

Subject: 60-Day Enforcement Discretion Period Announced for Laboratory Data Reporting

CMS Announces 60-Day Period of Enforcement Discretion for Reporting Applicable Information Under the Medicare Clinical Laboratory Fee Schedule

Today, the Centers for Medicare & Medicaid Services' Center for Medicare (CM) announced that it will exercise enforcement discretion until May 30, 2017, with respect to the data reporting period for reporting applicable information under the Medicare Clinical Laboratory Fee Schedule (CLFS) and the application of the Secretary's potential assessment of civil monetary penalties (CMPs) for failure to report applicable information. This enforcement discretion applies to entities that are subject to the data reporting requirements adopted in the Medicare Clinical Diagnostic Laboratory Tests Payment System final rule published on June 23, 2016 (81 FR 41036).

Industry feedback suggests that many reporting entities will not be able to submit a complete set of applicable information to CMS by the March 31, 2017 deadline, and that such entities require additional time to review collected data, address any issues identified during such review, and compile the data into CMS's required reporting format. This 60-day enforcement discretion period is the maximum amount of time CMS can permit to still have sufficient time to calculate the CLFS payment rates scheduled to go into effect on January 1, 2018.

This enforcement discretion period does not prevent reporting entities prepared to report applicable information from doing so before May 30, 2017. CMS is committed to the successful implementation of the new private payor rate-based CLFS and looks forward to working with the laboratory industry to ensure accurate payment rates. CMS will continue to closely monitor this process and provide guidance as necessary.

For additional information on the CLFS data reporting requirements, the data reporting system for submitting private payor data to CMS, the laboratory test codes subject to the data reporting requirements and how to determine applicable laboratory status, please visit the [CLFS](#) website.

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Medicare Clinical Laboratory Fee Schedule Provider Outreach and Education

The Clinical Laboratory Fee Schedule (CLFS) final rule entitled, “Medicare Program: Medicare Clinical Diagnostic Laboratory Tests Payment System” (CMS-1621-F), was published in the Federal Register on June 23, 2016. The final rule implements section 216(a) of the Protecting Access to Medicare Act (PAMA) of 2014, which generally requires Medicare payment amounts for tests on the CLFS to be calculated based on rates that private payors pay for the tests, as reported by applicable laboratories that furnish the tests. The implementation date of the CLFS private payor rate-based system is January 1, 2018. Since publication of the final rule, CMS has provided extensive outreach and educational resources to laboratories and other stakeholders. Important resources for information related to the CLFS data collection and reporting requirements are available on the [CLFS PAMA Regulations](#) webpage.

Resources available on the web page include:

- Medicare Clinical Diagnostic Laboratory Test Payment System Final Rule
- Fact Sheet
- Frequently Asked Questions (continuously updated)
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- Medicare Learning Network (MLN) Matters® Special Edition Articles –
 - Guidance to Laboratories for Data Collection and Reporting (MLN SE1619)
 - Additional Guidance for Clinical Laboratories as Data Reporting Begins (MLN SE17002)
- CLFS Data Collection System User Guide
- CLFS Applicable Information HCPCS Codes for Reporting
- CLFS Data Reporting Template

Questions regarding the CLFS final rule, data collection and reporting requirements should be submitted to the following mailbox: CLFS_Inquiries@cms.hhs.gov

Additionally, there is a dedicated Help Desk for assistance accessing, registering, submitting, and certifying data through the CLFS data collection system:

- E-mail: CLFSHelpDesk@dcca.com and Phone: 844-876-0765
 - 9AM-6PM Eastern, Non-Peak
 - 9AM-9PM Eastern, Peak (i.e., January-May 2017)

CMS has also conducted three National Provider Calls. The most recent was held on November 2, 2016 and was focused on data reporting and the data collection system. Presentations and transcripts of the calls are available on the [CLFS Sponsored Events](#) webpage.

Periodic reminders regarding the CLFS data reporting period deadline have been posted in the *MLN Connects Provider eNews* since November, 2016.

CMS encourages laboratories and their vendors to visit the [CLFS PAMA Regulations](#) webpage and register an email address in the box at the bottom right of the page to receive notifications of updates to the page.

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