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

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Housekeeping

- All lines are muted
- Submit questions using the Q&A icon (bottom of your zoom screen)
  - We will answer questions throughout today's presentation
- After the meeting, email questions to: CLFS_Inquiries@cms.hhs.gov
- Closed Captioning is available using the link provided in the chat
- Transcript and recording will be available on our PAMA regulations website

Agenda

1. Overview of Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Data Collection and Reporting (Parts 1 & 2)
2. Overview of Data Collection System
3. Selected Frequently Asked Questions

Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Data Collection and Reporting (Part 1)

Rasheeda Arthur

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.

Big Picture: Where are we now?

- 2nd round of data collection and reporting
- We experienced 2 statutory delays
- A few policy revisions

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)

- 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), with respect to the ADLTs they furnish.

Revisions to the Definition of Applicable Laboratory

- Final Physician Fee Schedule rule1 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:

- 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;
  – 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

- TINs must report applicable information for all of its component applicable laboratories.
- Voluntary reporting is not permitted.
- Reporting applicable information is not discretionary.

Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Data Collection and Reporting (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 Clinical Diagnostic Laboratory Tests (CDLTs) 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.

Current/Upcoming Data Collection and Reporting Schedule

- Data collection period: January 1, 2019 through June 30, 2019.
- Typically, there's a 6-month review and validation period.
- Data reporting period: January 1, 2022 through March 31, 2022.
- Payment rates implemented: January 1, 2023.
- Subsequent data collection and reporting
- Same as initial corresponding to the applicable update year.
  - Example: For update year CY 2025; data collection = January 1, 2024 – June 30, 2024; reporting = January 1, 2025 – March 31, 2025.

CLFS Payment Methodology for CDLTs

- Using applicable information 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 would use crosswalking or gapfilling to price the test.

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).
- The statutory phase-in of payment reductions resulting from private payor rate implementation is extended, that's, through CY 2024. There's a 0.0 percent reduction for CY 2021, and we won't reduce payment by more than 15% for CYs 2022 through 2024

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 2022

- 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 2022

- Final CY CLFS payment rates.

