

Summary of Private Payor Rate-Based Medicare Clinical Laboratory Fee Schedule-Updated

I. Introduction

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 under the Clinical Laboratory Fee Schedule (CLFS).

In general, the payment amount for a test on the CLFS furnished on or after January 1, 2018, is equal to the weighted median of private payor rates determined for the test, based on the applicable information that is collected by applicable laboratories during a data collection period and reported by reporting entities to CMS during a data reporting period. For most laboratory tests, the private payor rate-based CLFS is updated every three years. The next private payor rate-based CLFS update for most tests will be effective January 1, 2026.

Since December of 2019, Congress has passed a series of legislation to modify statutory requirements under Section 1834A of the Act related to the data reporting period and phase-in of payment reductions under the CLFS for clinical diagnostic laboratory tests (CDLTs) that are not advanced diagnostic laboratory tests (ADLTs). Most recently, the Further Continuing Appropriations and Other Extensions Act of 2024 (Pub.L. 118-22, enacted on November, 16, 2023) further delayed the reporting requirement under Section 1834A of the Act and also delayed the application of the 15% phase-in reduction. Under these statutory provisions, the next data reporting period for CDLTs that are not ADLTs will be January 1, 2025 through March 31, 2025, and will be based on the most recent data collection period of January 1, 2019 through June 30, 2019. After this data reporting period, the three-year data reporting cycle for these tests will resume (that is, 2028, 2031, etc.).

The series of legislation passed since December 2019 also modified the phase-in of payment reductions resulting from private payor rate implementation so that a 0.0 percent reduction limit was applied for CYs 2021 through 2023, as compared to the payment amounts for a test the preceding year. The Further Continuing Appropriations and Other Extensions Act of 2024 further applied a 0.0 percent reduction limit for CY 2024. Consequently, payment may not be reduced by more than 15 percent per year for CYs 2025 through 2027 as compared to payment amount established for a test the prior year.

This summary of the private payor rate-based CLFS provides an overview of key terms and concepts used under the private payor rate-based CLFS. It also includes information on how to determine whether your laboratory is an applicable laboratory as well as collecting applicable information and reporting applicable information. The list of laboratory test codes subject to the data collection and data reporting requirements may be found under the “How do I report” section of the CLFS Reporting web page, <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-Applicable-Information-HCPCS-Codes.zip>

Additional information regarding requirements under PAMA and the private payor rate-based CLFS is also available on the CLFS website at <https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule/clfs-pama-educational-resources>

II. Key Terms Used under the Private Payor Rate-based CLFS

The information below provides an overview of key concepts and terms used under the private payor rate-based CLFS.

Applicable Laboratory. An applicable laboratory is a laboratory (as defined under the Clinical Laboratory Improvement Amendments (CLIA) regulatory definition of a laboratory in 42 C.F.R. § 493.2) that:

- Bills Medicare Part B under its own National Provider Identifier (NPI); or, for hospital outreach laboratories, bills Medicare Part B on the Form CMS-1450 under type of bill (TOB) 14x; and
- Meets the “majority of Medicare revenues” threshold (that is, receives more than 50 percent of its Medicare revenues from one or a combination of the CLFS or the Physician Fee Schedule (PFS) in a data collection period; and
- Meets or exceeds the low expenditure threshold (that is, it receives at least \$12,500 of its Medicare revenues from the CLFS in a data collection period).

Hospital Outreach Laboratory. For purposes of determining applicable laboratory status under the Medicare CLFS, a hospital outreach laboratory refers to a hospital-based laboratory that furnishes laboratory tests to patients other than admitted inpatients or registered outpatients of the hospital and bills for Medicare Part B services furnished to non-hospital patients using the Form CMS-1450 14x TOB.¹

Applicable Information. Applicable information is the data that applicable laboratories are required to collect during the data collection period, and the reporting entity is required to report, during the data reporting period. Applicable information includes:

- The specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test;
- Each private payor rate for which final payment has been made during the data collection period; and
- The associated volume tests performed corresponding to each private payor rate.

Final Paid Claim. A final paid claim is the final amount paid by a private payor for a laboratory test during the data collection period. If a private payor pays a laboratory for a test but subsequent post payment activities during the data collection period change that initial payment amount, the final

¹ The Form CMS-1450 14x is a TOB as defined by the National Uniform Billing Committee. It is used in hospital claims submission and is associated with hospital laboratory services provided to non-hospital patients. See Copyright/Disclaimer at the end of this document.

payment is 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 the private payor corrects the initial claim 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.

