Clinical Laboratory Fee Schedule (CLFS)

Data Collection and Reporting Webinar

April 16, 2026

Welcome

Thank you for joining our **Clinical Laboratory Fee Schedule (CLFS) Data Collection and Reporting Webinar.**

This session will be recorded and posted.

- Participants can submit questions via the Q&A feature.
- This is approximately a 1-hour session with time for questions at the end.

Agenda

Topic	Presenter
Introductory Remarks	Sarah Shirey-Losso, CMS
• Program Overview • Data Collection and Reporting Process • CLFS System Overview	Sarah Harding, CMS
• Timeline • Resources • Next Steps	Maria Durham, CMS
Q&A Session	CMS and Contractor Team

Goals

- Provide an overview of the:
  - Laboratory reporting requirements
  - Registration process
  - Available resources
- Demonstrate how to:
  - Prepare for data collection
  - Access the CLFS Data Collection System
  - Report clinical diagnostic laboratory tests (CDLT) data to CMS
- Answer your questions

PAMA Requirement

- Section 1834A of the Social Security Act (the Act), as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), requires applicable laboratories to report applicable information to CMS for each clinical diagnostic laboratory test that the laboratory furnishes.
- The first round of data collection and reporting took place in 2017.
- On February 3, 2026, section 6226 of the Consolidated Appropriations Act (CAA) was passed, announcing that the next data reporting period would be from May 1, 2026, to July 31, 2026.
- This round of data collection and reporting will set the Clinical Laboratory Fee Schedule for Calendar Years 2027 to 2029.

Applicable Information

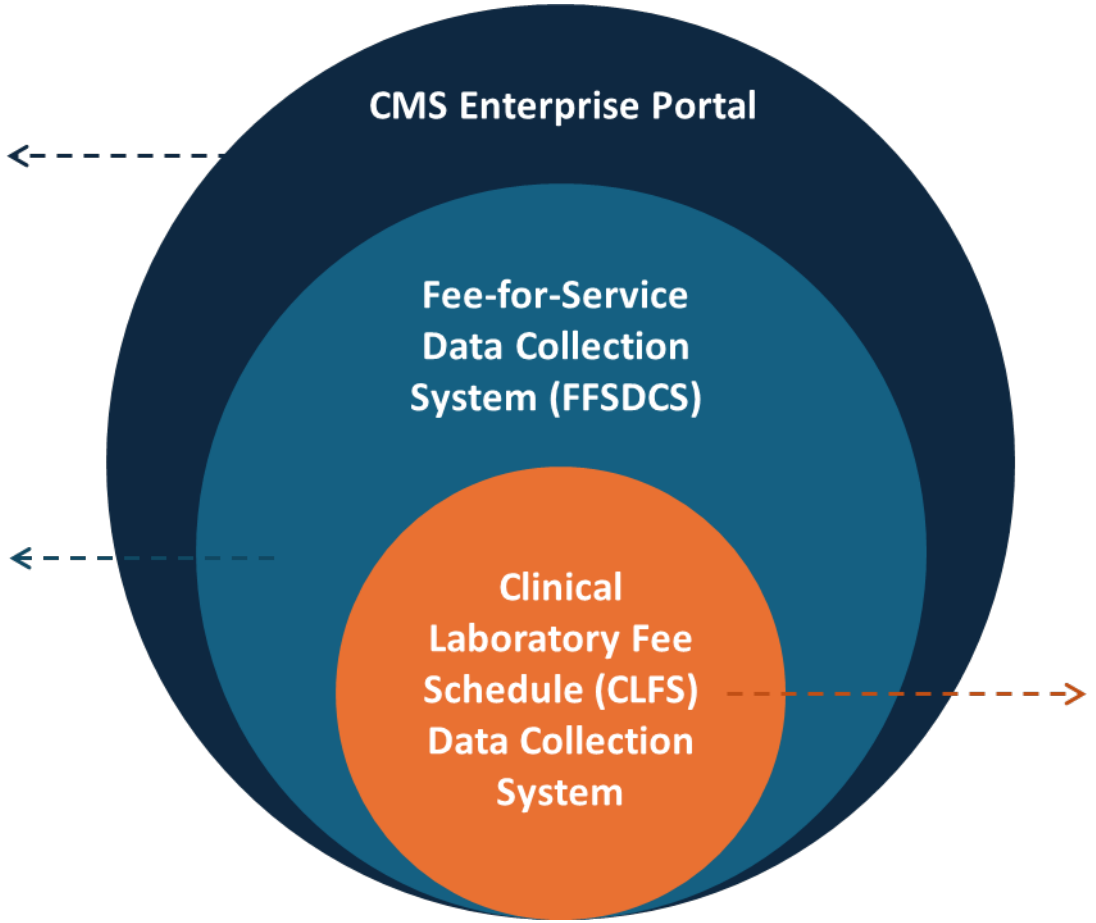
January 1, 2025, through June 30, 2025

CDLTs	Clinical diagnostic laboratory tests (CDLTs): the specific HCPCS code associated with the test
PAYMENT RATE	Each private payor rate for which the final payment has been made during the data collection period
UNITS	The associated volume of tests performed corresponding to each private payor rate

Data Collection System

The CMS Enterprise Portal hosts all CMS applications and verifies individuals through the Identity Management System (IDM).

The FFSDCS collects data for Medicare Fee-for-Service Programs.



The CLFS Data Collection System collects data from applicable laboratories.

Getting Started

1

Verify Applicable Status

Confirm billing status, calculate the majority of Medicare threshold, and confirm CLFS revenues meet or exceed the low expenditure threshold.

2

Identify Submitter and Certifier

Identify two individuals to create accounts in the CMS Enterprise Portal, verify their identities, and request access to the CLFS Module.

3

Prepare Data

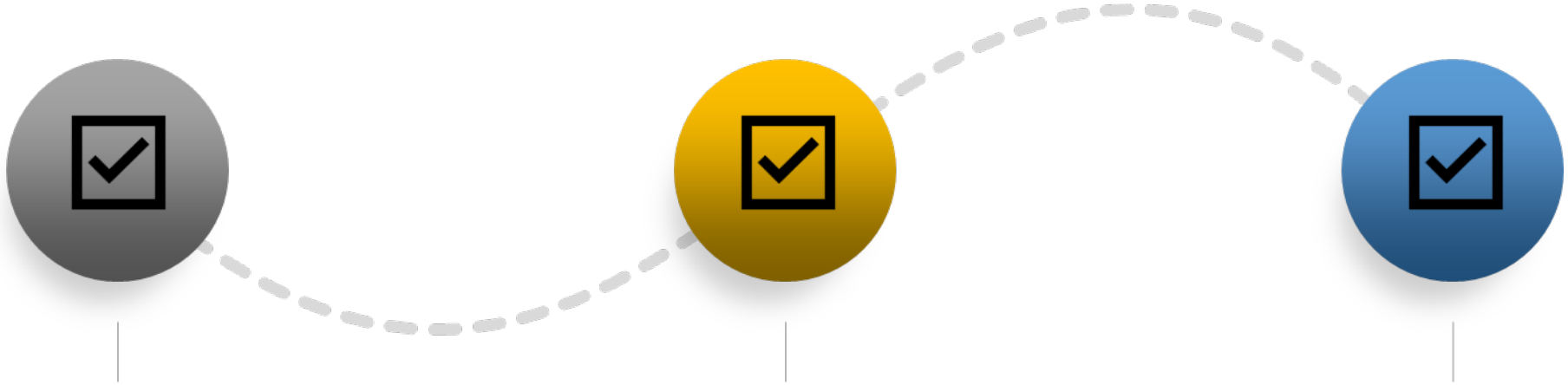
Work with your internal team to gather private payor data using the provided template.