Codes without Data

- Codes without data– we will bring our Annual Laboratory Meeting in 2022

Overview of the 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

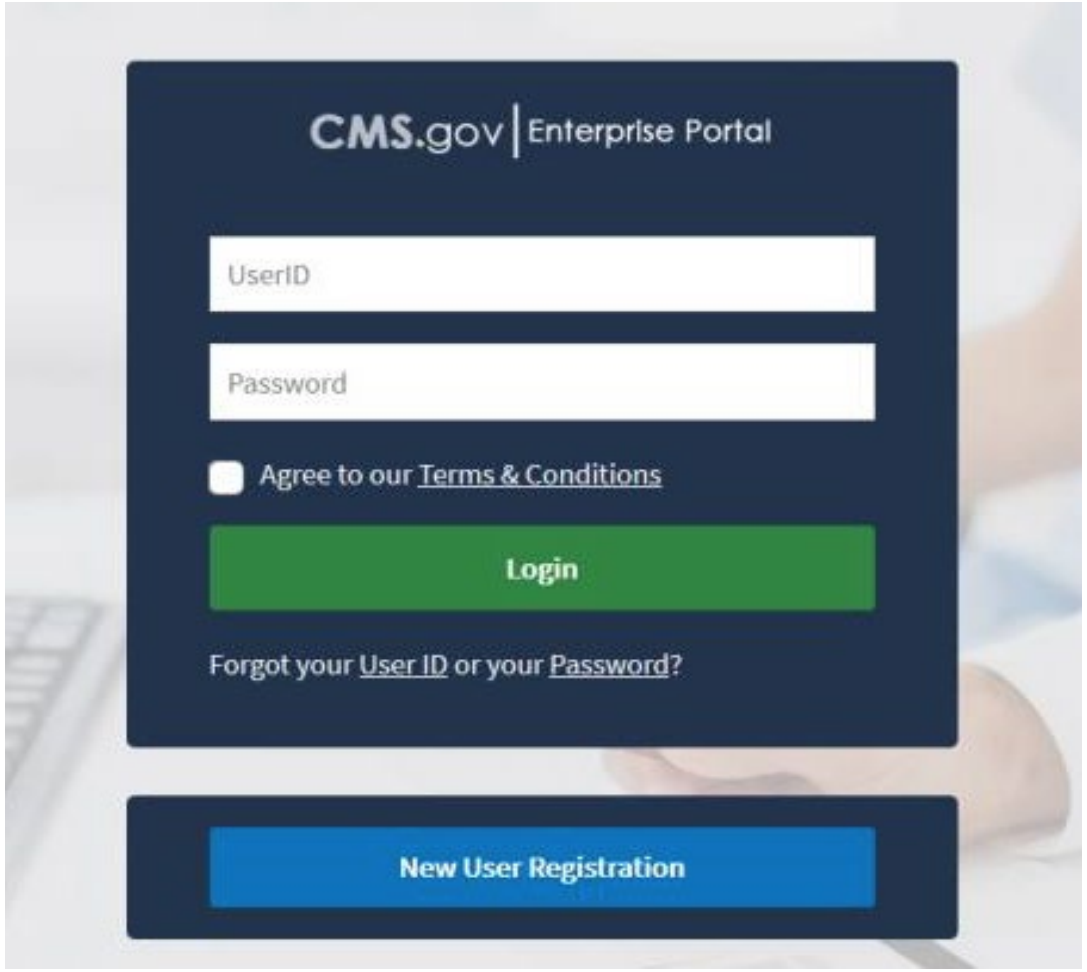
IDM Registration

- CMS Identity Management
  - https://portal.cms.gov

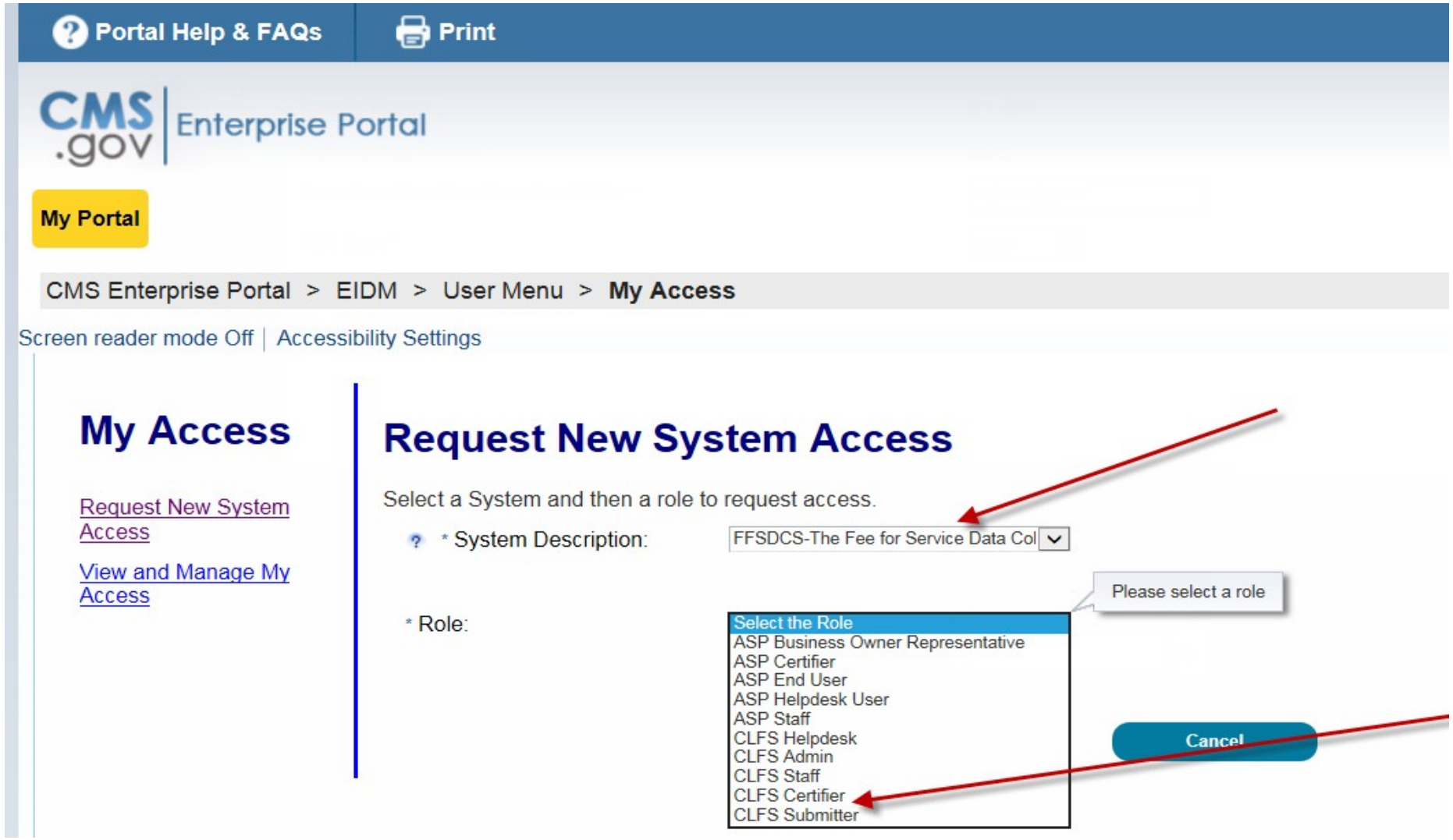
- Registration is currently open to establish user names and passwords.

