rates—CMS borrows from the Clinical Laboratory Improvement Amendments (“CLIA”) of 1988.⁴ The CDLT proposed rule defines a laboratory as either (a) an entity that meets the definition of laboratory under CMS’s existing CLIA regulation (42 C.F.R. § 493.2), or (b) an entity that “has at least one component that is a laboratory, as defined in § 493.2.”⁵ The CLIA regulation defines “laboratory” as:

[A] facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

Not all facilities meeting this definition of laboratory would be required to collect and report applicable information to CMS. “Applicable laboratories” must also meet a revenue threshold. Specifically, the laboratory must receive more than 50 percent of its Medicare revenues from services under the CLFS or the Physician Fee Schedule in a data collection period.⁶ CMS does not expect hospital laboratories to meet the definition if the majority of their services are

³ § 1834A(a)(1) of the Act.

⁴ 80 Fed. Reg. at 59391. The current CLIA definition of laboratory is found at 42 C.F.R. § 493.2.

⁵ 80 Fed. Reg. at 59420.

⁶ The two fee schedules at issue are defined at 42 C.F.R. Part 414, Subparts B & G. See Proposed 42 C.F.R § 414.502.

provided to inpatients or registered outpatients for whom Medicare payments are based on other methodologies, such as hospital prospective payment systems.⁷

Low volume laboratories would be excluded from the definition of applicable laboratories and are defined as laboratories receiving less than \$50,000 in Medicare CLFS revenues for an annual collection period (or less than \$25,000 in the 2015 initial data collection period, which is six months). CMS estimates that 17 tests would be excluded from reporting requirements because of this dollar threshold.⁸

In addition, CMS would require applicable laboratories to be identified by their Taxpayer Identification Number (“TIN”). This, according to the agency, would be less burdensome to laboratories and would capture National Provider Identifiers (“NPIs”) associated with the entity.

In evaluating the impact of the proposed changes, CMS estimates that 52 percent of independent laboratories and 94 percent of physician office laboratories would not meet its definition of “applicable laboratory” and, therefore, would not be required to report applicable information.⁹ The agency further estimates that this figure nonetheless would retain a high percentage of the Medicare utilization—96 percent of CLFS spending on physician office laboratories and 99 percent of CLFS spending on independent laboratories.¹⁰

“Applicable Information” and “Private Payor”

PAMA requires applicable laboratories to report “applicable information” and defines this term as the payment rate that was paid by each private payor for each test during the data collection period. Applicable information also includes the volume of the tests for each private payor rate, and the rate must reflect discounts, rebates, coupons, free goods and other price concessions.¹¹ “Applicable information” would not include information about a test for which payment is made on a capitated basis.

The proposed rule would refer to the reportable private payor payments as “private payor rates” to distinguish them from the Medicare payment amounts.¹² These rates would not only account for all price concessions, but also would include patient cost sharing amounts, such as deductible and coinsurance amounts, if applicable.¹³ The rates would be reported using the Healthcare Common Procedure Coding System (“HCPCS”) or current procedural terminology (“CPT”) code associated with each CDLT. Because unlisted or “not otherwise classified” (“NOC”) codes are not associated with a particular test, NOC CPT codes would not be used for reporting purposes.¹⁴ To address coding issues raised by PAMA’s data collection and rate-setting for CDLTs, CMS proposes some new coding policies, which we discuss below in the section on the coding process.

⁷ 80 Fed. Reg. at 59393. The agency refers to its recent bundling of most hospital outpatient laboratory services under the outpatient prospective payment system.

⁸ 80 Fed. Reg. at 59394.

⁹ *Id.*

¹⁰ *Id.*

¹¹ § 1834A(a)(3)-(6) of the Act.

¹² 80 Fed. Reg. at 59395.

¹³ *Id.*

¹⁴ See Proposed 42 C.F.R § 414.502.

