

**HLWI Advisory Group Meeting**  
***Tuesday, September 24, 2019***  
**10:00 - 11:30 am**

**Via Conference Call**

Call-In Number: 720-707-2699

Meeting ID: 618 669 150#

**AGENDA**

<b><u>ITEM</u></b>	<b><u>TIME</u></b>	<b><u>SUBJECT</u></b>	<b><u>REPORTING</u></b>	<b><u>PAGE</u></b>
<b>I.</b>	10:00 - 10:05 am	<b>WELCOME AND INTRODUCTIONS</b> A. Introductions and welcome	Martin	2
<b>II.</b>	10:05 - 10:25 am	<b>UPDATE ON ROI STUDY FOR CLINICAL TRAINING</b> A. Review first draft, provide feedback	Chapman/Bowen	8
<b>III.</b>	10:25 - 10:45 am	<b>FEDERAL UPDATE</b> A. Revised Guidance for Hospital Outreach Laboratory CLFS Reporting	Howard	13
<b>IV.</b>	10:45 - 10:55 am	<b>LEGISLATIVE UPDATE</b> A. A review of laboratory and workforce legislative proposals, (SB 334)	Martin	
<b>I.</b>	10:55 - 11:15 am	<b>LANDSCAPE UPDATES</b> A. All members: emerging issues and trends B. LFS update	All	
<b>II.</b>	11:15 - 11:30 am	<b>OTHER BUSINESS</b> A. CHA staffing	Martin	
<b>III.</b>	11:30 am	<b>ADJOURNMENT</b>	Martin	

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**HLWI Advisory Group Meeting**  
**Wednesday, March 6, 2019**  
**California Hospital Association**  
**1215 K Street, Board Room**  
**Sacramento, CA**

**10:00 am - 2:00 pm**

**Draft Minutes**

**Participants:** Sharon Arase, Danny Arimboanga, Winnie Carino, Dora Goto, Tim Hamill, Deb Lial, Fe Mallari, Fernando Mendoza, Cindy Martin, Valerie Ng, Erica Padilla, Jason Pedro, Danielle Pollard, Deanna Reinacher, Olive Romero, Karla Theis, Cindy Wong

**Guests:** Susan Chapman, Robert Thomas, Mary Wogec

**CHA Staff:** Michele Coughlin, Cathy Martin

**Regional Association Staff:** Megan Howard, Lisa Mitchell, Rebecca Rozen, Judith Yates

**Welcome and Introductions**

Dr. Hamill welcomed participants and the meeting began at 10:03 a.m. Individual introductions followed. Participants were asked to review the roster for changes. Several roster updates were submitted.

**Approval of minutes from September 10, 2018 HLWI conference call**

Dr. Hamill requested that participants bring forth any changes to the meeting minutes from the September 20 meeting. Valerie Ng submitted edits to the minutes. Once the edits have been completed, the document will be finalized.

**Landscape Update**

HLWI members engaged in a group discussion on emerging trends and issues related to laboratory workforce. During this update, a discussion on blood smear review/complexity levels took place. During this discussion, Robert Thomas explained that the law does not define levels of complexity and therefore the default will revert to High Complexity. Robert Thomas went on to explain that LFS gets many questions about various situations, but since the FDA determines the complexity of tests, there would need to be further follow up with the FDA.

- Cathy Martin and Tim Hamill will follow up with the FDA

Erica Padilla asked the group if they were aware that Medical Directors were not permitted to be in place on a temporary basis. She mentioned that any approvals during Medical Director's absence must wait until they return. While this system works for short-term absences, it could cause issues for medical leaves (or other extended absences) of Medical Directors.

Robert Thomas and Mary Wogec from Lab Field Services (LFS) shared that their department was working with new technology to assist with triaging incoming communications and to ultimately assist them in processing licensing renewals with a shorter turnaround time. Robert indicated that they had shut down their call center in order to focus on licensure (he indicated that the phones should be online again in May 2019). In the meantime, Mary Wogec suggested that users use the online system to communicate with LFS. Ultimately, their goal is to bring the renewal times down to a turnaround time of 2-3 weeks.

Cathy Martin asked LFS for an update on the status of the Personnel Regulations. Robert Thomas explained that, due to the size of the draft (400+ pages), they split it into 5 sections and would be handling the sections piece-by-piece. He went on to say that one of these sections had already gone to review at Agency. The other sections are currently in process. Once the entire package is completed, it will be cross-referenced by attorneys. Robert explained that the process itself was very tedious and lengthy, but he assured the group that progress was indeed taking place.

Cindy Wong then provided an update on the University of the Pacific CLS program. She shared that UOP was actively working to become a CLS school, and that they were currently looking for a Program Director in order to move this objective forward. She spoke briefly about a Valley CLS Consortium which was a formation of several colleges in the Central Valley that would be affiliated with the program.

### **Federal Update and Discussion**

Megan Howard from California Hospital's Washington DC Office provided a detailed update on the CLIA Fee increase, an update on CLFS Reporting Requirements, and on FLIA Proficiency Testing Proposed Rule. The group provided Megan with their impressions and feedback on the information she presented.

### **Federal ROI Update and Discussion**

Cathy Martin introduced Susan Chapman to the group and explained that Susan would be heading up a project to develop an ROI tool which would be used to capture the attention of hospitals and reinforce the message that they should be investing in clinical training now, rather than cutting in this area. The project will be funded with leftover Abbott money and ultimately aims drive home the importance of investing in the workforce through a commitment to clinical training.

### **Legislative Update**

Cathy Martin led the group through a review of laboratory and workforce legislative proposals. The group engaged in a discussion on the following:

- AB 822 – Authorizes trained phlebotomists to utilize new devices or procedures to withdraw blood (CHA will follow closely)
- SB 334 – Requires CDPH to establish a pathway program authorizing MLTs to apply their work experience and training from a department-approved MLT training programs towards the completion of a CLS training program. (CHA will support)

### **2019 Priorities**

Cathy Martin shared that the HLWI Advisory Group would focus on two areas of priority in 2019:

- The UCSF ROI Project on the training of CLSs and MLTs
- Gaining clarification from the FDA on text complexity

### **Other Business**

The next scheduled meeting is September 24, 2019 via conference call, however it is likely that another call will be scheduled, most likely in May, to update the group on the clarification gained from the FDA.

