



Medicare Part B Clinical Laboratory Fee Schedule: Revised Information for Laboratories on Collecting & Reporting Data for the Private Payor Rate-Based Payment System

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Note: We revised this Article to note that for CDLTs that aren't ADLTs, the data reporting is delayed by 1 year and must now be reported from January 1, 2023-March 31, 2023 (previously January 1, 2022-March 31, 2022). We've changed all references to the 2022 data reporting period to 2023. You'll find substantive content updates in dark red font (see pages 2,14,15 and 20-23). There are no other changes to the substance of the Article.

Provider Type Affected

This MLN Matters Article is for Medicare Part B clinical laboratories that must report private payor rate data to CMS.

Provider Action Needed

Make sure your staff knows about:

- Clarifications for deciding whether a hospital outreach laboratory meets the requirements to be an “applicable laboratory”
- Applicable information (private payor rate data) that you must collect and report to us
- The entity responsible for reporting applicable information to us
- The data collection and reporting periods
- Information about our online data collection system
- Our schedule for implementing the next private payor-rate based Clinical Laboratory Fee Schedule (CLFS) update
- Information about the condensed data reporting option for reporting entities

Background

[Section 1834A](#) of the Social Security Act (the Act), as established by [Section 216 of the Protecting Access to Medicare Act of 2014 \(PAMA\)](#), required significant changes to how Medicare pays for clinical diagnostic laboratory tests (CDLTs) under the CLFS. The CLFS final rule [Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule](#) (CMS-1621-F) implemented Section 1834A of the Act.

Under the CLFS final rule, reporting entities must report to us certain private payor rate information (applicable information) for their component applicable laboratories. In general, the payment amount for a test on the CLFS you provide on or after January 1, 2018, is equal to the weighted median of private payor rates for the test. We base the calculations on the applicable information that laboratories collect during a data collection period and report to us during a data reporting period. We use crosswalking or gapfilling methods to establish payment amounts for new CDLTs and CDLTs for which we don't get applicable information.

We published the Physician Fee Schedule (PFS) final rule entitled [Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2019 \(CMS-1693-F\)](#) on November 23, 2018. In this rule, we made 2 revisions to the regulatory definition of applicable laboratory:

- We excluded Medicare Advantage plan revenues from total Medicare revenues, the denominator of the majority of Medicare revenues threshold
- Hospitals that bill for their non-patient laboratory services use Medicare revenues from the Form CMS-1450 Type of Bill (TOB) 14x to decide whether its hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold

[Section 105 \(a\) of the Further Consolidated Appropriations Act, 2020 \(FCAA\)](#) (Pub. L. 116-94, enacted December 19, 2019) and [Section 3718 of the Coronavirus Aid, Relief, and Economic Security \(CARES\) Act](#) (Pub. L. 116-136, enacted March 27, 2020) made several revisions to the next data reporting period for CDLTs that aren't Advanced Diagnostic Laboratory Tests (ADLTs) and the phase-in of payment reductions under the Medicare private payor rate-based CLFS. **On December 10, 2021, the [Protecting Medicare and American Farmers from Sequester Cuts Act](#) (S. 610) further delayed the reporting requirement under Section 1834A of the Act and also delayed the application of the 15% phase-in reduction. In summary the revisions are:**

- We'll base the next data reporting period of January 1, 2023-March 31, 2023, on the original data collection period of January 1, 2019-June 30, 2019.
- After the next data reporting period, there's a 3-year data reporting cycle for CDLTs that aren't ADLTs, (that's, 2026, 2029, and so on).
- The statutory phase-in of payment reductions resulting from private payor rate implementation is extended through Calendar Year (CY) 2024. There was a 0.0% reduction for CY 2021, and we won't reduce payment by more than 15% for CYs 2023-2025.

Also, for the January 1, 2023-March 31, 2023 (previously January 1, 2022-March 31, 2022) data reporting period, we allow reporting entities the option to condense certain applicable information at the Tax Identification Number (TIN)-level, instead of reporting for each applicable laboratory individually at the National Provider Identifier (NPI) level.

Applicable Laboratory

[Section 1834A](#) of the Act defines an applicable laboratory as one that gets the majority of its Medicare revenues under the CLFS and, or PFS. It also provides the authority to set a low volume or low expenditure threshold.

Under the revised final policies for the Medicare CLFS, an applicable laboratory is a laboratory as defined under the Clinical Laboratory Improvement Amendments (CLIA) regulatory definition of a laboratory ([42 CFR 493.2](#)) that bills Medicare Part B under its own NPI or for hospital outreach laboratories, bills Part B on the Form CMS-1450 TOB 14x. Also, the laboratory must meet a “majority of Medicare revenues” threshold. This means that in a data collection period it gets more than 50% of its Medicare revenues from 1 or a combination of the CLFS or the PFS. It also must meet a low expenditure threshold – it gets at least \$12,500 of its Medicare revenues from the CLFS in a data collection period.

For purposes of deciding applicable laboratory status under the CLFS, a hospital outreach laboratory is a hospital-based laboratory that provides laboratory tests to patients other than admitted inpatients or registered outpatients of the hospital. A hospital outreach laboratory bills for Part B services it provides to non-hospital patients using the Form CMS-1450 TOB 14x.¹

I. Determination of Applicable Laboratory Status Based on the NPI

This section includes information on how independent laboratories and physician office laboratories that bill Part B under their own NPI and hospital outreach laboratories that bill Part B under their own NPI (separate from the hospital’s NPI) decide whether they’re an applicable laboratory. As we discuss later in this Article, hospital outreach laboratories that bill Part B using the hospital’s NPI must decide applicable laboratory status based on its revenues attributed to the Form CMS-1450 TOB 14x.

