



Clinical Laboratory Fee Schedule: Reporting Private Payor Data



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Clinical Laboratory Fee Schedule

Section 216 of the [Protecting Access to Medicare Act of 2014](#) changed how Medicare pays for clinical diagnostic laboratory tests (CDLTs) under the Medicare Part B Clinical Laboratory Fee Schedule (CLFS). The [CLFS final rule](#) implemented changes that require reporting entities to report certain private payor rate information for their component applicable laboratories to us. We use this information to update the CLFS payment amounts.

In addition, the CLFS final rule established:

- The definitions for:
 - Applicable lab
 - Reporting entity
 - Applicable information
 - Advanced diagnostic laboratory tests (ADLTs)
- The private payor rate data collection and data reporting schedule requirements
- The condensed data reporting option for reporting entities

We revised the definition of applicable laboratory, including how to calculate the required thresholds, in the [CY 2019 Physician Fee Schedule \(PFS\) final rule](#).

Applicable Lab

A lab is applicable if it:

- Meets the Clinical Lab Improvement Amendments (CLIA) definition of a lab at [42 CFR 493.2](#)
- Bills Part B in 1 of these ways:
 - Under its own NPI
 - On the [UB-04 Uniform Bill \(CMS-1450\)](#) under type of bill (TOB) 14X if it's a hospital outreach lab

A hospital outreach lab is a hospital-based lab that provides lab tests to patients other than admitted hospital inpatients or registered outpatients.

- Meets the majority of Medicare revenues threshold, getting more than 50% of its total Medicare revenues from the CLFS, the PFS, or both in a data collection period
- Meets the low expenditure threshold, getting at least \$12.5K in Medicare revenues from the CLFS in a data collection period

If your lab doesn't meet these requirements, the lab isn't applicable, and you don't need to collect or report applicable information.

Determining Applicable Lab Status

STEP 1 | Is the Lab CLIA Certified?

CLIA applies to all labs testing human specimens for a health purpose. A lab must be CLIA certified to get Medicare payment.

Note: Per 42 CFR 493.2, we consider any facility with any CLIA certificate (including a CLIA certificate of waiver) to be a lab.

STEP 2 | Does the CLIA-Certified Lab Bill Part B Under Its Own NPI?

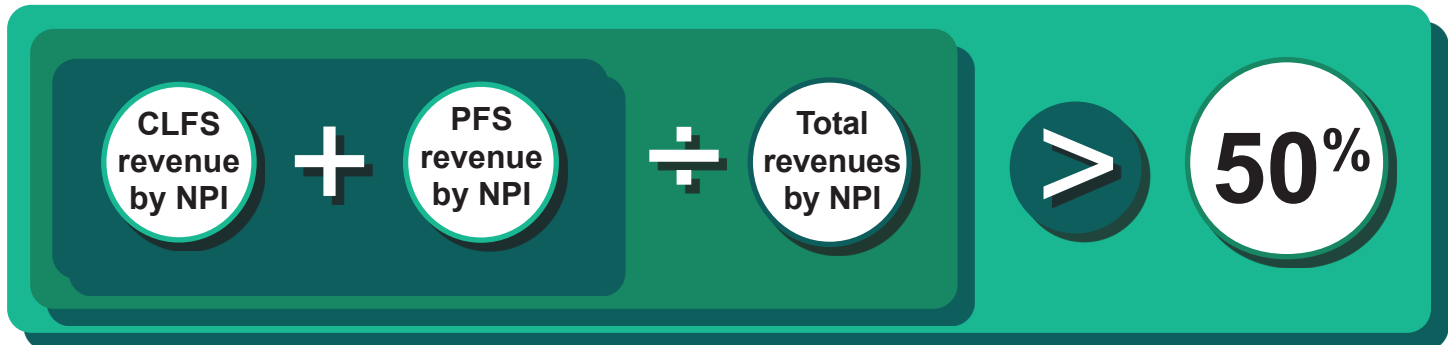
The NPI is the standard unique health identifier providers use for billing Medicare and other payors. Physician office labs can refer to [CLFS: PAMA Reporting FAQs](#) and the examples in this section for how to determine if your lab bills Part B under its own NPI.

STEP 3 | Does the Lab Meet the Majority of Medicare Revenues Threshold?

Labs meet the majority of Medicare revenues threshold by getting more than 50% of its total Medicare revenues from payments under the CLFS or PFS. This means when you add your revenue from the CLFS and PFS, it's more than 50% of your total Medicare revenues.

