



CENTER FOR MEDICARE

DATE: March 17, 2026
TO: Potential Applicable 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 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 Reporting website (address listed below) for more information:

Step 1: Verify Your Laboratory is an Applicable Laboratory

An applicable 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, and meets the "majority of Medicare revenues" threshold. This 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. Here is how you determine if you meet the "majority of Medicare" revenues:

- Hospital outreach laboratories: Medicare CLFS revenues + Medicare PFS revenues received from the 14X TOB / Total Medicare revenues received from the 14X TOB
- All other laboratories: Medicare CLFS + Medicare PFS revenues received by your NPI / Total Medicare revenues received by your NPI

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.

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 lab, you are required to report. CMS will collect data using 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) 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.

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. A full list of HCPCS codes and a Data Template are available on the CLFS Reporting website. We encourage applicable laboratories to download and complete the Data Template as soon as possible, so it is ready for easy upload once the CLFS Module opens on May 1, 2026.

Step 4: Submit Your Data

Starting on May 1, 2026, the CLFS Module will be open to accept your data. While you may begin the registration and data collection processes now, the system will not accept data uploads until reporting begins on May 1. All data must be submitted to CMS via the CLFS Module by 11:59 p.m. Eastern Standard Time (EST) on July 31, 2026.

CMS plans to host a webinar to demonstrate the system, discuss preparation activities, and answer user questions. We will announce the webinar via X (@CMS.gov), the MLN Connects newsletter, email, and the CLFS Reporting website:

<https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule/clfs-reporting>. Please visit our website regularly for the latest news on this important initiative.

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

Thank you in advance for your cooperation,



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