There are 4 steps in deciding whether you meet the requirements to be an applicable laboratory based on your own billing NPI:

- Is the laboratory certified under CLIA
- Does the CLIA-certified laboratory bill Part B under its own NPI
- Does the laboratory meet the majority of Medicare revenues threshold
- Does the laboratory meet the low expenditure threshold

¹ The Form CMS-1450 14x is a type of bill as defined by the National Uniform Billing Committee. Hospitals use it in hospital claims submission and it is associated with hospital laboratory services provided to non-hospital patients.

Step 1: CLIA Certification

CLIA applies to all laboratories performing testing on human specimens for a health purpose. A laboratory must be a CLIA-certified laboratory to get Medicare payment. So, the first step in identifying an applicable laboratory is to decide whether the laboratory is CLIA-certified. The CLIA regulatory definition of a laboratory is codified in regulation in [42 CFR 493.2](#). **Note that we consider a facility that gets any CLIA certificate (including a CLIA certificate of waiver) a laboratory as defined in [42 CFR 493.2](#).**

Step 2: NPI

The second step is to decide whether the CLIA-certified laboratory bills Medicare Part B under its own NPI. We use the laboratory's own billing NPI as the mechanism for defining an applicable laboratory.

Step 3: Majority of Medicare Revenues Threshold

For a CLIA-certified laboratory that bills 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 gets more than 50% of its **total** Medicare revenues from payments under the Medicare CLFS and or PFS. The CLFS and PFS are under Medicare Part B, also known as Original Medicare or Fee-For-Service (FFS) Medicare.

To decide whether a laboratory meets the majority of Medicare revenues threshold, the laboratory must look to its final Medicare paid claims they get from their Medicare Administrative Contractor (MAC) under their own billing NPI during the data collection period. See the Applicable Information Section below for more information on the concept of final paid claims.

The 3 steps to decide whether a laboratory meets the majority of Medicare revenues threshold are:

- First, sum the CLFS and PFS payment amounts the laboratory gets on its 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 aren't 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 the laboratory gets on its billing NPI during the data collection period. Total Medicare revenues include the sum of all FFS payments under Medicare Parts A and B, prescription drug payments under Medicare Part D, and any associated Medicare patient deductible or coinsurance for services you provided 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 you got during the data collection period. We give more information on the data collection period below.

Note: Effective January 1, 2019, don't include Medicare Advantage plan payments under Medicare Part C in the total Medicare revenues component of the majority of Medicare revenues threshold calculation.

If the Medicare revenues you got from the CLFS and, or PFS are greater than 50% of the total Medicare revenues for the laboratory's billing NPI, you meet the majority of Medicare revenues threshold.

The majority of Medicare revenues threshold equation is:

If:

$$\frac{\text{Medicare CLFS revenues (for billing NPI) + Medicare PFS revenues (for billing NPI)}}{\text{Total Medicare revenues (for billing NPI)}} \text{ is } >50\%$$

Then: The laboratory meets the majority of Medicare revenues threshold.

Step 4: Low Expenditure Threshold

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

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

The low expenditure threshold equation is:

$$\text{Medicare CLFS revenues (for billing NPI)} \geq \$12,500.$$

These are examples on how the majority of Medicare revenues threshold and low expenditure threshold apply to the CLIA-certified laboratory's own billing NPI for purposes of deciding 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, apply the majority of Medicare revenues threshold and low expenditure threshold to each NPI in the laboratory organization. You must individually decide whether each laboratory meets the majority of revenues threshold and low expenditure threshold. Even though all 5 laboratories may be under the same TIN, we consider each to be a separate laboratory for purposes of deciding an applicable laboratory because each bills Part B for laboratory tests using its 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, apply the majority of Medicare revenues threshold and low expenditure threshold 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, we consider all 5 CLIA-certified laboratories in the laboratory organization to be a single laboratory because they all bill 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 provided by all 5 laboratories in the laboratory organization. In this example, apply the majority of Medicare revenues threshold and low expenditure threshold to the 1 NPI used for billing all tests the laboratory organization provides.

Example 4: An entity consists of 5 physician offices and 1 CLIA-certified laboratory. All 5 physician offices and the CLIA-certified laboratory have the same NPI and bill for services under the same NPI. In this example, apply the majority of Medicare revenues threshold and low expenditure threshold 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 Part B under the same NPI, we consider the entity to be 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, apply the majority of Medicare revenues threshold and low expenditure threshold only 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 has its own unique NPI separate from the hospital's NPI. The hospital outreach laboratory bills Part B for laboratory tests it provides to non-hospital patients using its own unique NPI. In this example, apply the majority of Medicare revenues threshold and low expenditure threshold to the hospital outreach laboratory's own unique NPI and not to the hospital's NPI.

Example 7: A hospital includes 3 CLIA-certified hospital outreach laboratories that perform laboratory services for non-hospital patients. Each CLIA-certified hospital outreach laboratory has the same NPI, separate from the hospital's NPI, and bills Part B separately for laboratory tests under the same NPI for each of its CLIA-certified hospital outreach laboratories. In this example, apply the majority of Medicare revenues threshold and low expenditure threshold based on the combined revenues of all CLIA-certified hospital outreach laboratories of the hospital that use the same billing NPI that's separate from the hospital's NPI. For purposes of applying the applicable laboratory thresholds, we consider all 3 CLIA-certified hospital outreach laboratories of the hospital to be a single laboratory because they all bill Part B using the same unique billing NPI.

Example 8: A hospital includes 3 CLIA-certified hospital outreach laboratories. Each CLIA-certified hospital outreach laboratory has its own unique NPI separate from the hospital's NPI. However, the 3 CLIA-certified outreach laboratories use only 1 outreach laboratory's NPI for billing all laboratory tests provided by all 3 hospital outreach laboratories of the hospital. In this example, apply the majority of Medicare revenues threshold and low expenditure threshold to the 1 NPI used for billing all tests provided by the 3 hospital outreach laboratories of the hospital.

