

**Frequently Asked Questions  
CY 2019 Medicare Physician Fee Schedule Final Rule  
Revisions to the Medicare Clinical Diagnostic Laboratory Tests Payment System**

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 \(CMS-1693-F\)](#) was published on November 23, 2018. In this final rule, CMS made two revisions to the regulatory definition of applicable laboratory, effective January 1, 2019: 1) Medicare Advantage (MA) plan revenues are excluded from total Medicare revenues, the denominator of the majority of Medicare revenues threshold; and (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.

A compilation of frequently asked questions (FAQs) regarding the changes made to the private payor rate-based CLFS and the CMS responses are provided below. To go directly to a category of questions in this document, please click on the category link.

Please note that this document focuses on FAQs regarding the recent changes to the private payor rate-based CLFS as discussed in the CY 2019 PFS final rule (CMS-1693-F). **Additional FAQs pertaining to the private payor rate-based CLFS are also available on the CLFS website.** <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html>

Select: [Frequently Asked Questions \(Updated 3/09/2017\) \[PDF, 651KB\]](#)

Additional information regarding the private payor rate-based CLFS may be found on the CLFS website under the PAMA regulations tab via the following link:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html>

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## **Section 1: General Information**

### **Q1.1. What is an applicable laboratory?**

A1.1. Under the revised final policies for the new Medicare CLFS, an applicable laboratory is a laboratory (as defined under the CLIA regulatory definition of a laboratory in 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 TOB 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 PFS during the data collection period. It also must meet a low expenditure threshold, that is, it receives at least \$12,500 of its Medicare revenues from the CLFS during the data collection period.

### **Q1.2. What private payor data must be reported to CMS?**

A1.2. The reporting entity must report applicable information for each clinical diagnostic laboratory tests (CDLT) furnished by its component applicable laboratories. Applicable information is the private payor rate for each test for which final payment has been made during the data collection period, the associated volume for each test, and the specific HCPCS code associated with the test. If an applicable laboratory has more than one payment rate for the same private payor for the same test, or more than one payment rate for different payors for the same test, the reporting entity will report each such payment rate and the volume for the test at each such rate.

### **Q1.3. What is a private payor?**

A1.3. 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 MA 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).

### **Q1.4. What entity is responsible for reporting applicable information to CMS?**

A1.4. The TIN-level entity must report 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.

### **Q1.5. What is the data collection period and when does the next data collection period occur?**

A1.5. The data collection period is the period where applicable information for an applicable laboratory is obtained from private payor claims for which the laboratory received final payment

during the period. The next data collection period is from January 1, 2019, through June 30, 2019.

**Q1.6. What is the “6-month window” and what should the laboratory do during this time?**

A1.6. The “6-month window” is a review and validation period that follows the data collection period and precedes the data reporting period (the period where applicable information must be submitted to CMS). The next 6-month window occurs from July 1, 2019 through December 31, 2019.

During the 6-month window 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 a laboratory component of the TIN 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.

**Q1.7. What is the data reporting period and when does the next data reporting period occur?**

A1.7. The data reporting period is the period where the reporting entity reports applicable information for its component applicable laboratory(s) to CMS. The next data reporting period is from January 1, 2020, through March 31, 2020.

**Q1.8. How are laboratory tests paid under the private payor rate-based CLFS?**

A1.8. In general, the payment amount for a test on the CLFS furnished on or after January 1, 2018, is equal to the weighted median of private payor rates determined for the test, based on the applicable information that is collected during a data collection period and reported to CMS during a data reporting period. Crosswalking or gapfilling methodologies will be used to establish payment amounts for new CDLT and CLDTs for which CMS receives no applicable information.

**Q1.9. When is the next private payor rate-based CLFS update scheduled to occur?**

A1.9. The next data collection and data reporting cycle will be used to determine CLFS payment rates for CY 2021 through CY 2023.

**Section 2: Change to the Majority of Medicare Revenues Threshold**

**Q2.1. What modification did CMS make to the majority of Medicare revenues threshold?**

A2.1. Effective January 1, 2019, MA plan payments under Medicare Part C are no longer considered “Medicare Revenues” for purposes of determining whether a laboratory meets the majority of Medicare revenues threshold under the private payor rate-based CLFS.

**Q2.2. Why did CMS exclude MA plan payments from the total Medicare revenues component (the denominator) of the majority of Medicare revenues threshold?**

A2.2. We modified the definition of applicable laboratory to exclude MA plan payments from total Medicare revenues, the denominator of the majority of Medicare revenues threshold, so that more types of laboratories may qualify as an applicable laboratory. This change is consistent with our goal of obtaining a broader representation of laboratories that could potentially qualify as an applicable laboratory and report data. Specifically, excluding MA plan payments could allow additional laboratories of all types serving a significant population of beneficiaries enrolled in Medicare Part C to meet the majority of Medicare revenues threshold and potentially qualify as an applicable laboratory (if they also meet the low expenditure threshold) and report data to CMS during the data reporting period.

**Q2.3. How does excluding MA plan payments from total Medicare revenues potentially increase the number of applicable laboratories under the CLFS?**

A2.3. Since MA plan payments are now excluded from the total Medicare revenues calculation, the denominator amount (total Medicare revenues) would decrease. If the denominator amount decreases, the likelihood increases that a laboratory would qualify as an applicable laboratory. This is because the laboratory's PFS and CLFS revenues are being compared to a lower total Medicare payment amount (than what they would have been compared to if MA plan payments remained in the denominator).