CMS would define “private payor” to mirror PAMA’s definition: a health insurance issuer, as defined in section 2791(b)(2) of the Public Health Service (“PHS”) Act; a group health plan, as defined in section 2791(a)(1) of the PHS Act; a Medicare Advantage plan under Medicare Part C, as defined in section 1859(b)(1) of the Social Security Act; or a Medicaid managed care organization, as defined in section 1903(m)(1)(A) of the Social Security Act.¹⁵

“Advanced Diagnostic Laboratory Test” (“ADLT”)

PAMA defines an ADLT as a CDLT that is 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:
 - 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;
 - the test is cleared or approved by the FDA; or
 - the test meets other similar criteria established by the Secretary.¹⁶

In its proposed rule, CMS would further parse out the third prong of the statutory criteria. The testing of multiple DNA or RNA biomarkers must be a “molecular pathology” test that analyzes the expression, function or regulation of a gene. When combined with an algorithm, it must be an empirically-derived algorithm criterion that “predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies).” The molecular pathology test must provide for “new clinical diagnostic information that cannot be obtained from any other test or combination of tests.” Finally, the molecular pathology test “may include other assays.”¹⁷

Alternatively, under the third prong of the statutory criteria, the test may meet the ADLT definition if it has successfully completed the FDA’s 510(k) or premarket approval application process. At this time, though PAMA provides authority to establish other criteria to classify ADLTs, CMS is not exercising this authority, and notes that if it does so in the future, it would be through notice and comment rulemaking.¹⁸

CMS believes that PAMA intended to award special payment status to the laboratory that expends the resources for all aspects of the test, and the agency has used this as a guiding principle in crafting the proposed rule’s definition of an ADLT. For example, to ensure that CMS grants ADLT status only to the one laboratory that “offers and furnishes” a particular test, the proposed rule would require the facility to have a single CLIA certificate.¹⁹ Entities with multiple CLIA certificates would not qualify as a single laboratory. Similarly, the proposed rule would

¹⁵ *Id.*

¹⁶ § 1834A(d)(5) of the Act. At this time, though PAMA provides authority to establish other criteria to classify ADLTs, CMS is not exercising this authority, but notes that if it does so in the future, it would be through notice and comment rulemaking.

¹⁷ Proposed 42 C.F.R § 414.502. See 80 Fed. Reg. at 59397-98.

¹⁸ Proposed 42 C.F.R § 414.502. See 80 Fed. Reg. at 59398-99.

¹⁹ 80 Fed. Reg. at 59396. CLIA certificates are described in 42 C.F.R. § 493.43(a)-(b).

require the laboratory to be the only entity to design, market, perform, and sell the test. If more than one laboratory was engaged at any step of the process, the test would not meet the criteria for an ADLT.²⁰ CMS expects to develop an application process for ADLT classification using subregulatory guidance.

Data Collection and Data Reporting Periods

PAMA requires applicable laboratories to report applicable information on CDLTs that are not ADLTs every 3 years and to report every year for ADLTs.²¹ The proposed rule establishes a timetable for these reporting periods and also designates the data collection period. There is a 2-year lag between the data collection period and the rate year—the effective date of the new payment amount.

In light of the CMS delays in promulgating its rule, to meet the 2017 start date, CMS proposes an initial data collection period from July 1, 2015 through December 31, 2015. Following this initial period, subsequent data collection periods would cover a full calendar year. All information would be due to CMS by March 31 of the year following the data collection period. The rates would first be available for public comment (tentatively, in September) and the final version would be published in November.²²

CMS proposes that the President, CEO or CFO of the applicable laboratory or the delegated authority reporting to them must sign a certification assuring the accuracy, completeness and truthfulness of the information reported. The processes would be specified in subregulatory guidance.²³

General Time Tables for Collection and Reporting

Table 1a—Data Collection and Reporting Periods for CDLTs

Data Collection Period	Data Reporting Period	Used for CLFS Rate Years
7/1/2015 – 12/31/2015	1/1/2016 – 3/31/2016	2017 – 2019
1/1/2018 – 12/31/2018	1/1/2019 – 3/31/2019	2020 – 2022
Continues every 3rd subsequent calendar year	Continues every 3rd subsequent calendar year	New CLFS rate every 3rd year for 3 years

²⁰ See Proposed 42 C.F.R § 414.502.

²¹ § 1834A(a)(1) of the Act.