Example 9: A hospital includes 3 CLIA-certified hospital outreach laboratories. Only 1 (out of the 3) has its own unique NPI separate from the hospital's NPI and bills Part B for laboratory services it performs for non-hospital patients using its own unique NPI. Two (out of the 3) hospital outreach laboratories bill for laboratory services they perform for non-hospital patients using the hospital's NPI. In this example, the hospital outreach laboratory that bills Part B under its own unique NPI separate from the hospital's NPI uses the Medicare revenues attributed to its own billing NPI to decide whether it meets the majority of Medicare revenues threshold and low expenditure threshold.

The 2 hospital outreach laboratories that bill for laboratory services performed for non-hospital patients under the hospital's NPI must decide applicable laboratory status based on revenues attributed to the Form CMS-1450 TOB 14x. Below, we give instructions for deciding applicable laboratory status for hospital outreach laboratories that bill Part B using the hospital's NPI.

II. Hospital Outreach Laboratories That Bill Medicare Part B under the Hospital's NPI

Similar to the preceding section, in order for hospital outreach laboratories that bill Part B using the hospital's NPI to be an applicable laboratory, the hospital outreach laboratory must be a laboratory based on the CLIA regulatory definition of a laboratory in [42 CFR 493.2](#) and meet the majority of Medicare revenues threshold and low expenditure threshold.

However, a hospital outreach laboratory that bills Part B using the hospital's NPI must decide if it meets the majority of Medicare revenues threshold and low expenditure threshold based on revenues attributed to the Form CMS-1450 TOB 14x. In other words, when using CMS Form-1450 TOB 14x for deciding applicable laboratory status, the majority of Medicare revenues threshold and low expenditure threshold only applies to the hospital outreach laboratory portion of the hospital's NPI, rather than to the NPI of the entire hospital.

So, if a CLIA-certified hospital outreach laboratory that bills Part B under the hospital's NPI meets the requirements of an applicable laboratory, we only consider the hospital outreach laboratory to be an applicable laboratory. The hospital laboratory components providing laboratory services to hospital patients aren't part of the applicable laboratory determination.

Majority of Medicare Revenues Threshold

To be an applicable laboratory, a hospital outreach laboratory that bills Part B under the hospital's NPI must meet the majority of Medicare revenues threshold. A hospital outreach laboratory, by its revenues attributed to the Form CMS-1450 TOB 14x, meets the majority of Medicare revenues threshold if it gets more than 50% of its total Medicare revenues from payments under the Medicare CLFS and, or Medicare PFS. The CLFS and PFS are under Part B.

To decide whether the hospital outreach laboratory (that bills using the hospital's NPI) meets the majority of Medicare revenues threshold, the laboratory must look to its final Medicare paid claims from the MAC for the TOB 14x received during the data collection period. See the Applicable Information Section below for more information on the concept of final paid claims.

You use the same 3 steps (as discussed earlier) to decide whether a hospital outreach laboratory (that bills Part B under the hospital's NPI) meets the majority of Medicare revenues threshold:

- First, sum the CLFS and PFS payment amounts the hospital outreach laboratory gets due to the TOB 14x during the data collection period. The sum of CLFS and PFS revenues is the numerator of the majority of Medicare revenues threshold equation.
- Next, sum the total Medicare revenues the hospital outreach laboratory gets under the TOB 14x during the data collection period. Total Medicare revenues include the sum of all FFS payments under Parts A and B, prescription drug payments under Part D, and any associated Medicare patient deductible or coinsurance for services you provided during the data collection period. The sum of total Medicare revenues is the denominator of the majority of Medicare revenues threshold equation. As noted previously, effective January 1, 2019, don't include Medicare Advantage plan payments under Part C in the total Medicare revenues component of the majority of Medicare revenues threshold calculation.
- Finally, divide the sum of CLFS and PFS revenues by the sum of total Medicare revenues you got during the data collection period. We provide more information on the data collection period below.

If the Medicare revenues you got from the CLFS and or PFS are greater than 50% of the total Medicare revenues you got during the data collection period, you meet the majority of Medicare revenues threshold.

For hospital outreach laboratories that bill Part B under the hospital's NPI, the majority of Medicare revenues threshold equation is:

If:

$$\frac{\text{Medicare CLFS revenues (based on 14x TOB) + Medicare PFS revenues (based on 14x TOB)}}{\text{Total Medicare revenues (based on 14x TOB)}} \text{ is } >50\%$$

Then: The laboratory meets the majority of Medicare revenues threshold.

NOTE: Hospital outreach laboratories that bill Part B under the hospital's NPI, and decide applicable laboratory status based on its Medicare revenues from TOB 14x, will most likely meet the majority of Medicare revenues threshold. This is 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, a hospital outreach laboratory that bills Part B under the hospital's NPI must also meet the low expenditure threshold requirement. A CLIA-certified hospital outreach laboratory meets the low expenditure threshold if, by the Form CMS-1450 TOB 14x, it gets 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 hospital outreach laboratory must look to its final Medicare paid claims it gets from its MAC under the TOB 14x during the data collection period.

To decide whether the hospital outreach laboratory that bills Part B under the hospital's NPI meets the low expenditure threshold, sum all final payments attributed to the TOB 14x it got from Medicare CLFS services during the data collection period.

It's important to note that the low expenditure threshold applies only to CLFS services. It doesn't include revenues you get under the PFS.