Use these formulas to calculate the majority of Medicare revenues threshold.

For labs that bill Part B under their own NPI:



1.

Add the CLFS and PFS payment amounts you got for your own billing NPI during the data collection period.

The revenues from the CLFS include payments for all lab services under the CLFS. The revenues from the PFS include all payments from all services paid under the PFS (for example, lab services and services that aren't lab services, such as pathology services, evaluation and management services, and radiology services). The sum of CLFS and PFS revenues is the numerator.

2.

Add the total Medicare revenues you got from your own NPI during the data collection period.

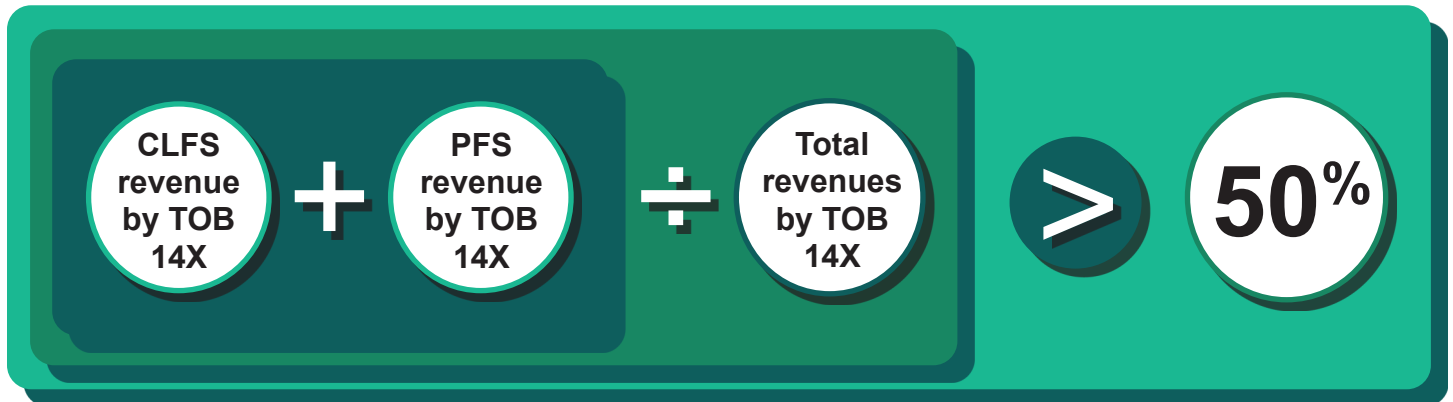
Total Medicare revenues include the sum of all Fee-for-Service payments under Medicare Part A and Part B, prescription drug payments under a Medicare drug plan (Part D), and any associated Medicare patient deductible or coinsurance for services you provided during the data collection period. The sum of total Medicare revenues is the denominator.

3.

Divide the sum of CLFS + PFS revenues by the total Medicare revenues you got during the data collection period.

Note: Don't include Medicare Advantage (MA) plan payments under Medicare Part C in the total Medicare revenues.

For hospital outreach labs that bill Part B under the hospital's NPI:



A hospital outreach lab that bills Part B under the hospital's NPI determines whether it meets the majority of Medicare revenues threshold based on revenues it gets from the CMS-1450 TOB 14X. The majority of Medicare revenues threshold only applies to the hospital outreach lab portion of the hospital's NPI, rather than to the NPI of the entire hospital.

Hospital outreach labs that bill Part B under the hospital's NPI will most likely meet the majority of Medicare revenues threshold because their Medicare revenues from TOB 14X are primarily, if not entirely, derived from the CLFS and PFS.

STEP

4

Does the Lab Meet the Low Expenditure Threshold?

Labs meet the low expenditure threshold by getting at least \$12.5K in Medicare revenues from the CLFS (under Part B) during the data collection period.

To determine this, add all revenues you got by your own NPI (or TOB 14X if you're a hospital outreach lab) for CLFS services during the data collection period.

Note: The low expenditure threshold applies only to **CLFS services**. It doesn't include revenues you get under the PFS.