4

Submit Data

Submit your CDLT data in the Data Collection System starting May 1, 2026.

Applicable Laboratory



Bill Medicare Part B

Your laboratory bills Medicare Part B either under its own National Provider Identifier (NPI), or on the Form-1450 under type of bill (TOB) 14X, if a hospital outreach laboratory.

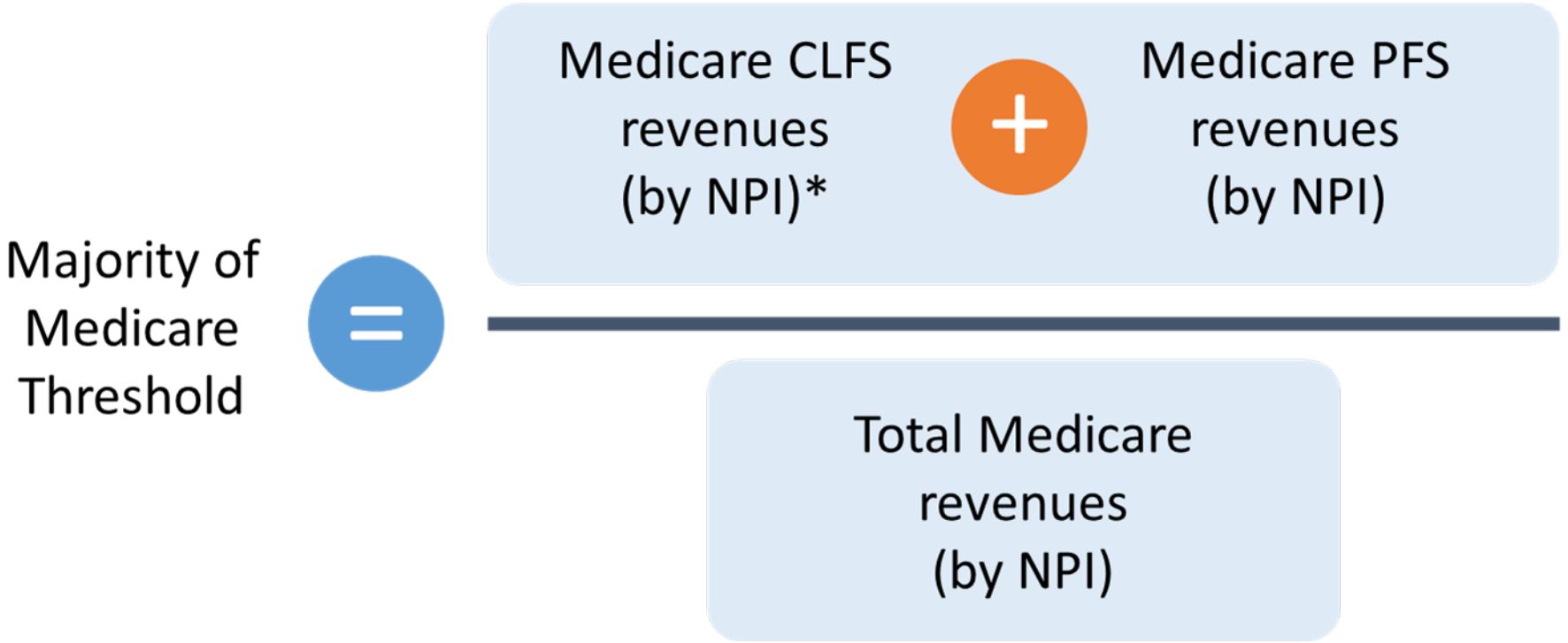
Majority of Medicare

Your laboratory meets the "majority of Medicare revenues" threshold, which means when you add your revenue from Medicare CLFS and Medicare Physician Fee Schedule (PFS), it is more than 50 percent of your total Medicare revenues.

Low Expenditure Threshold

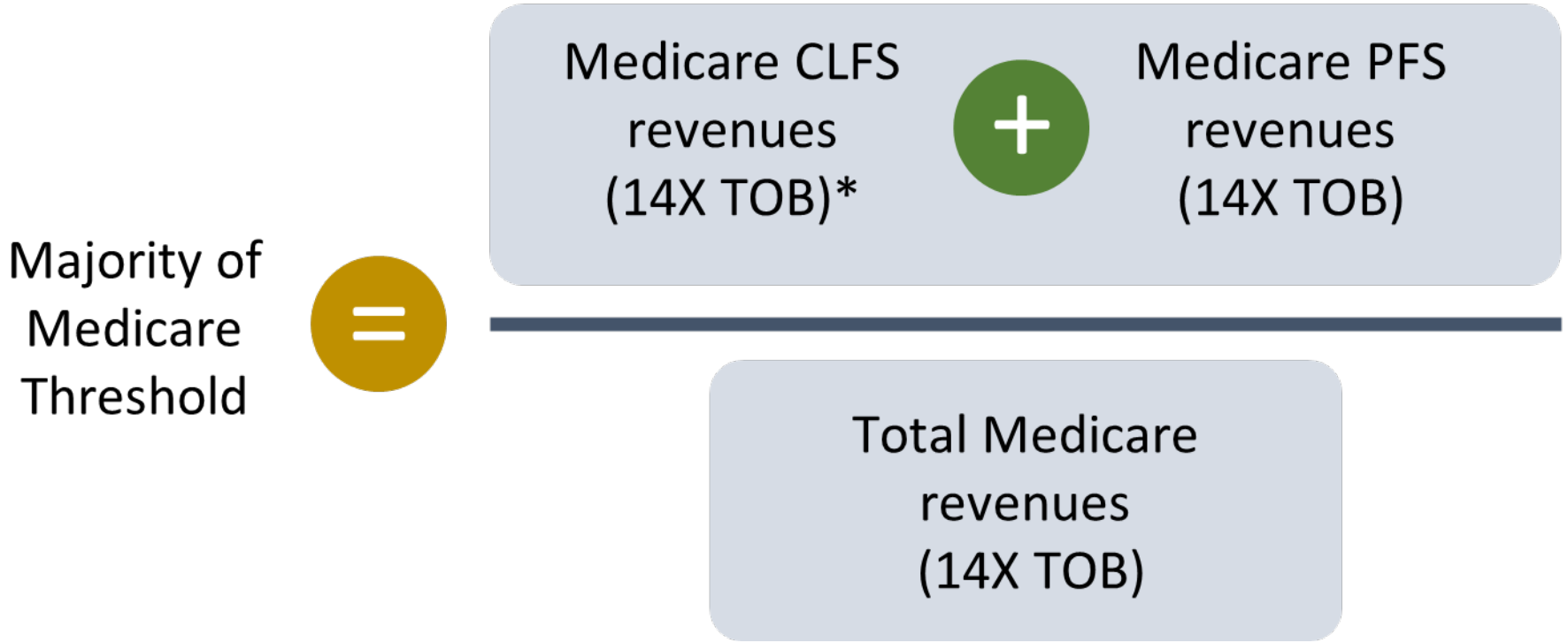
Once you complete the calculation, you are an applicable laboratory if your Medicare CLFS revenues (for billing NPI) meet or exceed the low expenditure threshold of $12,500.

