CMS Releases Final Rule Implementing Reforms to Medicare CLFS Payment Rates Under PAMA

By Charles C. Dunham, IV

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On June 23, 2016, the Centers for Medicare & Medicaid Services (“CMS”) released a final rule implementing Section 216 of the Protecting Access to Medicare Act of 2014 (“PAMA”), which established a new payment methodology for determining the Medicare Clinical Laboratory Fee Schedule (“CLFS”) and implements other significant changes to the Medicare payment system for clinical diagnostic laboratory tests (“CDLT”).

The final rule includes significant revisions and clarifications to the proposed rule. Of particular importance is the decision by CMS to postpone the implementation date for a new Medicare CLFS payment rate until January 1, 2018. The one-year delay was intended to give lab entities sufficient time after the publication of the final rule to prepare internal operations and develop the technology needed to comply with the collection and reporting obligations under the law.

Once implemented, the new payment methodology is anticipated to negatively impact all lab entities paid under the CLFS. In addition to the expenses associated with the new collection and reporting requirements, CMS estimates that a new CLFS payment rate will result in payment reductions under the Medicare Part B program by $390 million in the first fiscal year (2018) and $3.93 billion over 10 years. This will have a significant financial impact on all lab entities paid under the CLFS for laboratory services performed on or after January 1, 2018.

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This Client Alert is intended to provide a summary of the more notable revisions and clarifications in the final rule and key takeaways.

I. Notable Revisions and Clarifications

Implementation Date

Despite the January 1, 2017, statutory deadline, CMS has postponed the implementation date for a new Medicare CLFS payment rate for CDLTs furnished on or after January 1, 2018. Accordingly, CMS amends the phase-in payment reduction timetable for the estimated reduction in the CLFS rates (not more than 10 percent per year from the prior year’s CLFS rate for years 2018 through 2020 and not more than 15 percent per year from the prior year’s CLFS rate for years 2021 through 2023).

Definition of “Applicable Laboratory”

PAMA requires an “applicable laboratory” to collect and report to CMS “applicable information” (as defined below). PAMA defines an “applicable laboratory,” in part, as a lab entity that derives a majority of its Medicare revenue under the CLFS (42 U.S.C. 1395I and 42 U.S.C. 1395m-1) and the Physician Fee Schedule (42 U.S.C. 1395w–4).

CMS makes significant changes to the criteria defining an “applicable laboratory”:

- **NPI Level Entity.** CMS revises the proposed rule to identity a lab entity by National Provider Identifier ("NPI") rather than Taxpayer Identification Number ("TIN"). This switch to a NPI-level entity was done with the specific intent to include hospital outreach laboratories (furnishing laboratory services to patients other than inpatients or outpatients of the hospital) within the definition of “applicable laboratory.” The inclusion of hospital outreach laboratories, in order to include private payor rates paid to such lab entities, was a major issue of considerable concern and debate in the industry.

- **Reduction of Low Expenditure Threshold.** CMS revises the amount of the low expenditure threshold from $50,000 to $12,500 of Medicare revenues from the CLFS during the data collection period because the threshold will (i) be applied at the NPI level as opposed to the TIN level and (ii) reflect a six-month data collection period instead of a full calendar year. As such, a lab entity that collects less than $12,500 of its Medicare revenues from the CLFS during the data collection period would be excluded from the definition of “applicable laboratory.”

- **No Low Expenditure Threshold Applied to Advanced Diagnostic Laboratory Tests.** CMS clarifies that for a lab entity that offers and furnishes advanced diagnostic laboratory tests ("ADLTs"), the $12,500 threshold will not apply with respect to the ADLTs. This means that a lab entity may otherwise meet the definition of an “applicable laboratory” with respect to the ADLTs that it offers and furnishes and must report applicable information for its ADLT but not meet the
threshold to be considered an applicable laboratory with respect to all the other CDLTs that it furnishes.

- **No Volume Threshold.** CMS confirmed its intent not to exercise its discretion to establish a volume threshold but indicated that this issue would be reconsidered after implementation.