These are examples on how the majority of Medicare revenues threshold and low expenditure threshold apply to the CLIA-certified hospital outreach laboratory using the Form CMS-1450 TOB 14x for purposes of deciding whether the hospital outreach laboratory is an applicable laboratory:

Example 1: A CLIA-certified hospital outreach laboratory that performs laboratory services for non-hospital patients bills Part B using the same NPI as the hospital. In other words, laboratory services you performed for non-hospital patients are billed on the TOB 14x using the hospital's NPI. In this example, apply the majority of Medicare revenues threshold and low expenditure threshold to the hospital outreach laboratory's Medicare revenues it got from the TOB 14x.

Example 2: A CLIA-certified hospital outreach laboratory that performs laboratory services for non-hospital patients has its own unique NPI separate from the hospital's NPI but doesn't use it to bill Part B. Instead, the hospital outreach laboratory continues to bill Medicare Part B for laboratory tests it provides to non-hospital patients using the hospital's NPI. In this example, apply the majority of Medicare revenues threshold and low expenditure threshold to Medicare revenues you got from the TOB 14x. Since you bill laboratory services performed for non-hospital patients using the hospital's NPI (and not the hospital outreach laboratory's own unique billing NPI), apply the majority of Medicare revenues threshold and low expenditure threshold to the hospital outreach laboratory's Medicare revenues it got from the TOB 14x.

Example 3: A hospital includes 3 CLIA-certified hospital outreach laboratories that perform laboratory services for non-hospital patients. Each CLIA-certified hospital outreach laboratory bills Part B under the hospital's NPI. In this example, apply the majority of Medicare revenues threshold and low expenditure threshold based on the combined revenues attributed to the 14x TOB of all CLIA-certified hospital outreach laboratories of the hospital.

In summary, you must collect and report applicable information (as discussed in the next section) from all applicable laboratories during the data collection period and reported by reporting entities to us during the data reporting period. We use the applicable information you report to establish payment rates under the CLFS. All CLIA-certified laboratories (both applicable laboratories and laboratories that aren't applicable laboratories) are subject to the Part B private payor rate-based CLFS.

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 us.

Applicable information includes 3 major components:

- The specific HCPCS code associated with the test
- The private payor rate for each test for which final payment has been made during the data collection period
- The associated volume for each test

Private Payor Defined

The definition of the term "private payor" is 1 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 Social Security Act](#) (the Act)
- A Medicaid Managed Care Organization (MCO) (as defined in [Section 1903\(m\) of the Act](#))

Note: Applicable information doesn't include information on tests for which we make payment on a capitated basis, where payments don't reflect specific HCPCS code-level amounts. (See below for more information on payments made on a capitated basis.) So, we consider private payor rates from Medicaid MCO plans applicable information only to the extent that you can identify an individual HCPCS code for the test, private payor rate specific to the test, and the volume paid at the specific rate for the test.

We include these specific private payor claims data as applicable information:

- **Laboratory tests subject to the data collection and reporting requirements.** 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. There's a [list of laboratory tests](#) subject to the data collection and data reporting requirements. At that site, select: [CLFS Applicable Information HCPCS Codes \[ZIP, 57KB\]](#).
- **Final amount paid by a private payor for laboratory tests after applying all private payor price concessions.** A final paid claim is the final amount a private payor paid 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 payment is the private payor rate for purposes of deciding applicable information. For example, if an initial claim was paid in error 3 months before a data collection period and then the initial claim is corrected, with final payment made by the private payor during the data collection period, consider the final corrected payment amount for the test as the private payor rate for purposes of deciding 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 isn't a private payor rate for purposes of applicable information and you don't report it to us.

- **Payments from secondary insurance payors.** We consider final payments from secondary insurance payors in calculating private payor rates if the final payment was made during the data collection period. The private payor rate is 100% of the primary private payor's fee schedule amount which includes the final amount the primary private payor paid for the test, any patient cost sharing responsibilities the primary private payor requires (such as patient deductible and coinsurance amounts) and any payments gotten from a secondary insurer (if applicable). The important concept here is the reporting entity reports 100% of the primary private payors' fee schedule amount for the laboratory test. Don't report payments you get from secondary insurers separately.
- **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 the private payor requires (for instance, patient deductible and, or coinsurance amounts). As noted above, the private payor rate is 100% of the private payor's fee schedule amount for the test.
- **Multiple payment rates for the same test.** If an applicable laboratory gets more than 1 payment rate from the same private payor for the same test or more than 1 payment rate from different private payors for the same test, include each unique payment rate along with the associated volume for the test code at each such rate as applicable information.
- **Appeals resolved during the data collection period.** Include payment rates (and the associated volume of tests) for claims under appeal as applicable information if the private payor decides and pays the final payment amount during the data collection period. For example, if a laboratory filed an appeal for a test it provided prior to a data collection period and resolved the appeal so that it made final payment for the test during the data collection period, consider the final rate paid as applicable information.
- **Non-contracted amounts for out-of-network laboratories or services.** Applicable information includes private payor rates for out-of-network laboratories if the private payor made final payment for the laboratory test 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).

Exclude these specific private payor claims data from applicable information:

- **Private payor rates for laboratory test codes paid only under the PFS.** If payment for a laboratory test code isn't 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 isn't applicable information.
- **Price concessions applied by a laboratory.** Don't factor a laboratory's decision to waive a patient's deductible, copay, and, or coinsurance responsibility for a given test(s) into the determination of the private payor rate for a test. Although laboratories may provide concessions to patients, it doesn't reflect the rates paid by private payors. As noted above, the private payor rate is 100% 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, don't consider payments of \$0.00 a private payor rate for purposes of deciding applicable information under the new CLFS. Report only the final paid claim amount and the associated volume of tests paid at the final paid claim amount.
- **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 already paid isn't considered a final payment rate and so isn't considered applicable information. If the appeal was settled during the data collection period but the private payor didn't make final payment until after the data collection period, the payment amount can't be used for a private payor rate and so is excluded from 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 patient in the plan for a given period, regardless of whether the patient gets services during the period covered by the payment. Payment is typically made on a capitated basis under a managed care arrangement. As there's no way to decide payment specifically for a given test, don't report it as applicable information.
- **Payments where you can't decide the associated test volume.** 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 can't be discerned by a laboratory from the private payor's remittance, we don't consider those payment amounts as applicable information. Don't report them to us.
- **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 isn't represented by another HCPCS code, those payments aren't applicable information.