Laboratories with their own NPI



**Medicare CLFS revenues (for billing NPI) meet or exceed the low expenditure threshold of $12,500.*

Laboratories That Share the Hospital's NPI

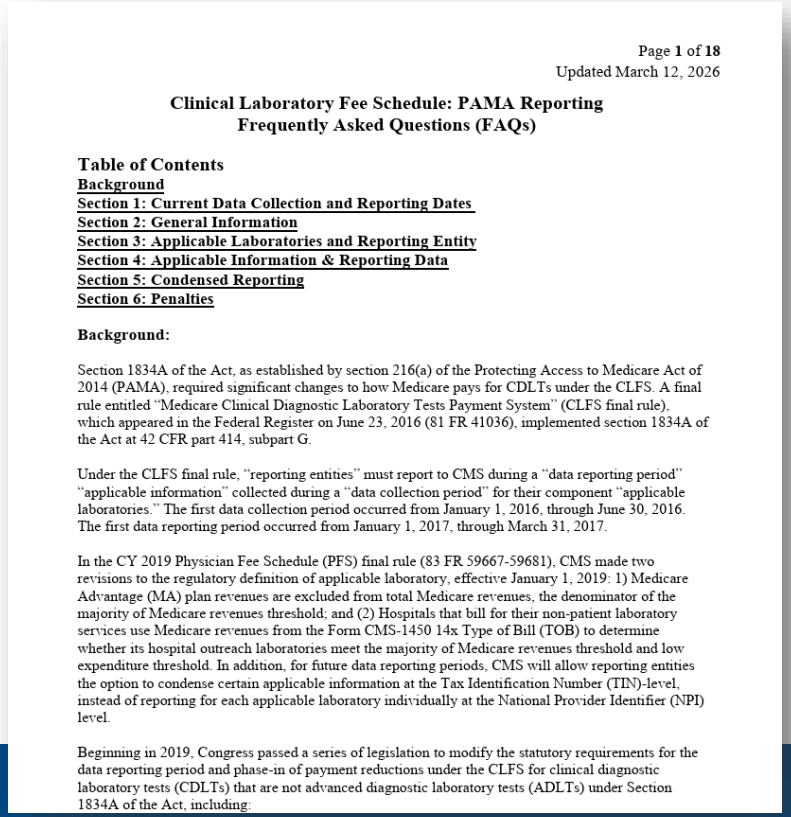


**Medicare CLFS revenues (for billing NPI) meet or exceed the low expenditure threshold of $12,500.*

How to Determine Applicability

Because CMS cannot verify all information to determine applicable lab status, Independent, Physician's Office, and Hospital-outreach laboratories are asked to determine whether they are applicable labs and, if so, are required to report. CMS created several resources for labs to use when determining their applicable status.

Frequently Asked Questions (Section 3)



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Updated March 12, 2026

Clinical Laboratory Fee Schedule: PAMA Reporting Frequently Asked Questions (FAQs)

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Background
Section 1: Current Data Collection and Reporting Dates
Section 2: General Information
Section 3: Applicable Laboratories and Reporting Entity
Section 4: Applicable Information & Reporting Data
Section 5: Condensed Reporting
Section 6: Penalties

Background:

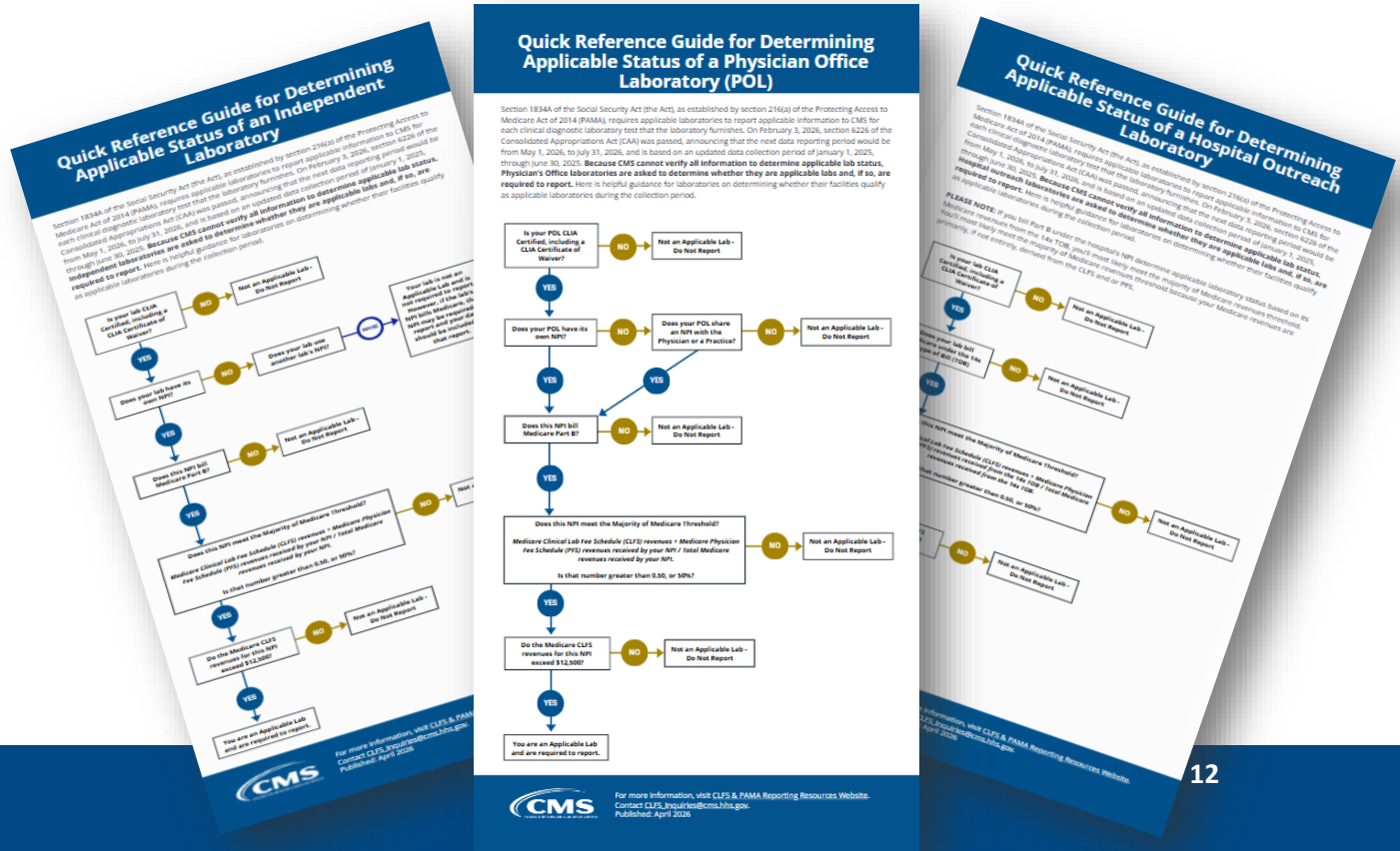
Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. A final rule entitled "Medicare Clinical Diagnostic Laboratory Tests Payment System" (CLFS final rule), which appeared in the Federal Register on June 23, 2016 (81 FR 41036), implemented section 1834A of the Act at 42 CFR part 414, subpart G.