**Creation of Reporting Entity**

CMS clarifies that the TIN-level entity will be the “reporting entity” (now defined separately from the “applicable laboratory”) and is responsible for reporting applicable information for all of its component NPI-level entities that meet the definition of “applicable laboratory.” CMS confirms that the President, CEO, or CFO of the reporting entity, or an individual who has been delegated authority to sign for, and who reports directly to, such an officer, will have to sign a certification statement and be responsible for assuring that the applicable information provided is accurate, complete, and truthful and meets all the reporting parameters set forth under final rule and anticipated guidance. CMS did not include details and instructions on the certification process for submission of applicable information in the final rule but rather indicated that all the details will be provided through subregulatory guidance prior to January 1, 2018 (without providing a time frame).

**Definition of “Applicable Information”**

PAMA defines the term “applicable information” as the private payor rates for each CDLT and the corresponding volumes of such tests by payment rate. Additionally, PAMA defines “private payor” as (i) a health insurance issuer and a group health plan, (ii) a Medicare Advantage plan under Part C, and (iii) a Medicaid managed care organization. CMS confirms that the term “group health plan” is defined in Section 2791 of the Public Health Service Act and would include an employer self-funded plan.

In the final rule, CMS clarifies the following terms:

- **The Definition of “Paid.”** The term “paid” means when the applicable laboratory collects final payment from the private payor for the test during the data collection period. CMS provides the following examples: (i) if the applicable laboratory is denied payment within the collection period, this should not be reported as a final payment; (ii) if a test is performed during a data collection period, but a final payment is not made until after the data collection period, that payment amount would not be considered paid during the data collection period; (iii) if an initial claim was paid in error three months before a data collection period and then corrected, with final payment being made during the data collection period, the final corrected payment amount for the test would be considered paid during the data collection period; (iv) if a laboratory test claim is still under review by the private payor or is under appeal during a data collection period, the amount that has already been paid would not be considered paid during the data collection period.
period; and (v) if the appeal is settled during the data collection period, but final payment is not made by the private payor until after the data collection period, the payment amount would not be considered paid during the data collection period.

- **Cost-Sharing Amounts.** The private payor rate would include any patient cost-sharing amounts (i.e., deductible, coinsurance, and copayment). CMS clarifies that the patient cost-sharing amount owed by the patient does not necessarily have to be collected by the applicable laboratory in order to be counted in calculating the private payor rate.

- **HCPCS Codes Under CLFS.** Only CDLTs paid for under the CLFS must be considered for reporting private payor rates. As such, payment rates for CDLTs paid only under the Physician Fee Schedule, and not under the CLFS, would not be private payor rates and should not be reported as applicable information. CMS intends to publish a list of HCPCS codes on the CLFS website for which applicable laboratories must report private payor rates.

- **Individual HCPCS Code.** The applicable information must be reported by the payment for the individual HCPCS code. As such, where a private payor reimburses under a capitation rate or groups test-level payments into a claim-level payment, instead of by individual HCPCS code, those rates would not be deemed applicable information.

**Definition of “Advanced Diagnostic Laboratory Test”**

PAMA distinguishes a category of CDLTs referred to as ADLTs from other CDLTs for purposes of reporting, coverage, and other requirements. The definition of an “advanced diagnostic laboratory test” is a two-part test. First, the ADLT must be a CDLT covered under Medicare Part B that is offered and furnished only by a “single laboratory” and not sold for use by a lab entity other than the original developing lab entity (or a successor owner). Second, the ADLT must be a CDLT that meets one of the following criteria: (i) 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 (i.e., molecular pathology analysis of DNA or RNA); (ii) the test is cleared or approved by the U.S. Food and Drug Administration; or (iii) the test meets other similar criteria established by the Secretary of the U.S. Department of Health and Human Services (“HHS”).

CMS makes significant changes to the criteria defining an “ADLT”:

- **Definition of “Single Laboratory.”** CMS revises the proposed rule related to the definition of a “single laboratory” for ADLT status. CMS defines a “single laboratory” to mean a laboratory as defined by the Clinical Laboratory Improvement Amendments of 1988, which includes the entities that own the laboratory or that the laboratory owns, which may design, offer, and sell the
ADLT. This change will allow multiple laboratories located in different locations throughout the country, under common ownership, to qualify as a single laboratory and furnish the ADLT at each laboratory site.

- **Clarification of Criteria.** CMS eliminated the requirement that the CDLT be a molecular pathology analysis in order to permit protein-only based tests to also qualify for ADLT status under Criteria A.

