

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



MLN Matters® Number: MM9837

Related Change Request (CR) #: CR 9837

Related CR Release Date: March 23, 2017

Effective Date: January 1, 2018

Related CR Transmittal #: R3740CP

Implementation Date: July 3, 2017

FISS Implementation of the Restructured Clinical Lab Fee Schedule

Note: This article was revised on July 18, 2017, to add a reference to a related MLN Matters Article [MM10057](#). MM10057 instructs Medicare's Multi-Carrier System (MCS) maintainers to incorporate into the shared system, the revised CLFS containing the National fee schedule rates. A link to [SE17002](#) which provides additional guidance in meeting the new requirements under Section 1834A of the Social Security Act (the Act) for the Medicare Part B CLFS was also added. All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for clinical laboratory providers submitting claims to Medicare Administrative Contractors (MACs) for services paid under the Clinical Lab Fee Schedule (CLFS) and provided to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 9837 informs MACs about the changes to the Fiscal Intermediary Shared System (FISS) to incorporate the revised CLFS containing the National fee schedule rates. Make sure that 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 CLFS. The Centers for Medicare & Medicaid Services (CMS) published the CLFS final rule “[Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule](#)”

Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents. CPT only copyright 2015 American Medical Association. All rights reserved.

(CMS-1621-F) was displayed in the Federal Register on June 17, 2016, and was published 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 will be required to submit private payor rate data to CMS. (See MLN Matters Article [SE1619](#) for further details of the laboratory data reporting requirements.) 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, CR9837, issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3740CP.pdf>.

MLN Matters Article SE1619 has more details at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1619.pdf>.

The final regulation for the revised CLFS is available at <https://www.gpo.gov/fdsys/pkg/FR-2016-06-23/pdf/2016-14531.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/>.

Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents. CPT only copyright 2015 American Medical Association. All rights reserved.

Document History

Date of Change	Description
July 18, 2017	The article was revised to add a reference to a related MLN Matters Article MM10057 . MM10057 instructs Medicare's Multi-Carrier System (MCS) maintainers to incorporate into the shared system, the revised CLFS containing the National fee schedule rates. A link to SE17002 which provides additional guidance in meeting the new requirements under Section 1834A of the Social Security Act (the Act) for the Medicare Part B CLFS was also added
March 23, 2017	Article revised to reflect revised CR9837. In the article, the CR release date, transmittal number, and the Web address of the CR are revised.
November 10, 2016	Initial article released

Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents. CPT only copyright 2015 American Medical Association. All rights reserved.