Under the CLFS final rule, "reporting entities" must report to CMS during a "data reporting period" "applicable information" collected during a "data collection period" for their component "applicable laboratories." The first data collection period occurred from January 1, 2016, through June 30, 2016. The first data reporting period occurred from January 1, 2017, through March 31, 2017.

In the CY 2019 Physician Fee Schedule (PFS) final rule (83 FR 59667-59681), CMS made two revisions to the regulatory definition of applicable laboratory, effective January 1, 2019: 1) Medicare Advantage (MA) plan revenues are excluded from total Medicare revenues, the denominator of the majority of Medicare revenues threshold; and (2) Hospitals that bill for their non-patient laboratory services use Medicare revenues from the Form CMS-1450 14x Type of Bill (TOB) to determine whether its hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold. In addition, for future data reporting periods, CMS will allow reporting entities the option to condense certain applicable information at the Tax Identification Number (TIN)-level, instead of reporting for each applicable laboratory individually at the National Provider Identifier (NPI) level.

Beginning in 2019, Congress passed a series of legislation to modify the statutory requirements for the data reporting period and phase-in of payment reductions under the CLFS for clinical diagnostic laboratory tests (CDLTs) that are not advanced diagnostic laboratory tests (ADLTs) under Section 1834A of the Act, including:

Quick Reference Guides: Determining Applicable Status



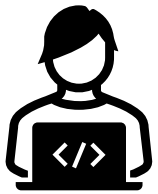
Quick Reference Guide for Determining Applicable Status of an Independent Laboratory

Quick Reference Guide for Determining Applicable Status of a Physician Office Laboratory (POL)

Quick Reference Guide for Determining Applicable Status of a Hospital Outreach Laboratory

CLFS Roles

CMS has identified two main roles for this survey initiative.



The **Submitter** is an individual selected by the laboratory who will create an account in the CMS Enterprise Portal, request the Submitter role in the CLFS module, submit data on behalf of their TIN, and notify the Certifier once data have been submitted. There may only be one Submitter per TIN. A Submitter may submit on behalf of multiple TINs.

The **Certifier** is a President or Chief Financial Officer (CFO) of the applicable laboratory, or an individual designated by the President or CFO, who will create an account in the CMS Enterprise Portal, request the Certifier role in the CLFS module, review the submitted data on behalf of their TIN, and attest to the data's accuracy. There may only be one Certifier per TIN. A Certifier may certify on behalf of multiple TINs.

CMS Enterprise Portal Account

IDM Registration Guide

The Submitter and Certifier for each TIN will follow the steps as outlined in the Registration Guide to create a CMS Enterprise Portal Account and request access to the CLFS Module.

- Create Username and Password
- Set up Multifactor Authentication
- Request Access to FFSDCS as a CLFS Submitter or CLFS Certifier
- Verify Identity using **Personal Information**

Prepare Data

STEP 01

Establish your team.

STEP 02

Run reports for the HCPCS codes.

STEP 03

Calculate the associated volume of tests performed corresponding to each final private payor rate in the data collection period.

STEP 04

Use the template provided to organize your data.

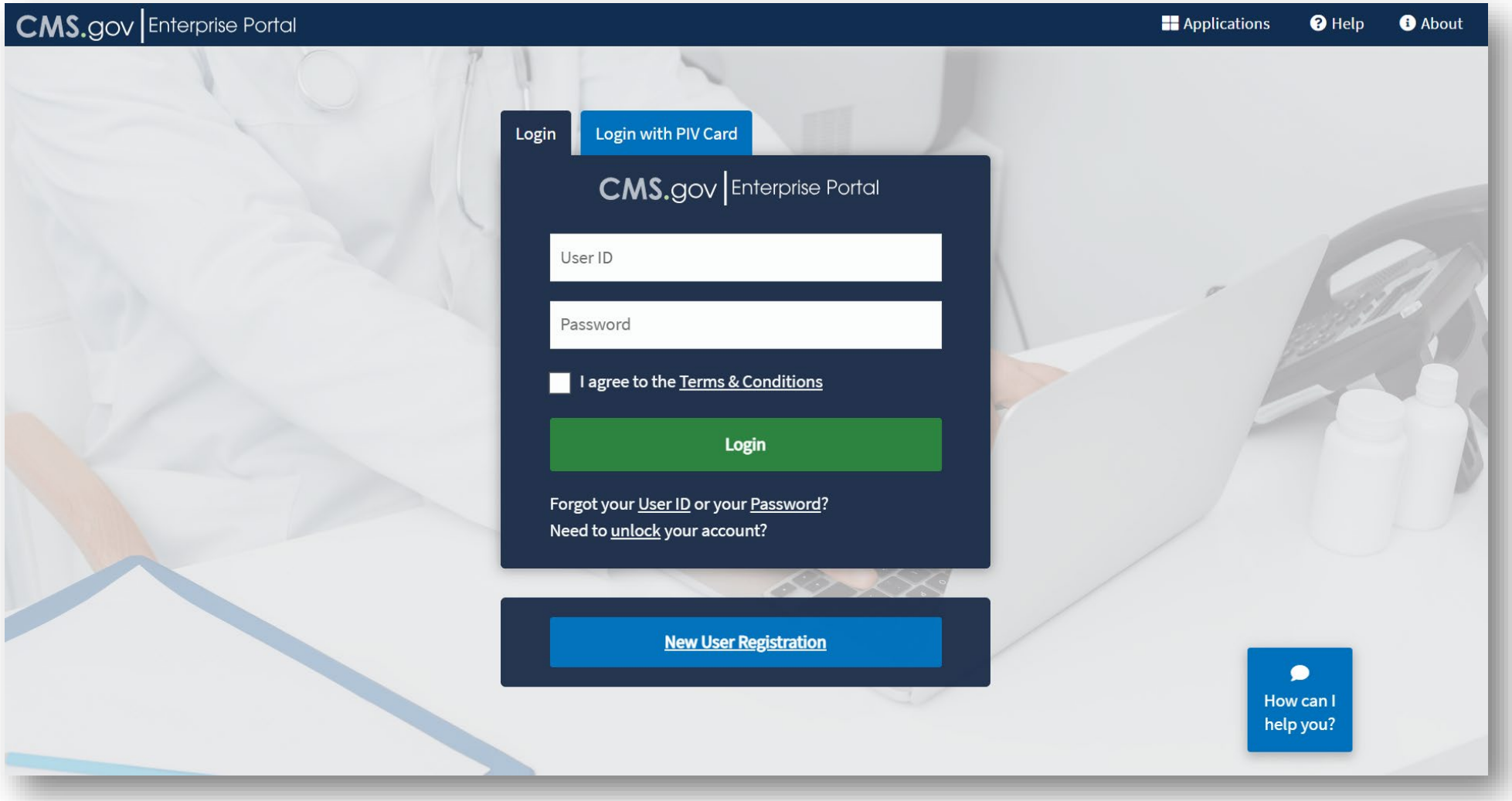
CLFS Data Reporting Template

A	B	C	D
HCPCS Code (5-alpha numeric characters)	**Payment Rate (1-5 numeric characters and two decimal places)**	**Volume (1-6 numeric characters)**	**NPI (National Provider Identifier) (10 numeric characters)**
12345	12.34	200	1234567890
23456	23.45	315	1234567890
34567	34.56	102	1234567890
45678	4.56	2004	1234567890
56789	567.89	15	1234567890
67890	6.78	5890	1234567890

