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Medicare Part B Clinical Laboratory Fee Schedule: Guidance to Laboratories for Collecting and Reporting Data for the Private Payor Rate-Based Payment System

Note: This article was revised on January 12, 2017, to add a reference to MLN Matters® Article MM9837. That article informs MACs about the changes to the Fiscal Intermediary Shared System (FISS) to incorporate the revised Clinical Laboratory Fee Schedule (CLFS) containing the National Fee Schedule Rates. 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.

Provider Action Needed

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). It includes clarifications for determining whether a laboratory meets the requirements to be an "applicable laboratory," the applicable information (that is, private payor rate data) that must be collected and reported to the Centers for Medicare & Medicaid Services (CMS), the entity responsible for reporting applicable information to CMS, the data collection and reporting periods, and the schedule for implementing the new CLFS. CMS will issue additional information about the CLFS data collection system and advanced diagnostic laboratory tests (ADLTs) through separate guidance.

Background

The CLFS was first established in 1984 based on historical charge data. It was updated to only establish payment rates for new tests or to make statutorily-required across-the board updates. Payment for new tests established after 1984 is based on crosswalking or gapfilling methodologies. For crosswalking, an existing test or combination of tests with similar methodology and resources is used as a basis for the payment amount. Gapfilling is used when there is no other test with similar methodology and resources. In this case, MACs develop a payment amount for the test.

Section 1834A of the Act, as established by Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), requires significant changes to how Medicare pays for clinical diagnostic laboratory tests under the CLFS. The CLFS final rule "**Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule**" (CMS-1621-F) was displayed in the Federal Register on June 17, 2016, and was published on June 23, 2016. The CLFS final rule implements Section 1834A of the Act. Under the final rule, private payor rates from applicable laboratories will be the basis for the revised CLFS beginning January 1, 2018.

Based on applicable information (that is, private payor rates) from applicable laboratories, the payment amount for a test on the new CLFS will be equal to the weighted median private payor rate for each test. However, for new tests or when no data is reported for an existing test, crosswalking or gapfilling methodologies will be used to establish a payment amount for the test.

Applicable Laboratory

Section 1834A of the Act defines an applicable laboratory as a laboratory with the majority of its Medicare revenues received under the CLFS and/or Medicare Physician Fee Schedule (PFS). It also provides the authority to establish a low volume or low expenditure threshold. Under the final policies for the new Medicare CLFS, an applicable laboratory is a laboratory as defined under the Clinical Laboratory Improvement Amendments (CLIA) that bills Medicare Part B under its own National Provider Identifier (NPI) and meets the majority of Medicare revenues threshold and the low expenditure threshold. Accordingly, there are four steps in determining whether a laboratory meets the requirements to be an applicable laboratory: (1) Is the laboratory certified under CLIA?, (2) Does the CLIA- certified laboratory bill Medicare Part B under its own NPI?, (3) Does the laboratory meet the majority of Medicare revenues threshold?, and (4) Does the laboratory meet the low expenditure threshold?

Step 1: CLIA Certification

The CLIA applies to all laboratories performing testing on human specimens for a health purpose. To be paid under Medicare, a laboratory must be a CLIA-certified laboratory. Therefore, the first step in identifying an applicable laboratory is to determine whether the laboratory is CLIA certified. The CLIA regulatory definition of a laboratory is codified in regulation in 42 CFR 493.2. **Note that a facility that receives any CLIA certificate (including a CLIA certificate of waiver) is considered a laboratory as defined at 42 CFR 493.2.**

Step 2: NPI

The second step is to determine whether the CLIA-certified laboratory bills Medicare Part B under its own NPI. The NPI is the standard unique health identifier used by health care providers for

billing Medicare and other payors. The NPI is assigned by the National Plan and Provider Enumeration System in 45 CFR 162. The laboratory's own billing NPI is used as the mechanism for defining an applicable laboratory.

Step 3: Majority of Medicare Revenues Threshold

For a CLIA-certified laboratory that bills Medicare Part B under its own NPI to be an applicable laboratory, it must meet the majority of Medicare revenues threshold. A laboratory, by its own billing NPI, meets the majority of Medicare revenues threshold if it receives more than 50 percent of its **total** Medicare revenues from payments under the Medicare CLFS and/or Medicare PFS. The CLFS and PFS are included under Medicare Part B, also known as Original Medicare or Fee-For-Service (FFS) Medicare.

