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National Provider Call

Overview of CMS-1621-F Medicare Clinical Diagnostic Laboratory Test Payment System Final Rule

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Agenda

1. Overview of Final Policies Regarding CMS-1621-F
2. Overview of Data Collection System
3. Question & Answer Session

New Medicare Clinical Laboratory Fee Schedule (CLFS)–Private Payor Based Payment Rates

Rasheeda Johnson

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

- On June 17, 2016 CMS announced its final rule implementing section 216 of the Protecting Access to Medicare Act of 2014 (PAMA; enacted April 1, 2014).
- Requires private payor rates paid to applicable laboratories for clinical diagnostic laboratory tests to be reported to CMS and used to calculate Medicare payment rates.
- Medicare payment amounts for clinical diagnostic laboratory tests will be based on this data beginning January 1, 2018.

Definition of Applicable Laboratory

Statutory Provision

- PAMA defines laboratories subject to the new reporting requirements (“an applicable laboratory”) as having the majority of its Medicare revenues paid under the CLFS or the Physician Fee Schedule (PFS).

Finalized as proposed

- CLIA regulatory definition of laboratory to define a laboratory.
- Majority of Medicare revenues threshold.

Definition of Applicable Laboratory (continued)

Revised from proposed rule

- National Provider Identifier (NPI) used as the mechanism for defining applicable laboratory.
- Tax Identification Number (TIN) required to report payment data.
- Low Expenditure Threshold = \$12,500.
- Majority of Medicare revenue and low expenditure thresholds are applied at NPI-level.
- Low expenditure threshold does not apply to single laboratory furnishing ADLTs, with respect to the ADLTs they furnish.

Applicable Information

Applicable information includes:

- The specific HCPCS code associated with the test;
- Each private payor rate for which **final payment** has been made during a data collection period (by date of final payment);
- The associated volume of tests performed corresponding to each private payor rate;
- Examples:
 - Multiple payment rates for the same test
 - Resolved Appeals;
 - Non-contracted amounts for out-of-network laboratories or services.

Applicable Information (continued)

Applicable Information **Does Not** Include:

- Unresolved Appeals;
- Payments that do not reflect specific HCPCS code-level amounts;
- Remittances where the payor has grouped test-level payments into an encounter (claim-level) payment;
- Denied Payments.

Private Payor

PAMA defines the term private payor 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)).

Private Payor Rate

- Includes ...
 - **ALL** payment rates;
 - Final amount paid by a private payor for a CDLT after all private payor price concessions are applied;
 - Only private payor payment rates for CDLTs paid for under the CLFS;
 - Any patient cost sharing amounts, if applicable.
- Does Not Include ...
 - Price concessions applied by a laboratory;
 - Example: Waiving of patient deductible and or coinsurance.
 - Information about denied payments.

Reporting Applicable Information

- TINs must report applicable information for all components NPIs that are applicable laboratories.
- Voluntary reporting is not permitted.
- Reporting applicable information is not discretionary.

Frequency of Data Collection and Reporting

Finalized as proposed

- 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

Initial Data Collection and Reporting Schedule

- Data collection period: January 1, 2016 through June 30, 2016.
- 6-Month Window: July 1, 2016 through December 31, 2016.
- Data reporting period: January 1, 2017 through March 31, 2017.
- Implementation date: January 1, 2018

Subsequent data collection and reporting

- Same as initial corresponding to the applicable update year.
 - Example: For update year CY 2021; data collection = January 1, 2019 – June 30, 2019; reporting = January 1, 2020 – March 31, 2020.

New CLFS Payment Methodology for CDLTs and ADLTs

Craig Dobyski

New CLFS Payment Methodology

Finalized as proposed

- Using applicable information CMS will calculate a weighted median private payor rate for each test.
- Weighted median becomes the new CLFS payment rate.

Payment Methodology When No Data Are Received for a Test

Finalized as proposed

- If CMS receives no applicable information for a given CDLT or ADLT; CMS would use crosswalking or gapfilling to price the test.

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)

Single laboratory

- Did not adopt proposal to define as a laboratory with single CLIA certificate.
- *Final Definition:* Laboratory that furnishes ADLT including the entity that owns the laboratory and the entity that is owned by the laboratory.

Successor owner

- Partnership; unincorporated sole proprietorship, or corporation.
- Successor to a successor.

Definition of ADLT (continued)

Criterion A

- Final rule includes tests solely comprised of proteins.
- Removed requirement that the test must be a molecular pathology analysis.
- All other requirements under criterion A were finalized as proposed.

Criterion B - FDA Clearance or Approval

- Finalized as proposed.

