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Centers for Medicare & Medicaid Services

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Fee-For-Service Data Collection System: Clinical Laboratory Fee Schedule Data Reporting Template

Note: This article was revised December 6, 2016, to add a reference to MLN Matters Article SE1619 that provides guidance to assist the laboratory community in meeting requirements under Section 1834A of the Social Security Act (the “Act”) for the Medicare Part B Clinical Laboratory Fee Schedule (CLFS). It includes clarifications for determining whether a laboratory meets the requirements to be an “applicable laboratory” in addition to other clarifications. All other information is unchanged.

Provider Types Affected

This article is intended for Medicare Part B clinical laboratories who submit claims to Medicare Administrative Contractors (MACs) for services furnished to Medicare beneficiaries.

What You Need to Know

This guidance is intended to assist 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 Quick User Guide, which includes guidance for the Fee-For-Service Data Collection System (FFSDCS) CLFS data reporting template, is included as an attachment in this article.

NOTE: The FFSDCS is undergoing its final stage of testing and will not be accessible to the public until November 2016. Laboratories can view the required format for reporting their data through the FFSDCS on the Clinical Laboratory Fee Schedule web page.

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Additional Information

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 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 any questions, please contact your MAC at their toll-free number. That number is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html.

Document History

<table>
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<tr>
<th>Date of Change</th>
<th>Description</th>
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<tbody>
<tr>
<td>December 6, 2016</td>
<td>This article was revised to add a reference to MLN Matters® Article SE1619 that provides guidance to assist 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). It includes clarifications for determining whether a laboratory meets the requirements to be an “applicable laboratory” in addition to other clarifications. All other information is unchanged.</td>
</tr>
<tr>
<td>September 14, 2016</td>
<td>The article was revised to update the attached manual. The illustrations for the notepad and excel were changed. In the table on page 3 the field name &quot;test name&quot; was removed.</td>
</tr>
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<td>Initial article released</td>
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Quick User Guide

Fee-For-Service Data Collection System:
Clinical Laboratory Fee Schedule Data Reporting Template

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1 OVERVIEW

Section 1834A of the Social Security Act (the Act), added by Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), significantly changes how Medicare payment rates are set for clinical diagnostic laboratory tests (CDLTs) paid under the Medicare Clinical Laboratory Fee schedule (CLFS). In general, the Centers for Medicare & Medicaid Services (CMS) will establish Medicare payment rates for CDLTs on the Clinical Laboratory Fee Schedule (CLFS) based on the weighted median of the rates that private payors pay for the test during a specified data collection period. Applicable laboratories must collect applicable information (that is, private payor rates and associated volume for covered tests identified by HCPCS codes) for the period beginning January 1, 2016, through June 30, 2016. Applicable laboratories must report their data to CMS beginning January 1, 2017, through March 31, 2017. CMS will use this data to calculate payment rates for the calendar year 2018 CLFS update.

The CLFS data reporting template provides the required data fields for reporting applicable information for the CLFS private payor rate-based system. “Comma Separated Value” (.csv) is the available format for data submission through a file upload process. Alternatively, data may be submitted through an online interface. Data must be reported to CMS through the Fee-For-Service Data Collection System (FFSDCS) CLFS System at https://portal.cms.gov. For detailed guidance on data collection and reporting, refer to Medicare Part B Clinical Laboratory Fee Schedule: Guidance to Laboratories for Collecting and Reporting Data for the Private Payer Rate-Based Payment System.

NOTE: The requirements under Section 1834A of the Act and the data reported on this form are exempt from the requirements of the Paperwork Reduction Act (Chapter 35 of Title 44, United States Code).

2 NAVIGATING THE TEMPLATE

- The template file is named “CLFS-Lab Data-Collection-Final.csv”. You can access it in the Downloads section on the Clinical Laboratory Fee Schedule web page.
- The CLFS .csv template may be opened using a text editor, such as Notepad or a spreadsheet application such as MS Excel.
• The template opened with Notepad:

![Figure 1 – The CLFS template view using Notepad](image)

3 TEMPLATE CONSTRAINTS

• The template may be populated through system generated content or manually via an online interface
• Do not manipulate the Header Row (Row 1)
• Report data in the order specified by the template
• A comma must separate each value
• The CLFS System will not recognize any formatting or manipulation in Excel
• The CLFS System will validate data fields as defined by “Field Definition” in Table 1

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4 FIELD DEFINITIONS
You must enter properly formatted data through the provided template.

Table 1: Field Definitions for CLFS Template

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Definition</th>
<th>Value Values</th>
<th>Required Field</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HCPCS Code</strong></td>
<td>Standardized coding system used to represent medical procedures performed on a patient or non-physician services.</td>
<td>5 alphanumeric characters are accepted.</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Payment Rate</strong></td>
<td>Each unique private payor rate for each test.</td>
<td>Only numeric values are accepted. Values include numeric characters with 2 decimal places. Formatted as XXXXX.XX.</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Volume</strong></td>
<td>Number of lab tests paid at each unique private payor rate.</td>
<td>Only positive numeric values including 0 are accepted. Values include numeric characters, no decimal places. Formatted as XXXXX.</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>National Provider Identifier</strong></td>
<td>A unique 10-digit identification number required by HIPAA for all health care transactions by providers in the United States.</td>
<td>10 numeric digits are accepted.</td>
<td>Yes</td>
</tr>
</tbody>
</table>

5 TEMPLATE REQUIREMENTS

1. Do not add additional columns to the template.
2. Do not add, remove, or otherwise change columns or column headings within the template.
3. Do not submit blank rows between data entries. You must submit all data in contiguous rows.