Examples of Final Paid Claims during the Data Collection Period:

- Example 1: A private payor pays the initial claim before the data collection period on December 12, 2018 and corrects the initial claim with a final payment made during the data collection period on March 3, 2019. The final corrected payment amount for the test made on March 3, 2019 is considered the private payor rate for purposes of determining applicable information.
- Example 2: A private payor pays the initial claim during the data collection period on February 1, 2019 and corrects the initial claim with a final payment also made during the data collection period on May 3, 2019. The final corrected payment amount for the test made on May 3, 2019 is considered the private payor rate for purposes of determining applicable information.
- Example 3: A private payor pays the initial claim in error on June 1, 2019 and corrects the initial claim with a final payment made after the data collection period on July 20, 2019. Since the final paid claim was made after the data collection period, this payment amount is not a private payor rate for purposes of applicable information and, therefore, is not reported to CMS.

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.

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.

Private Payor. The term “private payor” is defined as any of the following:

- A health insurance issuer as defined in Section 2791(b)(2) of the Public Health Service (PHS) Act);
- A group health plan as defined in Section 2791(a)(1) of the PHS Act);
- A Medicare Advantage Plan under Part C as defined in section 1859(b)(1) of the Act; or
- A Medicaid Managed Care Organization (as defined in Section 1903(m) of the Act).

Data Collection Period. The data collection period is the 6 months from January 1 through June 30 during which applicable information is collected.

Reviewing Window. A review and validation period follows the data collection period and precedes the data reporting period (the period where applicable information must be submitted to CMS).

During the review and validation period, laboratories should assess whether the applicable laboratory thresholds are met. That is, each laboratory, along with its reporting entity should determine whether the laboratory meets the majority of Medicare revenues threshold and low expenditure threshold. During this time, applicable laboratories and their reporting entity should review and validate applicable information (private payor data) before reporting it to CMS.

Data Reporting Period. The data reporting period is the 3-month period, January 1 through March 30, during which a reporting entity reports applicable information to CMS. Applicable information reported during the data reporting period will be used to calculate payment rates effective January 1, of the following calendar year.

Reporting Entity. The reporting entity is the entity that reports tax-related information to the Internal Revenue Service using its Taxpayer Identification Number (TIN) for its components that are applicable laboratories.

The TIN-level entity (reporting entity) along with its applicable laboratory(s) should establish their own approach for ensuring that the reporting entity can report applicable information to CMS. 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.

Note: The reporting entity reports only applicable information for laboratory components that are applicable laboratories (that is, laboratories that meet the definition of an applicable laboratory). Reporting entities do not report applicable information for laboratories that do not meet the definition of an applicable laboratory. In other words, if your laboratory is not an applicable laboratory, it does not collect applicable information and is not permitted to report applicable information.

Current Data Collection and Reporting Periods. This table illustrates the current and future data collection and reporting periods for CDLTs that are not ADLTs.

Data Collection Period	Reviewing Window*	Data Reporting Period	Used for CLFS Rate Years
1/1/2019 – 6/30/2019	7/1/2019 – 12/31/2019	1/1/2025 – 3/31/2025	2026 – 2028
1/1/2027 – 6/30/2027	7/1/2027 – 12/31/2027	1/1/2028 – 3/31/2028	2029 - 2031
Continues every third subsequent calendar year	Continues every third subsequent calendar year	Continues every third subsequent calendar year	New CLFS rate every third year

*The reviewing window is the six-month period between the end of the data collection period and beginning of the data reporting period, and should be used to assess, review, and validate the applicable information before reporting it to CMS.

III. Information for Laboratories Billing Medicare Part B under their own NPI

Note that “Section III” provides instructions for independent laboratories and physician office laboratories that bill Medicare Part B under their own NPI and hospital outreach laboratories that bill Medicare Part B under their own NPI (separate from the hospital’s NPI). The next section “Section IV” provides instructions for hospital outreach laboratories that bill Medicare Part B under the hospital’s NPI.

If your laboratory is CLIA certified, bills Medicare Part B under its own NPI, and based on its revenues attributed to its own NPI during the data collection period, meets the majority of Medicare revenues threshold and low expenditure threshold, then your laboratory is an applicable laboratory.