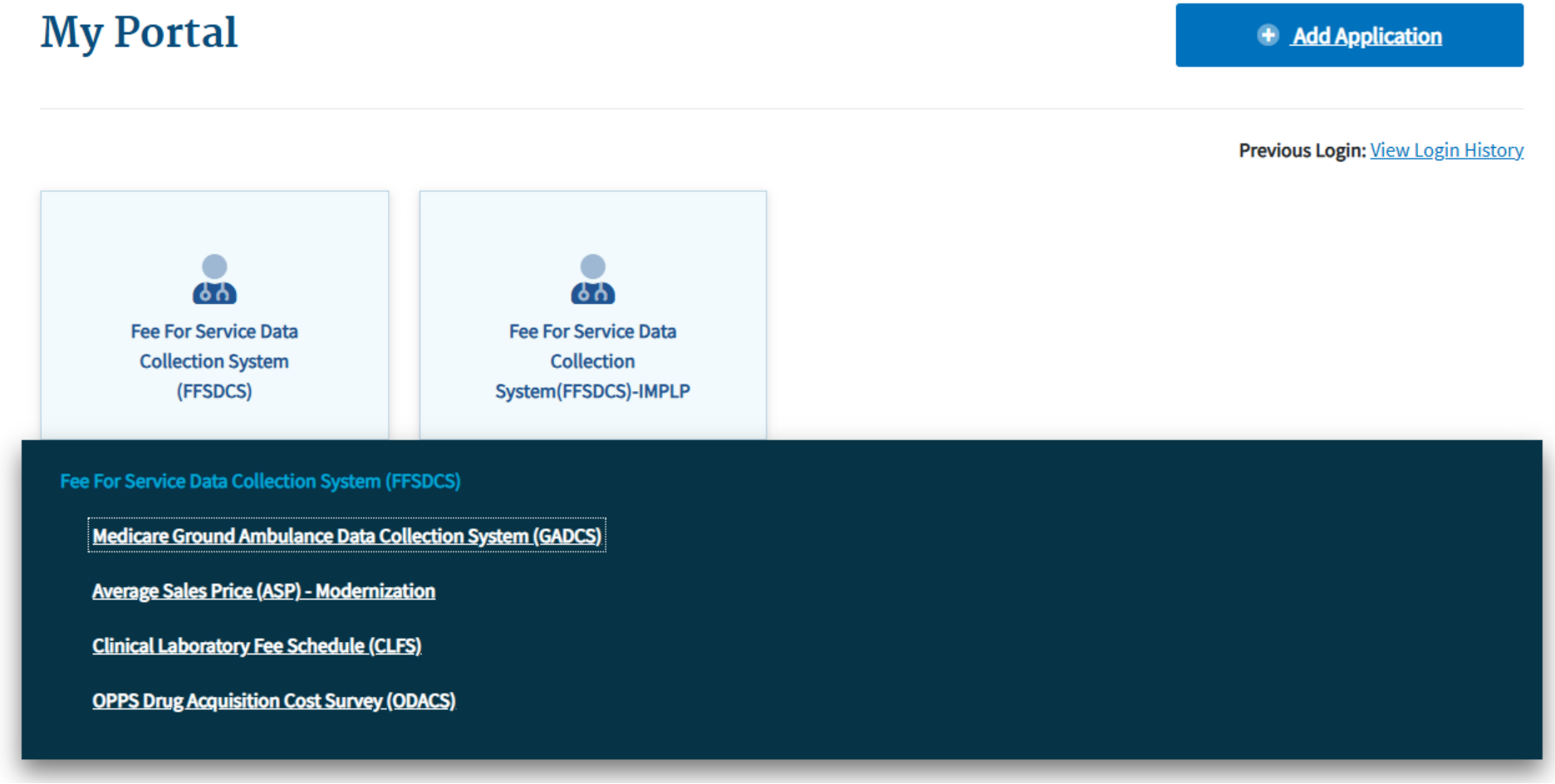
Template Tips

- Submit **only one TIN** per file.
- You may have multiple NPIs per file.
- Do not alter the **formatting** of the Excel file. The system will reject files if the formatting is incorrect.
  - Do not add additional columns to the template.
  - Do not add, remove, or otherwise change columns or column headings within the template.
  - Do not submit blank rows between data entries.
- Enter the Healthcare Common Procedure Coding System (HCPCS) Code, Payment Rate, Volume, and NPI, according to the requirements outlined in the template. They are also listed in the Submitter User Guide.