### **Adjourn**

The meeting adjourned at 1:32 pm.

# **HLWI Mission Critical Staffing Solution**

## **Executive Summary**

An investment in the development of clinical laboratory testing personnel will provide a favorable return-on-investment (ROI), and it will also ensure that hospitals have the necessary technical staff for providing laboratory services to an aging patient population with increasingly more complex diagnoses. Clinical Laboratory Scientists (CLS) and Medical Laboratory Technicians (MLT) are licensed to perform diagnostic tests and quality control of test methods, report patient results, and maintain test equipment. ROI analyses show that investing in the CLS and MLT workforce results in lower labor costs when compared to the cost of hiring and training temporary staff.

## **The Issue**

Licensed CLS and MLT staff are essential for a California hospital when the clinical laboratory performs diagnostic tests for hospital inpatients, emergent patients, and surgical patients. Diagnosis and effective treatment of all patients depends on the accuracy and efficiency of laboratory testing. Hospital accrediting agencies require clinical laboratories to be staffed with individuals who meet the education, training, and work experience requirements of the agencies. Applicants from out-of-state must meet California certification and licensure requirements. Hospitals can incur higher costs when hiring an out-of-state applicant. The technical expertise of CLS and MLT staff is essential to prepare clinical laboratories for accreditation inspections. Multi-disciplinary hospital committees that perform on-going quality management activities include CLS and MLT staff, who can analyze laboratory utilization for its impact on patient outcomes, as well as, for its cost-effectiveness.

## **Clinical Laboratory Staff Shortages**

Data show that shortages in clinical laboratory staff are a national problem and are particularly acute in California. The most recent national survey from the American Society for Clinical Pathology (ASCP) Vacancy Survey of Medical Laboratories includes all types of medical laboratories. CLS and MLT vacancy rates for the Far West Region, which consists primarily of data from California laboratories, ranged from 6.5% to 9.9% for various CLS and MLT specialties. Although this number may not seem alarming, it does not account for the large number of anticipated retirements. Anticipated retirement rates over the next 5 years for CLS and MLT staff nationwide range from 14.7% to 23.8%. The US Bureau of Labor Statistics (BLS) reported that the demand for medical and clinical laboratory technologists and technicians between 2018 and 2028 is expected to grow by 11%. Respondents to the ASCP Survey indicated that the number of applicants trained in accredited programs is relatively fixed. Increasing retirement rates make it imperative to



recruit next generation technologists and technicians into accredited training programs.  
*(Some of these data will be made into table for the final brief)*

## **California Hospital Vacancies**

According to the 2019 Q1 California Hospital Association (CHA) Workforce Data Report, the CLS vacancy rate was 3.7% and the MLT vacancy rate was 3.4%. Survey respondents stated that these vacancy rates are artificially low, because positions remain open so long that they are eliminated. In fact, there were 32 (0.8%) CLS lay-offs during this survey period and two hospitals reportedly sold their hospital out patient business to a commercial laboratory. For this reason, we sent a follow-up survey in August 2019 to CHA member laboratories to gain a better understanding of the vacancy rate data.

Preliminary data from the recent survey showed that out of 130 CLS vacancies only 99 (76%) were filled with permanent CLS staff while 31 (24%) positions were filled with temporary CLS staff, some for as long as 24 months. It is interesting to note that only five of the twenty-nine respondents had invested in hospital-based CLS Training Programs. A commitment to a program of this type provides the hospital with a pool of CLS and MLT candidates who are already familiar with the hospital policies and procedures.

Nearly every county participating in the 2019 CHA Q1 Survey listed CLS as a “Difficult to Fill/Hard to Recruit” position due to the low number of qualified applicants. Contracting for temporary CLS staff is commonly done to fill vacant night and weekend shifts when permanent CLS staff is not available. Hourly rates for temporary CLS staff are approximately two times the hourly wage of an experienced CLS. *(This sentence could be highlighted in a text box.)* A separate ROI calculation for a CLS training program is appended to this brief.

## **Opportunity to Change Skill Mix in the Clinical Laboratory**

Respondents to the August 2019 CHA-member survey indicated that MLT staff numbers are approximately 28 full time equivalents (FTE) and CLS staff numbers are approximately 684 FTE. While the circumstances among laboratories vary, changes to the California Business and Professions Code (B&PC 1260.3), effective January 1, 2019, have broadened MLT scope of practice. An opportunity to change the mix of testing personnel within the clinical laboratory has been created by allowing an MLT to perform additional routine tests. A CLS vacancy can potentially be filled by a MLT, as long as the workload and supervision meet the regulatory requirements, leading to a reduction in labor costs. MLT hourly wages average 40% less than CLS wages. A separate ROI calculation for a MLT training program is appended to this brief. *(This paragraph could be made part of the solution.)*

## **The Solution**

A “Grow Your Own” strategy has proven successful in providing qualified CLS and MLT staff. Offering career development opportunities to currently unlicensed staff and funding of a hospital-based training program or internship for individuals who have completed the necessary college-level courses are two possible approaches to this strategy. Hospitals often compensate trainees at an intern rate during training and offer an employment incentive upon successful completion of training. The advantages of hiring an individual after completion of an internship go beyond the individual’s knowledge of IT systems and instrumentation. Existing staff sees the training program as an opportunity for career advancement and a sustainable solution to staff shortages, which will eventually result in fewer voluntary terminations.

## **Return on Investment**

Two “Grow Your Own” success stories came out of the August 2019 CHA-member survey. One respondent stated that their laboratory recently graduated their first class of four CLS interns and that all four graduates were hired as permanent CLS staff. Another respondent stated that two unlicensed staff members with BS degrees were encouraged to apply for a Limited CLS Training License. Both staff members succeeded in obtaining a Limited CLS training license, which allows them to train as a CLS in their area of expertise. Upon completion of training and the licensing exam, these individuals can fill CLS roles.

ROI calculations for CLS and MLT training programs are appended to this brief. Both show that two interns are needed in a training program to yield a favorable ROI in less than one year.

## **Summary**

There are critical shortages of qualified CLS and MLT candidates and shortages will worsen within five years given the number of projected retirements. Hospital leadership is able to mitigate these shortages by budgeting for CLS and MLT training programs and supporting existing staff efforts to fulfill licensing requirements. Both of these solutions take 12-18 months to implement, so it is imperative to take action in the immediate future.

