

CLFS Webinar Q&As

Question	Answer	Category
Does this apply to CLIA labs?	An applicable laboratory is defined as a CLIA certified laboratory (which includes a facility that receives a CLIA certificate of waiver).	Applicability / Eligibility
What are the requirements to determine if my laboratory is an applicable laboratory?	<p>Applicable laboratory means an entity that:</p> <ul style="list-style-type: none"> (1) Is a laboratory, (2) Bills Medicare Part B under its own National Provider Identifier (NPI); or for hospital outreach laboratories, bills Medicare Part B on the Form CMS-1450 under Type of Bill (TOB) 14x; (3) In a data collection period [1/1/25-6/30/25], receives more than 50 percent of its Medicare revenues, which includes fee-for-service payments under Medicare Parts A and B, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period from Medicare Clinical Laboratory Fee Schedule (CLFS) revenues or Physician Fee Schedule (PFS) revenues, the formula for this is: $(\text{Medicare CLFS revenues} + \text{Medicare PFS revenues}) \div \text{Total Medicare revenues}$, (4) Receives at least \$12,500 of its Medicare revenues from CLFS during the data collection period. 	Applicability / Eligibility
If a physician's office or clinic has the same NPI as the laboratory, is that lab an applicable lab?	Yes, if the practice and the lab have the same NPI, the lab could be considered an applicable laboratory.	Applicability / Eligibility
Can you provide clarification on what is included in the numerator in the formula to determine if my lab is an applicable lab?	The numerator is the sum of the Medicare CLFS revenues plus the Medicare PFS revenues you got from your own NPI (or on the 14x TOB, if you're a hospital outreach laboratory) during the data collection period.	Applicability / Eligibility
Can you clarify what the total Medicare revenues are in the denominator of the formula used to determine whether my lab is an applicable lab?	<p>The denominator is the total Medicare revenues you got from your own NPI (or on the 14x TOB, if you're a hospital outreach laboratory) during the data collection period.</p> <p>For purposes of determining whether a laboratory meets the majority of Medicare revenues threshold, total Medicare revenues includes the sum of all fee for service payments under Medicare Part A and B, Part D prescription drug payment, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period.</p>	Applicability / Eligibility
What if you don't bill on the 1450 form? We only bill on the 1500. Does that mean we are not applicable?	No. Most laboratories and physician practices bill on the 1500 and you should follow the steps to determine if the lab is an applicable lab in Q3.	Applicability / Eligibility

Question	Answer	Category
Does this include labs that are part of an FQHC and bill under the FQHC's NPI or for labs that are independent?	Although RHCs and FQHCs may be required to furnish certain laboratory services, laboratory services are not within the scope of the RHC or FQHC benefit and are not billed under the RHC or FQHC payment methodologies. Therefore, if the laboratory is CLIA certified, has its own National Provider Identifier (NPI) and its laboratory services are billed under the laboratory's own NPI, the laboratory must determine whether it qualifies as an applicable laboratory for purposes of reporting applicable information to CMS.	Applicability / Eligibility
If we have a lab NPI and an organization NPI, which should we use?	If you bill Medicare Part B for lab services under the lab NPI then you will determine your applicability based on the lab NPI.	Applicability / Eligibility
If our laboratory bills Medicare Part B under our physician practice NPI and does not have its own NPI, are we required to report?	You will need to do the applicable lab threshold formula based on the practice NPI. If you meet the greater than 50% and the \$12,500 threshold in the data collection period (January - June 2025) then you will need to report.	Applicability / Eligibility
How do you define "hospital outreach laboratory"?	For purposes of determining applicable laboratory status under the private payor rate-based CLFS, a hospital outreach laboratory means a hospital-based laboratory that furnishes laboratory tests to patients other than inpatients or registered outpatients of the hospital. A hospital outreach laboratory bills for Medicare Part B services furnished to non-hospital patients using the Form CMS-1450 14x Type of Bill (TOB).	Applicability / Eligibility
If the laboratory is no longer operating as of January 2026, are we still required to report ?	A laboratory that was in operation during the data collection period of January 1, 2025, through June 30, 2025, would need to determine if it was an applicable laboratory, and thus required to report data, by following the calculation steps provided. However, if there is any uncertainty about your applicable status, we recommend consulting with legal counsel.	Applicability / Eligibility
Will there be a penalty if we cannot complete the reporting by the deadline?	The statute authorizes CMS to impose civil monetary penalties of up to \$10,000 per day, adjusted for inflation as required by the Inflation Adjustment Act Improvements Act of 2015, for each failure to report or each misrepresentation or omission in reporting applicable information.	Applicability / Eligibility
What about reference labs where you send out samples?	The billing NPI makes the determination of applicable lab status; if the reference lab is the billing entity, the reference lab would make the determination of whether it is applicable.	Applicability / Eligibility
When we say 50% of revenue, are we talking revenue on the 14X TOB or revenue across my TIN?	For hospital outreach labs: $(\text{Medicare CLFS revenues from 14x TOB} + \text{Medicare PFS revenues from 14x TOB}) \div \text{Total Medicare revenues from 14x TOB}$.	Applicability / Eligibility