For more information, refer to our quick reference guides for determining applicable status:

- [Physician Office Laboratory](#)
- [Independent Laboratory](#)
- [Hospital Outreach Laboratory](#)

Determining Applicable Lab Status Examples

For labs that bill under their own NPI:

- 1** **Example 1:** A lab organization includes 5 CLIA-certified labs. Each lab has its own NPI and bills Medicare (and other payors) for lab tests separately under each NPI. In this example, we apply the majority of Medicare revenues threshold and low expenditure threshold to each NPI to individually determine whether the lab meets both thresholds. Even if all 5 labs are under the same Taxpayer Identification Number (TIN), we treat each as a separate lab when determining an applicable lab because each bills Part B for lab tests using its own NPI.
- 2** **Example 2:** A lab organization includes 5 CLIA-certified labs. Each CLIA-certified lab has the same NPI and bills for lab tests under the same NPI. In this example, we apply the majority of Medicare revenues threshold and low expenditure threshold based on the combined revenues of all CLIA-certified labs in the organization that use the same billing NPI. In applying the applicable lab thresholds, we consider all 5 CLIA-certified labs in the lab organization to be a single lab because they all bill Part B using the same NPI.
- 3** **Example 3:** A lab organization includes 5 CLIA-certified labs. Each lab has its own NPI, but the organization bills all lab tests under 1 lab's NPI. In this example, we apply the majority of Medicare revenues threshold and low expenditure threshold to the 1 NPI used for billing.
- 4** **Example 4:** An entity has 5 physician offices and 1 CLIA-certified lab. They bill under the same NPI. In this example, we apply the majority of Medicare revenues threshold and low expenditure threshold using the combined revenues billed under that NPI. Because all components bill under the same NPI, we treat the entity as a single lab when applying each threshold.
- 5** **Example 5:** An entity has 5 physician offices and 1 CLIA-certified lab. Each component has a different NPI. The lab bills for lab tests under its own NPI. In this example, we apply the majority of Medicare revenues threshold and low expenditure threshold only to the CLIA-certified lab's billing NPI.
- 6** **Example 6:** A CLIA-certified hospital outreach lab that performs lab services for non-hospital patients has its own NPI separate from the hospital's NPI. The hospital outreach lab bills Part B for lab tests it provides to non-hospital patients using its NPI. In this example, we apply the majority of Medicare revenues threshold and low expenditure threshold to the hospital outreach lab's NPI and not the hospital's NPI.
- 7** **Example 7:** A hospital has 3 CLIA-certified hospital outreach labs that perform lab services for non-hospital patients. All 3 labs bill Part B under the same NPI (separate from the hospital's NPI). In this example, we apply the majority of Medicare revenues threshold and low expenditure threshold based on the combined revenues of all 3 CLIA-certified hospital outreach labs billing under that NPI. We treat the 3 outreach labs as a single lab.

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Example 8: A hospital has 3 CLIA-certified hospital outreach labs. Each has its own NPI (separate from the hospital's NPI), but all 3 use only 1 outreach lab's NPI for billing all lab tests. In this example, we apply the majority of Medicare revenues threshold and low expenditure threshold to the 1 NPI used for billing.

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Example 9: A hospital includes 3 CLIA-certified hospital outreach labs.

- 1 of the CLIA-certified hospital outreach labs has its own NPI separate from the hospital's NPI and bills Part B for lab services performed for non-hospital patients using its NPI. We apply the majority of Medicare revenues threshold and low expenditure threshold to the hospital outreach lab's NPI and not the hospital's NPI.
- 2 of the CLIA-certified hospital outreach labs bill for lab services performed for non-hospital patients under the hospital's NPI using the CMS-1450 TOB 14X. We apply the majority of Medicare revenues threshold and low expenditure threshold based on the combined revenues attributed to the TOB 14X for both outreach labs.

For hospital outreach labs that bill Part B under the hospital's NPI:

1

Example 1: A CLIA-certified hospital outreach lab provides lab services to non-hospital patients and bills Part B under the hospital's NPI using the CMS-1450 TOB 14X. In this example, we apply the majority of Medicare revenues threshold and low expenditure threshold to the hospital outreach lab's Medicare revenues from TOB 14X.

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Example 2: A CLIA-certified hospital outreach lab that provides lab services to non-hospital patients has its own NPI separate from the hospital's NPI but bills Part B under the hospital's NPI. In this example, we apply the majority of Medicare revenues threshold and low expenditure threshold to the outreach lab's Medicare revenues from TOB 14X (because the lab services are billed under the hospital's NPI).