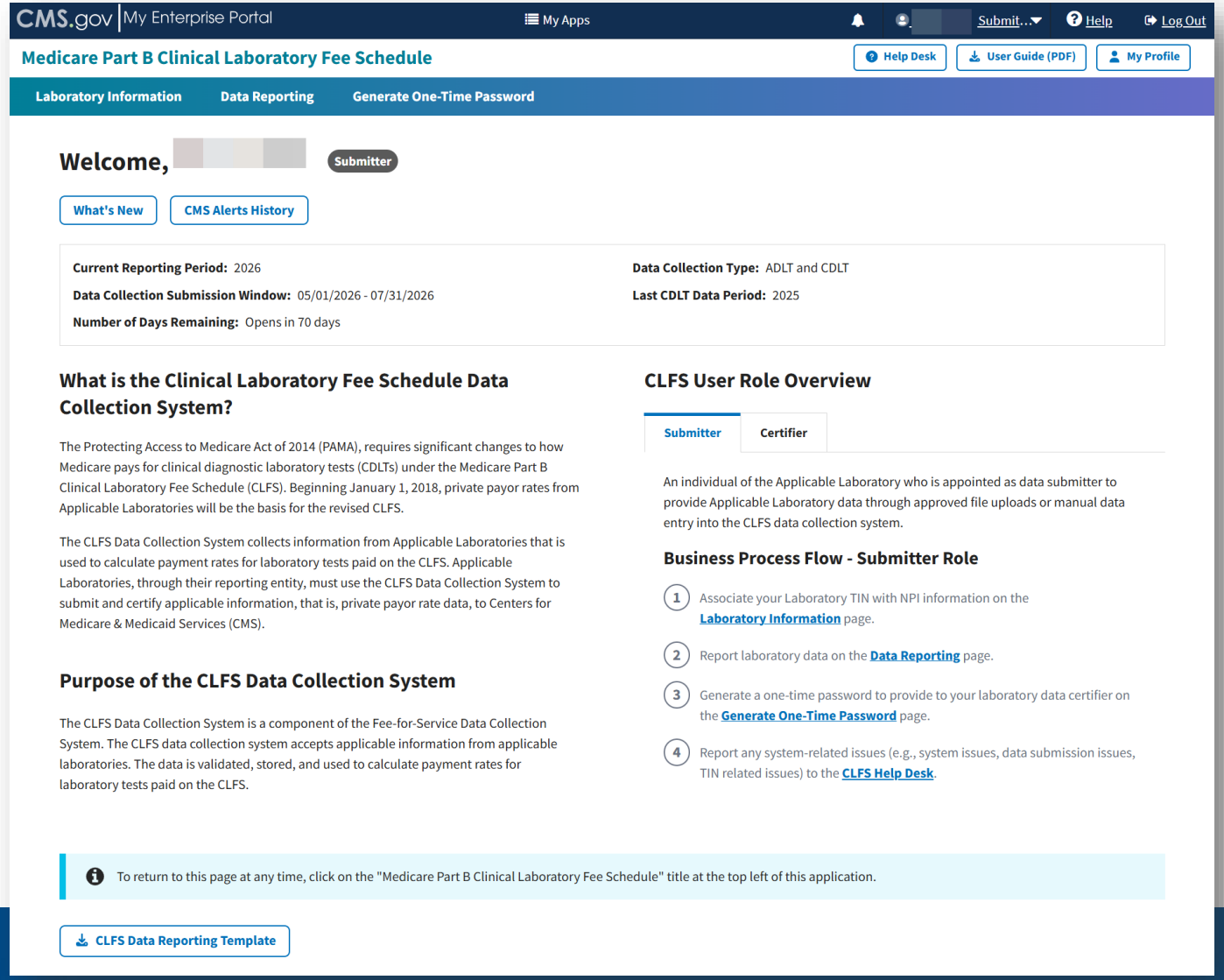
CMS Enterprise Portal



FFSDCS Tile, CLFS Link



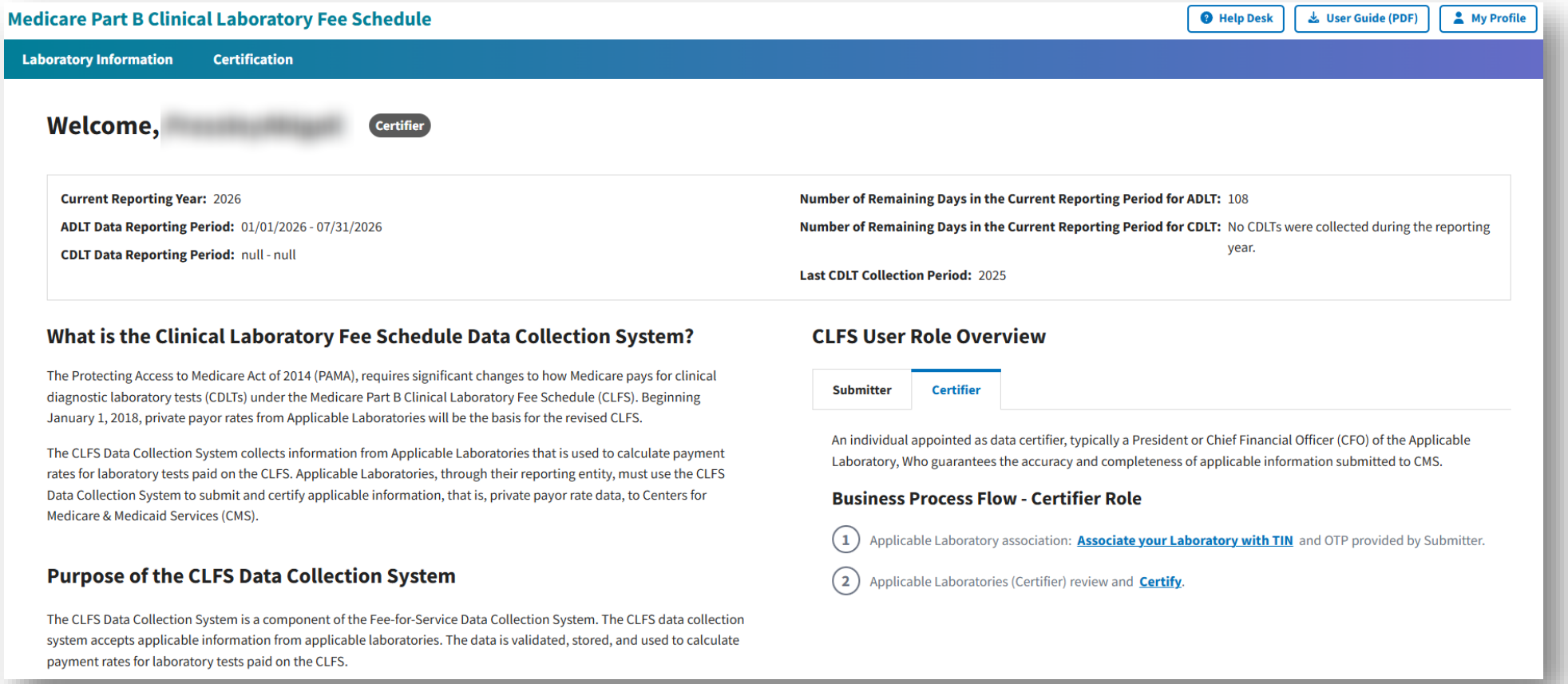
CLFS Welcome Page - Submitter



Submitter: Data Entry Steps

1. Associate your laboratory TIN(s) with NPI information on the **Laboratory Information** page.
2. Report laboratory data using the template provided on the **Data Reporting** page and upload it into the system.
3. Generate a one-time password (OTP) to provide to your Certifier on the **Generate One-Time Password** page.