Question	Answer	Category
Does the revenue calculation include Medicare Advantage plans or only traditional Medicare?	For purposes of determining whether your laboratory meets the criteria of an applicable laboratory, Medicare Advantage data should not be included in the calculation. If your laboratory is determined to be an applicable laboratory and is required to report, then you would report private payor rates, which include Medicare Advantage plans as well as other private payors.	Applicability / Eligibility
Our lab meets 2 out of the 3 criteria. Are we an applicable lab?	If you do not meet all three criteria, you are not an applicable lab and do not have to report.	Applicability / Eligibility
On the denominator (The Total MC revenue by NPI), does that include all revenue outside of the lab test? Like office visits and procedures like injections?	Yes. The denominator is the total Medicare revenues you got from your own NPI (or on the 14x TOB, if you're a hospital outreach laboratory) during the data collection period. For purposes of determining whether a laboratory meets the majority of Medicare revenues threshold, total Medicare revenues includes the sum of all fee for service payments under Medicare Part A and B, Part D prescription drug payment, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period.	Applicability / Eligibility
What is the timeframe for the data we should use to determine if we qualify? Is it the full year from January 1, 2025, through December 31, 2025?	You should pull data only from the collection period of January 1, 2025, through June 30, 2025, to determine your applicable status, and if applicable for your reported data.	Applicability / Eligibility
If we need to change the submitter or certifier, how do we change or update?	Please send an email to the CLFS Data Collection System Help Desk at clfshelpdesk@dcca.com .	CLFS Module
Can the submitter and certifier be the same person?	The Submitter and Certifier need to be two different people.	CLFS Module
Can a third party biller representative be the submitter for the TIN or does it have to be an employee of the lab?	The Submitter is an individual selected by the laboratory who will create an account in the CMS Enterprise Portal, request the submitter role in the CLFS module, submit data on behalf of their TIN, and notify the certifier once data has been submitted. The submitter can be a third-party individual selected by the laboratory. There may only be one Submitter per TIN. A Submitter may submit on behalf of multiple TINs.	CLFS Module
Can you provide the link to begin registration in the system?	To register in the CMS Enterprise Portal, please visit https://portal.cms.gov/portal/ .	CLFS Module
For the certifier - what level in the organization should certify (e.g. director, VP, CFO)?	We recommend that the Certifier be a President or Chief Financial Officer (CFO) of the applicable laboratory, or an individual designated by the President or CFO.	CLFS Module