ROI CLS Training Program	Hourly Rate	Annual Salary	Benefits	Annual Salary With Benefits
CLS Trainer Float - Median Annual Salary	\$60.000	\$124,800.00	\$37,440.00	\$162,240.00
CLS Trainee #1	\$13.000	\$27,040.00	\$0.00	\$27,040.00
CLS Trainee #2	\$13.000	\$27,040.00	\$0.00	\$27,040.00
<b>Total Annual Salary Cost</b>				<b>\$216,320.00</b>
Option 1 - Hiring New Grad CLS at Low Range	\$50.000	\$104,000.00	\$31,200.00	\$135,200.00
Option 2 - Hiring Experienced CLS at Mid-Range	\$65.000	\$135,200.00	\$40,560.00	\$175,760.00
Option 3 - Hiring A Temp CLS at Current Rate	\$130.000	\$270,400.000	\$0.00	\$270,400.000
Salary difference between 1 New Grad and 1 Experienced CLS hired at mid-range	A*			(\$40,560.00)
Salary difference between 2 New Grads and 2 Experienced CLSs hired at mid-range	B*			(\$81,120.00)
Salary difference between 1 New Grad and 1 Temp Agency CLS	C*			(\$135,200.000)
Salary difference between 2 New Grads and 2 Temp Agency CLSs	D*			(\$270,400.00)
Return of Investment*				ROI in years
A - hiring 1 new grad CLS vs1 Experienced CLS				5.33
B - hiring 2 new grad CLSs vs 2 Experienced CLSs				2.67
C - hiring 1 new grad CLSs vs 1 Temp CLS				1.60
D - hiring 2 new grad CLSs vs 2 Temp CLSs				0.80
Note: ROI formatted by Danny Arimboagna of John Muir Lab				

ROI MLT Training Program	Hourly Rate	Annual Salary	Benefits	Annual Salary With Benefits
MLT Trainer Float - Median Annual Salary	\$60.000	\$124,800.00	\$37,440.00	\$162,240.00
MLT Trainee #1	\$11.500	\$23,920.00	\$0.00	\$23,920.00
MLT Trainee #2	\$11.500	\$23,920.00	\$0.00	\$23,920.00
<b>Total Annual Salary Cost</b>				<b>\$210,080.00</b>
Option 1 - Hiring New Grad MLT at Low Range	\$25.000	\$52,000.00	\$15,600.00	\$67,600.00
Option 2 - Hiring Experienced MLT at Mid-Range	\$30.000	\$62,400.00	\$18,720.00	\$81,120.00
Option 3 - Hiring A Temp MLT at Current Rate	\$85.000	\$176,800.000	\$0.00	\$176,800.000
Salary difference between 1 New Grad and 1 Experienced MLT hired at mid-range	A*			(\$13,520.00)
Salary difference between 2 New Grads and 2 Experienced MLT hired at mid-range	B*			(\$27,040.00)
Salary difference between 1 New Grad and 1 Temp Agency MLT	C*			(\$109,200.000)
Salary difference between 2 New Grads and 2 Temp Agency MLTs	D*			(\$218,400.00)
Return of Investment*				ROI in years
A - hiring 1 new grad MLT vs1 Experienced MLT				15.54
B - hiring 2 new grad MLTs vs 2 Experienced MLTs				7.77
C - hiring 1 new grad MLT vs 1 Temp MLT				1.92
D - hiring 2 new grad MLTs vs 2 Temp MLTs				0.96
Note: ROI formattd by Danny Arimboagna of John Muir Lab				



September 16, 2019

TO: Hospital Laboratory Workforce Initiative Advisory Group

FROM: Megan Howard, Senior Policy Analyst

SUBJECT: Revised Guidance for Hospital Outreach Laboratory CLFS Reporting Requirements

The Centers for Medicare & Medicaid Services (CMS) has issued the attached revised guidance for laboratories that are required to report private payer data for laboratory tests under the clinical laboratory fee schedule (CLFS). **In response to advocacy from CHA, CMS revised its guidance for hospital outreach laboratories on reporting applicable information attributed to non-patients. CMS states that the guidance was revised to “delete incorrect information.”**

Specifically, CMS deleted information included its February 27, 2019 guidance that would have been burdensome for hospital outreach laboratories, requiring them to identify, collect, and report on separately payable private payer rates for payers that do not require the use of Form CMS-1450 14x Type of Bill (14x TOB). Below is the previous language, red-lined to reflect the language deleted in the new guidance:

*Only Applicable Information Attributed to non-Hospital Patients is Reported*

*As discussed previously in this publication, a CLIA certified hospital outreach laboratory that bills Medicare Part B using the hospital’s NPI must determine 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 Medicare Part B under the hospital’s NPI meets the requirements of an applicable laboratory, only the hospital outreach laboratory component of the hospital laboratory (that is, laboratory tests furnished to non-hospital patients) is considered an applicable laboratory. Therefore, report only applicable information attributed to the laboratory’s non-hospital patients to CMS.*

*The reporting entity for the hospital outreach laboratory that bills Medicare Part B under the hospital’s NPI, and therefore determines 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.*

~~*In circumstances in which a private payor does not require a hospital outreach laboratory to use the Form CMS 1450 14x TOB, the hospital must distinguish between private payor fee for service payments (and the associated volume) made for laboratory tests furnished to non-patients (the applicable laboratory) from private payor fee for service payments (and associated test volume) for laboratory tests furnished to hospital patients.*~~

~~Even if a private payor's rate is the same for a given laboratory test code in each setting, that is, the outreach laboratory setting for non-patients, outpatient hospital setting for hospital outpatients and the inpatient hospital setting for hospital inpatients, only the volume of services for hospital outreach laboratory services (non-hospital patient laboratory testing) is permitted to be reported to CMS.~~

~~It is the hospital's responsibility to identify, collect and report the separately payable private payor rates (and the volume of tests paid at those rates) that are associated with only the outreach laboratory portion of the hospital's laboratory business.~~

~~Example 1: A private payor does not require the Form CMS-1450 14x TOB for hospital outreach laboratory services. The private payor's final paid claim amount during the data collection period for the HCPCS code of a test is \$20 for both hospital outpatients and non-hospital patients. The volume of services paid at \$20 for tests furnished to hospital outpatients is 200 and the volume of services paid at \$20 for tests furnished to non-hospital patients is 250. In this example, the reporting entity reports the HCPCS code for the test, payment rate \$20, volume 250. Do not report the volume associated with tests furnished to hospital patients (200).~~

