

Medicare Part B Clinical Laboratory Fee Schedule

Guidance to Laboratories for Collecting and Reporting Data for the Private Payor Rate Based Payment System

The guidance contained in this publication is intended to assist the laboratory community in meeting the new requirements under section 1834A of the Social Security Act for the Medicare Part B clinical laboratory fee schedule (CLFS). Included are 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 CMS, the entity responsible for reporting applicable information to CMS, the data collection and reporting periods, and the schedule for implementing the new CLFS. Additional information regarding the CLFS data collection system and advanced diagnostic laboratory tests (ADLTs) will be issued through separate guidance.

Background

The CLFS was first established in 1984 based on historical charge data. The CLFS has only been updated to establish payment rates for new tests or to make statutorily required across the board updates. Payment for new tests established after 1984 are 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, Medicare Administrative Contractors 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 entitled “Medicare Program: Medicare Clinical Diagnostic Laboratory Tests Payment System” (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 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 4 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 National Provider Identifier; (3) Does the laboratory meet the majority of Medicare revenues threshold; and (4) Does the laboratory meet the low expenditure threshold.

The 4 steps for determining an applicable laboratory under the new Medicare CLFS are discussed in more detail below.

Step 1: CLIA Certification

The Clinical Laboratory Improvement Amendments of 1988 (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 493.2.**

Step 2: National Provider Identifier

The second step is to determine whether the CLIA certified laboratory bills Medicare Part B under its own National Provider Identifier (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 (NPPES) in 45 CFR part 162. The laboratory's own billing NPI is used as the mechanism for defining an applicable laboratory.

Step 3. Majority of Medicare Revenues Threshold

In order 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 physician fee schedule (PFS). The CLFS and PFS are included under Medicare Part B, sometimes referred to as original Medicare and or fee for service 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. Additional guidance regarding final paid claims is provided under the Applicable Information section of this publication.

There are 3 steps for determining whether a laboratory meets the majority of Medicare revenues threshold. These steps are outlined below.

- 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 paid on the CLFS. The revenues from the PFS include all payments from all services paid on the PFS (for instance, laboratory services and services that are not laboratory services such as pathology services, evaluation and management services, radiology services, and so on). 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 fee-for-service 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. (Additional information on the data collection period is provided later in this publication.)

If the Medicare revenues received from the CLFS and or PFS is greater than 50 percent of the total Medicare revenues for the laboratory's billing NPI, then the laboratory would meet the majority of Medicare revenues threshold.

The majority of Medicare revenues threshold equation is reflected below:

- $\text{CLFS revenues (for billing NPI) + PFS revenues (for billing NPI) / Total Medicare Revenues (for billing NPI)} > 50 \text{ percent.}$

Step 4: Low Expenditure Threshold

The final step in determining whether a laboratory meets the requirements to be an applicable laboratory is to determine whether the laboratory meets the low expenditure threshold. 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. As noted above, for 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 CLFS services during the data collection period (which has already been done under step 3-- the majority of Medicare revenues threshold). It is important to note that the low expenditure threshold applies to **CLFS services only**. It does **not** include revenues received from the PFS. In other words, in order to meet the low expenditure threshold, the laboratory's own billing NPI must receive at least \$12,500 from only the CLFS during the data collection period. As discussed later in this publication, a list of laboratory tests

payable under the Medicare CLFS is published on the CLFS website under the PAMA regulations tab.

The low expenditure threshold equation is provided below.

- CLFS revenues (for billing NPI) = or > \$12,500.

The following provides examples of 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 5 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 would be 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 5 laboratories may be under the same Tax Identification Number (TIN), they are each considered separate laboratories for purposes of determining an applicable laboratory because they each bill Medicare Part B for laboratory tests using their own unique NPI.

Example 2: A laboratory organization includes 5 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 would be 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 5 CLIA certified laboratories in the laboratory organization would be considered a single laboratory because they all bill Medicare Part B using the same NPI.

Example 3: A laboratory organization includes 5 CLIA certified laboratories. Each CLIA certified laboratory has its **own unique NPI**. However, **only 1 laboratory's NPI is used for billing** all laboratory tests furnished by all 5 laboratories in the laboratory organization. In this example, the majority of Medicare revenues threshold and low expenditure threshold would be applied to the **1 NPI** used for billing all tests furnished by the laboratory organization.

Example 4: An entity consists of 5 physician offices and 1 CLIA certified laboratory. All 5 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 would be 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 would be considered as a single laboratory for purposes of applying the majority of Medicare revenues threshold and low expenditure threshold.

Example 5: An entity consists of 5 physician offices and 1 CLIA certified laboratory. Each of the 5 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 would only be 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 would be 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 would be applied to the **NPI of the entire hospital**. In this circumstance, it is unlikely that the hospital laboratory would qualify as an applicable laboratory because the majority of Medicare revenues for the NPI would be received from the hospital inpatient prospective payment system and or hospital outpatient prospective payment system and 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 **only from the CLFS**). In other words, in order to qualify to be 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 could not qualify to be an applicable laboratory if no services are billed to Medicare Part B under its own NPI because there would be no revenues attributed to the NPI 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, will be subject to the new Medicare Part B CLFS payment rates once they are established and implemented on January 1, 2018.

Additional guidance on applicable information, the data collection and reporting periods and the reporting entity is provided below.

Applicable Information

The applicable laboratory along with its reporting entity (as discussed later in this publication) are responsible for collecting applicable information and reporting that data to CMS.

Applicable information includes 3 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; and
- (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; and
- (3) A Medicaid managed care organization (as defined in section 1903(m) of the Social Security Act).