²² 80 Fed. Reg. at 59400.

²³ 80 Fed. Reg. at 59402. See Proposed 42 C.F.R § 414.504(d).

Table 1b—Data Collection and Reporting Periods for ADLTs

Data Collection Period	Data Reporting Period	Used for CLFS Rate Years
7/1/2015 – 12/31/2015	1/1/2016 – 3/31/2016	2017
1/1/2016 – 12/31/2016	1/1/2017 – 3/31/2017	2018
Continues every subsequent calendar year	Continues every subsequent calendar year	New CLFS rate every year

Time Table for Collection and Reporting New ADLTs

A separate collection and reporting timetable would govern new ADLTs, which CMS defines as those ADLTs for which no payment has been made under the CLFS prior to January 1, 2017. PAMA directs payment for ADLTs to be based on the actual list price for an “initial period” of 3 quarters,²⁴ and requires applicable laboratories to report applicable information by Q2 of the initial period.²⁵ CMS proposes separate collection and reporting requirements for new ADLTs so that all payment rates (CDLTs and ADLTs) could be posted at the same time.

The collection period for new ADLTs would begin on the first day of the first full calendar quarter following the first day on which a new ADLT is performed. Applicable information for new ADLTs would be reported by the last day of Q2 of the initial period.²⁶ The table below provides an example of a data collection and reporting timetable for a new ADLT that is first performed by an applicable laboratory on February 4, 2017.

Table 2—Data Collection and Reporting Periods for New ADLTs

ADLT first performed	Initial Period	Data Collection Period	Data Reporting Period	Used for CLFS Rate year
02/04/2017	04/01/2017–12/31/2017	04/01/2017 – 09/30/2017	By 09/30/2017	2018 – 2019
		01/01/2018 – 12/31/2018	01/01/2019 – 03/31/2019	2020

²⁴ § 1834A(d)(1) of the Act.

²⁵ *Id.*

²⁶ Proposed 42 C.F.R. § 414.504(a)(3).

Collection and Reporting Penalties

Similar to penalties in place for drug manufacturer reporting of average sales price, applicable laboratories that fail to report applicable information could be subject to a civil monetary penalty of up to \$10,000 per day for each failure to report or for each material misrepresentation or omission.²⁷

Confidentiality

CMS intends to use the reported applicable information to set CLFS payment rates and intends to make available publicly a list of test codes and the CLFS payment rates associated with those codes. Except for limited situations, CMS would not reveal the identity of a specific payor or laboratory or prices charged or payments made to a specific laboratory.²⁸

Protections from disclosures would address applicable information only and no other information submitted by laboratories. CMS notes that its publishing of codes and associated CLFS payment rates for ADLTs could indirectly disclose the identity of specific laboratories selling those tests. The proposed rule observes that CMS “cannot prevent the public from associating CLFS payment information for an ADLT to the single laboratory offering and furnishing the test.”²⁹

Coding Process to Identify Certain CDLTs

PAMA addresses the assignment of codes for each existing ADLT and CDLT that is approved or cleared by the FDA and that is (1) not already assigned a unique HCPCS code, and (2) for which payment is made under Medicare Part B as of April 1, 2014 (PAMA’s enactment date). CMS is required both to assign a unique HCPCS code for these tests and to publicly report the payment rate for the test by January 1, 2016.³⁰ To implement PAMA’s coding directives, the proposed rule contemplates integrating CMS’s current HCPCS processes.³¹

CMS notes in its proposed rule that because an ADLT is defined as a single test, each such existing ADLT without a code must be assigned its own unique G code. For existing FDA approved or cleared CDLTs, CMS acknowledges that there may be situations where the test already has a code, but not a “unique” code. For these existing tests, CMS would assign a separate and unique G code.

To publicly report the payment rates for the existing ADLTs and FDA approved or cleared CDLTs by January 1, 2016, CMS proposes to use the electronic CLFS payment files made available on its website. CMS indicates in the proposed rule that it is considering how to present the information and may use a separate field with a special identifier to indicate when a HCPCS

²⁷ § 1834A(d)(1) of the Act. Proposed 42 C.F.R. § 414.504(e).