To determine whether a laboratory meets the majority of Medicare revenues threshold, the laboratory must look to its **final paid claims** received by its own billing NPI during the data collection period. See the Applicable Information Section below for additional guidance on final paid claims.

The three steps to determine whether a laboratory meets the majority of Medicare revenues threshold are:

- First, sum the CLFS and PFS payment amounts received by the laboratory's own billing NPI during the data collection period. The revenues from the CLFS include payments for all laboratory services under the CLFS. The revenues from the PFS include all payments from all services paid under the PFS (for instance, laboratory services and services that are not laboratory services such as pathology services, evaluation and management services, and radiology services). The sum of CLFS and PFS revenues is the numerator of the majority of Medicare revenues threshold equation.
- Next, sum the total Medicare revenues received by the laboratories own billing NPI during the data collection period. Total Medicare revenues include the sum of all FFS payments under Medicare Parts A and B, Medicare Advantage payments under Medicare Part C, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period. The sum of total Medicare revenues is the denominator of the majority of Medicare revenues threshold equation.
- Finally, divide the sum of CLFS and PFS revenues by the sum of total Medicare revenues received during the data collection period. We provide additional information on the data collection period below.

If the Medicare revenues received from the CLFS and/or PFS are greater than 50 percent of the total Medicare revenues for the laboratory's billing NPI, the laboratory meets the majority of Medicare revenues threshold.

The majority of Medicare revenues threshold equation is:

CLFS revenues (for billing NPI) + PFS revenues (for billing NPI)/total Medicare revenues (for billing NPI) > 50 percent.

Step 4: Low Expenditure Threshold

An applicable laboratory must meet the low expenditure requirements. A laboratory (as defined under the CLIA regulations) meets the low expenditure threshold if, by its own billing NPI, receives at least $12,500 in **Medicare** revenues from the **CLFS** (under Medicare Part B) during the data collection period. To meet the low expenditure threshold, the laboratory must look to its **final paid claims** received by its own billing NPI during the data collection period.

To determine whether the laboratory meets the low expenditure threshold, sum all final payments for the laboratory's own billing NPI received from Medicare CLFS services during the data collection period (completed under Step 3: Majority of Medicare Revenues Threshold). It is important to note that the low expenditure threshold applies only to **CLFS services**. It does **not** include revenues received under the PFS. In other words, to meet the low expenditure threshold, the laboratory's own billing NPI must receive at least $12,500 under only the CLFS during the data collection period.

The low expenditure threshold equation is:

Medicare CLFS revenues (for billing NPI) = > $12,500.

These are examples on how the majority of Medicare revenues threshold and low expenditure threshold are applied to the CLIA-certified laboratory's own billing NPI for purposes of determining whether the laboratory is an applicable laboratory:

Example 1: A laboratory organization includes five CLIA-certified laboratories. Each CLIA-certified laboratory has its **own unique NPI** and bills the Medicare Program (and other payors) for laboratory tests separately under each NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to **each NPI** in the laboratory organization. That is, individually determine whether each laboratory meets the majority of revenues threshold and low expenditure threshold. Even though all five laboratories may be under the same Tax Identification Number (TIN), each is considered a separate laboratory for purposes of determining an applicable laboratory because each bills Medicare Part B for laboratory tests using its own unique NPI.

Example 2: A laboratory organization includes five CLIA-certified laboratories. Each CLIA-certified laboratory has the **same NPI** and bills for laboratory tests under the same NPI for each of its CLIA-certified laboratories. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied based on the combined revenues of all CLIA-certified laboratories in the organization that use the same billing NPI. In other words, for purposes of applying the applicable laboratory thresholds, all five CLIA-certified laboratories in the laboratory organization are considered a single laboratory because they all bill Medicare Part B using the same NPI.

Example 3: A laboratory organization includes five CLIA-certified laboratories. Each CLIA-certified laboratory has its **own unique NPI.** However, **only one laboratory's NPI is used for billing** all laboratory tests furnished by all five laboratories in the laboratory organization. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to the **one NPI** used for billing all tests furnished by the laboratory organization.