~~Example 2: A private payor does not require the Form CMS-1450 14x TOB for hospital outreach laboratory services. The private payor pays one rate for tests furnished to hospital patients and pays a different rate for testing furnished for non-hospital patients. The private payor's final paid claim amount during the data collection period for the HCPCS code of a test is \$20 for hospital outpatients and \$18 for non-hospital patients. The volume of services paid at \$20 for tests furnished to hospital outpatients is 200 and the volume of services paid at \$18 for tests furnished to non-hospital patients is 250. In this example, the reporting entity reports the HCPCS code for the test, payment rate \$18 with a volume of 250. Do not report the payment rate for hospital patients of \$20 and volume paid at that rate (200).~~

CHA continues to urge any hospital with a laboratory that bills Medicare on a 14x TOB of Bill to carefully review the guidance to determine if it meets the definition of applicable laboratory and is subject to CLFS private payer reporting requirements. As a reminder, any hospital laboratory that bills \$12,500 or more in Medicare revenue on the 14x TOB is likely to be considered an applicable laboratory. Additional information is available on [CMS' website](#).

### Questions

Please contact me at [mhoward@calhospital.org](mailto:mhoward@calhospital.org) or (202) 488-3742 with any questions.



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

MLN Matters Number: SE19006 Revised

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Related CR Transmittal Number: N/A

Implementation Date: N/A

**Note: We revised this article on September 5, 2019, 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.**

### PROVIDER TYPE AFFECTED

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This article is for Medicare Part B clinical laboratories who submit claims to Medicare Administrative Contractors (MACs) for services furnished to Medicare beneficiaries.

### PROVIDER ACTION NEEDED

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This article will assist the laboratory community in meeting the requirements under Section 1834A of the Social Security Act (the Act) for the Medicare Part B Clinical Laboratory Fee Schedule (CLFS). It includes clarifications for determining whether a hospital outreach laboratory meets the requirements to be an “applicable laboratory,” the applicable information (that is, private payor rate data) that must be collected and reported to the Centers for Medicare & Medicaid Services (CMS), the entity responsible for reporting applicable information to CMS, the data collection and reporting periods, and the schedule for implementing the next private payor-rate based CLFS update. Also, this revised article includes information about the condensed data reporting option for reporting entities. CMS previously issued additional information about the CLFS data collection system and Advanced Diagnostic Laboratory Tests (ADLTs) through separate instructions.

## BACKGROUND

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Section 1834A of 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 under the CLFS. The CLFS final rule [Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule](#) (CMS-1621-F) was displayed in the Federal Register on June 17, 2016, and was published on June 23, 2016. The CLFS final rule implemented Section 1834A of the Act.

Under the CLFS final rule, reporting entities must report to CMS certain private payor rate information (applicable information) for their component applicable laboratories. In general, the payment amount for a test on the CLFS furnished on or after January 1, 2018, is equal to the weighted median of private payor rates determined for the test, based on the applicable information that laboratories collect during a data collection period and report to CMS during a data reporting period. CMS uses crosswalking or gapfilling methods to establish payment amounts for new Clinical Diagnostic Laboratory Tests (CDLTs) and CDLTs for which CMS receives no applicable information.

CMS 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 \(CMS-1693-F\)](#) November 23, 2018. In this final rule, CMS made two revisions to the regulatory definition of applicable laboratory:

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

In addition, for the January 1, 2020, through March 31, 2020 data reporting period, CMS will 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

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Section 1834A of the Act defines an applicable laboratory as a laboratory which receives the majority of its Medicare revenues under the CLFS and/or PFS. It also provides the authority to establish 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 (that is, 42 C.F.R. § 493.2) that bills Medicare Part B under its own NPI or for hospital outreach laboratories, bills Medicare Part B on the Form CMS-1450 under bill type 14x. In addition, the laboratory must meet a “majority of Medicare revenues” threshold, that is, in a data collection period it receives more than 50 percent of its Medicare revenues from one or a combination of the CLFS or the PFS. It also must meet a low expenditure threshold, that is, it receives at least \$12,500 of its Medicare revenues from the CLFS in a data collection period.

For purposes of determining applicable laboratory status under the CLFS, a hospital outreach laboratory is a hospital-based laboratory that furnishes laboratory tests to patients other than admitted inpatients or registered outpatients of the hospital. A hospital outreach laboratory bills for Medicare Part B services it furnishes to non-hospital patients using the Form CMS-1450 14x Type of Bill (TOB).<sup>1</sup>

## I. Determination of Applicable Laboratory Status Based on the NPI

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

There are four steps in determining whether a laboratory meets the requirements to be an applicable laboratory based on the laboratory's own billing NPI:

- (1) Is the laboratory certified under CLIA?
- (2) Does the CLIA- certified laboratory bill Medicare Part B under its own NPI?
- (3) Does the laboratory meet the majority of Medicare revenues threshold?
- (4) Does the laboratory meet the low expenditure threshold?

### *Step 1: CLIA Certification*

The CLIA applies to all laboratories performing testing on human specimens for a health purpose. A laboratory must be a CLIA-certified laboratory to receive Medicare payment. Therefore, the first step in identifying an applicable laboratory is to determine whether the laboratory is CLIA certified. The CLIA regulatory definition of a laboratory is codified in regulation in 42 CFR 493.2. **Note that a facility that receives any CLIA certificate (including a CLIA certificate of waiver) is considered a laboratory as defined in 42 CFR 493.2.**

### *Step 2: NPI*

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<sup>1</sup> The Form CMS-1450 14x is a type of bill as defined by the National Uniform Billing Committee. It is used in hospital claims submission and is associated with hospital laboratory services provided to non-hospital patients.

The second step is to determine whether the CLIA-certified laboratory bills Medicare Part B under its own NPI. The NPI is the standard unique health identifier used by health care providers for billing Medicare and other payors. The National Plan and Provider Enumeration System assigns NPIs, per 45 CFR 162. CMS uses 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 Medicare Part B under its own NPI, to be an applicable laboratory it must meet the majority of Medicare revenues threshold. A laboratory, by its own billing NPI, meets the majority of Medicare revenues threshold if it receives more than 50 percent of its **total** Medicare revenues from payments under the Medicare CLFS and/or Medicare PFS. The CLFS and PFS are under Medicare Part B, also known as Original Medicare or Fee-For-Service (FFS) Medicare.

