

# Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment

MLN Matters Number: M12285 Related Change Request (CR) Number: 12285

Related CR Release Date: June 15, 2021 Effective Date: July 1, 2021

Related CR Transmittal Number: R10853CP Implementation Date: July 6, 2021

### **Provider Types Affected**

This MLN Matters Article is for laboratories, other providers, and suppliers submitting clinical laboratory claims to Medicare Administrative Contractors (MACs) for services provided to Medicare patients.

#### **Provider Action Needed**

This Article tells you about the quarterly update to the CLFS, effective July 1, 2021. Make sure that your billing staffs are aware of these changes.

# **Background**

#### Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests —DELAYED

See <u>MLN Matters Article MM12612</u> for more current information on this reporting period.

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) required significant changes to how Medicare pays for Clinical Diagnostic Laboratory Tests (CDLTs) under the CLFS. CMS published the CLFS final rule, Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule (CMS-1621-F), in the Federal Register on June 23, 2016. The CLFS final rule implemented Section 1834A of the Act. Under the CLFS final rule, reporting entities must report to CMS certain private payer rate information (applicable information) for their component applicable laboratories. The data collection period (the period where applicable information for an applicable laboratory is obtained from claims for which the laboratory received final payment during that time) was from January 1, 2019 through June 30, 2019.

Section 105 (a) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116-94, enacted December 19, 2019) and Section 3718 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Pub. L. 116-136, enacted March 27, 2020) made several revisions to the next data reporting period for CDLTs that aren't advanced diagnostic laboratory tests (ADLTs)





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and the phase-in of payment reductions under the Medicare private payor rate-based CLFS.

The revisions are as follows:

- We'll base the next data reporting period of January 1, 2022, through March 31, 2022, on the original data collection period of January 1, 2019, through June 30, 2019
- After the next data reporting period, there's a 3-year data reporting cycle for CDLTs that aren't ADLTs (that is 2025, 2028, and so on)
- We extended the statutory phase-in of payment reductions resulting from private payor rate implementation through CY 2024. There's a 0.0% reduction for CY 2021, and we won't reduce payment by more than 15% for CYs 2022 through 2024.

#### Clinical Laboratory Fee Schedule Beginning January 1, 2018

Effective January 1, 2018, CLFS rates are based on weighted median private payor rates as required by (<u>PAMA</u>). The Part B deductible and coinsurance don't apply for services we pay for under the CLFS. The <u>PAMA Regulations</u> give more details.

We'll make the <u>quarterly CLFS</u> available. Other interested parties, such as the Medicaid State agencies, the Indian Health Service, the United Mine Workers, and the Railroad Retirement Board, may want to retrieve the <u>quarterly CLFS</u>. It will be available in multiple formats:

- Excel®
- Text
- Comma delimited.

The CLFS includes separately payable fees for certain specimen collection methods (codes 36415, P9612, and P9615). We established the fees in accordance with <u>Section 1833(h)(4)(B) of the Act</u>. We may add more specimen collection codes as we discuss below during the Public Health Emergency (PHE).

#### New Codes Effective July 1, 2021 Proprietary Laboratory Analysis (PLAs)

Please see the table which is part of <u>CR 12285</u> entitled CY 2021 CLFS Quarterly Updates, Tab New Codes Effective 07-01-2021. We added the listed new codes to the national HCPCS file with an effective date of July 1, 2021. These new codes are contractor-priced (where applicable) until they're nationally priced and undergo the CLFS annual payment determination process in accordance with the Social Security Act, <u>Section 1833(h)(8)</u>, <u>Sections 1834A(c)</u> and 1834(A)(f). MACs will only price PLA codes for laboratories within their jurisdiction. The table includes the laboratory, long descriptor, short descriptor, and Type of Service (TOS) of each new code.

#### **New Codes**

Please see the table attached to <u>CR 12285</u> entitled New Codes Effective July 1, 2021, Tab New Codes. We added the additional listed new codes to the national HCPCS file with an effective date of July 1, 2021 (code G0327), and April 1, 2021 (code 0017M), in addition to the PLA codes. These new codes are contractor-priced (where applicable) until they're nationally priced and undergo the CLFS annual payment determination process in





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accordance with the Social Security Act, <u>Section 1833(h)(8)</u>, <u>Section 1834A(c)</u> and 1834(A)(f). MACs will only price PLA codes for laboratories within their jurisdiction. The table includes the laboratory, long descriptor, short descriptor, and TOS of each new code.

#### **More Information**

We issued <u>CR 12285</u> to your MAC as the official instruction for this change.

For more information, contact your MAC.

## **Document History**

Date of Change	Description
March 15, 2022	We revised this Article to add a link to <u>Article MM12612</u> , which has current information on the Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests. All other information is the same.
June 15, 2021	We revised this Article due to a revised CR 12885. The CR revision modified language in the policy section of the CR. We revised that language in the Article using red font on page 3. Also, we revised the CR release date, transmittal number, and the web address of the CR. All other information is the same.
May 24, 2021	Initial article released.

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