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Example 3: A hospital has 3 CLIA-certified hospital outreach labs that provide lab services to non-hospital patients. All 3 labs bill Part B under the hospital's NPI. In this example, we apply the majority of Medicare revenues threshold and low expenditure threshold using the combined revenues attributed to the TOB 14X for all 3 outreach labs.

Reporting Entity

The reporting entity reports tax-related information to the Internal Revenue Service using its TIN for applicable laboratories. The TIN-level entity and its applicable labs should establish their own approach to ensure the entity can report applicable information to us. Applicable labs and their reporting entity should determine the best approach to collect applicable information from final paid claims data and submit it to us during the data reporting period.

Reporting Examples for an Applicable Lab That Bills Part B Under Its Own NPI

These examples illustrate reporting entities that must report applicable information individually for all NPI-level components that are applicable labs.

- 1** **Example 1:** A TIN-level entity has 5 CLIA-certified labs, each billing under its own NPI. All 5 labs individually meet both the majority of Medicare revenues threshold and low expenditure threshold, so each is an applicable lab. In this case, the reporting entity reports applicable information separately for each NPI during the data reporting period.
- 2** **Example 2:** A TIN-level entity has 5 CLIA-certified labs, each billing for services under its own NPI. Only 3 labs individually meet both the majority of Medicare revenues threshold and low expenditure threshold, while the other 2 labs don't individually meet the low expenditure threshold because they get less than \$12.5K of revenue under the CLFS during the data collection period. This TIN-level entity consists of 3 unique applicable labs. In this case, the reporting entity reports applicable information separately for each applicable lab and doesn't report information on the 2 labs that aren't applicable labs.
- 3** **Example 3:** A TIN-level entity has 5 CLIA-certified labs, and each lab bills Part B under the same NPI. Collectively, the 5 labs meet the majority of Medicare revenues threshold and low expenditure threshold, so the entity has 1 applicable lab. In this case, the reporting entity reports applicable information for all 5 labs as a single applicable lab under that NPI.
- 4** **Example 4:** A TIN-level entity has 3 CLIA-certified hospital outreach labs, each billing Part B under its own NPI (separate from the hospital's NPI). All 3 labs individually meet both the majority of Medicare revenues threshold and low expenditure threshold, so each is an applicable lab. In this case, the reporting entity reports applicable information separately for each lab's NPI during the data reporting period.
- 5** **Example 5:** A TIN-level entity has 3 CLIA-certified hospital outreach labs, each billing for services under its own NPI (separate from the hospital's NPI). Only 2 labs individually meet both the majority of Medicare revenues threshold and low expenditure threshold, while the remaining lab doesn't meet the threshold because it doesn't get at least \$12.5K in revenues from the CLFS during the data collection period. This entity has 2 applicable labs. In this case, the reporting entity reports applicable information separately for each applicable lab's NPI and doesn't report information on the lab that isn't an applicable lab.
- 6** **Example 6:** A TIN-level entity includes 3 CLIA-certified hospital outreach labs, each billing Part B under the same NPI (separate from the hospital's NPI). Collectively, the 3 labs meet the majority of Medicare revenues threshold and low expenditure threshold, so the entity has 1 applicable lab. In this case, the reporting entity reports applicable information for all 3 outreach labs associated as a single applicable lab under the outreach labs' NPI.

Reporting Examples for Hospital Outreach Labs That Bill Part B Under the Hospital's NPI

These examples illustrate reporting entities reporting applicable information for hospital outreach labs that are applicable labs and bill Part B under the hospital's NPI.

- 1** **Example 1:** A TIN-level entity has a CLIA-certified hospital outreach lab that provides lab services to non-hospital patients and bills Part B using the hospital's NPI. Based on its Medicare revenues attributed to the CMS-1450 TOB 14X, the hospital outreach lab meets the majority of Medicare revenues threshold and low expenditure threshold and is an applicable lab. In this example, the reporting entity reports applicable information for this lab under the hospital's NPI.
- 2** **Example 2:** A TIN-level entity has 3 CLIA-certified hospital outreach labs, and each lab bills Part B under the hospital's NPI. Collectively, the 3 CLIA-certified hospital outreach labs meet the majority of Medicare revenues threshold and low expenditure threshold, so the entity consists of 1 applicable lab. In this example, the reporting entity collectively reports applicable information for all 3 hospital outreach labs under the hospital's NPI.
- 3** **Example 3:** A TIN-level entity has 3 CLIA-certified hospital outreach labs. Two hospital outreach labs bill Part B under the hospital's NPI for lab services they provide to non-hospital patients. Collectively, these 2 labs meet the majority of Medicare revenues threshold and low expenditure threshold. However, 1 lab bills Part B using its own unique NPI (separate from the hospital's NPI) for lab services it provides to non-hospital patients and meets the majority of Medicare revenues threshold and low expenditure threshold. This entity consists of 2 applicable labs.

