



**Centers for Medicare & Medicaid
Services**

Clinical Laboratory Fee Schedule (CLFS)

Certifier User Manual

**Version 6.0
03/02/2026**

Document Number: DCCA.FFSDCS.CLFS Certifier User Manual.6.0

Contract Number: HHSM-500-2016-00028I

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1. Introduction

1.1 What is the Clinical Laboratory Fee Schedule Data Collection Module?

The Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare calculates payment rates for clinical diagnostic laboratory tests (CDLTs) and advanced diagnostic laboratory tests (ADLTs) under the Medicare Part B Clinical Laboratory Fee Schedule (CLFS). Beginning January 1, 2018, private payor rates from applicable laboratories became the basis for the revised CLFS.

The CLFS module collects information from applicable laboratories that is used to calculate payment rates for laboratory tests paid on the CLFS. Applicable laboratories, through their reporting entity, must use the CLFS module to submit and certify applicable information, that is, private payor rate data, to the Centers for Medicare & Medicaid Services (CMS).

This document provides guidance that will assist users during the completion of the following processes:

- Register as a CLFS Certifier
- Report Applicable Information
- Certify Reported Applicable Information

1.2 Purpose of the CLFS module

The CLFS module is a component of the Fee-for-Service Data Collection System (FFSDCS).

The CLFS module accepts applicable information from applicable laboratories. The data are validated, stored, and used to calculate payment rates for laboratory tests paid on the CLFS.

The CLFS module supports the following business processes:

- CLFS User Registration
- CLFS Applicable Laboratory Data Reporting
- CLFS Applicable Laboratory Data Certification

The following high-level business requirements for CLFS are implemented:

- Applicable Laboratories through their reporting entity shall report applicable information to CMS
- The CLFS module shall identify consistency errors found in submitted data

1.3 Points of Contact

FFSDCS (CLFS) Module Helpdesk

- Email: CLFSHelpDesk@dcca.com
- Phone: 844-876-0765
- Policy and Legal questions: CLFS_Inquiries@cms.hhs.gov

2. CLFS Module Welcome Page

The CLFS module Welcome Page displays content based on user role – Submitter or Certifier – and the privileges assigned to the user role. The CLFS module Welcome Page Screen is shown in Figure 1 for CLFS Certifiers.

The Welcome Page displays important alerts, information about CLFS, and the business process flow. From here, you can navigate to the Laboratory Information and Certification pages. Refer to Figure 1.

The screenshot shows the CMS.gov My Enterprise Portal interface for a Certifier user. The header includes the CMS.gov logo, 'My Enterprise Portal', 'My Apps', a notification bell, a user profile icon, and links for 'Certifier', 'Help', and 'Log Out'. The main content area is titled 'Welcome, [User Name] Certifier'. It features a summary box with the following information: Current Reporting Period: 2026; Data Collection Submission Window: 05/01/2026 - 07/31/2026; Number of Days Remaining: Opens in 70 days; Data Collection Type: ADLT and CDLT; Last CDLT Data Period: 2025. Below this, there are two main sections: 'What is the Clinical Laboratory Fee Schedule Data Collection System?' and 'CLFS User Role Overview'. The 'What is the Clinical Laboratory Fee Schedule Data Collection System?' section contains two paragraphs explaining the PAMA act and the CLFS Data Collection System. The 'CLFS User Role Overview' section has tabs for 'Submitter' and 'Certifier', with the 'Certifier' tab selected. It describes the role of a data certifier and lists a 'Business Process Flow - Certifier Role' with two steps: 1. Associate your Laboratory with TIN and OTP provided by Submitter. 2. Applicable Laboratories (Certifier) review and Certify. A light blue information banner at the bottom states: 'To return to this page at any time, click on the "Medicare Part B Clinical Laboratory Fee Schedule" title at the top left of this application.'

Figure 1: CLFS Application Welcome Page - CLFS Certifier

2.1 First Time Users

If you are certifying data for the first time, you will need the following information before you begin:

- Taxpayer Identification Number (TIN) used when you completed your IDM registration (If you have not yet completed the CMS Identity Management registration, please stop here and finish that first. The user guide for this process is available on the [CLFS Reporting](#) webpage.)
- One-Time Passcode (OTP) from the Submitter of your laboratory. You should have one OTP for every TIN you are certifying.