Criterion C - Other Criteria

- Did not finalize any additional criteria to qualify tests as an ADLT.

New ADLTs Vs. Existing ADLTs

New ADLT

- Payment not made under the CLFS prior to January 1, 2018.

Existing ADLT

- Paid for under the CLFS prior to January 1, 2018.

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 **later of** the date a Medicare Part B coverage determination is made for the test or ADLT status is granted by CMS.

Example: If a test is covered under Medicare Part B on February 15 and granted ADLT status on March 1, the new ADLT initial period would begin on April 1 and end December 31.

Payment for New ADLTs

Finalized as Proposed:

Prior to New ADLT Initial Period

- MACs would determine payment amount for the test.

During New ADLT Initial Period

- Payment amount is actual list charge for the test.

After New ADLT Initial Period

- Payment amount based on weighted median private payor rate.

Payment for Existing ADLTs

- Prior to January 1, 2018, existing ADLTs paid based on crosswalking or gapfilling.
- Beginning January 1, 2018 payment based on weighted median private payor rate.

ADLT Recoupment Provision

- PAMA requires recoupment of payments when actual list charge substantially exceeds private payor rates.
- Applies when actual list charge is greater than 130 percent of the weighted median private payor rate calculated during the new ADLT initial period.
- CMS will recoup the difference between ADLT actual list charge and 130 percent of the weighted median private payor rate.

ADLT Data Collection and Reporting

Finalized as proposed:

New ADLTs During New ADLT Initial Period

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

Revised to reflect final data collection period:

Existing ADLTs and New ADLTs After New ADLT Initial Period

- Private payor data collected annually (January 1 – June 30).
- Reported to CMS during the data reporting period (January 1 – March 31).

Other Provisions

Sarah Harding

Coding under PAMA

Background

- The AMA creates CPT codes that are used primarily to identify medical services and procedures furnished by physicians, suppliers, and other health care professionals (including laboratory tests).
- CMS creates HCPCS level II codes for products, supplies, and services not included in the CPT codes.

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.

Finalized as proposed

- In the absence of an existing test code, CMS will establish G codes.

Limitation on Payment Reduction for Existing Laboratory Tests

Statutory Requirements

- Limits reduction of the payment amount for existing tests (as compared to the payment amount for the preceding year).
- First three years after implementation, statute limits the reduction to 10 percent.
- For the following three years reduction is limited to 15 percent.

Finalized to reflect January 1, 2018 implementation date

- Apply phased-in payment reduction limit per year for existing tests paid under the CLFS prior to 1/1/2018.
- 10 Percent reduction limit (2018-2020); 15 percent (2021-2023)
- Baseline Payment Amount: The 2017 national limitation amount (NLA) for the existing test.
- To determine the application of the phased-in payment reduction limit for a test, the weighted median private payor rate calculated for CY 2018 would be compared to the CY 2017 NLA.

Confidentiality

Finalized as proposed

- CMS and its contractors may not disclose reported applicable information in a form that would identify:
 - A specific private payor 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.

Public Release of Data

Early September

- Preliminary CLFS payment rates: weighted median private payor rates, before they are finalized.
- Summary (aggregate-level) private payor rate and volume data for each test code.
- Exploring whether we can make available a file of the raw data reported.

Early November

- Final CY CLFS payment rates.

Data Collection System

Sarah Harding

Fee for Service Data Collection System

- Web based data collection system available to applicable laboratories.
- Ability to collect all applicable information:
 - Upload .csv file;
 - Manual Data Entry

EIDM Registration

- Enterprise Identity Management
- Registration to begin as early as October 2016.
- Ready for data collection January 1, 2017

Question & Answer Session

Resources

- [CMS press release](#)
- [Fact Sheet](#)
- [Final Rule \(CMS-1621-F\)](#)
- [CLFS Website](#)

Acronyms in this Presentation

ADLT	Advanced Diagnostic Laboratory Test
AMA	American Medical Association
CBO	Congressional Budget Office
CDLT	Clinical Diagnostic Laboratory Test
CLFS	Clinical Laboratory Fee Schedule
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare & Medicaid Services
CPT	AMA's Current Procedural Terminology
DNA	Deoxyribonucleic Acid
EIDM	Enterprise Identification Management
FDA	Food and Drug Administration
HHS	Health and Human Services
MAC	Medicare Administrative Contractor
MedCAC	Medicare Evidence Development and Coverage Advisory Committee
NLA	National Limitation Amount
NPI	National Provider Identifier
OIG	Office of Inspector General
PAMA	Protecting Access to Medicare Act of 2014
PFS	Physician Fee Schedule
RNA	Ribonucleic Acid

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