PAMA Final Rule

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Market Based Payment for Clinical Diagnostic Laboratory Tests

Summary

On June 17, 2016 the Centers of Medicare & Medicaid Services (CMS) issued the long awaited Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule. The Final Rule implements the laboratory test payment provisions of the Protecting Access to Medicare Act of 2014 (PAMA), enacted into law on April 1, 2014. Section 216 of PAMA added section 1834A to the Social Security Act, which requires significant revisions to the payment methodologies for clinical diagnostic laboratory tests (CDLTs) paid under the Clinical Laboratory Fee Schedule (CLFS). Under section 1834A, certain clinical laboratories are required to report private payor payment rates and corresponding test volumes. PAMA directs CMS to establish parameters for payment rate reporting by June 30, 2015 and requires the market-based payment system to start on January 1, 2017. However, in the Final Rule, CMS has delayed the data collection and reporting requirements. The market-based payment rates for most laboratory tests currently paid on the CLFS will now take effect on January 1, 2018. The agency is planning to issue sub-regulatory guidance on additional topics, such as: a list of specific HCPCS codes for which laboratories must report data, the Advanced Diagnostic Laboratory Test (ADLT) application process, and manner and form for electronic reporting of private payer data. CMS estimates $390 million in savings in 2018, $1.7 billion over five years, and $3.9 billion over ten years.

Implementation Timeline

- **January 1, 2016 – June 30, 2016**: Initial data collection period for CDLTs.
- **July 18, 2016**: Advisory Panel on Clinical Laboratory Diagnostic Tests Meeting on ADLT Designation and Coding.
- **Prior to January 1, 2017**: CMS will issue sub-regulatory guidance on the list of specific HCPCS codes for which laboratories must report data, and the application for ADLT designation.
- **Prior to January 1, 2017**: Assign unique HCPCS codes and publish payment rates for existing ADLTs and existing FDA-cleared or approved CDLTs.
- **January 1, 2017 – March 31, 2017**: Initial data reporting period for CDLTs.
- **September 2017**: CMS publishes preliminary CLFS rates for CY 2018.
- **November 2017**: CMS posts final CY 2018 CLFS rates.
- **January 1, 2018**: Market-based payment rates effective.
    - ADLTs are on an annual cycle of collection, reporting, and payment
    - The CDLTs cycle takes place every three years.
- **January 1, 2018**: Payment system for new ADLTs effective.
    - Three quarters at Actual List Charge.
    - Private payor data collected during Q1 and Q2 must be reported by the end of Q2.
- **January 1, 2019 – June 30, 2019**: Next Data Collection Period for CDLTs.

A. Collection and Reporting

WHO HAS TO COLLECT AND REPORT?

PAMA requires "applicable laboratories" to report to CMS, and defines an "applicable laboratory" as a laboratory that receives a majority of its Medicare revenues during the data collection period from the CLFS or the Physician Fee Schedule. In the proposed rule, CMS defined applicable laboratories based on an entity's IRS Taxpayer Identification Number (TIN). In the Final Rule, in response to comments, CMS modified the definition of an applicable laboratory to be at the National Provider Identifier (NPI) level, not the TIN level. CMS stated that this would allow the inclusion of hospital outreach laboratories in the definition of "applicable laboratories."

CMS originally proposed a low expenditure threshold for applicable laboratories, which would exclude a laboratory from the definition of an applicable laboratory if it received less than $50,000 in CLFS revenues during a collection period. CMS reduced the low expenditure threshold from $50,000 to $12,500 in the Final Rule in part due to the shortening of the data collection period. Additionally, in response to comments, CMS exempted laboratories offering and furnishing ADLTs from the expenditure threshold with respect to those ADLTs. Applicable information about ADLTs can be reported from a laboratory that failed to meet the expenditure threshold, but information about other CDLTs cannot be.

PAMA authorized CMS to establish a low volume threshold in addition to a low expenditure threshold. However, CMS declined to exercise this authority at this time. Additionally, CMS rejected commenters' suggestion that it establish a physician office laboratory (POL) dependent test revenue threshold that would allow POLs that did not reach the low expenditure threshold to report applicable information for tests primarily performed in the POL setting. Finally, CMS rejected commenters' suggestions to permit voluntary reporting of applicable information from entities that do not qualify as applicable laboratories.

WHAT MUST BE COLLECTED AND REPORTED?