Gather this information before proceeding to the **Laboratory Information** tab.

NOTE: You must enter the Laboratory Information first. You will not be able to do any other tasks in the system until you do, and you will see the following error message:

 No Taxpayer Identification Number (TIN) registered. Register in the 'TIN Registration' tab.

3. Laboratory Information

The Laboratory Information page is where you will register a Taxpayer Identification Number (TIN) using the One-Time Password (OTP), view lab and National Provider Identifier (NPI) information, and unassign registered TINs if needed.

The following steps are to be used to register a TIN or TINs using the OTP sent by the Submitter:

1. From the Welcome Page, click on the Laboratory Information tab at the top of the screen to open the Laboratory Information page as shown in Figure 2.
2. Enter the TIN and then enter the OTP provided to you by the Submitter.

The screenshot shows the CMS.gov My Enterprise Portal interface. At the top, there is a navigation bar with 'My Apps', 'Jenn Certifier', 'Help', and 'Log Out'. Below this is a sub-header for 'Medicare Part B Clinical Lab Fee Schedule' with links for 'Help Desk', 'User Guide (PDF)', and 'My Profile'. The main content area has two tabs: 'Laboratory Information' (highlighted with a red box) and 'Certification'. Below the tabs is a 'Back to Welcome page' link. The 'Laboratory Information' section has two sub-tabs: 'TIN Registration' (active) and 'My TINs'. A light blue informational message states: 'Please register each TIN separately by entering the corresponding OTP received by the submitter. Ensure all TINs are registered before proceeding to the next step.' Below this message is a registration form with two input fields, both highlighted with a red box. The first field is labeled 'Tax Identification Number (TIN) (required)' and contains the value '10-0000003'. The second field is labeled 'OTP Provided by your data submitter (required)' and contains the value 'oRa9GNckRrqMoKBOCyGeng'. A blue 'Register' button is positioned below the form.