In this example, the reporting entity reports applicable information for the hospital outreach labs that bill Part B for non-hospital patients under the hospital's NPI separately from the hospital outreach lab that bills Part B under its own NPI.

Only Report Applicable Information Attributed to Non-Hospital Patients

If a CLIA-certified hospital outreach lab that bills Part B under the hospital's NPI meets the requirements of an applicable lab, only the hospital outreach lab component of the hospital lab (that is, lab tests provided to non-hospital patients) is considered an applicable lab. Therefore, report only applicable information attributed to the lab's non-hospital patients to us.

The reporting entity for the hospital outreach lab that bills Part B under the hospital's NPI and, therefore, determines applicable lab status based on Medicare revenues attributed to the TOB 14X shouldn't report applicable information for other parts of a hospital's lab business, such as testing performed for hospital outpatients or hospital inpatients.

Applicable Information

We use the applicable information applicable labs report to us to establish payment rates under the CLFS. We subject all CLIA-certified labs to the Part B private payor rate-based CLFS. The applicable lab and its reporting entity are responsible for collecting applicable information and reporting that data to us.

Applicable information includes:

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

Private payors are a:

- Health insurance issuer
- MA plan under Part C
- Group health plan
- Medicaid Managed Care Organization (MCO)

Include these specific private payor claims data as applicable information:

- **Lab tests we subject to the data collection and reporting requirements.**
- **The final amount paid by a private payor for lab tests after applying all private payor price concessions.** Use the final payment made by a private payor for a lab test during the data collection period as the private payor rate. If the private payor corrects an initial claim within the data collection period, report the adjusted payment. Don't report any payments corrected after the data collection period.
- **Payments from secondary insurance payors.** Include final payments from secondary insurers when calculating private payor rates if the secondary insurer makes the payment during the data collection period. The private payor rate equals 100% of the primary payor's fee schedule, which covers the payor's payment, patient cost sharing (deductibles and coinsurance), and any secondary insurer payments. Reporting entities should report only the total fee schedule amount from the primary payor and not separately list secondary insurer payments.
- **Any patient cost-sharing amounts, including deductible and coinsurance, if applicable.**
- **Multiple payment rates for the same test.** If a lab gets multiple payment rates for the same test from 1 or more private payors, it must report each unique rate and its corresponding volume for that test code.
- **Appeals resolved during the data collection period.** Include payment rates and test volumes for appealed claims if the private payor determines and pays the final amount during the data collection period. For example, if a lab's appeal for a test provided before the period is resolved with payment during the period, that final rate counts as applicable information.
- **Non-contracted amounts for out-of-network labs or services.** Include private payor rates for out-of-network labs if the private payor made final payment for the lab test during the data collection period. Non-contracted payments include any patient cost sharing amounts, such as deductible or coinsurance.

Exclude these specific private payor claims data from applicable information:

- **Private payor rates for lab test codes paid only under the PFS.** Don't include private payor rates for any lab test code not paid for under the CLFS but is paid for under the PFS.
- **When a lab applies price concessions.** Waiving a patient's deductible, copayment, or coinsurance for a test doesn't affect the private payor rate. Despite patient concessions, private payors still pay labs according to their full fee schedule for the test.
- **Information about denied payments.** If a private payor denies payment for a lab test, don't include \$0.00 as a private payor rate when reporting applicable information. Only report the final paid claim amount and the number of tests paid at that amount.
- **Unresolved appeals.** If a private payor is still reviewing a lab test claim or that claim is under appeal during the data collection period, don't count any payments as final rates or include them as applicable information. Similarly, exclude payment amounts from claims settled during the data collection period if the final payment occurs after the data collection period ends.
- **Capitated payments.** Sometimes health care services are paid on a capitated basis, which means they're paid a fixed amount per patient regardless of whether patients use services. Since these specific payments don't show the HCPCS code-level amounts for tests, don't include information on tests paid on a capitated basis.
- **Payments where the associated test volume can't be determined.** The volume of tests tied to each private payor rate is part of the definition of applicable information. If a lab can't determine this volume from the payor's remittance, then those payment amounts aren't applicable information, and you shouldn't report them.
- **Remittances where the payor has grouped individual HCPCS code payments into an encounter or a claim-level payment.** If a private payor combines payments for individual HCPCS codes into a single encounter or claim-level payment without another HCPCS code representing it, that payment isn't applicable information. Similarly, if a lab bills by individual codes but the payor groups them into bundles not represented by other codes, don't consider the bundled payment as applicable information.

