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**DATE:** June 17, 2026  
**TO:** Hospital Outreach Laboratories  
**FROM:** Maria Durham, Acting Deputy Director  
Medicare Technology, Coding, and Pricing Group  
**SUBJECT:** Action Required: Prepare for CLFS CDLT Data Reporting

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. 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, and is based on an updated data collection period of January 1, 2025, through June 30, 2025.

CMS is contacting potentially applicable hospital outreach laboratories to provide updates on the data collection initiative supporting improvements to Medicare’s payment methodology. **Action is required of you to verify your laboratory’s participation in this round of data collection.** Applicable laboratories that fail to submit data may be subject to civil monetary penalties. Follow the steps below and visit the [CLFS & PAMA Reporting Resources website](#) for more information:

**Step 1: Verify Your Laboratory is an Applicable Laboratory**

An applicable laboratory either bills Medicare Part B using its own NPI or, if sharing an NPI with the hospital on Form 1450 under type of bill (TOB) 14X and meets the “majority of Medicare revenues” threshold. This means when you add your revenue from the Medicare Clinical Laboratory Fee Schedule (CLFS) and the Medicare Physician Fee Schedule (PFS), it is more than 50 percent of your total Medicare revenues.

If you bill Part B under the hospital’s NPI determine applicable laboratory status based on its Medicare revenues from the 14x TOB, you’ll most likely meet the majority of Medicare revenues 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.

Even though CMS cannot make individual determinations about whether a specific laboratory is an “applicable laboratory”, as eligibility depends on entity-specific details (for example, billing structure and revenue data), CMS has created several resources to support each laboratory as they determine their applicable status:

- Quick Reference Guides for Determining Applicability - [Hospital Outreach Lab](#)

- [FAQs](#)
- [MLN Booklet: CLFS Reporting Private Payor Data](#) – This resource provides several scenarios and examples for reference.
- Video: [Is my Lab an Applicable Lab?](#)
- Webinar
  - [Slides](#)
  - [Recording](#) passcode: =8Jwys2\*

## **Step 2: Identify Two Individuals per Tax ID Number (TIN) to Register in the CLFS Module**

If you meet the criteria for being an applicable laboratory, you are required to report your data to CMS in the Fee-for-Service Data Collection System (FFSDCS) CLFS Module. The CLFS Module requires two separate individuals per TIN to register: a submitter and a certifier. The submitter is responsible for uploading or entering the required data and providing the certifier with a unique one-time password to view and verify the accuracy of their submission. The certifier carefully reviews the data entered into the system and certifies it on the laboratory's behalf. As soon as you have selected the appropriate individuals, they may begin the registration process by creating an account in the CMS Enterprise Portal ([www.portal.cms.gov](http://www.portal.cms.gov)) and requesting access to the FFSDCS CLFS Module. For your convenience, step-by-step instructions for registering are available in the Registration Guide on the CLFS Reporting website.

**Note:** If you already have an active user account in the CMS Enterprise Portal, which hosts all CMS applications, you do not need to create a new account; simply request the FFSDCS Application following the steps listed in the Registration Guide.

Use the “CLFS Data Collection System User Guides” to begin the account creation process for your submitter and certifier.

1. [IDM Registration \(PDF\)](#)
2. [CLFS Submitter User Guide \(PDF\)](#)
3. [CLFS Certifier User Guide \(PDF\)](#)

## **Step 3: Prepare Your Data**

CMS is collecting the private payor rate for which final payment has been made during the January 1, 2025, through June 30, 2025, data collection period, and the associated volume of tests performed corresponding to each private payor rate by Healthcare Common Procedure Coding System (HCPCS) codes. We encourage applicable laboratories to download and complete the Data Template for easy upload to the CLFS Module.

1. View the [CLFS applicable HCPCS codes \(ZIP\)](#) - updated 02/23/2026
2. Use the [CLFS Data Reporting Template \(ZIP\)](#) - Updated 03/12/2026

## **Step 4: Submit Your Data**

The CLFS Module is open to accept your data. All data must be submitted to CMS via the CLFS Module by 11:59 p.m. Eastern Standard Time (EST) on July 31, 2026.

Should you have any technical issues with registration or access to the CLFS Module, please contact [CLFSHelpDesk@dcca.com](mailto:CLFSHelpDesk@dcca.com). For all other policy-related questions, contact [CLFS\\_Inquiries@cms.hhs.gov](mailto:CLFS_Inquiries@cms.hhs.gov).

Thank you in advance for your cooperation,

*Maria Durham*

Maria Durham, *on behalf of the* Center for Medicare/Centers for Medicare & Medicaid Services