

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



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Additional Guidance for Clinical Laboratories as Data Reporting Begins

Note: We revised this article on February 28, 2019, to add a reference to MLN Matters Special Edition Article [SE19006](#). That article contains more current information about laboratories collecting and reporting data for the private payor rate-based payment system.

Provider Types Affected

This article is for Medicare Part B clinical laboratories that submit claims to Medicare Administrative Contractors (MACs) for services furnished to Medicare beneficiaries and are required to report private payor rate data to the Centers for Medicare & Medicaid Services (CMS).

Provider Action Needed

This article is intended to provide additional guidance to the laboratory community in meeting the new requirements under Section 1834A of the Social Security Act (the Act) for the Medicare Part B Clinical Laboratory Fee Schedule (CLFS). The data reporting period for the CLFS opened on January 1, 2017.

To help determine if your laboratory is considered an applicable laboratory, please refer to the guidance in MLN Matters Article [SE1619](#), “Medicare Part B Clinical Laboratory Fee Schedule: Guidance to Laboratories for Collecting and Reporting Data for the Private Payor Rate-Based Payment System.”

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Background

CMS has developed an online data collection system to assist laboratories in submitting data to CMS, which are due by March 31, 2017. A detailed user guide on how to access and use this system is available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html>.

Laboratories must designate both a CLFS submitter and CLFS certifier in the data collection system. These must be two different individuals. The CLFS submitter must be registered in Medicare's Provider Enrollment, Chain and Ownership System (PECOS) as a User or Authorized User on the PECOS Medicare Enrollment forms (in other words CLFS submitters must have their name appear within one of the following 855 application forms: A,B,C,I,R). The CLFS certifier does not need to be registered in PECOS.

A data reporting template is available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html>. Laboratories seeking to upload their data to the CLFS data collection system should use this template.

Tips for Smooth Data Submissions:

- Please follow the formatting guidelines outlined in the user guide and on the data collection template. The CLFS data collection system will identify formatting errors in your file before you are able to certify the data and submit it. However, for large volumes of data, this process may take several hours to validate. Thus, those files with fewer formatting errors will be processed more efficiently.
- Please use the CLFS Applicable Information HCPCS Codes file available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html>. The system will only accept HCPCS codes listed on this file.
- The cleaner the file, the smoother the upload process will be.

****Important information for large laboratories:** If your laboratory expects to submit over 100,000 lines of data in the .csv template, please first contact the CMS/CLFS helpdesk at clfshelpdesk@dcca.com.

Additional Information

More current information about this process is available at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/se19006.pdf>.

For more information about the new private payor rate based payment system including the CLFS final rule, related press release and fact sheet, frequently asked questions on our final policies, and a PowerPoint slide presentation of the new CLFS, visit

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<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html>.

If you have questions about requirements for the new CLFS, please email them to the CLFS Inquiries mailbox at CLFS_Inquiries@cms.hhs.gov.

If you have questions, your MACs may have more information. Find their website at <http://go.cms.gov/MAC-website-list>.

Document History

Date of Change	Description
February 28, 2019	We revised this article to add a reference to MLN Matters Special Edition Article SE19006. That article contains more current information about laboratories collecting and reporting data for the private payor rate-based payment system.
July 18, 2017	The article was revised to add a reference to a related MLN Matters Article, MM9837 . MM9837 informs MACs about the changes to the Fiscal Intermediary Shared System (FISS) to incorporate the revised CLFS, containing the National fee schedule rates. .
January 4, 2017	Initial Article Issued

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