Note: In general, if a laboratory can't correlate a private payor payment amount and the associated volume paid at that rate to a specific HCPCS code, that amount isn't a private payor rate for purposes of applicable information. Estimated private payor rates and volumes aren't considered applicable information.

Schedule for Data Collection & Reporting

The next data collection period (the period where applicable information for an applicable laboratory is obtained from claims for which the laboratory got final payment during the period) is from January 1, 2019-June 30, 2019. Typically, there's a 6-month review and validation period.

During the review and validation period between the end of the data collection period and the beginning of the data reporting period, you should assess whether you met the applicable laboratory thresholds. In other words, decide whether each laboratory component of the reporting entity meets the majority of Medicare revenues threshold and low expenditure threshold from final Medicare paid claims they got during the data collection period. Applicable laboratories and their reporting entity should also use this time to review and validate applicable information (private payor data) before reporting it to us.

Section 105 (a) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116-94, enacted December 19, 2019) and section 3718 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Pub. L. 116-136, enacted March 27, 2020) made several revisions to the next data reporting period for CDLTs that aren't ADLTs and the phase-in of payment reductions under the Medicare private payor rate-based CLFS.

On December 10, 2021, the "Protecting Medicare and American Farmers from Sequester Cuts Act" (S. 610) further delayed the reporting requirement under Section 1834A of the Act and also delayed the application of the 15% phase-in reduction. In summary, the revisions are:

- The next data reporting period of January 1, 2023-March 31, 2023, will be based on the original data collection period of January 1, 2019-June 30, 2019. After the next data reporting period, there's a 3-year data reporting cycle for CDLTs that aren't ADLTs (2026, 2029, and so on).
- The statutory phase-in of payment reductions resulting from private payor rate implementation is extended through CY 2024. There's a 0.0 percent reduction for CY 2021 and 2022, and payment may not be reduced by more than 15% for CYs 2023 through 2025.

Table 1 shows the next data collection and reporting periods for CDLTs.

Table 1: Data Collection and Reporting Periods for CDLTs

Data Collection Period	Six-Month Review and Validation Period	Data Reporting Period	Used for CLFS Rate Years
1/1/2019-6/30/2019	7/1/2019-12/31/2019	1/1/2023-3/31/2023	2024-2026
1/1/2025-6/30/2025	7/1/2025-7/31/2025	1/1/2026-3/31/2026	2027-2029
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 we require reporting every 3 years for CDLTs (that aren't 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). We have issued more information about ADLTs through separate instructions.

Online Data Collection System

We developed an online data collection system to help laboratories submit data to CMS. Data is due by March 31, 2023. Review the [detailed user guide](#) on how to access and use this system.

You must appoint both a CLFS submitter and CLFS certifier in the data collection system. These must be 2 different individuals.

A [data collection template](#) is available for your use. Laboratories looking to upload their data to the CLFS data collection system should use this template.

Tips for Smooth Data Submissions:

- Follow the formatting guidelines in the user guide and on the data collection template. The CLFS data collection system will find formatting errors in your file before you're able to certify the data and submit it. For large volumes of data, this process may take several hours to confirm. Files with fewer formatting errors will process more efficiently.
- Use the available [CLFS Applicable Information HCPCS Codes file](#). The system will only accept HCPCS codes listed on this file.
- The cleaner the file, the smoother the upload process.

Important information for large laboratories: If your laboratory expects to submit over 100,000 lines of data in the .csv template, first contact the CMS/CLFS helpdesk at clfshelpdesk@dcca.com.

Reporting Entity

The TIN-level entity reports applicable information individually for all its laboratory components that are applicable laboratories. As noted above, an applicable laboratory is a CLIA-certified laboratory and, using its billing NPI or the 14x TOB (in the case of a hospital outreach laboratory that bills Part B under the hospital's NPI), meets the majority of Medicare revenues threshold and low expenditure threshold. Note that we discuss a condensed data reporting option later in this section.

I. Reporting for an Applicable Laboratory That Bills Medicare Part B Under its Own NPI

This section provides examples of reporting entities reporting applicable information for independent laboratories and physician office laboratories that bill Part B under their own NPI and hospital outreach laboratories that bill Part B under their own NPI (separate from the hospital's NPI). The examples below show 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 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 consists of 5 unique applicable laboratories. In this case, the reporting entity reports applicable information associated with each individual NPI that's 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 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 don't individually meet the low expenditure threshold. In other words, 2 of the 5 CLIA-certified laboratories get less than \$12,500 of revenue under the CLFS during the data collection period. This TIN-level entity consists of 3 unique applicable laboratories. In this case, the reporting entity will report applicable information associated with each individual NPI that's an applicable laboratory, but won't report information on the 2 individual NPIs of the laboratories that aren't applicable laboratories. The reporting entity separates the applicable information by each NPI and submits 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 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 consists of 1 applicable laboratory. In this case, the reporting entity reports applicable information for all laboratories associated with the same NPI as a single applicable laboratory. In this example, we consider the 5 CLIA-certified laboratories as 1 applicable laboratory for purposes of reporting applicable information because they all have the same NPI and all bill Part B under the same NPI.

Example 4: A TIN-level entity includes 3 CLIA-certified hospital outreach laboratories. Each hospital outreach laboratory bills using its own unique NPI (separate from the hospital's NPI) and all 3 CLIA-certified hospital outreach laboratories individually meet both the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of 3 applicable laboratories. In this case, the reporting entity reports applicable information associated with each individual NPI that's 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 3 applicable laboratories.