To determine whether a laboratory meets the majority of Medicare revenues threshold, the laboratory must look to its final Medicare paid claims from their MAC received by their own billing NPI during the data collection period. See the Applicable Information Section below for additional information on the concept of final paid claims.

The three steps to determine whether a laboratory meets the majority of Medicare revenues threshold are:

- First, sum the CLFS and PFS payment amounts received by the laboratory's own billing NPI during the data collection period. The revenues from the CLFS include payments for all laboratory services 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 are not 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 received by the laboratories own 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 beneficiary deductible or coinsurance for services furnished during the data collection period. The sum of total Medicare revenues is the denominator of the majority of Medicare revenues threshold equation.

**Note: Effective January 1, 2019, Medicare Advantage plan payments under Medicare Part C shall not be included 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 received during the data collection period. We provide additional information on the data collection period below.

If the Medicare revenues received from the CLFS and/or PFS are greater than 50 percent of the total Medicare revenues for the laboratory's billing NPI, the laboratory meets the majority of Medicare revenues threshold.

The majority of Medicare revenues threshold equation is:

**If:**

Medicare CLFS revenues (for billing NPI) + Medicare PFS revenues (for billing NPI)

is >50%

Total Medicare revenues (for billing NPI)

**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, receives 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 laboratory must look to its final Medicare paid claims from the MAC received by its own billing NPI during the data collection period.

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

The low expenditure threshold equation is:

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

These are examples on how the majority of Medicare revenues threshold and low expenditure threshold are applied to the CLIA-certified laboratory's own billing NPI for purposes of determining whether the laboratory is an applicable laboratory:

**Example 1:** A laboratory organization includes five CLIA-certified laboratories. Each CLIA-certified laboratory has its own unique NPI and bills the Medicare Program (and other payors) for laboratory tests separately under each NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to each NPI in the laboratory organization. That is, individually determine whether each laboratory meets the majority of revenues threshold and low expenditure threshold. Even though all five laboratories may be under the same TIN, CMS considers each to be a separate laboratory for purposes of determining an applicable laboratory because each bills Medicare Part B for laboratory tests using its own unique NPI.

**Example 2:** A laboratory organization includes five CLIA-certified laboratories. Each CLIA-certified laboratory has the same NPI and bills for laboratory tests under the same NPI for each of its CLIA-certified laboratories. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied based on the combined revenues of all CLIA-certified laboratories in the organization that use the same billing NPI. In other words, for purposes of applying the applicable laboratory thresholds, CMS considers all five CLIA-certified laboratories in the laboratory organization to be a single laboratory because they all bill Medicare Part B using the same NPI.

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

**Example 4:** An entity consists of five physician offices and one CLIA-certified laboratory. All five physician offices and the CLIA-certified laboratory have the same NPI and bill for services under the same NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied based on the combined revenues of all components of the entity that bill for services under the same NPI. In other words, since the physician offices and CLIA-certified laboratory all have the same NPI and bill Medicare Part B under the same NPI, CMS considers 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 five physician offices and one CLIA-certified laboratory. Each of the five physician offices and the CLIA-certified laboratory have unique NPIs. The laboratory bills for laboratory tests under its own unique NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are only applied to the CLIA-certified laboratory's own billing NPI.

**Example 6:** A CLIA-certified hospital outreach laboratory that performs laboratory services for non-hospital patients has its own unique NPI separate from the hospital's NPI. The hospital outreach laboratory bills Medicare Part B for laboratory tests it furnishes to non-hospital patients using its own unique NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to the hospital outreach laboratory's own unique NPI and not to the hospital's NPI.

**Example 7:** A hospital includes three 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 Medicare Part B separately for laboratory tests under the same NPI for each of its CLIA-certified hospital outreach laboratories. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied based on the combined revenues of all CLIA-certified hospital outreach laboratories of the hospital that use the same billing NPI that is separate from the hospital's NPI. In other words, for purposes of applying the applicable laboratory thresholds, CMS considers all three CLIA-certified hospital outreach laboratories of the hospital to be a single laboratory because they all bill Medicare Part B using the same unique billing NPI.

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

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

The two hospital outreach laboratories that bill for laboratory services performed for non-hospital patients under the hospital's NPI must determine applicable laboratory status based on revenues attributed to the Form CMS-1450 14x TOB. Below, we provide instructions for determining applicable laboratory status for hospital outreach laboratories that bill Medicare 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 Medicare Part B using the hospital's NPI to be an applicable laboratory, the hospital outreach laboratory must be a laboratory as defined under the CLIA regulatory definition of a laboratory in 42 C.F.R. § 493.2 and meet the majority of Medicare revenues threshold and low expenditure threshold.

However, a hospital outreach laboratory that bills Medicare Part B using the hospital's NPI must determine whether it meets the majority of Medicare revenues threshold and low expenditure threshold based on revenues attributed to the Form CMS-1450 14x TOB. In other words, when using the CMS Form-1450 14x TOB for determining 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.

Therefore, if a CLIA-certified hospital outreach laboratory that bills Medicare Part B under the hospital's NPI meets the requirements of an applicable laboratory, CMS only considers the hospital outreach laboratory to be an applicable laboratory. The hospital laboratory components furnishing laboratory services to hospital patients are not part of the applicable laboratory determination.

#### *Majority of Medicare Revenues Threshold*

To be an applicable laboratory, a hospital outreach laboratory that bills Medicare 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 14x TOB, meets the majority of Medicare revenues threshold if it receives more than 50 percent of its total Medicare revenues from payments under the Medicare CLFS and/or Medicare PFS. The CLFS and PFS are under Medicare Part B, also known as Original Medicare or Fee-For-Service (FFS) Medicare.

To determine 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 14x TOB received during the data collection period. See the Applicable Information Section below for additional information on the concept of final paid claims.