Figure 2: Laboratory Information - TIN Registration

3. Click **Register**.
4. A green TIN Registered Successfully message will appear as shown in Figure 3.

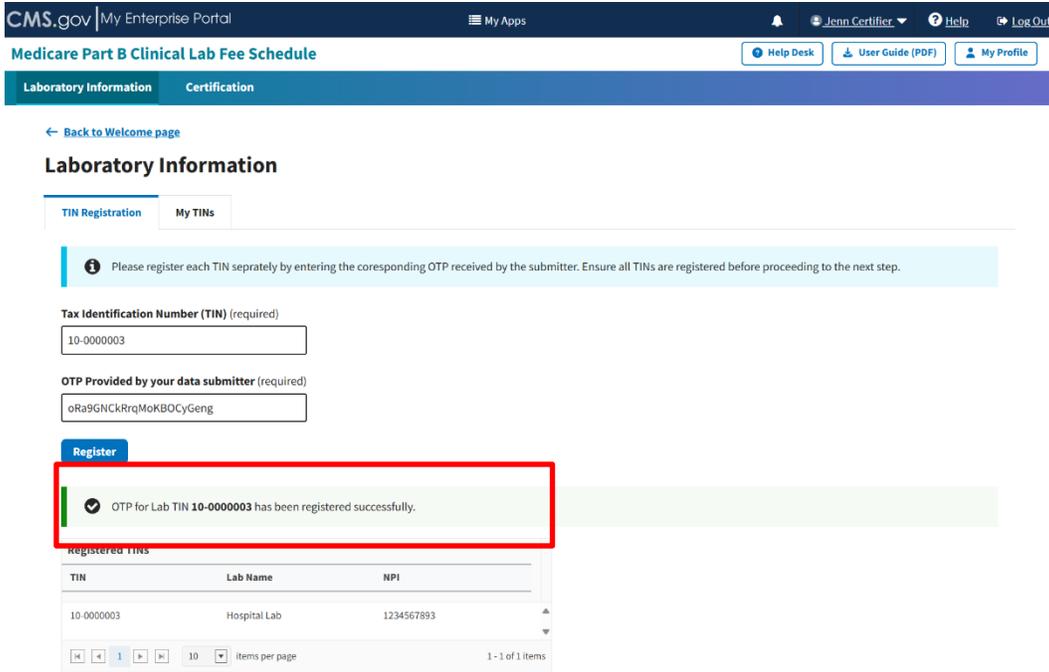


Figure 3: Laboratory Information - TIN Registered Successfully

5. To register additional TINs, repeat steps 1 – 4. Each TIN must have a unique OTP.
 - One CLFS Submitter and one CLFS Certifier per TIN is allowed.
 - A Certifier may be registered for multiple TINs.
6. Click on the **My TINs** tab to view all the TINs registered. By clicking on a TIN, you can view the lab name, associated NPI(s), and Hospital Lab and NPI information.

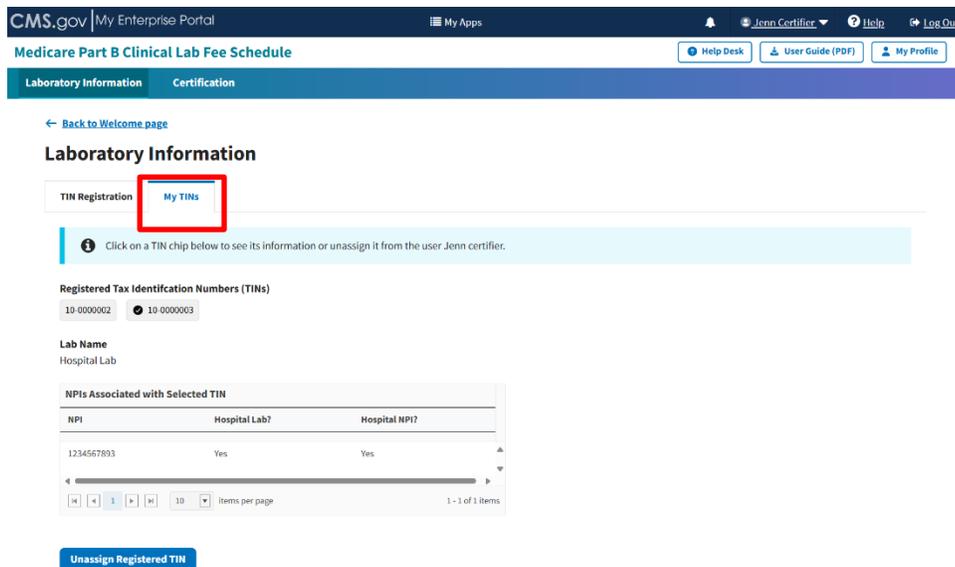


Figure 4: Laboratory Information - My TINs

7. If you registered a TIN in error or need to delete a TIN for any reason, follow these steps to unassign a TIN:
 - Click the TIN you want to unassign.
 - Click on the **Unassign Registered TIN button** at the bottom of the screen.

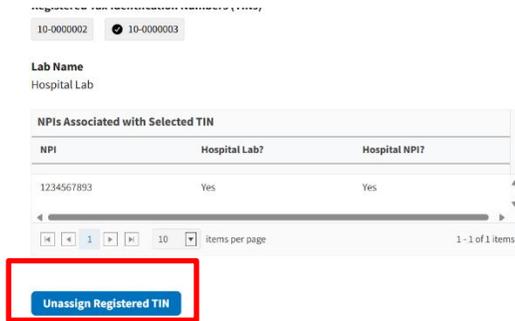


Figure 5: Unassign Registered TIN

A confirmation message will appear when the TIN has been unassigned.