Example 5: A TIN-level entity consists of 3 CLIA-certified hospital outreach laboratories, each billing for services under its own unique NPI (separate from the hospital's NPI). However, only 2 of the laboratories individually meet both the majority of Medicare revenues threshold **and** low expenditure threshold while the remaining laboratory doesn't individually meet the low expenditure threshold. In other words, 1 of the 3 CLIA-certified hospital outreach laboratories gets less than \$12,500 in revenues from the CLFS during the data collection period. This TIN-level entity consists of 2 applicable laboratories. In this case, the reporting entity will report applicable information associated with each individual NPI that's an applicable laboratory, but won't report information on the 1 individual NPI of the laboratory that isn't an applicable laboratory. The reporting entity separates the applicable information by each NPI and submits applicable information during the data reporting period for 2 applicable laboratories.

Example 6: A TIN-level entity includes 3 CLIA-certified hospital outreach laboratories and all 3 laboratories have the same unique NPI and bill Part B under the same unique NPI (separate from the hospital's NPI). Collectively, the 3 CLIA-certified hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of 1 applicable laboratory. In this case, the reporting entity reports applicable information for all 3 hospital outreach laboratories associated with the same NPI as a single applicable laboratory. In this example, we consider the 3 CLIA-certified hospital outreach laboratories as 1 applicable laboratory for purposes of reporting applicable information because they all have the same NPI (separate from the hospital's NPI) and all bill Medicare Part B under the same NPI.

Note: For a hospital outreach laboratory that bills Part B under its own unique billing NPI (separate from the hospital's NPI), the reporting entity reports applicable information by the hospital outreach laboratory's own unique billing NPI.

II. Reporting for Hospital Outreach Laboratories that Bill Medicare Part B Under the Hospital's NPI

This section provides examples of reporting entities reporting applicable information for hospital outreach laboratories that bill Part B under the hospital's NPI. The examples below show reporting entities that must report applicable information for hospital outreach laboratories that bill Part B under the hospital's NPI that are applicable laboratories:

Example 1: A TIN-level entity includes a CLIA-certified hospital outreach laboratory that performs laboratory services for non-hospital patients and bills Part B using the hospital's NPI. Based on its Medicare revenues attributed to the Form CMS-1450 14x TOB, the hospital outreach laboratory meets the majority of Medicare revenues threshold and low expenditure threshold and so is an applicable laboratory. In this example, the reporting entity reports applicable information for its hospital outreach laboratory that bills Part B under the hospital's NPI.

Example 2: A TIN-level entity consists of 3 CLIA-certified hospital outreach laboratories and each laboratory bills Part B under the hospital's NPI. Collectively, the 3 CLIA-certified hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of 1 applicable laboratory. In this example, the reporting entity collectively reports applicable information for its 3 hospital outreach laboratories that bill Part B under the hospital's NPI.

Example 3: A TIN-level entity includes 3 CLIA-certified hospital outreach laboratories. Two (of the 3) hospital outreach laboratories bill for laboratory services performed for non-hospital patients using the hospital's NPI. Collectively, the 2 CLIA-certified hospital outreach laboratories that bill using the hospital's NPI meet the majority of Medicare revenues threshold and low expenditure threshold. However, 1 (out of the 3) bills Part B for laboratory services performed for non-hospital patients using its own unique NPI (separate from the hospital's NPI) and meets the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of 2 applicable laboratories. In this example, the reporting entity reports applicable information for the hospital outreach laboratories that bill Part B for non-hospital patients under the hospital's NPI separately from the hospital outreach laboratory that bills Part B under its own unique NPI.

Note: You must **report** applicable information for hospital outreach laboratories that are applicable laboratories based on the NPI used for billing Part B. For hospital outreach laboratories that bill Medicare Part B under the hospital's NPI, (and so decides applicable laboratory status based on its Medicare revenues attributed to the 14x TOB) the reporting entity **reports** applicable information by the **hospital's NPI**.

Only Applicable Information Attributed to non-Hospital Patients is Reported

As discussed previously in this Article, a CLIA-certified hospital outreach laboratory that bills Part B using the hospital's NPI must decide whether it meets the majority of Medicare revenues threshold and low expenditure threshold based on its Medicare revenues attributed to the Form CMS-1450 14x TOB. If a CLIA-certified hospital outreach laboratory that bills Part B under the hospital's NPI meets the requirements of an applicable laboratory, only the hospital outreach laboratory component of the hospital laboratory (laboratory tests provided to non-hospital patients) is considered an applicable laboratory. So, report only applicable information attributed to the laboratory's non-hospital patients to us.

The reporting entity for the hospital outreach laboratory that bills Part B under the hospital's NPI, and finds applicable laboratory status based on Medicare revenues attributed to the 14x TOB, may **not** report applicable information for other parts of a hospital's laboratory business such as testing performed for hospital outpatients or hospital inpatients.

III. Additional Reporting Instructions That Apply to All Applicable Laboratories

This section provides additional reporting instructions for reporting entities reporting applicable information for its component applicable laboratory(s).

Reporting Entity Must Ensure Accurate Collection and Reporting of Applicable Information

The TIN-level entity along with its applicable laboratory(s) should establish their own approach for making sure the TIN-level entity can report applicable information. To that end, applicable laboratories and their reporting entity should decide the best approach to collect applicable information from final paid claims data and for submitting applicable information to us during the data reporting period.

Voluntary Reporting isn't Permitted

The reporting entity reports only applicable information for laboratory components that are applicable laboratories (laboratories that meet the definition of an applicable laboratory). Don't report applicable information for laboratories that don't meet the definition of an applicable laboratory.

Example 1: 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 doesn't. In this example, the reporting entity reports applicable information for **only** the 3 NPI-level entities that are applicable laboratories.