Question	Answer	Category
What specific HCPCS codes does this apply to?	Please review if your code is listed here https://www.cms.gov/medicare/medicare-fee-for-service-payment/clinicallylabfeesched/downloads/clfs-applicable-information-hcpcs-codes.zip .	Data Collection
What do we do when the same HCPCS code is paid by multiple private payors?	While submitting data you can report the same HCPCS code multiple times associating the same HCPCS code with each different payment rate.	Data Collection
Should we report only HCPCS codes, or should CPT codes be included as well?	CPT codes are a subset of HCPCS codes, so for purposes of this reporting, our materials refer to HCPCS for completeness. Please refer to the list of HCPCS codes subject to private payor rate implementation: https://www.cms.gov/medicare/medicare-fee-for-service-payment/clinicallylabfeesched/downloads/clfs-applicable-information-hcpcs-codes.zip .	Data Collection
What are the reportable labs under CLFS?	The CLFS applicable HCPCS codes are available for download as a ZIP file at https://www.cms.gov/medicare/medicare-fee-for-service-payment/clinicallylabfeesched/downloads/clfs-applicable-information-hcpcs-codes.zip .	Data Collection
If we are a part of a multi-hospital system with a laboratory in each, should the data be submitted as a system or as individual laboratory?	Condensed reporting is permitted at the Tax Identification Number (TIN) level for each NPI. For additional information, please refer to section 5 of the FAQs: https://www.cms.gov/files/document/clinical-laboratory-fee-schedule-pama-reporting-frequently-asked-questions-faqs.pdf .	Data Collection
Please clearly define private payor.	For purposes of the private payor rate-based CLFS, the term “private payor” is defined as: (1) A health insurance issuer as defined in Section 2791(b)(2) of the Public Health Service (PHS) Act); Or (2) A group health plan as defined in Section 2791(a)(1) of the PHS Act); Or (3) A Medicare Advantage Plan under Part C as defined in section 1859(b)(1) of the Social Security Act (the Act); Or (4) A Medicaid Managed Care Organization (MCO) (as defined in Section 1903(m) of the Act).	Data Collection
If we did not perform the test, do we have to report on it?	If you are an applicable laboratory and were paid by a private payor for the test, you have to report on it.	Data Collection
We performed other tests in addition to the ones listed on the HCPCS code list. Should we add them to our report?	No. Please only report on the HCPCS codes provided on the CLFS and PAMA reporting resources website. https://www.cms.gov/medicare/medicare-fee-for-service-payment/clinicallylabfeesched/downloads/clfs-applicable-information-hcpcs-codes.zip .	Data Collection

Question	Answer	Category
Is the volume that we display, the volume for the test at that specific payment, or the total volume of tests regardless of payment?	It is the volume for the test at that specific rate.	Data Collection
For the data collection period of January 1, 2025, through June 30, 2025: Is this service date or payment date?	It is final payments received during the data collection period.	Data Collection
Do we need to include denied payments in the report?	No. When a private payor denies payment for a laboratory test, payments of \$0.00 are not considered applicable information.	Data Collection
For the payment rate, should we be using the allowed amounts, or the actual payment we received from the private payor?	For purposes of applicable information, the private payor rate for a test should include any patient cost sharing required by the private payor.	Data Collection
We have determined we are not an applicable lab. Do we need to let CMS know? Do we have to register in the system to attest?	You do not have to take any action or report anything to CMS if you determine that your lab is not an applicable lab using the provided criteria.	Reporting Process & Deadlines
If we are not an applicable lab, can we still report?	Only applicable information of applicable laboratories may be reported. Applicable information may not be reported for an entity that does not meet the definition of applicable laboratory.	Reporting Process & Deadlines
Why are we doing this?	On February 3, 2026, Section 6226 of the CAA, 2026 was passed and updated the data reporting requirements for clinical diagnostic laboratory tests (CDLTs) that are not advanced diagnostic laboratory tests (ADLTs).	Reporting Process & Deadlines
Are there ramifications if the lab doesn't believe they are an applicable lab but they are actually required to report?	The statute authorizes CMS to impose civil monetary penalties of up to \$10,000 per day, adjusted for inflation as required by the Inflation Adjustment Act Improvements Act of 2015, for each failure to report or each misrepresentation or omission in reporting applicable information.	Reporting Process & Deadlines
What is the filing deadline?	The CLFS module will begin accepting submissions starting on May 1. All data are due by July 31, 2026.	Reporting Process & Deadlines