CLFS Welcome Page - Certifier



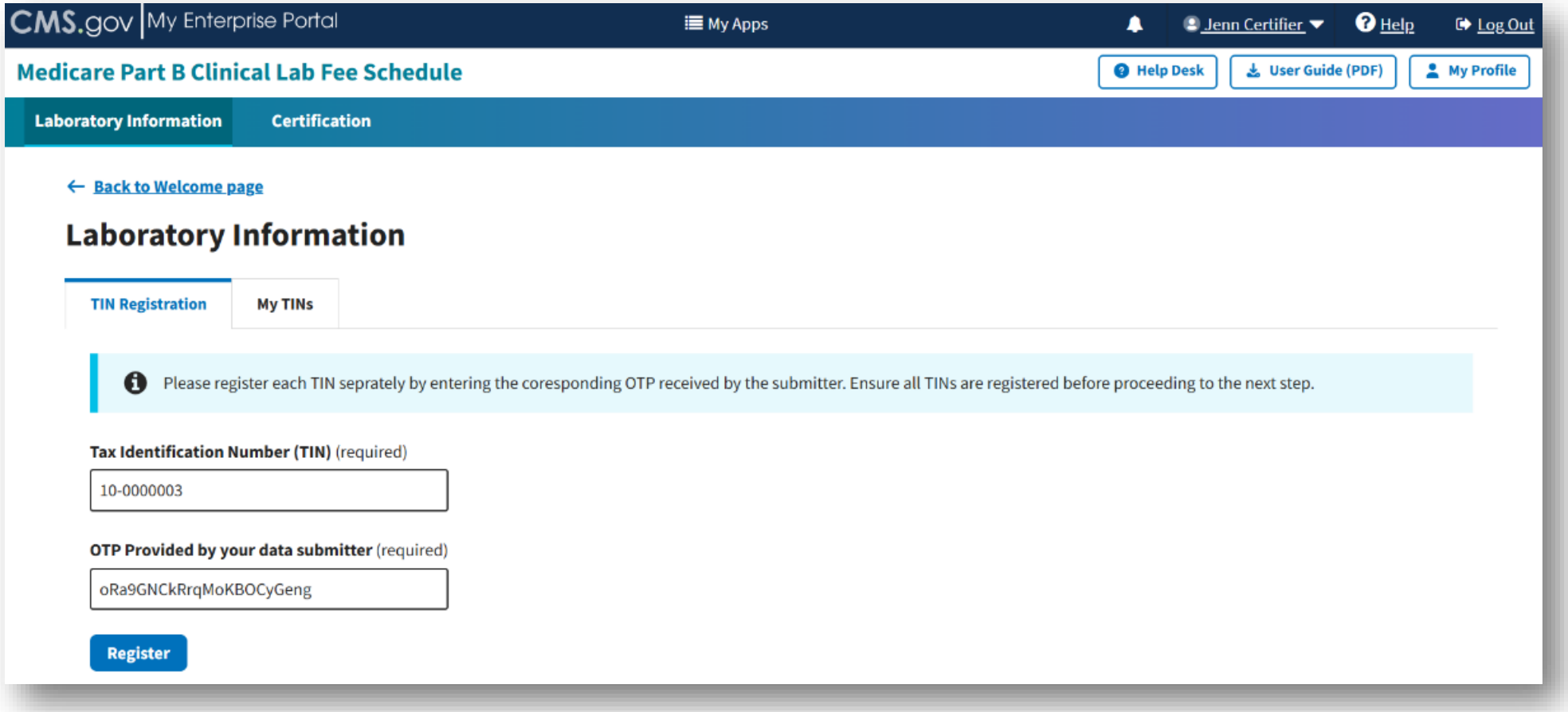
Certifier: Certification Steps

1. Associate your laboratory TIN(s) with NPI information and the one-time password (OTP) from your submitter on the **Laboratory Information** page.

2. Review and certify your data on the **Certification** page.

3. Review the **Data Certification Statement**, click the box next to “I agree to the above certification statement,” and then click the **Submit** button.

One-Time Password (OTP)



Data Review Tips

- Review the file **prior** to having the Submitter upload it to the system.
- After uploading, if any errors are found, they must be corrected by the Submitter.
- The OTP is valid for 7 days. After 7 days, the Submitter will need to generate and send a new OTP.
- Certification can only happen in the Data Collection System, and reporting is not complete without certification.
- Once the Certifier has certified the data for the current period, data submission is closed, and no more data can be entered for that TIN. If corrections are needed after certification, please contact the CLFS helpdesk.

Timeline and Resources

Timeline

Now

Labs determine their applicable status and begin preparing the data.

Submitters and Certifiers create an account in the CMS Enterprise Portal.

May 1, 2026

The CLFS Data Collection System goes live. Submitters upload the template into the Data Collection System, and Certifiers verify the submission.

July 31, 2026

All submissions are due to CMS in the CLFS Data Collection System by 11:59 p.m. EST.

Summer 2026

- Data are analyzed
- Public meeting
- FACA meeting

Fall 2026

Payment determinations are proposed and finalized.

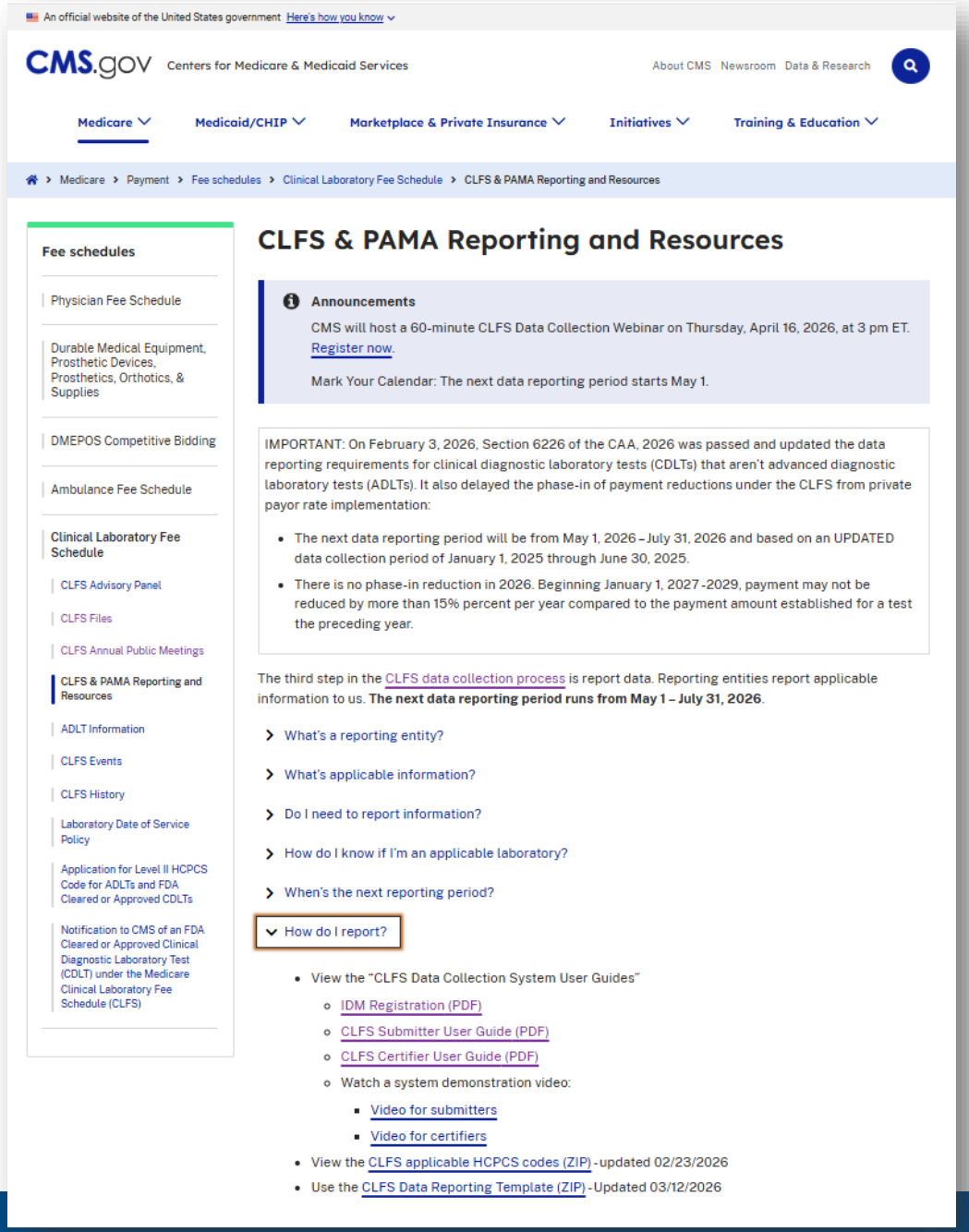
January 1, 2027

Clinical Laboratory Fee Schedule payment rates are effective.

Resources

How do I report?