The same three steps (as discussed in the previous section) are used to determine whether a hospital outreach laboratory (that bills Medicare Part B under the hospital's NPI) meets the majority of Medicare revenues threshold:

- First, sum the CLFS and PFS payment amounts received by the hospital outreach laboratory attributed to the 14x TOB 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 received by the hospital outreach laboratory under the 14x TOB 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 beneficiary deductible or coinsurance for services furnished during the data collection period. The sum of total Medicare revenues is the denominator of the majority of Medicare revenues threshold equation. As noted previously, effective January 1, 2019, Medicare Advantage plan payments under Medicare Part C shall not be included 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 received during the data collection period. We provide additional information on the data collection period below.



If the Medicare revenues received from the CLFS and/or PFS are greater than 50 percent of the total Medicare revenues received during the data collection period, the hospital outreach laboratory meets the majority of Medicare revenues threshold.

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

**If:**

Medicare CLFS revenues (based on 14x TOB) + Medicare PFS revenues (based on 14x TOB)

is >50%

Total Medicare revenues (based on 14x TOB)

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

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

### *Low Expenditure Threshold*

To be an applicable laboratory, a hospital outreach laboratory that bills Medicare 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 14x TOB, receives 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 from the MAC received under the 14x TOB during the data collection period.

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

It is important to note that the low expenditure threshold applies only to CLFS services. It does not include revenues received under the PFS. In other words, to meet the low expenditure threshold, the hospital outreach laboratory must receive at least \$12,500 under only the Medicare CLFS during the data collection period.

These are examples on how the majority of Medicare revenues threshold and low expenditure threshold are applied to the CLIA-certified hospital outreach laboratory using the Form CMS-1450 14x TOB for purposes of determining 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 Medicare Part B using the same NPI as the hospital. In other words, laboratory services performed for non-hospital patients are billed on the Form CMS-1450 14x TOB using the hospital's NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to the hospital outreach laboratory's Medicare revenues received from the 14x TOB.

**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 does not use it to bill Medicare Part B. Instead, the hospital outreach laboratory continues to bill Medicare Part B for laboratory tests it furnishes to non-hospital patients using the hospital's NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to Medicare revenues received from the 14x TOB. In other words, since laboratory services performed for non-hospital patients are billed using the hospital's NPI (and not the hospital outreach laboratory's own unique billing NPI), the majority of Medicare revenues threshold and low expenditure threshold are applied to the hospital outreach laboratory's Medicare revenues received from the 14x TOB.

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

In summary, applicable information (as discussed in the next section) from all applicable laboratories must be collected during the data collection period and reported by reporting entities to CMS during the data reporting period. CMS uses the applicable information reported to CMS to establish payment rates under the CLFS. All CLIA-certified laboratories (that is, both applicable laboratories and laboratories that are not applicable laboratories) are subject to the Medicare Part B private payor rate-based CLFS.

## APPLICABLE INFORMATION

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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 CMS.

Applicable information includes three major components:

1. The specific HCPCS code associated with the test;



2. The private payor rate for each test for which final payment has been made during the data collection period;
3. The associated volume for each test.

*Private Payor Defined*

The definition of the term “private payor” is:

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).

**Note:** Applicable information does not include information on tests for which payment is made on a capitated basis, where payments do not reflect specific HCPCS code-level amounts. (See below for additional information on payments made on a capitated basis.) Therefore, private payor rates from Medicaid MCO plans are considered applicable information only to the extent that the individual HCPCS code for the test, private payor rate specific to the test, and the volume paid at the specific rate for the test can be identified.

These specific private payor claims data are **included** 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. You can find a list of laboratory tests subject to the data collection and data reporting requirements at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html> and select: [CLFS Applicable Information HCPCS Codes \[ZIP, 57KB\]](#).

- **Final amount paid by a private payor for laboratory tests after all private payor price concessions are applied.** A final paid claim is the final amount paid by a private payor for a laboratory test during the data collection period. If a private payor pays a laboratory for a test but subsequent post-payment activities during the data collection period change that initial payment amount, the final payment is the private payor rate for purposes of determining applicable information. For example, if an initial claim was paid in error 3 months before a data collection period and then the initial claim is corrected, with final payment made by the private payor during the data collection period, the final corrected payment amount for the test is considered the private payor rate for purposes of determining applicable information. However, if an initial claim was paid in error during a data collection period and then corrected, with final payment made after the data collection period, the payment amount is not a private payor rate for purposes of applicable information and, therefore, is not reported to CMS.
- **Payments from secondary insurance payors.** Final payments from secondary insurance payors are considered in calculating private payor rates if the final payment was made during the data collection period. The private payor rate is 100 percent of the primary private payors' fee schedule amount which includes the final amount the primary private payor paid for the test, any patient cost sharing responsibilities required by the primary private payor (such as patient deductible and coinsurance amounts) and any payments received from a secondary insurer (if applicable). The important concept here is the reporting entity reports 100 percent of the primary private payors' fee schedule amount for the laboratory test. Reporting entities should not report payments received 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 required by the private payor (for instance, patient deductible and/or coinsurance amounts). In other words, as noted above, the private payor rate is 100 percent of the private payor's fee schedule amount for the test.
- **Multiple payment rates for the same test.** If an applicable laboratory receives more than one payment rate from the same private payor for the same test or more than one payment rate from different private payors for the same test, each unique payment rate along with the associated volume for the test code at each such rate is included as applicable information. In this case, the reporting entity must report each unique payment rate and the associated volume for the test at each such rate.
- **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 final payment amount is determined and paid by the private payor during the data collection period. For example, if a laboratory filed an appeal for a test furnished prior to a data collection period and resolved the appeal so that final payment for the test was made during the data collection period, the final rate paid is considered 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 a laboratory test code is not 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 is not applicable information.
- **Price concessions applied by a laboratory.** A laboratory's decision to waive a patient's deductible, copay, and/or coinsurance responsibility for a given test(s) must not be factored into the determination of the private payor rate for a test. Although laboratories may provide concessions to patients, it does not reflect the rates paid by private payors. As noted above, the private payor rate is 100 percent of the private payor's fee schedule amount for the test.
- **Information about denied payments.** When a private payor denies payment for a laboratory test, payments of \$0.00 are not considered a private payor rate for purposes of determining applicable information under the new CLFS. In other words, when the final determination by the private payor during the data collection period is to deny the claim and therefore does not make a payment, do not report \$0.00 for a laboratory test code. 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 that has already been paid is not considered a final payment rate and therefore is not considered applicable information. Additionally, if the appeal was settled during the data collection period but final payment was not made by the private payor until after the data collection period, the payment amount cannot be used for a private payor rate and therefore 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 beneficiary in the plan for a given period, regardless of whether the beneficiary receives services during the period covered by the payment. Payment is typically made on a capitated basis under a managed care arrangement. As there is no way to determine payment specifically for a given test, it cannot be reported as applicable information. Therefore, applicable information does not include information about a test for which payment is made on a capitated basis.