- **No ADLT Application Guidance.** A lab entity will need to apply to CMS for ADLT status and submit documentation with its application that demonstrates that the CDLT meets the two-part test. CMS did not include such details and instructions for lab entities in the final rule but rather indicated that all the details will be provided through subregulatory guidance prior to January 1, 2018 (without providing a time frame).

  *Note that labs may mark information provided to demonstrate ADLT status as confidential and proprietary; however, the information may still be subject to disclosure under PAMA, the Freedom of Information Act, and other applicable federal laws.*

**Data Collection and Reporting Periods—New and Existing CDLTs and Existing ADLTs**

CMS revises all data collection periods for new and existing CDLTs to the first six months of the year preceding the data reporting period (January 1 to June 31).

The same data collection periods for new and existing CDLTs will apply to existing ADLTs, except that private payor rates for ADLTs will be on an annual basis using the first six months of the year immediately preceding the data reporting period (January 1 to June 31).

CMS provides the following chart for reference:

<table>
<thead>
<tr>
<th>Data collection period</th>
<th>Six-month window</th>
<th>Data reporting period</th>
<th>CLFS rate years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continues every 3rd subsequent calendar year</td>
<td>Continues every 3rd subsequent calendar year</td>
<td>Continues every 3rd subsequent calendar year</td>
<td>New CLFS rate every 3rd year</td>
</tr>
</tbody>
</table>
Data Collection and Reporting Periods—New ADLTs

Due to the postponement of the implementation date, a “new ADLT” would be an ADLT for which payment has not been made under the CLFS prior to December 31, 2017.

With regard to the initial data collection period, CMS revises the initial data collection period for new ADLTs to begin on the first day of the first “full calendar quarter” after both the date that a Medicare Part B coverage determination is made and ADLT status is granted, whichever is later. CMS recognized that to start the initial period from the date the new ADLT is first performed would not be appropriate due to the potentially lengthy process of qualifying as an ADLT and CMS providing Medicare coverage.

CMS provides the following chart for reference:

<table>
<thead>
<tr>
<th>Test is covered by Medicare Part B</th>
<th>ADLT status is granted</th>
<th>New ADLT initial period</th>
<th>Data collection period</th>
<th>Data reporting period</th>
<th>Data used for CLFS</th>
</tr>
</thead>
</table>

Civil Monetary Penalties

CMS has the discretionary authority to impose a civil monetary penalty (“CMP”) in an amount of up to $10,017 per day per violation (to be adjusted annually) if it is determined that an applicable laboratory has failed to report, or made a misrepresentation or omission in reporting, applicable information. CMS indicates that the provisions for CMPs that apply in general to the Medicare program under 42 U.S.C. 1320a–7b would apply in the same manner to the laboratory data reporting process.

The reporting entity and the person executing the certification will be subject to the CMPs that may be applied in the event of a failure to submit or intentional omission or misrepresentation. CMS states in the final rule that “in situations where our review reveals that the data submitted is incomplete or incorrect, we will work with the [Office of the Inspector General] to assess whether a CMP should be applied, and if so, the appropriate amount based on the specific circumstances,” and “we do not intend to assess CMPs for minor errors.”

CDLTs’ Payment Rates

CMS provides pertinent clarification to the determination of CDLT payment rates:

- **Volume-Weighted Median Rate.** Under the new payment methodology, the CLFS rate for each CDLT (except new ADLTs) would be determined by calculating a weighted median of private payor rates and associated volume
(number of tests) reported by applicable laboratories. The CLFS rate would not be subject to any adjustment (including any currently utilized adjustments, such as geographic, budget neutrality, annual update, or other adjustment) or any administrative or judicial review of the established amount.

- **New CDLTs’ Payment Rates.** The CLFS payment rate for a CDLT (excluding ADLTs) that is assigned a new or substantially revised HCPCS code and furnished between April 1, 2014, and December 31, 2017, will be set by the HHS Secretary based on the crosswalking or gapfilling methods. The HHS Secretary will also consider recommendations from the newly created Clinical Laboratory Payment Advisory Panel when determining the CLFS rate for such CDLT tests. The advisory panel would also provide input to CMS on the establishment of CLFS rates for new CDLTs, the factors to determine coverage and payment for new CDLTs, and other matters. The HHS Secretary is also required to make available to the public an explanation of the CLFS rate for a new CDLT, including an explanation of how the gapfilling criteria, if applicable, are applied and how the recommendations of the advisory panel are applied. CMS proposes to publish such information via the existing CMS CLFS website.