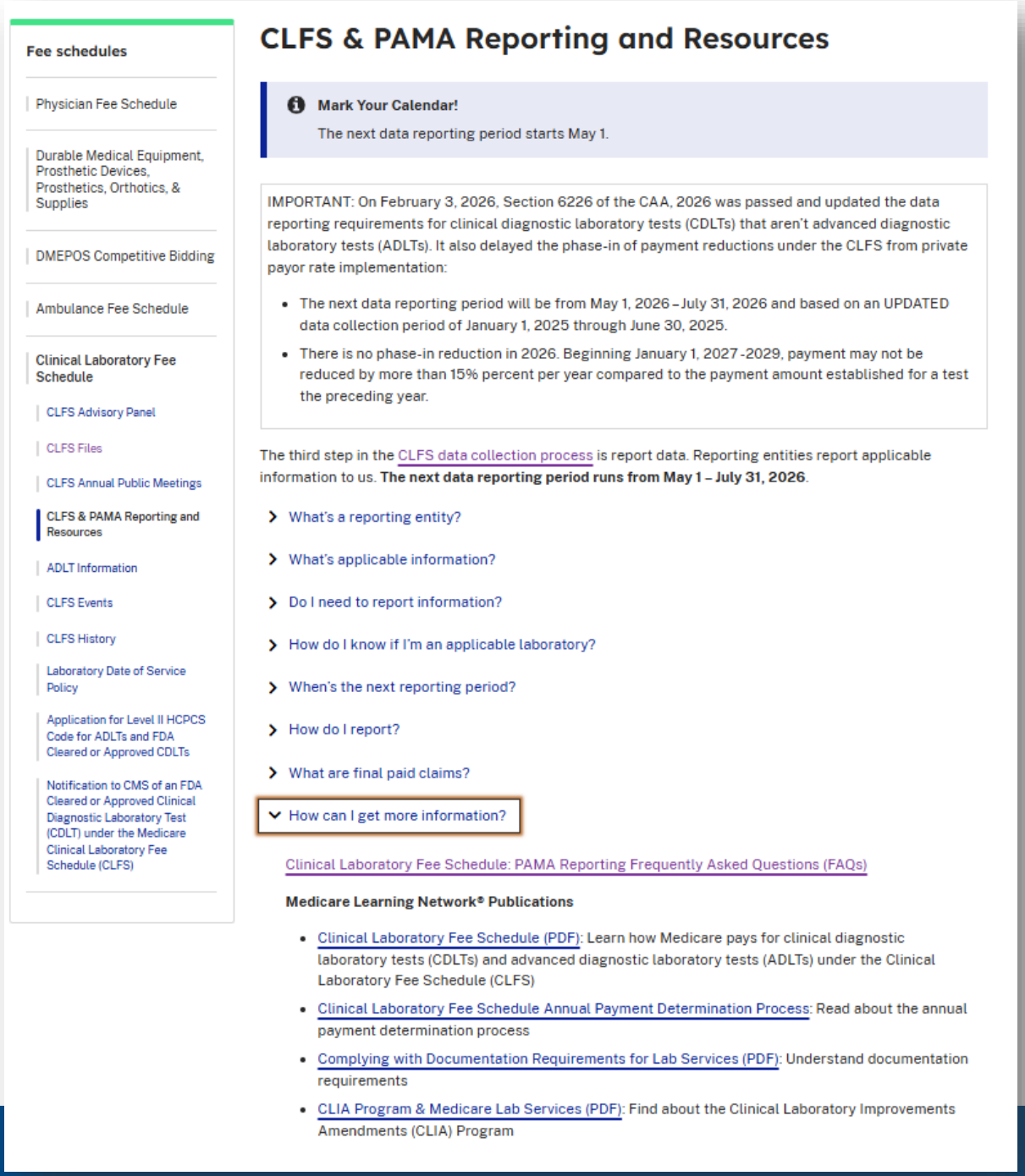
- Registration Guide
- Submitter User Guide
- Certifier User Guide
- HCPCS Codes
- Reporting Template
- System Videos



Resources
(continued)

How can I get more information?

- FAQs
- Clinical Laboratory Fee Schedule and other PDFs
- Webinar Recording



Fee schedules

Physician Fee Schedule

Durable Medical Equipment, Prosthetic Devices, Prosthetics, Orthotics, & Supplies

DMEPOS Competitive Bidding

Ambulance Fee Schedule

Clinical Laboratory Fee Schedule

CLFS Advisory Panel

CLFS Files

CLFS Annual Public Meetings

CLFS & PAMA Reporting and Resources

ADLT Information

CLFS Events

CLFS History

Laboratory Date of Service Policy

Application for Level II HCPCS Code for ADLTs and FDA Cleared or Approved CDLTs

Notification to CMS of an FDA Cleared or Approved Clinical Diagnostic Laboratory Test (CDLT) under the Medicare Clinical Laboratory Fee Schedule (CLFS)

CLFS & PAMA Reporting and Resources

Mark Your Calendar!

The next data reporting period starts May 1.

IMPORTANT: On February 3, 2026, Section 6226 of the CAA, 2026 was passed and updated the data reporting requirements for clinical diagnostic laboratory tests (CDLTs) that aren't advanced diagnostic laboratory tests (ADLTs). It also delayed the phase-in of payment reductions under the CLFS from private payor rate implementation:

- The next data reporting period will be from May 1, 2026 – July 31, 2026 and based on an UPDATED data collection period of January 1, 2025 through June 30, 2025.
- There is no phase-in reduction in 2026. Beginning January 1, 2027 -2029, payment may not be reduced by more than 15% percent per year compared to the payment amount established for a test the preceding year.

The third step in the CLFS data collection process is report data. Reporting entities report applicable information to us. **The next data reporting period runs from May 1 – July 31, 2026**.

- What's a reporting entity?
- What's applicable information?
- Do I need to report information?
- How do I know if I'm an applicable laboratory?
- When's the next reporting period?
- How do I report?
- What are final paid claims?
- How can I get more information?

Clinical Laboratory Fee Schedule: PAMA Reporting Frequently Asked Questions (FAQs)

Medicare Learning Network® Publications

- Clinical Laboratory Fee Schedule (PDF): Learn how Medicare pays for clinical diagnostic laboratory tests (CDLTs) and advanced diagnostic laboratory tests (ADLTs) under the Clinical Laboratory Fee Schedule (CLFS)
- Clinical Laboratory Fee Schedule Annual Payment Determination Process: Read about the annual payment determination process
- Complying with Documentation Requirements for Lab Services (PDF): Understand documentation requirements
- CLIA Program & Medicare Lab Services (PDF): Find about the Clinical Laboratory Improvements Amendments (CLIA) Program

Outreach

- Certified letter
- Email communications
- MLN Connects news articles
- X (formerly Twitter)
- Professional organizations (such as ACLA, NILA, CLC, AAFP, AMA, POCTA, and MGMA)

Support

- **Technical Support (DCCA)**
  - clfshelpdesk@dcca.com
  - 1-844-876-0765
- **Feedback and Other Questions**
  - CLFS_Inquiries@cms.hhs.gov

What's Next?

- ✓ Verify Applicable Lab status.
- ✓ Select the Submitter and Certifier for each TIN.
- ✓ Begin creating an account in the CMS Enterprise Portal.
- ✓ Gather your data.
- ✓ Visit the CLFS & PAMA Reporting and Resources website.
  - User Guides (Registration, Submitter, and Certifier)
  - FAQs
  - Data Template
  - Quick Reference Guides
  - Webinar Recording
  - System Demonstration Video

Q&A