²⁸ 80 Fed. Reg. at 59402-03.

²⁹ *Id.* at 59402. CMS proposes to implement the confidentiality requirements of § 1834A(a)(10) of the Act with Proposed 42 C.F.R. § 414.504(f).

³⁰ § 1834A(e)(2) of the Act.

³¹ 80 Fed. Reg. at 59404. See § 1834A(e)(1) - (3) of the Act.

or CPT code uniquely describes the existing laboratory test. CMS may instead identify the codes in separate documentation.³²

For new tests that are ADLTs or FDA approved or cleared CDLTs, which do not have an assigned CPT or HCPCS Level II code, CMS proposes to establish a temporary HCPCS “G” code. To meet PAMA directives, these temporary G codes would be in effect for up to 2 years, but would be continued if the American Medical Association has not established a CPT code by then.³³

PAMA also requires the establishment of unique identifiers for ADLTs and FDA approved or cleared CDLTs for purposes of tracking and monitoring.³⁴ CMS interprets the PAMA provision as being met through assignment of unique HCPCS codes. CMS proposes that if a laboratory or manufacturer specifically requests a unique identifier for tracking and monitoring, CMS would assign a unique HCPCS code if the test does not already have one.³⁵ To the extent identifiers separate from HCPCS codes are needed, stakeholders should consider submitting comments and suggestions to CMS on this proposal.

Payment Methodology

Calculation of Weighted Median

For existing laboratory tests on the CLFS, payment amounts would be determined by calculating a weighted median of private payor rates using reported private payor rates and the associated volume (number of tests). CMS proposes that each payment rate would be in effect for one calendar year for ADLTs and three calendar years for all other CDLTs.³⁶

The weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory.³⁷ Once calculated, the rates would not be subject to any adjustment, such as geographic, budget neutrality and annual update.³⁸

Phased-in Payment Reduction

To dampen potential reductions in the first stages of the new payment methodology, PAMA requires that implementation of the new payment methodology for affected CDLTs to be phased in over the first 6 years of payment (2017 through 2022).³⁹ The applicable dampening percentage is 10 percent for 2017 through 2019 and 15 percent for 2020 through 2022.

CMS discusses options it considered for implementing the phase-in, including whether the starting point should be the national limitation amount (“NLA”) or the geographical amount that reflects the specific Medicare contractor rate. The agency opted for the NLA because it allows

³² 80 Fed. Reg. at 59404.

³³ 80 Fed. Reg. at 59403.

³⁴ § 1834A(e)(3) of the Act.

³⁵ 80 Fed. Reg. at 59404.

³⁶ Proposed 42 C.F.R. § 414.507(a).

³⁷ Proposed 42 C.F.R. § 414.507(b).

³⁸ Proposed 42 C.F.R. § 414.507(c).

³⁹ § 1834A(b)(3) of the Act.

for the setting of a single national fee schedule amount and limits regional variations. Using the 2016 NLA as the starting point, the proposed rule would then apply the phase-in reduction percentage to each subsequent year's rate to determine the reduction ceiling for years 2017 through 2022. For example, if the 2016 payment rate for the test is \$20, the maximum reduction for 2017 would be \$2 (10 percent of \$20), resulting in an \$18 payment rate. For 2018, the maximum payment reduction would be \$1.80 (10 percent of \$18), resulting in a \$16.20 payment rate.⁴⁰

Payment for New ADLTs

For new ADLTs, payment would be based on the "actual list charge" of the test for 3 calendar quarters, defined under the PAMA as the "publicly available rate on the first day at which the test is available for purchase by a private payor."⁴¹ CMS proposes that the amount would be one that is readily accessible in such forums as the laboratory website, test registry or price listing. The proposed rule also would define the publicly available rate as the lowest amount charged for the ADLT.⁴² This amount would be one that is readily available to a consumer on the first day of availability for purchase. The test need not actually be performed by the laboratory on that date.⁴³

The laboratory would attest to the actual list charge and the date the ADLT was first performed in its application for status as an ADLT. As noted above, CMS intends to outline the application process in subregulatory guidance and intends to have this process in place before 2017.⁴⁴