PAMA requires laboratories to report "applicable information," which includes information regarding private payor rates for a test and the volume of tests for each payor. If a laboratory has more than one payment rate from the same payor for a test or more than one payment rate from different payors for a test, all rates must be reported.

CMS finalized its proposal to define "applicable information" to also include the specific HCPCS code associated with each test. "Specific HCPCS code" excludes unlisted CPT codes and "not otherwise classified" (NOC) codes. In response to comments, CMS stated that it would list HCPCS codes for which applicable laboratories must report private payor rates on the CLFS website to clarify that only the specific codes on this list will need to be reported during the initial data collection period.

Importantly, CMS also clarified that laboratories are to only report "final payments" made during the data collection period for calculating the private payor weighted median rate. CMS clarified that private payor rates should include all final rates including non-contracted amounts paid to laboratories. CMS explained that claims under review by or appeal before the private payor are not deemed final and should not be reported. Additionally, private payor amounts for tests that are not correlated to a specific HCPCS code are not considered private payor rates for purposes of applicable information. Denied claims, or "zero payments," are also not included in applicable information under the Final Rule.

Further, the private payor rates to be reported are required to reflect all discounts, rebates and other price concessions, as well as any patient cost sharing amounts. CMS also made clear in the Final Rule that only private payor price concessions are included in the rate. As a result, any concessions by the laboratory, such as patient assistance programs, are not included.

WHEN MUST DATA BE COLLECTED AND REPORTED?

In the Final Rule, CMS elected to shorten the data collection period to six months in order to give laboratories a six-month window to ensure the completeness and accuracy of data. The data collection period is now from January 1 through June 30 for CDLTs with specific HCPCS codes. CMS stated in the Final Rule that it will re-evaluate the length of the data collection period in future rulemakings, including whether the 6 month review period before the reporting period is necessary. Laboratories must report the data to CMS by March 31, 2017. CMS will provide sub-regulatory guidance to specify the manner and form for reporting applicable information prior to the first reporting period. Although CMS will use NPI to determine an applicable laboratory, reporting will still be done by the TIN level entity.

B. Market-Based Payment Calculation

Under PAMA, the payment amount for a CDLT furnished on or after January 1, 2017 is the median of all private payor rates reported for each test weighted by volume for each private payor and each laboratory. CMS clarified that MACs would not be permitted to adjust the market based payment amounts.

PAMA limits the year over year reduction in payment amounts for a CDLT through 2022. In the Final Rule, CMS changed the payment reduction limitations to reflect the delay in implementation, setting the limitation at 10% of the national limitation amount (NLA) for 2018 through 2020 and 15% of the NLA for 2021through 2023. These limitations will not apply to new ADLTs or new CDLTs.

In response to comments, CMS clarified that the preliminary payment amounts for the CLFS published in September would reflect the full median private payor rate (without the phased-in reduction). The final rate published in November will only reflect the application of the phased-in payment reduction for the next calendar year.

To address concerns regarding transparency, CMS intends to release aggregate private payor rate and volume data, including the unweighted median rate, range of rates, and median and mean volume other than for tests provided by only a few laboratories or a single laboratory (such as for new ADLTs).

CMS also finalized its proposal to price tests without any applicable information reported by using crosswalking and gapfilling processes.

Advanced Diagnostic Laboratory Tests

PAMA creates a special payment category of "advanced diagnostic laboratory tests" that includes CDLTs covered under Part B that are offered and furnished only by a single laboratory and not sold for use by a laboratory other than the developing laboratory or a successor owner. To be an ADLT, a test must also meet detailed regulatory criteria for multiple biomarker tests (criterion A) or be FDA cleared or approved (criterion B). The Final Rule provides detailed guidance on the definition of an ADLT. Although PAMA allows the Secretary to establish similar criteria, CMS will not exercise that authority at this time.

A. Definition of ADLT

"OFFERED AND FURNISHED"

Under the Proposed Rule, CMS defined "offered and furnished" as requiring that an ADLT only be marketed and performed by a single laboratory. In response to comments, the Final Rule replaced the requirement that the test be "marketed and performed" with the statutory language "offered and furnished." CMS explained that this regulatory definition of single laboratory would not preclude a test that would otherwise qualify as an ADLT from being an ADLT simply because the single laboratory hires a third party to market the test. In that situation, the single laboratory would still be the entity expending the resources for the test.

Additionally, CMS rejected comments urging it to permit a test initially discovered by an academic institution and licensed to another entity for further development and commercialization to be eligible for ADLT status.