1. How to determine whether your laboratory is an applicable laboratory.

For a CLIA certified laboratory that bills Medicare Part B under its own NPI, the laboratory (along with its reporting entity) must determine whether the laboratory qualifies as an applicable laboratory based on the Medicare revenues attributed to its own billing NPI based on the following:

Majority of Medicare Revenues Threshold. To be an applicable laboratory, your laboratory must receive more than 50 percent of its total Medicare revenues from the CLFS and/or PFS during a data collection period. To determine whether your laboratory meets the majority of Medicare revenues threshold follow the steps below.

- First, sum the Medicare CLFS revenues + Medicare PFS revenues received by your own NPI during the data collection period (the numerator).
- Next, sum the total Medicare revenues received by your own NPI during the data collection period (the denominator).

For purposes of determining whether a laboratory meets the majority of Medicare revenues threshold, total Medicare revenues includes the sum of all fee for service payments under Medicare Parts A and B, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period.

- Finally, divide the Medicare CLFS revenues + Medicare PFS revenues received by your own NPI during the data collection period (the numerator) by the total Medicare revenues received by your own NPI during the data collection period (the denominator).

Equation:

Medicare CLFS + Medicare PFS revenues received by your NPI / Total Medicare revenues received by your NPI.

If Medicare CLFS revenues + Medicare PFS revenues are greater than 50 percent of total Medicare revenues, then the laboratory would meet the majority of Medicare revenues threshold.

Low Expenditure Threshold. To be an applicable laboratory, laboratories that bill Medicare Part B under their own NPI must also meet the low expenditure threshold, that is, receive at least \$12,500 in Medicare CLFS revenues during a data collection period.

- To determine whether your laboratory meets the low expenditure threshold, total up all revenues received by your own NPI for Medicare CLFS services during the data collection period.

If your Medicare CLFS revenues attributed to your own NPI are at least \$12,500 during the data collection period, then your laboratory meets the low expenditure threshold.

2. Collecting Applicable Information

If your laboratory is an “applicable laboratory” you must collect applicable information received during the data collection period. The current data collection period is January 1, 2019 through June 30, 2019. Applicable information includes three major components: (1) The specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test; (2) Each private payor rate for which final payment has been made during the data collection period; and (3) The associated volume of tests performed corresponding to each private payor rate.

Applicable laboratories (along with their reporting entities) should collect applicable information from all private payors for each laboratory test code subject to the data collection and data reporting requirements. The reviewing window, between the end of the data collection period and beginning of the data reporting period should be used to assess, review and validate the applicable information before reporting it to CMS.

3. Reporting Applicable Information

During the data reporting period, the reporting entity (TIN-level entity) must report applicable information for its laboratory components that are an applicable laboratory. For laboratories that bill Medicare Part B under its own NPI, the reporting entity reports applicable information by the applicable laboratory’s NPI.

Specifically, for each laboratory test code subject to the data collection and data reporting requirements, the reporting entity must report the applicable laboratory’s NPI, the HCPCS code, each private payor rate for a specific HCPCS code and the volume paid at each specific rate for each specific HCPCS code.

Table 1 illustrates the data reporting template under the CMS data collection system. Note that each private payor rate for each specific HCPCS code and the volume associated with each private payor rate for each HCPCS code is reported.

Table 1: Data Reporting Template for Applicable Laboratories Billing Medicare Part B under its own NPI

NPI	HCPCS Code	Payment Rate	Volume
Applicable Laboratory's NPI	Lab Test Code (1)	\$15.00	500
Applicable Laboratory's NPI	Lab Test Code (1)	\$17.00	200
Applicable Laboratory's NPI	Lab Test Code (2)	\$21.00	300
Applicable Laboratory's NPI	Lab Test Code (2)	\$22.50	100

IV. Information for Hospital Outreach Laboratories Billing Medicare Part B under the Hospital's NPI)

Note that “Section IV” only applies to hospital outreach laboratories that bill Medicare Part B under the hospital's NPI.

If your hospital outreach laboratory is CLIA certified, bills Medicare Part B under the hospital's NPI, and based on its revenues received from its 14x TOB during the data collection period, meets the majority of Medicare revenues threshold and low expenditure threshold, then your laboratory is an applicable laboratory. Applicable laboratories are required to collect certain private payor data (applicable information) during the data collection period, and the reporting entity is required to report applicable information to CMS during the data reporting period.