In general, if a lab 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 applicable information. Don't consider estimated private payor rates and volumes to be applicable information.

Data Collection & Reporting

For most tests, the CLFS payment rate equals the weighted median of private payor rates for the test. We use information from applicable labs and reporting entities to update the payment rate for each test on the CLFS.

Data collection, reporting, and payment updates typically happen every 3 years for CDLTs. The 3 steps in this data collection and reporting process are:

1. Collect data (data collection period): Laboratories collect applicable information.
2. Analyze data (review and validation period): Laboratories and their reporting entities determine whether they meet the majority of Medicare revenues and low expenditure thresholds. Be sure to review and validate applicable information before you report it.
3. Report data (data reporting period): Reporting entities report applicable information to us.

[Clinical Laboratory Fee Schedule](#) has the upcoming data collection and reporting periods.

During the review and validation period, labs and reporting entities should assess whether they're meeting the applicable lab thresholds. Specifically, labs should determine whether each lab component of the reporting entity meets the majority of Medicare revenues threshold and low expenditure threshold from final Medicare paid claims it got during the data collection period. Applicable labs and their reporting entity should also use this time to review and validate applicable information (private payor data) before reporting it to us.

After the data reporting period, we update the payment rates in the CLFS, effective at the start of the next CY. These payment rates will be in effect for 3 years until we announce another data collection and reporting cycle.

We pay for most **ADLTs** using the same methods we use for CDLTs, but we get the private payor rate data from applicable labs differently.

Reporting entities must report applicable information **annually** for existing ADLTs.

We issued separate guidance on [ADLTs](#).

Data Reporting

Through their reporting entity, applicable laboratories report applicable information to us through the CLFS data collection system. Find a reporting template in the [CLFS module user manual](#) and [CLFS & PAMA Reporting and Resources](#).

Reporting entities may choose to condense reporting or submit individual reporting by lab. You must separate all applicable information files by TIN; however, each file may contain multiple NPIs for a reporting entity.

Individual Reporting

The individual applicable lab data reporting method separates each test code payment rate and volume data by each component that's an applicable lab.

Condensed Data Reporting

Reporting entities may combine data at the TIN level, reporting the volume paid at the same private payor rate for the same HCPCS code across component applicable laboratories rather than individually for each lab. For example, if we pay 3 labs the same rate for a specific code, 1 record can report the total volume, payment rate, and code across all labs. You must choose 1 applicable lab's NPI as the reporting NPI for each condensed record.

Note: You must report each unique private payor rate for each test code separately during the reporting period. We allow condensed reporting only when we pay more than 1 applicable lab under the same TIN the same rate for the same code; otherwise, you must individually report rates paid to only 1 lab.

Scenario 1

Private payors pay 3 applicable labs at the same payment rate for Lab Test Code 1.

Table 1a. Example of Individual Applicable Lab Reporting

HCPCS Code	Payment Rate	Volume	NPI
Lab Test Code (1)	\$15	400	1
Lab Test Code (1)	\$15	300	2
Lab Test Code (1)	\$15	200	3

The reporting entity reports applicable information individually for each component applicable lab.

Table 1b. Example of Condensed Reporting

HCPSC Code	Payment Rate	Volume	Reporting NPI
Lab Test Code (1)	\$15	900	Designated NPI for Condensed Reporting

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 labs) as the reporting NPI.

Scenario 2

Private payors pay 3 applicable labs 2 different payment rates (\$15 and \$17) for Lab Test Code 1.

Table 2a. Example of Individual Applicable Lab Reporting

HCPSC Code	Payment Rate	Volume	NPI
Lab Test Code (1)	\$15	400	1
Lab Test Code (1)	\$17	100	1
Lab Test Code (1)	\$15	300	2
Lab Test Code (1)	\$17	150	2
Lab Test Code (1)	\$15	200	3
Lab Test Code (1)	\$17	75	3

The reporting entity reports each HCPCS code, each unique private payor rate, and the volume paid at each unique private payor rate individually for each component applicable lab.