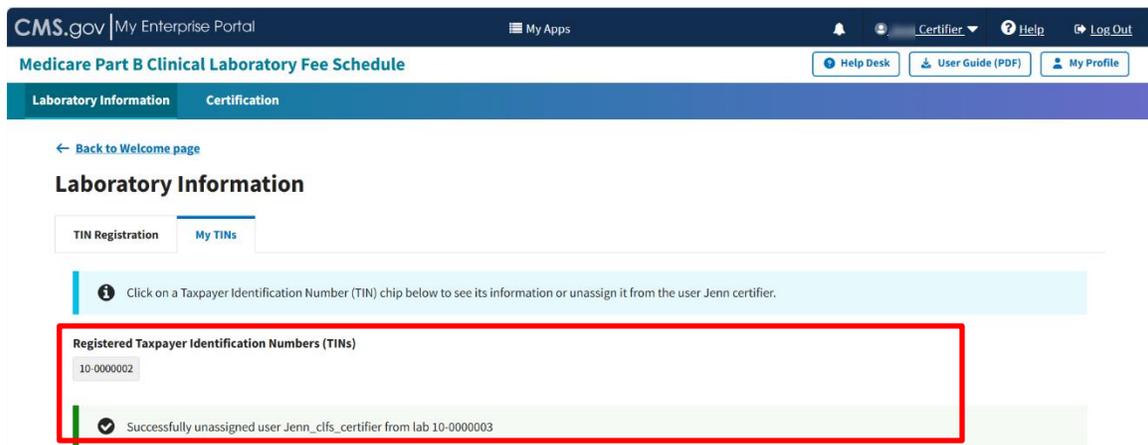


Figure 6: Laboratory Information - Successfully Unassigned TIN

4. Certification

To certify the data, follow these steps:

1. Click on **Certification** in the navigation bar. The **Certification** page appears.
2. Click on the TIN you are certifying.

← Back to Welcome page

Certification

Current Reporting Period
2025

Tax Identification Numbers (TINs) to Certify

10-0000002 (Pending) 10-0000003 (Pending)

Lab Name
Test Lab

HCPCS Code	Payment Rate	Volume	NPI
0172U	\$11,111.22	3524	1993999998
12356	\$1,254.23	3524	1993999998

1 - 2 of 2 items

Certify All

Figure 7: Certification

3. The data entered by the Submitter appears. Review the information for accuracy. If any errors are found, they **must** be corrected by the Submitter. The Certifier cannot make any changes to the data and must email the Submitter with a list of errors requiring correction.
4. After the Submitter corrects the data, the Certifier should re-examine the data for accuracy before proceeding with Certifying the data. The OTP is valid for 7 days, and the Certifier can use the same OTP for those 7 days. If the Certifier needs to re-examine the data past the expiration window, the Submitter must generate and send a new OTP.
5. To certify the data, click the **Certify All** button at the bottom of the screen.

Medicare Part B Clinical Laboratory Fee Schedule

Help Desk User Guide (PDF) My Profile

Laboratory Information Certification

← Back to Welcome page

Certification

Current Reporting Period
2025

Taxpayer Identification Numbers (TINs) to Certify
 10-0000003 (Pending)

Laboratory Name
Hospital Lab

HCPCS Code	Payment Rate	Volume	NPI
0172U	\$11,111.22	3524	1234567893
0080U	\$1,254.23	123451	1234567893

1 - 2 of 2 items

Certify All

Figure 8: Certify All

- The **Data Certification Statement** appears. Review the statement, click in the box next to “I agree to the above certification statement,” and then click on the **Submit** button.

Data Certification Statement

I certify that the reported applicable information is accurate and that all information and statements made in the submission are true, complete, and current to the best of my knowledge and belief and are made in good faith. I understand that information contained in this submission may be used for Medicare reimbursement purposes.

I agree to the above terms and conditions

Cancel **Submit**

Figure 9: Data Certification Statement

- A success message will appear notifying you that the certification for the TIN is complete.