1. How to determine whether your hospital outreach laboratory is an applicable laboratory.

If your CLIA certified hospital outreach laboratory bills Medicare Part B under the hospital's NPI, your laboratory must determine whether it qualifies as an applicable laboratory based on the hospital outreach laboratory's Medicare revenues attributed to the Form CMS-1450 14x TOB. Instructions for determining applicable laboratory status are outlined below.

Majority of Medicare Revenues Threshold. To be an applicable laboratory, your hospital outreach laboratory that bills Medicare Part B using the hospital's NPI must receive more than 50 percent of its total Medicare revenues from the CLFS and/or PFS during a data collection period. To determine whether your hospital outreach laboratory meets the majority of Medicare revenues threshold follow the steps below.

- First, sum the Medicare CLFS revenues + Medicare PFS revenues received on the 14x TOB during the data collection period (the numerator).

- Next, sum the total Medicare revenues received on the 14x TOB during the data collection period (the denominator).
- Finally, divide the Medicare CLFS revenues + Medicare PFS revenues received on the 14x TOB during the data collection period by the total Medicare revenues received on the 14x TOB during the data collection period.

Equation:

- Medicare CLFS revenues + Medicare PFS revenues received from the 14x TOB / Total Medicare revenues received from the 14x TOB

If Medicare CLFS revenues + Medicare PFS revenues are greater than 50 percent of total Medicare revenues, then the hospital outreach laboratory that bills Medicare Part B using the hospital's NPI would meet the majority of Medicare revenues threshold.

NOTE: Hospital outreach laboratories that bill Medicare Part B under the hospital's NPI, and therefore determine applicable laboratory status based on its Medicare revenues from the 14x TOB will most likely meet the majority of Medicare revenues threshold. They will most likely meet the majority of Medicare revenues threshold because their Medicare revenues are primarily, if not entirely, derived from the CLFS and or PFS. In other words, the revenues from the CLFS and or PFS services included in the numerator are essentially the same as the total Medicare revenues included in the denominator.

Low Expenditure Threshold. To be an applicable laboratory, hospital outreach laboratories that bill Medicare Part B under the hospital's NPI must also meet the low expenditure threshold, that is, receive at least \$12,500 in CLFS revenues during a data collection period.

- To determine whether your laboratory meets the low expenditure threshold, total up all revenues received on the 14x TOB for Medicare CLFS services during the data collection period.

If your Medicare CLFS revenues received from the 14x TOB are at least \$12,500 during the data collection period, then your laboratory meets the low expenditure threshold.

2. Collecting Applicable Information

If your laboratory is an "applicable laboratory" you must collect applicable information received during the data collection period. Applicable information includes three major components: (1) The specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test; (2) Each private payor rate for which final payment has been made during the data collection period; and (3) The associated volume tests performed corresponding to each private payor rate.

Applicable laboratories (along with their reporting entities) should collect applicable information from all private payors for each laboratory test code subject to the data collection (and data reporting)

requirements. The reviewing window, between the end of the data collection period and beginning of the data reporting period should be used to assess, review and validate the applicable information before reporting it to CMS.

3. Reporting Applicable Information

During the data reporting period, the reporting entity (TIN-level entity) must report applicable information for its hospital outreach laboratory that meets the definition of an applicable laboratory. For hospital outreach laboratories that bill Medicare Part B under the hospital’s NPI, (and therefore determines applicable laboratory status based on its Medicare revenues attributed to the 14x TOB) the reporting entity reports applicable information by the hospital’s NPI.

Specifically, for each laboratory test code subject to the data collection and data reporting requirements, the reporting entity must report the hospital’s NPI, the HCPCS code, each private payor rate for a specific HCPCS code and the volume paid at each specific rate for each specific HCPCS code.

Table 2 illustrates the data reporting template under the CMS data collection system. Notice that each private payor rate for each specific HCPCS code and the volume associated with each private payor rate for each HCPCS code is reported.

Table 2: Data Reporting Template for Hospital Outreach Laboratories Billing Medicare Part B under the Hospital’s NPI

NPI	HCPCS Code	Payment Rate	Volume
Hospital’s NPI	Lab Test Code (1)	\$15.00	500
Hospital’s NPI	Lab Test Code (1)	\$17.00	200
Hospital’s NPI	Lab Test Code (2)	\$21.00	300
Hospital’s NPI	Lab Test Code (2)	\$22.50	100

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