Example 4: An entity consists of five physician offices and one CLIA-certified laboratory. All five physician offices and the CLIA-certified laboratory are assigned the **same NPI** and bill for services under the same NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied based on the combined revenues of all components of the entity that bill for services under the same NPI. In other words, since the physician offices and CLIA-certified laboratory all have the same NPI and bill Medicare Part B under the same NPI, the entity is considered a single laboratory for purposes of applying the majority of Medicare revenues threshold and low expenditure threshold.

Example 5: An entity consists of five physician offices and one CLIA-certified laboratory. Each of the five physician offices and the CLIA-certified laboratory have **unique NPIs.** The laboratory bills for laboratory tests under its **own unique NPI**. In this example, the majority of Medicare revenues threshold and low expenditure threshold are only applied to the CLIA-certified laboratory's own billing NPI.

Example 6: A CLIA-certified hospital outreach laboratory that performs laboratory services for non-hospital patients is assigned its **own unique NPI** separate from the hospital's NPI. The hospital outreach laboratory bills Medicare Part B for laboratory tests furnished to non-hospital patients using its own unique NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to the **NPI of the hospital outreach laboratory** and not to the hospital's NPI.

Example 7: A CLIA-certified hospital laboratory that performs laboratory services primarily for its hospital inpatients and hospital outpatients has the **same NPI as the hospital**. Laboratory services performed for non-hospital patients are billed using the hospital's NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to the **NPI of the entire hospital**. In this circumstance, it is unlikely that the hospital laboratory qualifies as an applicable laboratory because the majority of Medicare revenues for the NPI are received from the Hospital Inpatient Prospective Payment System and/or Hospital Outpatient Prospective Payment System, not from the CLFS and/or PFS.

Applicable Laboratory Summary

An applicable laboratory is defined as a CLIA-certified laboratory (which includes a facility that receives a CLIA certificate of waiver) and, using its own billing NPI, meets the majority of Medicare revenues threshold (that is, greater than 50 percent of total Medicare revenues derived from the **CLFS and/or PFS**) and low expenditure threshold (at least $12,500 in revenue **from only the CLFS**). In other words, to qualify as an applicable laboratory, the CLIA-certified laboratory must be assigned an NPI and have its services billed to Medicare Part B under that NPI. The laboratory does not qualify as an applicable laboratory if no services are billed to Medicare Part B under its own NPI because no revenues attributed to the NPI are assigned to the laboratory.

Both the majority of Medicare revenues threshold and low expenditure threshold are applied to the CLIA-certified laboratory's own billing NPI based on **final claims paid** during a data collection period. If the laboratory's own billing NPI receives more than 50 percent of its total Medicare revenues under the CLFS and/or PFS and at least $12,500 from the CLFS during the data collection

period, the laboratory is considered an applicable laboratory. Applicable information (that is, private payor rate data) from applicable laboratories must be collected during the data collection period and reported by reporting entities to CMS during the data reporting period.

The applicable information reported to CMS will be used to establish payment rates under the new CLFS. All CLIA-certified laboratories (that is, both applicable laboratories and laboratories that are not applicable laboratories) are subject to the new Medicare Part B CLFS payment rates when they are established and implemented on January 1, 2018.

Applicable Information

The applicable laboratory along with its reporting entity (we provide more information about reporting entities below) are responsible for collecting applicable information and reporting that data to CMS.

Applicable information includes three major components:

(1) The specific HCPCS code associated with the test

(2) The private payor rate for each test for which **final** payment has been made during the data collection period
(3) The associated volume for each test

Private Payor Defined

The term "private payor" is defined as:

(1) A health insurance issuer and a group health plan (as defined in Section 2791 of the Public Health Service Act)
(2) A Medicare Advantage Plan under Part C
(3) A Medicaid Managed Care Organization (MCO) (as defined in Section 1903(m) of the Act)

Note: Applicable information does **not** include information on tests for which payment is made on a capitated basis, where payments do not reflect specific HCPCS code-level amounts (see below for additional information on payments made on a capitated basis). Therefore, private payor rates from Medicaid MCO plans are considered applicable information only to the extent that the individual HCPCS code for the test, private payor rate specific to the test, and the volume paid at the specific rate for the test can be identified.

These specific private payor claims data are **included** as applicable information:

- Laboratory tests associated with the CLFS. Applicable information includes the specific HCPCS code for the test, each different private payor rate for the test, and the volume associated with each private payor rate for the test. You can find a list of laboratory tests associated with the CLFS and therefore subject to the data collection and data reporting requirements at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.