Note: As discussed later in this section, applicable information does **not** include information about a test for which payment is made on a capitated basis, where payments do not reflect specific HCPCS code-level amounts. Therefore, private payor rates from Medicaid managed care plans would only be considered applicable information 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.

Specific private payor claims data **included** as applicable information are outlined below.

Included

- **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. A listing of laboratory tests associated

with the CLFS and therefore subject to the data collection and data reporting requirements is available from the CLFS website under the PAMA regulations tab.

- **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 would be 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 being made by the private payor during the data collection period, the final corrected payment amount for the test would be 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 not made until after the data collection period, that payment amount would not be a private payor rate for purposes of applicable information and, therefore, would not be reported to CMS.
- **Payments from secondary insurance payors.** Final payments from secondary insurance payors would also be 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 payors 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 (as discussed later) must report each unique payment rate and the associated volume for the test at each such rate.
- **Resolved appeals (resolved during the data collection period).** Payment rates (and the associated volume of tests) for claims under appeal would be 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 would be 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 would include any patient cost sharing amounts, for example deductible and coinsurance responsibilities, if applicable.

Specific private payor claims data **excluded** from applicable information are outlined below.

Excluded

- **Private payor rates for laboratory test codes paid only under the PFS.** If a laboratory test code is not paid under the CLFS (but 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 payors 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 would not be considered a final payment rate and would therefore not be 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 would be excluded from applicable information.
- **Payments made on a capitated bases.** 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 payors' remittance, those payment amounts would not be considered applicable information and should not be reported to CMS.

Remittances where the payor has grouped test-level payments into an encounter or claim-level payment. In circumstances where a private payor groups payments for multiple tests/HCPCS codes into a single encounter or claim-level payment, instead of by individual HCPCS code, those payments would not be applicable information. In other words, if multiple tests/HCPCS codes were billed by the laboratory and payments were bundled or grouped by the payor and the laboratory is unable to ungroup payment rates for the individual tests/HCPCS codes billed, the payor's bundled payment amount (and the associated volume) would not be considered applicable information. Estimated private payor rates and volumes are also 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.

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, as noted above, 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 would be 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 3rd subsequent calendar year.

The table below illustrates the data collection and reporting periods for CDLTs.

TABLE: 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 3 rd subsequent calendar year	Continues every 3 rd subsequent calendar year	Continues every 3 rd subsequent calendar year	New CLFS rate every 3 rd year

While reporting is required every three years for CDLTs (that are not ADLTs), reporting entities are required to report applicable information annually for ADLTs, except for an ADLT in its 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 in this publication, additional information regarding ADLTs will be issued through separate guidance.

Reporting Entity

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

Example 1: A TIN-level entity consists of 5 CLIA certified laboratories, each laboratory bills using its **own unique NPI**, and all 5 CLIA certified laboratories, **individually** meet both the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity would consist of **5 unique applicable laboratories**. In such case, the reporting entity shall report applicable information associated with each individual NPI that is an applicable laboratory (not collectively for all NPIs that are applicable laboratories under the TIN). In this example, the reporting entity would separate the applicable information by each NPI and submit applicable information during the data reporting period for 5 applicable laboratories.

Example 2: A TIN-level entity consists of 5 CLIA certified laboratories, each billing for services under its **own unique NPI**. However, only 3 of the laboratories **individually** meet both the majority of Medicare revenues threshold and low expenditure threshold while the remaining 2 laboratories do not individually meet the low expenditure threshold. In other words, 2 of the 5 CLIA certified laboratories receive less than \$12,500 of revenue under the CLFS during the data collection period. This TIN-level entity would **consist of 3 unique applicable laboratories**. In such case, the reporting entity shall report applicable information

associated with each individual NPI that is an applicable laboratory, but not for the 2 individual NPIs of the laboratories that are not an applicable laboratory. In this example, the reporting entity would separate the applicable information by each NPI and submit applicable information during the data reporting period for 3 applicable laboratories.

Example 3: A TIN-level entity consists of 5 CLIA certified laboratories and each laboratory has the same NPI and bills Medicare Part B under the **same NPI**. Collectively, the 5 CLIA certified laboratories meet the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity would consist of **1 applicable laboratory**. In such case, the reporting entity shall report applicable information for all laboratories associated with the same NPI as a **single applicable laboratory**. In other words, in this example, the 5 CLIA certified laboratories would be considered 1 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 shall only report applicable information for NPI-level components that are applicable laboratories, that is, NPIs that meet the definition of an applicable laboratory. Reporting entities shall **not** report applicable information for NPIs that do not meet the definition of an applicable laboratory.

Example: A TIN-level entity consists of 4 NPI-level entities. Three of the NPI-level entities meet the definition of an applicable laboratory, and 1 NPI-level entity does not meet the definition of an applicable laboratory. In this case, the reporting entity shall report applicable information to CMS **only** for the 3 NPI-level entities that are applicable laboratories.

Reporting Applicable Information is Not Discretionary

Reporting entities must report all applicable information for its NP-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 in “hard-copy” paper format only. The reporting entity along with its applicable laboratory perceives that reporting applicable information derived from the paper claims would have minimal impact on the final payment rate calculated for the tests. In such case, the reporting entity **cannot** selectively omit reporting applicable information because of 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

The schedule for implementing the new CLFS is outlined below.

- 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

Additional information regarding the new private payor rate based payment system including: the CLFS final rule; the related press release and fact sheet; frequently asked questions regarding our final policies, and a power point slide presentation of the new CLFS is available on the Medicare CLFS website under the “PAMA Regulations” tab:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html>