- **Unreported Tests.** CMS recognized that if a private payor does not cover and pay for the CDLT or the lab entity furnishing the CDLT does not meet the definition of an “applicable laboratory” required to report, then no private payor data would be reported to calculate a volume-weighted median. In such instances, CMS clarified that it would apply crosswalking or gapfilling methods to determine pricing but expressed that the data indicated that the number of CDLTs that would come under this scenario is not significant.

**New ADLTs’ Payment Rate and Recoupment**

CMS makes significant changes to the ADLTs’ payment rate and recoupment:

- **Interim Payments.** The CLFS payment rate for new ADLTs that are furnished between April 1, 2014, and December 31, 2017, will be based on the crosswalking or gapfilling methods.

- **Actual List Charge.** The CLFS rate for new ADLTs furnished on or after January 1, 2018, will be based upon the actual list charge made publicly available by the lab entity during its initial data collection period. Thereafter, the CLFS rate will be based on the applicable information to be reported not later than the last day of second quarter of the initial period. Additionally, CMS clarifies that the “publicly available rate,” which must be reported as the actual list charge amount, means “the amount charged for an ADLT that is readily accessible in such forums as a company Web site, test registry, or price listing, to anyone seeking to know how much a patient who does not have the benefit of a negotiated rate would pay for the test.” CMS clarifies that in the event there is more than one publicly available rate, the lowest amount charged and readily accessible to the public should be
the actual list charge amount reported to CMS. Finally, CMS clarifies that an ADLT would be deemed available for purchase even if the test has not been performed yet.

- **Recoupment.** CMS revises the proposed rule to recoup the entire amount of the difference between the actual list charge and the weighted median private payor rate. Instead, CMS will only recoup the entire amount of the difference between the actual list charge (paid by Medicare during the new ADLT initial period) and 130 percent of the weighted median private payor rate.

- **Unreported Tests.** CMS recognizes that if a private payor does not cover and pay for the new ADLT, then no private payor data would be reported during the new ADLT initial period to calculate a volume-weighted median. In such instances, CMS clarified that it would apply crosswalking or gapfilling methods to determine pricing and the recoupment provision would not be applicable.

**No MAC Consolidation Decision**

CMS has the discretionary authority to consolidate the number of Medicare Administrative Contractors (“MACs”) and task four or fewer MACs with the responsibility of both writing local coverage determinations for CDLTs and processing all CDLT claims. CMS has elected not to reduce the current number of MACs processing claims (at this time) because it would involve complex programmatic and operational issues that would require various analyses to determine the feasibility of such a consolidation.

**II. Key Takeaways**

In postponing the implementation date to January 1, 2018, CMS recognizes that lab entities required sufficient time after the publication of the final rule to build the information systems necessary to collect private payor rates and review and verify the data collected to ensure their accuracy. However, CMS provides no guidance or detail on how to collect and prepare applicable information for submission. CMS acknowledges that the agency received insufficient information from public comments to determine or define the appropriate collection methods or financial impact on an applicable laboratory to meet its reporting obligations. Therefore, lab entities are currently on their own to structure their collection activities in order to gather and organize the applicable information required to be reported.

With the first data collection period set to begin on January 1, 2017, each lab entity will need to make an initial determination of whether their operations will meet the definition of an “applicable laboratory” (with the understanding that some lab entities may not be able to make this determination until after the applicable collection period). Thereafter, applicable laboratories will need to ensure that they develop internal operations and adopt the technology systems needed for gathering the requisite private payor payment data. These system measures will depend on the size and scale of the business, and,
especially, on the number of private payors that the lab entity contracts with and/or receives payment from as an out-of-network laboratory.

CMS acknowledges that PAMA will increase administrative costs and decrease payments to lab entities paid under the CLFS. CMS indicates that the potential time commitment and costs associated with the projected recordkeeping, reporting, and other compliance requirements could be substantial, based on the potential volume of information to report, but the agency still has insufficient information to determine the full extent of the financial impact on lab entities to meet such reporting obligations. Furthermore, CMS projects that the changes to the CLFS payment rate will, overall, decrease the payments to lab entities paid under the CLFS.

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This Client Alert was authored by Charles C. Dunham, IV. For additional information about the issues discussed in this Client Alert, please contact the author or the Epstein Becker Green attorney who regularly handles your legal matters.

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