- Final amount paid by a private payor for laboratory tests after all private payor price concessions are applied. Applicable laboratories should look to their paid claims data from the billing NPI for which final payment was made during the data collection period. If a private payor pays a laboratory for a test but subsequent post-payment activities during the data collection change that initial payment amount, the final payment is the private payor rate for purposes of determining applicable information. For example, if an initial claim was paid in error 3 months before a data collection period and then corrected, with final payment made by the private payor during the data collection period, the final corrected payment amount for the test is considered the private payor rate for purposes of determining applicable information. However, if an initial claim was paid in error during a data collection period and then corrected, with final payment made after the data collection period, the payment amount is not a private payor rate for purposes of applicable information and, therefore, is not reported to CMS.
- Payments from secondary insurance payors. Final payments from secondary insurance payors are considered in calculating private payor rates if the final payment was made during the data collection period.
- Any patient cost sharing amounts, if applicable. For purposes of applicable information, the private payor rate for a test should include any patient cost sharing responsibilities required by the private payor (for instance, patient deductible and/or coinsurance amounts). In other words, the private payor rate is 100 percent of the private payor's fee schedule amount for the test.
- Multiple payment rates for the same test. If an applicable laboratory receives more than one payment rate from the same private payor for the same test or more than one payment rate from different private payors for the same test, each unique payment rate along with the associated volume for the test code at each such rate is included as applicable information. In this case, the reporting entity must report each unique payment rate and the associated volume for the test at each such rate.
- Appeals resolved during the data collection period. Payment rates (and the associated volume of tests) for claims under appeal are included as applicable information if the final payment amount is determined and paid by the private payor during the data collection period. For example, if a laboratory filed an appeal for a test furnished prior to a data collection period and the appeal was resolved so that final payment for the test was made during the data collection period, the final rate paid is considered applicable information.
- **Non-contracted amounts for out-of-network laboratories or services.** Applicable information includes private payor rates for out-of-network laboratories as long as the final payment for the laboratory test was made by the private payor during the data collection period. Non-contracted amounts paid to laboratories include any patient cost sharing amounts (for example, deductible and coinsurance responsibilities, if applicable).

These specific private payor claims data are excluded from applicable information:

- Private payor rates for laboratory test codes paid only under the PFS. If a laboratory test code is not paid under the CLFS and is paid under the PFS, the test code, private payor rate, and the test volume associated with the private payor rate is not applicable information.

- Price concessions applied by a laboratory. A laboratory's decision to waive a patient's deductible, copay, and/or coinsurance responsibility for a given test(s) must not be factored into the determination of the private payor rate for a test. Although laboratories may provide concessions to patients, it does not reflect the rates paid by private payors. As noted above, the private payor rate is 100 percent of the private payor's fee schedule amount for the test.
- Information about denied payments. When a private payor denies payment for a laboratory test, payments of $0.00 or "zero dollars" are not considered a private payor rate for purposes of determining applicable information under the new CLFS. Laboratories should not report "zero dollars" for a laboratory test code where a private payor has denied payment within a data collection period.
- Unresolved appeals. Where a laboratory test claim is still under review by the private payor or is under appeal during a data collection period, the amount that has already been paid is not considered a final payment rate and therefore is not considered applicable information. Additionally, if the appeal was settled during the data collection period but final payment was not made by the private payor until after the data collection period, the payment amount is not considered applicable information.
- Payments made on a capitated basis. Generally, a capitated payment is made for health care services based on a set amount for each enrolled beneficiary in the plan for a given period of time, regardless of whether the particular beneficiary receives services during the period covered by the payment. Payment is typically made on a capitated basis under a managed care arrangement. As there is no way to determine payment specifically for a given test, it cannot be reported as applicable information. Therefore, applicable information does not include information about a test for which payment is made on a capitated basis.
- Payments where the associated test volume cannot be determined. As discussed above, the associated volume of tests performed corresponding to each private payor rate is a component of the definition of applicable information. Where the associated volume of tests performed corresponding to each private payor rate cannot be discerned by a laboratory from the private payor's remittance, those payment amounts are not considered applicable information and should not be reported to CMS.
- Remittances where the payor has grouped individual HCPCS code payments into an encounter or claim level payment. When a private payor groups payments for individual HCPCS codes into a single encounter or claim-level payment that is not represented by another HCPCS code, those payments are not applicable information. In other words, if individual HCPCS codes are billed by the laboratory and the payor bundles the individual HCPCS codes into groups not represented by other HCPCS codes, the payor's bundled payment amount is not considered applicable information.