- System open for data January 1, 2022.

CLFS Data Collection System



System is Role-Based



What labs can do now

- Determine individuals for each role:
  - CLFS Submitter
  - CLFS Certifier
- Apply for user name and role in the IDM system (https://portal.cms.gov)
- Download excel template for data reporting and prep submission

HCPCS Code	Payment Rate	Volume	NPI

CLFS Reference Material

- On the PAMA webpage:
  - CLFS User Guide (updated guide coming soon!)
  - IDM User Guide
  - Data Template (Excel)

- CLFS helpdesk: clfshelpdesk@dcca.com; 844-876-0765

Selected Frequently Asked Questions

For a complete list of Frequently Asked Questions, please refer to **CMS PAMA webpage.**

Frequently Asked Questions

1. **Question**: How do I know if I meet the requirements to be an applicable laboratory base on my own billing NPI?

Answer: Follow 4 steps. Determine if…

1. the laboratory is certified under CLIA
2. the CLIA-certified laboratory bills Medicare Part B under its own NPI or a hospital lab billing on the 14X
3. the laboratory meet the majority of Medicare revenues threshold for the data collection period (1/1/2019-6/30/2019)
4. the laboratory meet the low expenditure threshold

(at least $12,500 from the CLFS)

Frequently Asked Questions

2. Question: How do I know if my laboratory meets the majority Medicare Revenues Threshold?

Answer: Use this equation.

If:

$$\frac{\text{Medicare CLFS revenues (for billing NPI)} + \text{Medicare PFS revenues (for billing NPI)}}{\text{Total Medicare revenues (for billing NPI)}} \text{ is } > 50\%$$

Then:

The laboratory meets the majority of Medicare revenues threshold

Frequently Asked Questions

3. Question: I am a hospital lab using the 14X TOB. How do I know if my hospital outreach laboratory meets the majority Medicare Revenues Threshold?

Answer: Use this equation.