The effective date of the "actual list charge" payment would be the first day of the next calendar quarter following the first day on which the new ADLT is performed. Therefore, there would be a lag time from the day the test is first performed until the effective date of the actual list price payment. During this new ADLT initial period, the Medicare Administrative Contractor ("MAC") would be responsible for setting the payment amount, based on information provided by the laboratory.⁴⁵

Following the first three quarters, the payment rate for the ADLTs would be determined using the new methodology of the weighted median of private payor rates and the associated volume (number of tests) reported. If the difference between the Medicare payment amounts for an ADLT during the new ADLT initial period based on actual list charge and the weighted median rate exceeds 130 percent, CMS will recoup the entire amount of the difference between the Medicare payment amounts. This threshold is required by PAMA. If the 130 percent statutory threshold is not met, there would be no recoupment.⁴⁶

⁴⁰ 80 Fed. Reg. at 59407.

⁴¹ § 1834A(d)(1)(B) of the Act.

⁴² Proposed 42 C.F.R. § 414.502.

⁴³ 80 Fed. Reg. at 59408.

⁴⁴ *Id.*

⁴⁵ Proposed 42 C.F.R. § 414.522(a)(2).

⁴⁶ Proposed 42 C.F.R. § 414.522(b)-(d).

Payment for New CDLTs that Are Not ADLTs and Tests Where No Applicable Information Is Reported

For CDLTs assigned new or substantially revised HCPCS codes prior to January 1, 2017, CMS proposes to continue using the current crosswalking and gapfilling processes. For CDLTs assigned a new or substantially revised HCPCS codes on or after January 1, 2017, CMS proposes to use comparable crosswalking and gapfilling processes with modification to reflect the new market-based methodology. If CMS receives no applicable information to calculate a market-based weighted median for a specific laboratory test, CMS proposes that payment rates also would be determined through crosswalking and gapfilling methods.⁴⁷

The proposed rule's modifications include the elimination of the use of NLAs or local fee schedule amounts to determine payments. CMS also indicates that for those tests that would undergo gapfilling, the CDLT code is paid at the median of the MAC-specific amounts in the second year, until the applicable private payor information is reported. CMS would retain the opportunity for stakeholders to request reconsideration on the basis for payment when crosswalking or gapfilling is used.⁴⁸

CMS must also consider recommendations from the new Advisory Panel on CDLTs.⁴⁹ The proposed rule would revise the current process of posting the explanation of payment rates to include an explanation of how CMS took into account the Advisory Panel's recommendations and an explanation of how the gapfilling criteria were applied. This information would be accessed on the CMS website.⁵⁰

Local Coverage Determinations

PAMA requires local coverage determinations ("LCDs") to be issued and appealed in accordance with the process already defined by the Medicare statute and Medicare appeal regulations.⁵¹ This includes, among other things, requirements such as posting of a draft, a public comment period and opportunities for public meetings.⁵² CMS offers no changes to current LCD policies to implement the PAMA provisions.

PAMA also authorizes the designation of one to four MACs to either establish LCDs for CDLTs or to establish LCDs and process claims for LCDs.⁵³ CMS estimates that reducing the number of MACs establishing LCDs would take 2 to 4 years, but reducing the number of MACs that process CDLT claims "would require complex changes to Medicare computer systems" and could take several years.⁵⁴ CMS notes that the complexities and volume of tests requires

⁴⁷ Proposed 42 C.F.R. § 414.507(g).

⁴⁸ 80 Fed. Reg. at 59411.

⁴⁹ § 1834A(f)(1) of the Act.

⁵⁰ 80 Fed. Reg. at 59412.

⁵¹ § 1834A(g)(1) of the Act (*citing* the definition of LCD under § 1869(f)(2) of the Act).

⁵² 80 Fed. Reg. at 59413.

⁵³ § 1834A(g)(2) of the Act.

⁵⁴ 80 Fed. Reg. at 59414.

serious considerations for consolidation and seeks stakeholder input, inviting comments on alternatives permissible within the scope of the legislative authority.⁵⁵

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⁵⁵ *Id.*