"SINGLE LABORATORY"

CMS proposed to implement the "single laboratory" component of the definition by restricting ADLT status to laboratories with a single CLIA certificate. Commenters urged CMS to permit a test to be designated as an ADLT even if the offering laboratory has multiple CLIA certificates.

In the Final Rule, CMS agreed with commenters that requiring laboratories to administer all aspects of a test at a single location was "inconsistent with how laboratories are structured and how they operate." The Final Rule instead defines "single laboratory" as including the laboratory itself as well as entities that own or that are owned by the laboratory. All entities in the "single laboratory organization" may design, offer, and sell the test, but only the entities that are laboratories under CLIA may furnish the test.

"MULTIPLE BIOMARKERS"

PAMA provides that to be designated an ADLT in the absence of FDA clearance or approval, a test must be an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result.

In the Proposed Rule, CMS had limited the definition of an ADLT to only molecular pathology tests that include an analysis of DNA or

RNA. In the Final Rule, CMS reversed its position to make clear that ADLTs include tests based on an analysis of only proteins.

"UNIQUE ALGORITHM"

Despite significant opposition from commenters and the CMS Advisory Panel, CMS finalized its proposal that to qualify for ADLT status under criterion A, a test must provide "new clinical diagnostic information" that cannot be obtained from any other test or combination of tests. CMS disagreed with the view that "unique algorithm" should only apply to the uniqueness of the algorithm itself and not to that of the patient-specific result, stating, among other things, that its requirement was necessary to prevent simple protein analyses from being considered ADLTs.

B. ADLT Designation Process

CMS will issue sub-regulatory guidance for laboratories on applying for ADLT status. Applicants submitting an application for designation under criterion A will be required to submit evidence of the empirically derived algorithm and show how a test provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests. CMS plans to consider the recommendations of the CDLT Advisory Panel in determining ADLT status and assigning codes to ADLTs. CMS will consider quarterly application submission and review schedule when it promulgates sub-regulatory guidance.

CMS maintains that PAMA's confidentiality provisions do not cover information provided to the Secretary for purposes of ADLT determination. However, information might be protected from release in a Freedom of Information Act (FOIA) request if it qualifies as trade secrets or exempt commercial or financial information. Additionally, for tests designated as an ADLT, CMS will not release to the public applicable information, in aggregate or raw form. CMS will, however, provide the HCPCS code and CLFS rate associated with those tests, consistent with its current annual publication of the CLFS file.

C. Payment for new ADLTs

CMS rejected stakeholder suggestions to retain the 2017 implementation date required by statute for ADLTs, and will implement the actual list charge payment methodology for new ADLTs starting in 2018. The Final Rule defines new ADLTs as ADLTs for which payment has not been made under the CLFS prior to January 1, 2018.

ACTUAL LIST CHARGE

PAMA requires that new ADLTs be paid based on the "actual list charge" for the laboratory test for an initial period of three quarters. The actual list charge is the publicly available rate on the first day on which the test is available for purchase by a patient covered by private insurance or is marketed to the public as a test a patient can receive (even if the test has not yet been performed). CMS defined "publicly available rate" as the lowest amount charged for an ADLT that is readily accessible. A laboratory seeking new ADLT status for a test must attest to the actual list charge in its application for ADLT status.

CMS proposed that the list charge payment begin on the first day of the calendar quarter after the date the test is first performed. In response to comments, CMS revised this proposal to commence the initial period on the first day of the calendar quarter immediately following the latter of the date the test is granted ADLT status and the date the test receives a coverage decision under Part B. This change will ensure that the new ADLT's three quarters at actual list charge start after the test is covered by Medicare. Between the triggering date and the beginning of the initial period, the payment amount for the test is determined by the MAC on the basis of information provided by the laboratory.

NEW ADLT REPORTING

PAMA requires that laboratories report applicable information for new ADLTs by the final day of the second quarter of the initial period to determine payment after the initial period. If no private payor data is reported for the test during this period, crosswalking and gapfilling will be used to determine the payment rate, as for other tests.

RECOUPMENT

Under PAMA, if the Medicare payment amount for an ADLT during the initial period is more than 130% of what those payments would have been at the weighted median payment rate, CMS must recoup the difference. In the Final Rule, CMS recognized that its proposal to recoup the entire difference between actual list charge and weighted median would potentially thwart the statute's purpose of awarding special payment status to ADLTs. CMS adopted stakeholders' suggestions to only recoup the difference between the payment amount

under the annual list charge and 130% of the payment amount under the weighted median. Further, the recoupment provision does not apply if no private payor data is reported during the initial period.

