American Hospital Association™
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Regulatory Advisory

November 30, 2021

Upcoming Hospital Clinical Laboratory Reporting Requirements: What You Need to Know

At A Glance

Please note, on Dec. 11, President Biden signed legislation that delays by one year (until Jan. 1, 2023) the clinical laboratory reporting requirements discussed in this advisory. It also delays for one year payment cuts under the CLFS that would have otherwise been imposed starting Jan. 1, 2022. The AHA and others have advocated for these requirements to be delayed. For more information on this legislation, please see the Special Bulletin sent to members on Dec. 9.

In the Centers for Medicare & Medicaid Services' (CMS) 2019 physician fee schedule (PFS) final rule, the agency made an important change to the Clinical Laboratory Fee Schedule (CLFS) that will require certain hospitals to report private payer rates and volumes for clinical laboratory services covered under the CLFS. **One such reporting period for hospitals is coming up in the first quarter of 2022**.

Specifically, hospitals will be required to collect and report certain private payer data if they bill Medicare for laboratory services on the CMS 1450 14X Type of Bill (TOB)[1] and received at least $12,500 in Medicare revenues from CLFS services on this bill type during the "data collection period" of Jan. 1, 2019 through June 30, 2019. These hospitals will be required to report data on private payer prices and the volume of laboratory services paid at each price during the "data reporting period" of Jan. 1, 2022 through March 31, 2022.

CMS has posted several updated documents and other resources to help hospitals determine if they need to report, and if so, how to report. The resources include:

- Summary – An overview of key terms and concepts and how to determine whether your laboratory is an applicable laboratory.
- CLFS Data Collection System User Guide – Updated guidance on registering as a CLFS submitter and CLFS certifier and reporting and certifying applicable information will be posted soon.
- MedLearn Matters Article – Medicare Part B CLFS: Revised Information for Laboratories on Collecting & Reporting Data for the Private Payor Rate Based Payment System.
- Frequently Asked Questions
- Webinar slides and a video recording of CMS' Nov. 10 webinar "CLFS Private Payor Data Collection and Reporting." The webinar password is W&KZ@=7?

What You Can Do:

[1] This TOB is used by hospital "outreach laboratories" that bill for non-patient (specimen only) laboratory services where the patient does not receive outpatient services on the same date of service.

- ✓ Share this advisory with your chief financial officer, director of clinical laboratory services and other members of your senior management team.
- ✓ Determine whether you have an “applicable laboratory” that needs to report “applicable data” during the upcoming data reporting period. Consult CMS’ resources for guidance.

Further Questions:
For additional questions, please contact Roslyne Schulman, AHA director of policy, at rschulman@aha.org.

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Background on Data Reporting Requirements

As required by Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), CMS sets CLFS payment rates based on the weighted median of private payer rates and volumes for covered clinical laboratory tests reported by each "applicable laboratory" during a designated "data reporting period." For the calendar year (CY) 2018 CLFS rates, CMS defined an applicable laboratory as a laboratory that billed Medicare Part B under its own national provider identifier (NPI) and received more than 50% of its Medicare revenues during a six-month data collection period from PFS and CLFS services. CMS also employs a "low expenditure threshold" under which clinical laboratories receiving less than $12,500 in Medicare revenues for CLFS services during a six-month data collection period are exempted from having to report. **Most hospital laboratories were not required to report their private payer data during the last data reporting period because they did not meet the definition of an applicable laboratory.**

However, some stakeholders expressed concerns that the CY 2018 CLFS payment rates were based on reporting from a relatively small and non-representative sample of laboratories and thus did not reflect rates for the entire spectrum of laboratories. They believe that unless more laboratories, particularly hospital outreach laboratories, are required to report in a future data reporting period, the CLFS rates will continue to be non-representative. Hospital outreach laboratories are those that bill for non-patient (i.e. referred specimen) laboratory services.

As a result of such concerns, in the CY 2019 PFS final rule, CMS amended the definition of an applicable laboratory *to include a hospital laboratory*.

Thus for the upcoming "data reporting period" of Jan. 1, 2022 - March 31, 2022, hospital laboratories required to collect and report certain private payer data are those that:

- Bill Medicare Part B under its own NPI; or, *for a hospital outreach laboratory[2], bill Medicare Part B on the Form CMS-1450 under TOB 14x;*
- Meet the "majority of Medicare revenues" threshold. That is, received more than 50% of its Medicare revenues from one or a combination of the CLFS or the PFS in the data collection period, which is Jan. 1, 2019 - June 30, 2019; and

[2] For purposes of determining applicable laboratory status under the Medicare CLFS, CMS defines hospital outreach laboratories as "a hospital-based laboratory that furnishes laboratory tests to patients other than admitted inpatients or registered outpatients of the hospital and bills for Medicare Part B services furnished to non-hospital patients using the Form CMS-1450 14x TOB."

- Meet or exceeds the low expenditure threshold. That is, it received at least $12,500 of its Medicare revenues from the CLFS in the data collection period of Jan. 1, 2019 through June 30, 2019.

These hospital-based applicable laboratories are required to report private payer "applicable information" during the upcoming data reporting period, including:

- The specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test;
- Each private payer rate for which final payment has been made during the data collection period; and
- The associated volume tests performed corresponding to each private payer rate, data on private payer prices and the volume of laboratory services paid at each price.

Next Steps: Getting Ready to Report Private Payer Data

In advance of the upcoming data reporting period, hospitals with applicable laboratories must register in order to be able to report data. CMS uses an enterprise "identity management system" (IDM) for these purposes. IDM registration is currently available for hospitals that believe they have one or more applicable laboratories. To register, navigate to https://portal.cms.gov to obtain a username and password.

The IDM system is "role-based", meaning applicable laboratories must sign up two different individuals to serve in two specific roles. The first role is a CLFS "submitter" – the individual authorized to submit applicable data through an approved ".csv" file upload or through manual data entry into the CLFS data collection system during the data reporting period. The second is the CLFS "certifier," who must be the president or chief financial officer of the applicable laboratory, or an individual appointed by these individuals for this role. The CLFS certifier certifies the accuracy and completeness of applicable information submitted to CMS.

Starting on Jan. 1, 2022, applicable laboratories that have their username and password, may start to report their applicable data to the CLFS data collection system.

Steps applicable laboratories can take to prepare now include:

- Determining which individuals will serve in each of the CLFS data reporting roles;
- Applying for username and password in the IDM system;
- Downloading the Excel CLFS Data Reporting Template in order to prepare for submission starting on Jan. 1, 2022. This template will be used to upload data to the PAMA CLFS private payer data reporting system; and
- Reviewing the CLFS Applicable Information HCPCS Codes for which private payer data must be reported.

CMS soon will post a step-by-step CLFS Data Collection System User Guide to assist users in registering as a CLFS submitter and CLFS certifier, reporting applicable

information and certifying reported applicable information. For technical help, applicable laboratories may contact the CLFS help desk at CLFSHelpDesk@dcca.com or call 844-876-0765. For policy questions about PAMA data submission, email CMS at clfs_inquiries@cms.hhs.gov.