Table 2b. Example of Condensed Reporting (TIN Level)

HCPSC Code	Payment Rate	Volume	Reporting NPI
Lab Test Code (1)	\$15	900	Designated NPI for Condensed Reporting
Lab Test Code (1)	\$17	325	Designated NPI for Condensed Reporting

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). You combine the private payor rate of \$15 with the associated volume, and you combine the private payor rate of \$17 with the associated volume.

Scenario 3

Private payors pay 3 applicable labs a payment rate of \$15 for Lab Test Code 1 and also pay the same 3 applicable labs a payment rate of \$17 for Lab Test Code 1. In addition, private payors pay 1 of the 3 applicable labs a payment rate of \$18.50, another applicable lab a payment rate of \$19.50, and another applicable lab a payment rate of \$20 for Lab Test Code 1.

Table 3a. Example of Individual Applicable Lab Reporting

HCPSC Code	Payment Rate	Volume	NPI
Lab Test Code (1)	\$15	400	1
Lab Test Code (1)	\$17	100	1
Lab Test Code (1)	\$18.50	50	1
Lab Test Code (1)	\$15	300	2
Lab Test Code (1)	\$17	150	2
Lab Test Code (1)	\$19.50	40	2
Lab Test Code (1)	\$15	200	3
Lab Test Code (1)	\$17	75	3
Lab Test Code (1)	\$20	30	3

The reporting entity reports the HCPSC code, each unique private payor rate, and the volume paid at each unique private payor rate individually for each component applicable lab.

Table 3b. Example of Condensed Reporting (TIN Level)

HCPSC Code	Payment Rate	Volume	Reporting NPI
Lab Test Code (1)	\$15	900	Designated NPI for Condensed Reporting
Lab Test Code (1)	\$17	325	Designated NPI for Condensed Reporting
Lab Test Code (1)	\$18.50	50	1
Lab Test Code (1)	\$19.50	40	2
Lab Test Code (1)	\$20	30	3

Report each unique private payor rate for every HCPCS code along with the volume paid at each rate. If more than 1 applicable lab under a TIN is paid the same rate for a specific test code, you can combine their volumes when reporting. For example, combine volumes for all 3 labs paid \$15 and those paid \$17.

However, if only 1 applicable lab under the TIN got a unique private payor rate for Lab Test Code 1, we don't allow condensed reporting. In these cases, report the rates and associated volumes individually: \$18.50 for NPI 1, \$19.50 for NPI 2, and \$20 for NPI 3.

Reporting Reminders

- **The reporting entity must ensure accurate collection and reporting of applicable information.** The TIN-level entity and its labs should set up a process to report applicable information based on final paid claims during the reporting period.

- **Voluntary reporting isn't permitted.** Reporting entities submit applicable information only for labs meeting the definition of an applicable lab. We exclude labs that don't qualify.

Example 1: If a TIN includes 4 NPIs, and only 3 are applicable labs, then you report information for only those 3.

Example 2: A hospital outreach lab bills under its hospital's NPI and meets the majority revenue threshold but not the low expenditure threshold. Since it doesn't qualify as an applicable lab, don't report information for it.

- **Reporting applicable information isn't discretionary.** Reporting entities must report all applicable information for labs that qualify as applicable labs. Selective omission isn't allowed.

Example: If an applicable lab has paper-only claims, reporting entities must submit information from those claims regardless of perceived impact on payment rates.

Crosswalking & Gapfilling

If we don't get any applicable information on lab test codes during a data reporting period, we base the payment rate on crosswalking or gapfilling until private payor rate data becomes available for the next update.

- Under **crosswalking**, we base the payment amount on an existing test or combination of tests with similar methods and resources.
- We use **gapfilling** when there's no other test with similar methods and resources. In this case, Medicare Administrative Contractors develop a payment amount for the test.

We discuss tests with no applicable information at public meetings.

Email the CLFS Inquiries mailbox at CLFS_Inquiries@cms.hhs.gov with any questions about requirements for the private payor rate-based CLFS.

Resources

- [CLFS](#)
- [CLFS final rule](#)
- [CY 2019 PFS final rule](#)
- [Clinical Lab Fee Schedule](#) fact sheet



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