PAYMENT FOR EXISTING ADLTS

PAMA requires that CMS publish payment rates for existing ADLTs and FDA cleared or approved tests by January 1, 2016. CMS extended this period to January 1, 2017, to reflect changes in the implementation timeline.

Commenters recommended that CMS use the existing MAC rates for existing ADLTs instead of gapfilling or crosswalking pricing methods. CMS disagreed, maintaining that this would not accomplish the statutory purpose of reflecting changes in market prices over time. Instead, CMS will use crosswalking and gapfilling to establish payment amounts for existing ADLTs. CMS is considering using a special identifier to indicate when a HCPCS code uniquely describes an existing test.

Payment for New CDLTs

CMS finalized its proposal to define a "new CDLT" as a CDLT that is assigned a new or substantially revised HCPCS code and which is not an ADLT. A "substantially revised HCPCS code" is a code for which there has been a substantive change to the definition of the test or procedure to which the code applies. For new CDLTs, CMS will determine payment rates using the existing crosswalking and gapfilling methodologies. New CDLTs would remain on this payment system until applicable information is reported for the CDLT and can be used to establish a payment amount under the weighted median methodology.

Coding

A. Coding for New Tests

CMS finalized its proposal to utilize the existing HCPCS coding process for new ADLTs and new FDA cleared or approved CDLTs. If tests in this category do not already have an assigned CPT or HCPCS Level II code, CMS will assign a temporary G code, which would be effective for up to two years, unless CMS believes it appropriate to continue to use that G code. CMS did not address the AMA CPT PLA proposal, but explained in the Final Rule that the agency will use HCPCS level I codes created and assigned by the CPT Editorial Panel for new tests on the CLFS whenever possible if they meet the agency's requirements for payment.

B. Unique Coding for Existing Tests

Under PAMA, by January 1, 2016, the Secretary must assign a unique HCPCS code and publicly report the payment rate for 1) each existing ADLT; and 2) each other existing CDLT that is cleared or approved by FDA and paid under Part B as of PAMA's enactment date. CMS interprets "unique" as a code that describes only a single test. As such, any new unique codes would be subject to the CLFS annual public meeting process.

Some commentators recommended that CMS not assign a unique code to tests if those tests already have a code that is being billed to Medicare. CMS maintains that the statute requires the statute requires CMS to assign a unique code for these tests. To alleviate stakeholder concerns CMS will not automatically assign a unique HCPCS code for an ADLT or other FDA-cleared or -approved test, and instead will allow laboratories to first indicate to the agency that its test requires a unique code.

C. Unique Identifiers on Request

PAMA requires that for tracking and monitoring purposes, if a laboratory or manufacturer requests a unique identifier for an ADLT or an FDA-cleared or approved laboratory test, CMS must utilize a means such as a HCPCS code or modifier to uniquely track the test. CMS finalized its proposal to utilize the existing HCPCS coding process to implement this requirement, meaning that if a laboratory or manufacturer specifically requests a unique identifier for tracking and monitoring an ADLT or other FDA-cleared or approved CDLT, CMS would assign the test a unique HCPCS code if it did not already have one.

Local Coverage Determinations (LCDs) and Designation of MACs

PAMA provides CMS with the authority to designate up to four MACs to establish LCDs and/or process Medicare claims for payment for CDLTs. Commenters were mixed on their support for consolidating LCD development and/or claims processing for CDLTs. CMS stated that they will give careful consideration to the input from stakeholders as the agency considers whether to downsize the number of MACs

developing LCDs and/or processing claims for CDLTs. At this time CMS will not exercise this authority. In the interim, CMS instructed MACs to develop and implement CDLT-related LCDs in accordance with the guidance set forth in Chapter 13 of the Medicare Program Integrity Manual.

Conclusion

The PAMA market-based payment system was intended to provide predictability and transparency to the pricing system for clinical diagnostic laboratory tests. While the implementation delay until 2018 will allow additional time for CMS and stakeholders to transition to the new market-based payment reporting requirements, some provisions like payment for new ADLTs at actual list charge will not be available for new innovative laboratories in 2017. The implementation work for laboratories will likely be significant, and sub-regulatory guidance will provide critical information on for the form and manner of data reporting and the process for ADLT applications. Additionally, with roughly half of the states participating in the MolDX program, CMS will need to continue to consider whether to utilize its authority to consolidate LCD development for CDLTs in a smaller number of MACs.

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