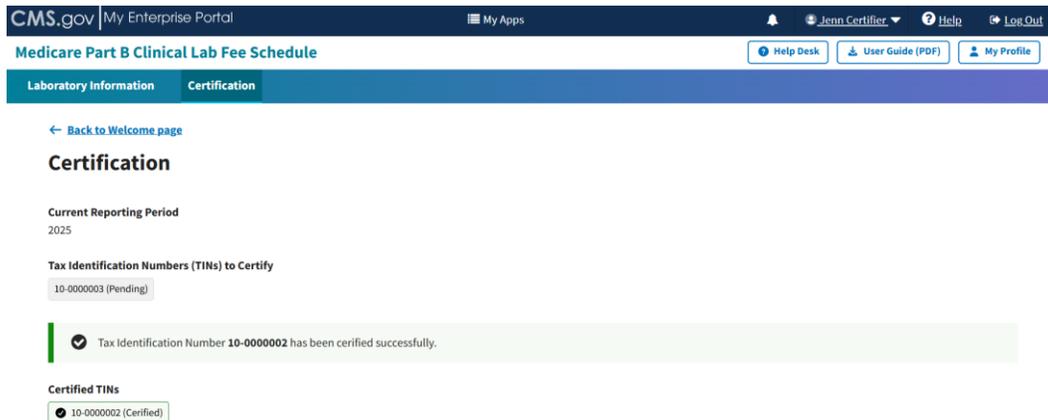


Figure 10: Certification - Successfully Certified

8. If you are certifying for multiple TINs, return to Step 1 and repeat all steps for each additional TIN.

Warning: Once the CLFS Certifier has certified the data for the current period, data submission is closed, and no more data can be entered for that TIN. Be sure that all applicable information is entered, accurate, and complete before certifying the data. If corrections need to be made post certification, please contact the CLFS helpdesk:

Module Help Desk

- E-mail: CLFSHelpDesk@dcca.com
- Phone: 844-876-0765
- 9AM-6PM Eastern, Non-Peak
- 9AM-9PM Eastern, Peak (i.e., May - July 2026)
- Policy and legal questions: CLFS_Inquiries@cms.hhs.gov

Appendix A: Acronyms

Table 1: Acronyms

Acronym	Literal Translation
ADLT	Advanced Diagnostic Laboratory Test
ARS	Acceptable Risk Safeguards
CCN	CMS Certification Number
CDLT	Clinical Diagnostic Laboratory Test
CFO	Chief Financial Officer
CLFS	Clinical Laboratory Fee Schedule
CM	Center for Medicare Management
CMS	Centers for Medicare & Medicaid Services
IDM	Identity Management
EIN	Employer Identification Number
EUA	Enterprise User Administration
FAQ	Frequently Asked Questions
FFSDCS	Fee for Service Data Collection System
HCPCS	Healthcare Common Procedure Coding System
IE	Internet Explorer
IT	Information Technology
IVR	Interactive Voice Response
NPI	National Provider Identifier
OTP	One Time Password
PAMA	Protecting Access to Medicare Act
PFS	Physician Fee Schedule
PII	Personal Identifiable Information
PTAN	Provider Transaction Access Number

Acronym	Literal Translation
RIPD	Remote Identity Proofing
SMS	Short Message Service
SSN	Social Security Number
TIN	Taxpayer Identification Number
URL	Uniform Resource Locator
VIP	Validation and Identity Protection

REVISION HISTORY

Version	Date	Point of Contact/Organization	Description of Changes
1.0	09/30/2016	Maureen Campbell/DCCA	Initial Issue
2.0	03/21/2017	Maureen Campbell/DCCA	Updated Introduction content, updated document for CLFS Release 4, added Help Desk, MFA, FAQ, and CLFS Reference Material sections. Made all screenshots 508-compliant. Added Section 7: Reports
3.0	03/30/2017	Maureen Campbell/DCCA	Updated Sections 4 (added sections 4.1 and 4.2), 5 (added 5.2 and 5.2.1 to include Large Volume submissions), 6.1, 7 (added Section 7.1) removed all references to Quick User Guide
4.0	11/15/2019	Maureen Campbell/DCCA	Added Section 5.3 and 5.3.1 to include Very Large Volume submissions.
5.0	10/15/2021	Jennifer Palmer/DCCA	Updated section 4 Laboratory information screenshots to reflect updates to the system. Added figure 4-11. Changed EIDM to IDM throughout document. Other minor copy edits/fact checking
6.0	9/15/2025	Jennifer Palmer/DCCA	CLFS underwent a modernization. Guide updated to reflect changes from the portal