



MCS Implementation of the Restructured Clinical Lab Fee Schedule

MLN Matters Number: MM10057

Related Change Request (CR) Number: CR10057

Related CR Release Date: May 12, 2017

Effective Date: January 1, 2018

Related CR Transmittal Number:
R1846OTN

Implementation Date: January 2, 2018

Note: This article was revised on July 18, 2017, 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. All other information is unchanged.

PROVIDER TYPES AFFECTED

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

PROVIDER ACTION NEEDED

Change Request (CR) 10057 instructs Medicare's Multi-Carrier System (MCS) maintainer to incorporate into the shared system, the revised Clinical Lab Fee Schedule (CLFS) containing the National fee schedule rates. Make sure your billing staffs are aware of these changes.

BACKGROUND

Section 216 of Public Law 113-93, the "Protecting Access to Medicare Act of 2014," added Section 1834A to the Social Security Act (the Act). This provision requires extensive revisions to the payment and coverage methodologies for clinical laboratory tests paid under the clinical laboratory fee schedule (CLFS). The Centers for Medicare & Medicaid Services (CMS) published Final Rule 81 FR 41035, pages 41035-41101 on June 23, 2016, which implemented the provisions of the new legislation.

The final rule set forth new policies for how CMS sets rates for tests on the CLFS and is **effective for dates of service on and after January 1, 2018**. Beginning on January 1, 2017, applicable laboratories were required to submit data to CMS which describes negotiated payment rates with private payers for any corresponding volumes of tests on the CLFS. In general, with certain designated exceptions, the payment amount for a test on the CLFS

furnished on or after January 1, 2018, will be equal to the weighted median of private payer rates determined for the test, based on data collected from laboratories during a specified data collection period. In addition, a subset of tests on the CLFS, advanced diagnostic laboratory tests (ADLTs), will have different data, reporting, and payment policies associated with them. In particular, the final rule discusses CMS' proposals regarding:

- Definition of “applicable laboratory” (who must report data under section 1834A of the Act)
- Definition of “applicable information” (what data will be reported)
- Data collection period
- Schedule for reporting data to CMS
- Definition of ADLT
- Data Integrity
- Confidentiality and public release of limited data
- Coding for new tests on the CLFS
- Phased in payment reduction

ADDITIONAL INFORMATION

The official instruction, CR10057, issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R1846OTN.pdf>.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/>.

For more information on the data collection aspects of the restructured CLFS, see MLN Matters Article SE17002 at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE17002.pdf>.

DOCUMENT HISTORY

Date of Change	Description
July 18, 2017	This article was revised to add a reference to a related MLN Matters Article, MM9837 . MM9837 informs MACs about the changes to the FISS to incorporate the revised CLFS containing the National fee schedule rates.
May 12, 2017	Initial article released.

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