- **Payments where the associated test volume cannot be determined.** As discussed above, the associated volume of tests performed corresponding to each private payor rate is a component of the definition of applicable information. Where the associated volume of tests performed corresponding to each private payor rate cannot be discerned by a laboratory from the private payor's remittance, CMS does not consider those payment amounts as applicable information and you should not report them to CMS.
- **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 is not represented by another HCPCS code, those payments are not applicable information. In other words, if a laboratory bills individual HCPCS codes and the payor bundles the individual HCPCS codes into groups not represented by other HCPCS codes, the payor's bundled payment amount is not considered applicable information.

**Note:** In general, if a laboratory cannot correlate a private payor payment amount and the associated volume paid at that rate to a specific HCPCS code, that amount is not a private payor rate for purposes of applicable information. Estimated private payor rates and volumes are also not considered applicable information.

## SCHEDULE FOR DATA COLLECTION AND REPORTING

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The next data collection period (the period where applicable information for an applicable laboratory is obtained from claims for which the laboratory received final payment during the period) is from January 1, 2019, through June 30, 2019. A 6-month review and validation period follows the data collection period and precedes the data reporting period (the period where applicable information must be submitted to CMS).

During the 6-month review and validation period between the end of the data collection period and the beginning of the data reporting period, laboratories and reporting entities should assess whether the applicable laboratory thresholds are met. That is, determine whether each laboratory component of the reporting entity meets the majority of Medicare revenues threshold and low expenditure threshold from final Medicare paid claims received 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 it is reported to CMS.

The next data reporting period (the period where applicable information for an applicable laboratory is reported to CMS) is from January 1, 2020, through March 31, 2020. CMS will use the next data collection and reporting cycle to determine CLFS payment rates for CY 2021 through CY 2023.

This table illustrates the next data collection and reporting periods for CDLTs.

**Data Collection and Reporting Periods for CDLTs**

<b>Data Collection Period</b>	<b>Six-Month Review and Validation Period</b>	<b>Data Reporting Period</b>	<b>Used for CLFS Rate Years</b>
1/1/2019 – 6/30/2019	7/1/2019 – 12/31/2019	1/1/2020 – 3/31/2020	2021 – 2023
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 reporting is required every 3 years for CDLTs (that are not 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 additional information about ADLTs through separate instructions.

## 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 Medicare Part B under the hospital's NPI), meets the majority of Medicare revenues threshold and low expenditure threshold. Please 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 Medicare Part B under their own NPI and hospital outreach laboratories that bill Medicare Part B under their own NPI (separate from the hospital's NPI). The examples below illustrate 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 five CLIA-certified laboratories. Each laboratory bills using its own unique NPI and all five CLIA-certified laboratories individually meet both the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of five unique applicable laboratories. In this case, the reporting entity reports applicable information associated with each individual NPI that is 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 five applicable laboratories.

**Example 2:** A TIN-level entity consists of five CLIA-certified laboratories, each billing for services under its own unique NPI. However, only three of the laboratories individually meet both the majority of Medicare revenues threshold and low expenditure threshold while the remaining two laboratories do not individually meet the low expenditure threshold. In other words, two of the five CLIA-certified laboratories receive less than \$12,500 of revenue under the CLFS during the data collection period. This TIN-level entity consists of three unique applicable laboratories. In this case, the reporting entity will report applicable information associated with each individual NPI that is an applicable laboratory, but will not report information on the two individual NPIs of the laboratories that are not applicable laboratories. The reporting entity separates the applicable information by each NPI and submits applicable information during the data reporting period for three applicable laboratories.

**Example 3:** A TIN-level entity consists of five CLIA-certified laboratories and each laboratory has the same NPI and bills Medicare Part B under the same NPI. Collectively, the five CLIA-certified laboratories meet the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of one 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 other words, in this example, CMS considers the five CLIA-certified laboratories as one applicable laboratory for purposes of reporting applicable information because they all have the same NPI and all bill Medicare Part B under the same NPI.

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



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

**Example 6:** A TIN-level entity includes three CLIA-certified hospital outreach laboratories and all three laboratories have the same unique NPI and bill Medicare Part B under the same unique NPI (separate from the hospital's NPI). Collectively, the three CLIA-certified hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of one applicable laboratory. In this case, the reporting entity reports applicable information for all three hospital outreach laboratories associated with the same NPI as a single applicable laboratory. In other words, in this example, CMS considers the three CLIA-certified hospital outreach laboratories as one 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 Medicare 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 Medicare Part B under the hospital's NPI. The examples below illustrate reporting entities that must report applicable information for hospital outreach laboratories that bill Medicare 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 Medicare 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 therefore is an applicable laboratory. In this example, the reporting entity reports applicable information for its hospital outreach laboratory that bills Medicare Part B under the hospital's NPI.

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

**Example 3:** A TIN-level entity includes three CLIA-certified hospital outreach laboratories. Two (out of the three) hospital outreach laboratories bill for laboratory services performed for non-hospital patients using the hospital's NPI. Collectively, the two CLIA-certified hospital outreach laboratories that bill using the hospital's NPI meet the majority of Medicare revenues threshold and low expenditure threshold. However, one (out of the three) bills Medicare 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 two applicable laboratories.

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

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

*Only Applicable Information Attributed to non-Hospital Patients is Reported*

As discussed previously in this publication, a CLIA certified hospital outreach laboratory that bills Medicare Part B using the hospital's NPI must determine 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 Medicare Part B under the hospital's NPI meets the requirements of an applicable laboratory, only the hospital outreach laboratory component of the hospital laboratory (that is, laboratory tests furnished to non-hospital patients) is considered an applicable laboratory. Therefore, report only applicable information attributed to the laboratory's non-hospital patients to CMS.