Example 2: A TIN-level entity includes 1 hospital outreach laboratory that bills Part B under the hospital's NPI. Based on revenues attributed to the Form CMS-1450 14x TOB, the hospital outreach laboratory meets the majority of Medicare revenues threshold but doesn't meet the low expenditure threshold. The hospital outreach laboratory doesn't get at least \$12,500 in revenues from the Medicare CLFS during the data collection period. So, the hospital outreach laboratory doesn't meet the definition of an applicable laboratory. Don't report applicable information to CMS for the hospital outreach laboratory.

Reporting Applicable Information isn't Discretionary

Reporting entities must report all applicable information for its laboratory components that are applicable laboratories. You don't 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 this case, the reporting entity **can’t** selectively omit reporting applicable information due to the perception that reporting such applicable information won’t influence the final weighted median private payor rates for a given test. In this example, you must report the applicable information obtained from the “paper-based” claims to us during the data reporting period.

IV. Condensed Data Reporting Option

For the next data reporting period, **January 1, 2023-March 31, 2023** (previously January 1, 2020-March 31, 2020), reporting entities may condense certain applicable information at the TIN-level, instead of reporting individually for each component that’s an applicable laboratory. You may use the condensed data reporting option when more than 1 applicable laboratory under the TIN is paid at the same private payor rate for a specific HCPCS code.

For example, if 3 of the reporting entity’s corresponding applicable laboratories get the same private payor rate for a specific HCPCS code, the reporting entity may report 1 record of data showing the HCPCS code, the payment rate, and the associated volume, across the 3 applicable laboratories, rather than reporting 3 separate records. In other words, the reporting entity may combine the volume paid at the same private payor rate for the same HCPCS code for its component applicable laboratories.

Under the condensed data reporting option, the reporting entity must select 1 NPI as the reporting NPI. That means, the reporting entity will designate 1 applicable laboratory’s NPI as the reporting NPI for each instance of condensed reporting. The reporting entity can select any NPI under the TIN that meets the definition of an applicable laboratory and designate that NPI as the reporting NPI for reporting the condensed applicable information.

Note you must report each unique private payor rate for each laboratory test code to us during the data reporting period. You may only use the condensed data reporting option when a specific laboratory test code is paid at the same private payor rate to more than 1 applicable laboratory under the same TIN. Unique private payor rates paid to only 1 applicable laboratory under the TIN, and the volume paid at such rate(s), must be reported individually by applicable laboratory.

Reporting entities have the option of condensing the volume paid at the same private payor rate for a specific HCPCS code during a data collection period across its components that are applicable laboratories. However, if the reporting entity prefers to report applicable information individually for each of its component applicable laboratories, they may continue to do so.

To show how reporting entities may report condensed applicable information when 3 different applicable laboratories under the same TIN get the same private payor rate for the same laboratory test code during a data collection period, see the comparative examples below in Tables 2a and 2b. These examples are meant to show the difference between the individual applicable laboratory data reporting method, by each component that's an applicable laboratory, and the condensed data reporting method and aren't intended to be representative of every possible scenario.

TABLE 2a: Example of Individual Applicable Laboratory Reporting for 2023 Data Submission

NPI	HCPCS Code	Payment Rate	Volume
1	Lab Test Code (1)	\$15.00	400
2	Lab Test Code (1)	\$15.00	300
3	Lab Test Code (1)	\$15.00	200

In this example of the individual applicable laboratory data reporting method, 3 applicable laboratories are paid the same private payor rate for "Lab Test Code 1". So, the reporting entity reports applicable information individually for each of its component applicable laboratories.

TABLE 2b- Example of Condensed Reporting for 2023 Data Submission (TIN-Level)

Reporting NPI	HCPCS Code	Payment Rate	Volume
Designated NPI for Condensed Reporting	Lab Test Code (1)	\$15.00	900

This example shows how the scenario presented in Table 2a would be reported under the condensed data reporting method. The reporting entity reports applicable information by combining the volume paid at the same private payor rate for the same HCPCS code at the reporting entity level (TIN-Level). The reporting entity designates 1 (of its 3 component applicable laboratories) as the reporting NPI.

TABLE 3a: Example of Individual Applicable Laboratory Reporting for 2023 Data Submission

NPI	HCPCS Code	Payment Rate	Volume
1	Lab Test Code (1)	\$15.00	400
1	Lab Test Code (1)	\$17.00	100
2	Lab Test Code (1)	\$15.00	300
2	Lab Test Code (1)	\$17.00	150
3	Lab Test Code (1)	\$15.00	200
3	Lab Test Code (1)	\$17.00	75

In this Table 3a example of the individual applicable laboratory data reporting method, 3 applicable laboratories are paid a private payor rate of \$15 for “Lab Test Code 1” and the same 3 applicable laboratories are also paid a private payor rate of \$17 for “Lab Test Code 1.” In this example, the reporting entity reports each HCPCS code and each unique private payor rate and the volume paid at each unique private payor rate individually for each of its component applicable laboratories.

TABLE 3b- Example of Condensed Reporting for 2023 Data Submission (TIN-Level)

Reporting NPI	HCPCS Code	Payment Rate	Volume
Designated NPI for Condensed Reporting	Lab Test Code (1)	\$15.00	900
Designated NPI for Condensed Reporting	Lab Test Code (1)	\$17.00	325

This Table 3b example shows how the scenario presented in Table 3a would be reported under the condensed data reporting method. The reporting entity reports applicable information by combining the volume paid at the same private payor rate for the same HCPCS code at the reporting entity level (TIN-Level). The private payor rate of \$15 and associated volume is combined, and the private payor rate of \$17.00 and associated volume is combined.