Note: In general, if a laboratory cannot correlate a private payor payment amount and the associated volume paid at that rate to a specific HCPCS code, that amount is not a private payor rate for purposes of applicable information. Estimated private payor rates and volumes are also not considered applicable information.

Schedule for Data Collection and Reporting

The first data collection period (the period where applicable information for an applicable laboratory is obtained from claims for which the laboratory received final payment during the period) is from January 1, 2016, through June 30, 2016. A 6-month window follows the data collection period and precedes the data reporting period (the period where applicable information must be submitted to CMS). The first data reporting period will be from January 1, 2017, through March 31, 2017.

During the 6-month window between the end of the data collection period and the beginning of the data reporting period, laboratories and reporting entities should assess whether the applicable laboratory thresholds are met. That is, determine whether each billing NPI-level component of the TIN meets the majority of Medicare revenues threshold and low expenditure threshold from final paid claims during the data collection period. Applicable laboratories and their reporting entity should also use this time to review and validate applicable information before it is reported to CMS.

For most clinical diagnostic laboratory tests (CDLTs) paid on the CLFS, the data collection and reporting schedule will be repeated every 3 years. For instance, the first data collection period is January 1, 2016, through June 30, 2016. The first 6-month window is July 1, 2016, through December 31, 2016, and the first data reporting period is January 1, 2017, through March 31, 2017. The first data collection and reporting cycle will be used to determine CLFS payment rates for calendar year (CY) 2018 through CY 2020.

The second data collection period will begin on January 1, 2019, and end on June 30, 2019, with the 6-month window starting July 1, 2019, and ending December 31, 2019. The second data reporting period is January 1, 2020, through March 31, 2020. Applicable information from the second data reporting period will be used to determine CLFS payment rates for CY 2021 through CY 2023. This data collection and reporting cycle continues every third subsequent CY.

This table illustrates the data collection and reporting periods for CDLTs.

Data Collection and Reporting Periods for CDLTs

Data Collection Period	Six Month Window	Data Reporting Period	Used for CLFS Rate Years
1/1/2016 – 6/30/2016	7/1/2016 – 12/31/2016	1/1/2017 – 3/31/2017	2018 – 2020
1/1/2019 – 6/30/2019	7/1/2019 – 12/31/2019	1/1/2020 – 3/31/2020	2021 – 2023
Continues every third subsequent calendar year	Continues every third subsequent calendar year	Continues every third subsequent calendar year	New CLFS rate every third year

While reporting is required every 3 years for CDLTs (that are not ADLTs), reporting entities must report applicable information annually for ADLTs, except for ADLTs in an initial data collection period (in which case a reporting entity will report by the end of the second quarter of the new ADLT initial period). As noted previously, we will issue additional information about ADLTs through separate guidance.

Reporting Entity

The mechanics of reporting applicable information to CMS is separate from the actual definition of an applicable laboratory. The TIN-level entity must report applicable information individually for all its NPI-level components that are applicable laboratories.

As noted above, an applicable laboratory is a CLIA-certified laboratory and, using its billing NPI, meets the majority of Medicare revenues threshold and low expenditure threshold. These are examples of reporting entities that must report applicable information **individually** for all NPI-level components that are applicable laboratories:

Example 1: A TIN-level entity consists of five CLIA-certified laboratories. Each laboratory bills using its **own unique NPI** and all five CLIA-certified laboratories **individually** meet both the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of **five unique applicable laboratories**. In this case, the reporting entity reports applicable information associated with each individual NPI that is an applicable laboratory (not collectively for all NPIs that are applicable laboratories under the TIN). The reporting entity separates the applicable information by each NPI and submits applicable information during the data reporting period for five applicable laboratories.

Example 2: A TIN-level entity consists of five CLIA-certified laboratories, each billing for services under its **own unique NPI**. However, only three of the laboratories **individually** meet both the majority of Medicare revenues threshold and low expenditure threshold while the remaining two laboratories do not individually meet the low expenditure threshold. In other words, two of the five CLIA-certified laboratories receive less than $12,500 of revenue under the CLFS during the data collection period. This TIN-level entity **consists of three unique applicable laboratories**. In such case, the reporting entity will report applicable information associated with each individual NPI that is an applicable laboratory, but will not report information on the two individual NPIs of the laboratories that are not applicable laboratories. The reporting entity separates the applicable information by each NPI and submits applicable information during the data reporting period for three applicable laboratories.

