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Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Data Collection and Reporting Policies

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January 22, 2019

Agenda

1. Overview of Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Data Collection and Reporting Policies (Parts 1 & 2)

2. Overview of Data Collection System

3. Question & Answer Session

CLFS Data Collection and Reporting Policies (Part 1)

Rasheeda Arthur

CLFS Requirements

- On June 17, 2016 CMS published its final rule implementing section 216 of the Protecting Access to Medicare Act of 2014 (PAMA) , which added a new section, 1834A, to the Social Security Act

- Requires applicable laboratories to report private payor rates paid for clinical diagnostic laboratory tests (CDLTs) to CMS so they can be used to calculate Medicare payment rates.

Definition of Applicable Laboratory

- 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).
- Clinical Laboratory Improvement Amendments (CLIA) regulatory definition of laboratory.
- Majority of Medicare revenues threshold.

Definition of Applicable Laboratory (continued)

- 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 Advanced Diagnostic Laboratory Tests (ADLTs) for the ADLTs they furnish (more on later slides).

Revisions to the Definition of Applicable Laboratory

Final PFS rule[1] published in 2018 made two revisions to the regulatory definition of "Applicable Laboratory", effective January 1, 2019.

(1) Medicare Advantage plan payments are excluded from total Medicare revenues (the denominator of the majority of Medicare revenues threshold)

(2) Hospital outreach laboratories that bill for their non-patient laboratory services using the hospital's NPI must use Medicare revenues from the Form CMS-1450 14x Type of Bill (TOB) to determine whether they meet the majority of Medicare revenues threshold and low expenditure threshold.

[1] Physician Fee Schedule (PFS) final rule entitled "Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2019" (CMS-1693-F)

Applicable Information

Includes:

- Specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test
- Each private payor rate for which **final payment** was made during a data collection period (by date of final payment)
- The associated volume of tests performed for each private payor rate
  - Examples:
    - Multiple payment rates for the same test
    - Resolved appeals
    - Non-contracted amounts for out-of-network laboratories or services
    - Final payments from secondary insurance payors

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

Reporting Applicable Information

- Report information for all of your TIN's component-applicable laboratories.
- You must report if you are an applicable laboratory.
- Not an applicable laboratory? Do not report.

CLFS Private Payor Data Collection and Reporting Policies (Part 2)

Sarah Harding

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

Frequency of Data Collection and Reporting

- CDLTs that are not ADLTs: every three years
- ADLTs: annually

Current/Upcoming Data Collection and Reporting Schedule

- Data collection period: January 1, 2019 through June 30, 2019
- Data reporting period: January 1, 2020 through March 31, 2020
- Payment rates implemented: January 1, 2021

Subsequent data collection and reporting

- Same timeline for each update year
  - Example: For update year CY 2024; data collection = January 1, 2022 – June 30, 2022; reporting = January 1, 2023 – March 31, 2023.

Definition of ADLT - Statutory Requirements

Part 1

- CDLT covered under Medicare Part B;
- Offered and furnished by a single laboratory (furnishes ADLT including the entity that owns the laboratory and the entity that is owned by the laboratory) and;
- For use only by original developing laboratory (or successor owner).
    - Partnership; unincorporated sole proprietorship, or corporation.
    - Successor to a successor

Definition of ADLT (continued)

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.

CLFS Payment Methodology for CDLTs

- CMS will calculate a weighted median private payor 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 will use crosswalking or gapfilling to price the test.

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/approved by the FDA.

- If there is no 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 prior to the implementation of the private payor rate-based CLFS (as compared to the payment amount for the preceding year).
- First three years after implementation, statue limited the reduction to 10 percent.
- For upcoming payment cycle three years reduction is limited to 15 percent.
- Phased-in payment reduction limit for a test will be based on the weighted median private payor rate calculated for CY 2021 compared to the CY 2020 weighted median private payor rate.

Confidentiality

- 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 2020

- 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

Early November 2020

- Final CY CLFS payment rates

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 2019
- Ready for data collection January 1, 2020

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
HCPCS	Healthcare Common Procedure Coding System
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
TIN	Tax Identification Number
TOB	Type of Bill

Resources

- Submit questions to CLFS_Inquiries@cms.hhs.gov
- Online resources available: PAMA Regulations webpage on CMS.gov

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