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National Provider Call

**Medicare Clinical Diagnostic Laboratory Test
Payment System Proposed Rule
Implementing the
Protecting Access to Medicare Act**

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Current Medicare Clinical Laboratory Fee Schedule (CLFS)

- The CLFS was first adopted in 1984.
- Payment rates were originally based on charge data.
- The CLFS is updated annually to establish payment amounts for new tests and/or statutory across-the-board updates to the fee schedule.
- Payment for a new test code on the CLFS established after 1984 is based on either crosswalking or gapfilling methodologies (42 CFR 414.508).

New CLFS Requirements

- PAMA enacted on April 1, 2014.
 - Required rulemaking to be complete by June 30, 2015.
 - Enactment of new fee schedule on January 1, 2017.
- Proposed Rule: September 25, 2015
- Comment Period ended November 24, 2015.
- Final Rule: In process.

General Requirements for Clinical Diagnostic Laboratory Tests

Definition of Applicable Laboratory

- “Applicable laboratory” has majority of its Medicare revenues paid under the CLFS or the Physician Fee Schedule (PFS).
- CMS proposed to use the CLIA definition of laboratory.
- CMS proposed to define a laboratory as any entity with at least one facility performing laboratory testing and meeting the CLIA definition.
- CMS proposed to rely on the Tax Identification Number (TIN) as a mechanism for defining “applicable laboratory” and the entity to report payment data.

Low Expenditure Threshold

Low Volume or Low Expenditure Threshold to be Exempt from Reporting:

- CMS proposed excludes all entities that receive less than \$50,000 per year from the CLFS from definition of applicable laboratory.

Applicable Information

- Applicable laboratories must report to CMS all private payer rates and the associated volume for each test.*
- PAMA defines the term private payer as:
 - (A): A health insurance issuer and a group health plan (as such terms are defined in section 2791 of the Public Health Service Act).
 - (B): A Medicare Advantage plan under Part C.
 - (C): A Medicaid managed care organization (as defined in section 1903(m)).
- Includes ALL payment rates (even if more than one payment rate for the same private payer for the same test, or more than one payment rate from different payers for the same test).

**Note: An excluded entity (that is, an entity that does not meet the “majority of revenues” or expenditure threshold) would not be permitted to report applicable information to CMS.*

Frequency of Data Collection and Reporting

- For most clinical diagnostic laboratory tests, every three years.
- For advanced diagnostic laboratory tests (ADLTs) annually.*

**ADLTs are discussed later in the presentation.*

Data Collection and Reporting Periods

- Proposed initial data collection July 1-December 31, 2015.
- Afterwards, data collection period will be a full calendar year.
- Data Reporting Period will be 3 full months immediately after every Data Collection Period.
- Proposed first Data Reporting Period: January 1, 2016 through March 31, 2016.

New CLFS Payment Methodology

- Using applicable information CMS will calculate a weighted median private payer rate for each test.
- Weighted median becomes the new CLFS payment rate.
- If CMS receives no applicable information for a given CDLT or ADLT; CMS would use crosswalking or gapfilling to price the test.

ADLTs

Definition of ADLT - Statutory Requirements

Part 1

- Clinical diagnostic laboratory test covered under Medicare Part B.
- Offered and furnished by a single laboratory.
- For use only by original developing laboratory (or successor owner).

Part 2

- 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.
 - (B) The test is cleared or approved by the FDA.
 - (C) The test meets other similar criteria established by the Secretary.

Definition of ADLT (Continued)

CMS Proposal for Criterion A

- Must be a molecular pathology analysis of multiple biomarkers of DNA or RNA.
- Predicts development of a certain condition(s) or response to a particular therapy(ies).
- Provides new clinical information.
- May include other assays.

Criterion B - FDA Clearance or Approval

- Premarket Notification Submission (used to demonstrate substantial equivalence).
- Premarket Approval Application (used to demonstrate safety and effectiveness).

Criterion C - Other Criteria

- Not proposing additional criteria at this time.

New ADLTs Vs. Existing ADLTs

New ADLT

- Payment not made under the CLFS prior to January 1, 2017.

Existing ADLT

- Paid for under the CLFS prior to January 1, 2017.

New ADLT Initial Period

Duration of New ADLT Initial Period

- Three full calendar quarters.

Start of New ADLT Initial Period

- Begins first day of the first full calendar quarter following the first day a new ADLT is performed.

Example: If an ADLT is first performed on February 15, the new ADLT initial period would begin on April 1 and end December 31.

Payment for New ADLTs

Prior to New ADLT Initial Period

- Medicare Administrative Contactors would determine payment amount for the test.

During New ADLT Period

- Payment amount is actual list charge for the test.

After New ADLT Initial Period

- Payment amount based on weighted median private payer rate.

Payment for Existing ADLTs

- Prior to January 1, 2017, existing ADLTs paid based on crosswalking or gapfilling.
- Beginning January 1, 2017 payment based on weighted median private payer rate.

ADLT Recoupment Provision

- PAMA requires recoupment of payments when actual list charge is greater than 130 percent of the weighted median private payer rate during the new ADLT initial period.
- CMS proposed recoupment of the entire difference between the actual list charge and the median private payer rate as specified by the law.

ADLT Data Collection and Reporting

New ADLTs During New ADLT Initial Period

- Private payer data collected and reported by the last day of second full calendar quarter.

Example: For a new ADLT initial period starting Q2 of 2017 (April 1, 2017) and ending last day Q4 of 2017 (December 31, 2017); the applicable laboratory would be required to report private payer data for the new ADLT by the end of Q3 of 2017 (September 30, 2017).

Existing ADLTs and New ADLTs After New ADLT Initial Period

- Private payer data collected annually on a calendar year basis.
- Reported to CMS during the data reporting period (January 1 through March 31).

Other Provisions

Coding under PAMA

Statutory Requirement

- PAMA requires temporary HCPCS codes to identify new and existing ADLTs and new and existing CDLTs (that are not ADLTs) that are cleared or approved by the FDA.
- For purposes of tracking and monitoring, PAMA allows a party to request a “unique identifier” for ADLTs and CDLTs cleared or approved by the FDA.

CMS Proposal

- Use G codes for new and existing ADLTs as well as new and existing CDLTs (that are not ADLTs) that are cleared or approved by the FDA.

Limitation on Payment Reduction for Existing Laboratory Tests

Statutory Requirements

- CY 2017 through CY 2019, statute limits the reduction to 10 percent.
- CY 2020 through CY 2022, reduction is limited to 15 percent.
- CMS: Proposed to apply maximum reduction annually from NLA until private payer price reached.

Confidentiality

- CMS and its contractors may not disclose reported applicable information in a form that would identify:
 - A specific private payer or laboratory;
 - Prices charged or payments made to a laboratory.
- Exception: As CMS determines necessary to implement section 1834A of the Act and to permit the Comptroller General, the Director of the CBO, the HHS OIG, the MedPAC, or other law enforcement entities such as the Department of Justice to review the information.

Civil Monetary Penalties

- The Secretary may apply a civil money penalty in an amount of up to \$10,000 per day for each failure to report or each such misrepresentation or omission of reporting of private payer data.