Example 3: A TIN-level entity consists of five CLIA-certified laboratories and each laboratory has the same NPI and bills Medicare Part B under the **same NPI**. Collectively, the five CLIA-certified laboratories meet the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of **one applicable laboratory**. In such case, the reporting entity reports applicable information for all laboratories associated with the same NPI as a **single applicable laboratory**. In other words, in this example, the five CLIA-certified laboratories are considered one applicable laboratory for purposes of reporting applicable information because they all have the same NPI and all bill Medicare Part B under the same NPI.

The TIN-level entity along with its applicable laboratory entities should establish their own approach for ensuring that the TIN-level entity can report applicable information to CMS. To that end, applicable laboratories and their reporting entity should determine the best approach to collect applicable information from final paid claims data and for submitting applicable information to CMS during the data reporting period.

Voluntary Reporting is Not Permitted

The reporting entity reports only applicable information for NPI-level components that are applicable laboratories (that is, NPIs that meet the definition of an applicable laboratory). Reporting entities do **not** report applicable information for NPIs that do not meet the definition of an applicable laboratory.

Example: A TIN-level entity consists of four NPI-level entities. Three of the NPI-level entities meet the definition of an applicable laboratory, and one NPI-level entity does not meet the definition of an applicable laboratory. In this case, the reporting entity reports applicable information to CMS for **only** the three NPI-level entities that are applicable laboratories. .

Reporting Applicable Information is Not Discretionary

Reporting entities must report all applicable information for its NPI-level components that are applicable laboratories. Reporting entities do **not** have the discretion to selectively omit reporting certain applicable information.

Example: An applicable laboratory has various final paid claims for laboratory tests from the data collection period that are only in "hard copy" paper format. The reporting entity along with its applicable laboratory perceives that reporting applicable information derived from the paper claims has minimal impact on the final payment rate calculated for the tests. In such case, the reporting entity **cannot** selectively omit reporting applicable information due to the perception that reporting such applicable information may not influence the final weighted median private payor rate for a given test. In this example, the reporting entity must report the applicable information obtained from the "paper-based" claims to CMS during the data reporting period.

Reporting Entity Summary

Applicable information, which is used to set payment amounts under the new CLFS, must be reported by the TIN-level entity for its NPI components that are applicable laboratories during the data reporting period. As discussed above, applicable information includes the specific HCPCS code for each test, the final payment rate that was paid by each private payor for the test during a data collection period, and the associated volume for each test. Voluntary reporting of applicable information derived from laboratories that are **not** applicable laboratories and omitting certain applicable information from laboratories that **are** applicable laboratories is not permissible. If the laboratory meets the definition of an applicable laboratory, the applicable information for that laboratory must be reported to CMS during the data reporting period.

Implementation Schedule

This is the schedule for implementing the new CLFS:

- First data collection period for determining CY 2018 CLFS payment rates: January 1, 2016, through June 30, 2016.
- First data reporting period for reporting entities to report private payor rate data to CMS for determining CY 2018 CLFS payment rates: January 1, 2017, through March 31, 2017.

- Annual laboratory public meeting for new tests: Mid-July 2017. CMS will use crosswalking or gapfilling to set rates for new tests for which there is no private payor data collected for the CY 2018 CLFS.
- CMS publishes preliminary CLFS rates for CY 2018: Early September 2017. The public will have approximately 30 days, through early October 2017, to submit comments on the preliminary CY 2018 rates.
- CMS makes final CY 2018 CLFS rates available on the CMS website: Early November 2017.
- Implementation date of new CLFS: January 1, 2018.

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

Date of Change	Description
January 12, 2017	This article was revised to add a reference to MLN Matters® Article **MM9837**. That article informs MACs about the changes to the Fiscal Intermediary Shared System (FISS) to incorporate the revised Clinical Laboratory Fee Schedule (CLFS) containing the National Fee Schedule Rates.
December 6, 2016	This article was revised to add a reference to MLN Matters Article SE1620 that contains "The Quick User Guide", which includes guidance for the Fee-For-Service Data Collection System (FFSDCS) CLFS data reporting template.
August 8, 2016	Initial article released