The reporting entity for the hospital outreach laboratory that bills Medicare Part B under the hospital's NPI, and therefore determines 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 ensuring that the TIN-level entity can report applicable information to CMS. To that end, applicable laboratories and their reporting entity should determine the best approach to collect applicable information from final paid claims data and for submitting applicable information to CMS during the data reporting period.

#### *Voluntary Reporting is Not Permitted*

The reporting entity reports only applicable information for laboratory components that are applicable laboratories (that is, laboratories that meet the definition of an applicable laboratory). Reporting entities do **not** report applicable information for laboratories that do not meet the definition of an applicable laboratory.

**Example 1:** A TIN-level entity consists of four NPI-level entities. Three of the NPI-level entities meet the definition of an applicable laboratory, and one NPI-level entity does not meet the definition of an applicable laboratory. In this example, the reporting entity reports applicable information to CMS for **only** the three NPI-level entities that are applicable laboratories.

**Example 2:** A TIN-level entity includes one hospital outreach laboratory that bills Medicare 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 does not meet the low expenditure threshold. In other words, the hospital outreach laboratory does not receive at least \$12,500 in revenues from the Medicare CLFS during the data collection period. Therefore, the hospital outreach laboratory does not meet the definition of an applicable laboratory. In this example, the reporting entity does **not** report applicable information to CMS for its hospital outreach laboratory.

#### *Reporting Applicable Information is Not Discretionary*

Reporting entities must report all applicable information for its laboratory components that are applicable laboratories. Reporting entities do **not** have the discretion to selectively omit reporting certain applicable information.

**Example:** An applicable laboratory has various final paid claims for laboratory tests from the data collection period that are 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 **cannot** selectively omit reporting applicable information due to the perception that reporting such applicable information may not influence the final weighted median private payor rates for a given test. In this example, the reporting entity must report the applicable information obtained from the “paper-based” claims to CMS during the data reporting period.

#### IV. Condensed Data Reporting Option

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

For example, if three of the reporting entity’s corresponding applicable laboratories are paid the same private payor rate for a specific HCPCS code, the reporting entity may report one record of data showing the HCPCS code, the payment rate, and the associated volume, across all three applicable laboratories, rather than reporting three separate records (that is, one for each component applicable laboratory). 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 one NPI as the reporting NPI. That is, the reporting entity will designate one 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 that each unique private payor rate for each laboratory test code must be reported to CMS during the data reporting period. The condensed data reporting option is only permitted when a specific laboratory test code is paid at the same private payor rate to more than one applicable laboratory under the same TIN. Unique private payor rates paid to only one 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 illustrate how reporting entities may report condensed applicable information when three different applicable laboratories under the same TIN are paid the same private payor rate for the same laboratory test code during a data collection period, see the comparative examples below. These examples are meant to show the difference between the individual applicable laboratory data reporting method that is, by each component that is an applicable laboratory, and the condensed data reporting method and are not intended to be representative of every possible scenario.

**TABLE 1a – Example of Individual Applicable Laboratory Reporting for 2020 Data Submission**

NPI	HCPSC 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, three applicable laboratories are paid the same private payor rate for “Lab Test Code 1”. Therefore, the reporting entity reports applicable information individually for each of its component applicable laboratories.

**TABLE 1b- Example of Condensed Reporting for 2020 Data Submission (TIN-Level)**

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

This example illustrates how the scenario presented in Table 1a 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 HCPSC code at the reporting entity level (TIN-Level). The reporting entity designates one (of its three component applicable laboratories) as the reporting NPI.

**TABLE 2a – Example of Individual Applicable Laboratory Reporting for 2020 Data Submission**

NPI	HCPSC 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 example of the individual applicable laboratory data reporting method, three applicable laboratories are paid a private payor rate of \$15 for “Lab Test Code 1” and the same three 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 2b- Example of Condensed Reporting for 2020 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 example illustrates 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). In other words, 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 3a – Example of Individual Applicable Laboratory Reporting for 2020 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 example of the individual applicable laboratory data reporting method, three applicable laboratories are paid a private payor rate of \$15 for “Lab Test Code 1” and the same three applicable laboratories are also paid a private payor rate of \$17 for “Lab Test Code 1”. In addition, one of the three 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 3b- Example of Condensed Reporting for 2020 Data Submission (TIN-Level)**

Reporting NPI	HCPSC 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 example illustrates how the scenario presented in Table 3a 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 HCPSC code and the associated volume paid at each such rate. Since some private payor rates are paid to only one 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 one 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 three applicable laboratories for the private payor rate of \$15.00 may be combined and the volume among the three applicable laboratories for the private payor rate of \$17.00 may be combined.

However, condensed reporting would **not** be permitted for the unique private payor rates for “Lab Test Code 1” that are paid to only one applicable laboratory under the same TIN. Therefore, 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 determining CY 2021 CLFS payment rates: January 1, 2019, through June 30, 2019.
- Data reporting period for reporting entities to report private payor rate data to CMS for determining CY 2021 CLFS payment rates: January 1, 2020, through March 31, 2020.

- Annual laboratory public meeting for new tests: June/July 2020. CMS will use crosswalking or gapfilling to set rates for new tests and existing tests for which there is no private payor data collected for the CY 2021 CLFS.
- CMS publishes preliminary CLFS rates for CY 2021: Early September 2020. The public will have approximately 30 days, through early October 2020, to submit comments on the preliminary CY 2021 rates.
- CMS makes final CY 2021 CLFS rates available on the CMS website: Early November 2020.
- Implementation date for the next private payor rate-based CLFS update: January 1, 2021.

## ADDITIONAL INFORMATION

For 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, a PowerPoint slide presentation of the private payor rate-based CLFS and ADLTs, visit <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html>.

The CLFS final rule entitled Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule (CMS-1621-F) is available at <https://www.gpo.gov/fdsys/pkg/FR-2016-06-23/pdf/2016-14531.pdf>.

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) is available at <https://www.govinfo.gov/content/pkg/FR-2018-11-23/pdf/2018-24170.pdf>.

If you have questions about requirements for the private payor rate-based CLFS, please email them to the CLFS Inquiries mailbox at [CLFS\\_Inquiries@cms.hhs.gov](mailto:CLFS_Inquiries@cms.hhs.gov).

If you have questions, your MACs may have more information. Find their website at <http://go.cms.gov/MAC-website-list>.

## DOCUMENT HISTORY

Date of Change	Description
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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