If:

$$\frac{\text{Medicare CLFS revenues (for 14X)} + \text{Medicare PFS revenues (for 14X)}}{\text{Total Medicare revenues (for 14X)}} \text{ is } > 50\%$$

Then:

The laboratory meets the majority of Medicare revenues threshold

Frequently Asked Questions

4. Question: What is the definition of a hospital outreach laboratory?

Answer: For purposes of determining applicable laboratory status under the private payor rate-based CLFS, a hospital outreach laboratory means a hospital-based laboratory that furnishes laboratory tests to patients other than inpatients or registered outpatients of the hospital. A hospital outreach laboratory bills for Medicare Part B services furnished to non-hospital patients using the Form CMS-1450 14x TOB.

Frequently Asked Questions

5. Question: For a hospital lab that has determined it is an applicable lab based on the 14X TOB, for reporting private payor data, should hospitals include payments received for non-patient services billed to commercial insurers on the 13X TOB?

Answer: The reporting entity reports identifiable applicable information attributed to non-hospital patients. For a hospital outreach laboratory that bills under the hospital's NPI, the reporting entity reports private payor data that can be distinguished from testing performed for hospital patients.

Frequently Asked Questions

6. Question: I am a Critical Access Hospital. Am I required to report?

Answer: If your laboratory has its own NPI or is a hospital lab billing under the 14X TOB, you will need to make the determination if your lab is an applicable lab. Based on your NPI or 14X billing, meeting the majority of Medicare revenues, and the low expenditure threshold, you may be required to report.

Frequently Asked Questions

7. Question: I only perform CLIA waived tests, do I need to report?

Answer: CLIA waived tests are included in the list of HCPCS codes. You will need to determine if you are an applicable lab and if yes, you will need to report the private payor rates for the CLIA waived tests.

Frequently Asked Questions

8. Question: I am a new laboratory that recently opened and to perform COVID-19 testing, do I need to report?

Answer: If you do not meet the majority of Medicare revenues during the data collection period, January 1, 2019-June 30, 2019, then you would not be required to report. However, you may be required to report during the next data collection period in 2024 and report your data in 2025.

Frequently Asked Questions

9. Question (Updated 11-19-2021):
Answer: The statute provides that the applicable information for each clinical diagnostic laboratory test (CDLT) furnished during a data collection period by an applicable laboratory must be reported in a data reporting period (see section 1834A(a)(1) of the Social Security Act). The regulations codify this requirement by providing that, in a data reporting period, a reporting entity must report the applicable information for each CDLT furnished by its component applicable laboratories in a data collection period (see 42 C.F.R. § 414.504(a)).

If a reporting entity acquires an applicable laboratory, the reporting entity must report the applicable information for each CDLT furnished by that laboratory in the data collection period, regardless of the date of the change of ownership. This means, if an applicable laboratory becomes a component of the reporting entity after a data collection period, the reporting entity must report that laboratory's applicable information even though the applicable laboratory was not a component of the reporting laboratory during the data collection period.

Frequently Asked Questions

Example for Question and Answer 9:

For example, an independent laboratory (Laboratory #1) purchases another laboratory (Laboratory #2) on April 10, 2021. Both are applicable laboratories. Laboratory #1 is the reporting entity, meaning the entity that reports tax-related information to the Internal Revenue Service using its Taxpayer Identification Number for its components that are applicable laboratories (see 42 C.F.R. § 414.502), and Laboratory #2 is a component of Laboratory #1. As the reporting entity, Laboratory #1 must report the applicable information for each CDLT furnished in the data collection period of January 1, 2019 to June 30, 2019 for all component applicable laboratories during the next data reporting period of January 1, 2022 to March 31, 2022. Even though Laboratory #2 was not a component of Laboratory #1 during the data collection period, Laboratory #1 must report its applicable information because Laboratory #2 is a component of Laboratory #1 at the time of the data reporting period.

General Resources

- Links to Useful PAMA Documents
  - MLN Matters® Special Edition Article SE19006 – (Updated 11/04/2021)
  - Summary of Private Payor Rate-Based CLFS (PDF) - (Updated 04/20/2021)
  - Frequently Asked Questions CY 2021 CLFS (PDF) - (Updated 04/20/2021)
- CLFS_Inquiries@cms.hhs.gov

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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