TABLE 4a – Example of Individual Applicable Laboratory Reporting for 2023 Data Submission

NPI	HCPCS Code	Payment Rate	Volume
1	Lab Test Code (1)	\$15.00	400
1	Lab Test Code (1)	\$17.00	100
1	Lab Test Code (1)	\$18.50	50
2	Lab Test Code (1)	\$15.00	300
2	Lab Test Code (1)	\$17.00	150
2	Lab Test Code (1)	\$19.50	40
3	Lab Test Code (1)	\$15.00	200
3	Lab Test Code (1)	\$17.00	75
3	Lab Test Code (1)	\$20.00	30

In this Table 4a example of the individual applicable laboratory data reporting method, 3 applicable laboratories are paid a private payor rate of \$15 for “Lab Test Code 1” and the same 3 applicable laboratories are also paid a private payor rate of \$17 for “Lab Test Code 1”. Also, 1 of the 3 applicable laboratories is paid a private payor rate of \$18.50, another applicable laboratory is paid a private payor rate of \$19.50, and another applicable laboratory is paid a private payor rate of \$20 for “Lab Test Code 1”. The reporting entity reports the HCPCS

code and each unique private payor rate and the volume paid at each unique private payor rate individually for each of its component applicable laboratories.

TABLE 4b- Example of Condensed Reporting for 2023 Data Submission (TIN-Level)

Reporting NPI	HCPCS Code	Payment Rate	Volume
Designated NPI for Condensed Reporting	Lab Test Code (1)	\$15.00	900
1 Designated NPI for Condensed Reporting	Lab Test Code (1)	\$17.00	325
1	Lab Test Code (1)	\$18.50	50
2	Lab Test Code (1)	\$19.50	40
3	Lab Test Code (1)	\$20.00	30

This Table 4b example shows how the scenario presented in Table 4a would be reported under the condensed data reporting method. As discussed previously, the reporting entity must report each unique private payor rate for each specific HCPCS code, and the associated volume paid at each such rate. Since some private payor rates are paid to only 1 applicable laboratory under the TIN, a combination of the condensed data reporting method and individual applicable laboratory reporting is used to report applicable information.

The condensed data reporting method may be used when more than 1 applicable laboratory under the TIN is paid the same private payor rate for a specific laboratory test code. In this example, the volume among the 3 applicable laboratories for the private payor rate of \$15.00 may be combined and the volume among the 3 applicable laboratories for the private payor rate of \$17.00 may be combined.

However, condensed reporting **wouldn't** be permitted for the unique private payor rates for "Lab Test Code 1" that are paid to only 1 applicable laboratory under the same TIN. So, the private payor rate of \$18.50 paid to "NPI 1"; the private payor rate of \$19.50 paid to "NPI 2"; the private payor rate of \$20.00 paid to "NPI 3" and the associated volume paid at each of these unique private payor rates must be reported individually for each applicable laboratory.

Implementation Schedule

This is the schedule for implementing the next private payor rate-based CLFS update:

- Data collection period for deciding CY 2024 CLFS payment rates: January 1, 2019-June 30, 2019
- Data reporting period for reporting entities to report private payor rate data to CMS for deciding CY 2024 CLFS payment rates: January 1, 2023-March 31, 2023

- Annual laboratory public meeting for new tests: June/July 2022. We'll use crosswalking or gapfilling to set rates for new tests and existing tests for which there's no private payor data collected for the CY 2024 CLFS
- We'll publish preliminary CLFS rates for CY 2024: Early September 2023. The public will have approximately 30 days, through early October 2023, to submit comments on the preliminary CY 2024 decisions
- We'll make final CY 2024 CLFS rates available on the CMS website: Early November 2023
- Implementation date for the next private payor rate-based CLFS update: January 1, 2024

More Information

See [more information](#) about the private payor rate-based payment system including a summary of the private payor rate-based CLFS, the CLFS final rule, related press release and fact sheet, frequently asked questions on our final policies, and a PowerPoint slide presentation of the private payor rate-based CLFS and ADLTs.

See the [CLFS final rule](#) entitled Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule (CMS-1621-F) and the [PFS final rule](#) entitled Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2019 (CMS-1693-F).

If you have questions about requirements for the private payor rate-based CLFS, send an email to the CLFS Inquiries mailbox at CLFS_Inquiries@cms.hhs.gov.

For more information, [find your MAC's website](#).

Document History

Date of Change	Description
March 24, 2022	We revised this Article to note that for CDLTs that aren't ADLTs, the data reporting is delayed by 1 year and must now be reported from January 1, 2023-March 31, 2023 (previously January 1, 2022-March 31, 2022). All references to the 2021 data reporting period have been changed to 2023. You'll find substantive content updates in dark red font (see pages 2,14,15 and 20-23). There are no other changes to the substance of the Article.

Date of Change	Description
November 4, 2021	We revised this Article to note that for CDLTs that are not ADLTs, the data reporting is delayed by one year and must now be reported from January 1, 2022 through March 31, 2022 (previously January 1, 2021 through March 31, 2021). All references to the 2021 data reporting period have been changed to 2022. In addition, we included information about the Online Data Collection System. You'll find substantive content updates in dark red font (see pages 2, 3,13-15 and 21-23). There are no other changes to the substance of the Article.
January 8, 2020	We revised this Article to note that for CDLTs that are not ADLTs, the data reporting is delayed by one year and must now be reported from January 1, 2021 through March 31, 2021 (previously January 1, 2020 through March 31, 2020). All references to the 2020 data reporting period have been changed to 2021. We added the "CLFS Data Reporting Period Delayed" Section on page 24 to summarize the changes. All other information remains the same.
September 5, 2019	We revised this Article to delete incorrect information in the section titled Only Applicable Information Attributed to non-Hospital Patients is Reported, which is on page 18. All other information remains the same.
February 27, 2019	Initial Article released

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