**Q2.4. How does removal of MA plan payments change the total Medicare revenues component (the denominator) of the majority of Medicare revenues threshold?**

A2.4. Effective January 1, 2019, MA plan payments under Medicare Part C are not included in the total Medicare revenues component of the majority of Medicare revenues threshold calculation. In other words, for purposes of determining whether a laboratory meets the majority of Medicare threshold under the CLFS, "Total Medicare revenues" now includes the sum of all fee-for-service payments under Medicare Parts A and B, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period. Additional information regarding the majority of Medicare revenues threshold is available from the CLFS website.

**Section 3: Hospital Outreach Laboratories**

**Q3.1. Why did CMS make changes to the definition of applicable laboratory to include the Form CMS-1450 14x TOB?**

A3.1. Consistent with our goal of obtaining a broader representation of laboratories that could potentially qualify as an applicable laboratory and report data to us, we believe permitting the Form CMS-1450 14x TOB to define an applicable laboratory provides an opportunity for more hospital outreach laboratories to report applicable information for calculating CLFS rates.

**Q3.2. Why was it previously difficult for hospital outreach laboratories to meet the definition of an applicable laboratory?**

A3.2. Prior to this rule change, a hospital outreach laboratory that did not bill Medicare Part B under its own unique NPI (separate from the hospital's NPI) was required to determine whether it met the majority of Medicare revenues threshold based on Medicare revenues attributed to the hospital's NPI. As a result, the majority of Medicare revenues threshold and low expenditure threshold were applied to the NPI of the entire hospital. In this circumstance, it was unlikely that the hospital outreach laboratory could qualify as an applicable laboratory because the majority of Medicare revenues for the hospital's NPI were received from the Hospital Inpatient Prospective Payment System and/or Hospital Outpatient Prospective Payment System, not from the CLFS and/or PFS.

**Q3.3. How does this regulatory change to the definition of applicable laboratory potentially increase the number of hospital outreach laboratories reporting applicable information?**

A3.3. Using the Medicare revenues attributed to the Form CMS-1450 14x TOB to determine applicable laboratory status separates the hospital's outreach laboratory business from its total hospital business. As a result, the majority of Medicare revenues threshold and low expenditure threshold is calculated based on Medicare revenues attributed to the 14x TOB rather than from revenues attributed to the entire hospital.

**Q3.4. If a hospital laboratory has the same NPI as the hospital, is that considered the laboratory's own billing NPI?**

A3.4. If the outreach laboratory bills Medicare Part B using the hospital's NPI, then the hospital's NPI serves as the outreach laboratory's own billing NPI, making it difficult for hospital outreach laboratories to qualify as an applicable laboratory. Under the new policy, if the outreach laboratory bills Medicare Part B for testing performed on non-hospital patients under the hospital's NPI, the determination of applicable laboratory status for the outreach laboratory is based on its Medicare revenues attributed to the 14x TOB (not the hospital's NPI).

**Q3.5. What is the definition of a hospital outreach laboratory?**

A3.5. 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 TOB.

**Q3.6. What is the definition of non-patient?**

A3.6. For purposes of determining whether a hospital outreach laboratory is an applicable laboratory under the private payor rate-based CLFS, a non-patient is a non-hospital patient. That is, the patient is neither a registered hospital outpatient nor an admitted hospital inpatient.

**Q3.7. How does a hospital outreach laboratory that bills Medicare Part B using the hospital's NPI determine applicable laboratory status under the private payor rate-based CLFS?**

A3.7. A hospital outreach laboratory that bills Medicare Part B under the hospital's NPI would 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.

**Q3.8. If a hospital has more than one outreach laboratory that bills Medicare Part B under the hospital's NPI, how would applicable laboratory status be determined?**

A3.8. If a hospital has more than one hospital outreach laboratory that bills Medicare Part B for non-hospital patients under the hospital's NPI, the determination of applicable laboratory status is based on the combined revenues received from CMS Form-1450 14x TOB. For example, if a hospital includes three CLIA-certified hospital outreach laboratories that bill Medicare Part B under the hospital's NPI, the majority of Medicare revenues threshold and low expenditure threshold are applied based on the combined Medicare revenues that are attributed to the 14x TOB for all three CLIA-certified hospital outreach laboratories.

**Q3.9. How does a hospital outreach laboratory that bills Medicare Part B under its own unique NPI (separate from the hospital's NPI) determine applicable laboratory status under the private payor rate-based CLFS?**

A3.9. A hospital outreach laboratory that bills Medicare Part B under its own unique NPI (separate from the hospital's NPI), would continue to determine whether it meets the majority of Medicare revenues threshold and low expenditure threshold based on the Medicare revenues attributed to its own billing NPI.

**Q3.10. If a hospital includes an outreach laboratory that bills Medicare Part B under its own NPI (separate from the hospital's NPI) and another outreach laboratory that bills Medicare Part B under the hospital's NPI, how would applicable laboratory status be determined?**

A3.10. In this scenario, the hospital has two potential applicable laboratories. In other words, applicable laboratory status would be determined for the hospital outreach laboratory that bills Medicare Part B for testing furnished to non-hospital patients using its own NPI separately from the hospital outreach laboratory that bills Medicare Part B for non-hospital patients under the hospital's NPI.

For example, if a hospital includes an outreach laboratory that bills for laboratory services performed for non-hospital patients using the hospital's NPI, applicable laboratory status must be determined based on the revenues attributed to the Form CMS-1450 14x TOB. If the hospital also includes another hospital outreach laboratory that bills for laboratory services performed for non-hospital patients using its own unique NPI (separate from the hospital's NPI) the determination of applicable laboratory status for this laboratory is based on the revenues attributed to the outreach laboratory's unique billing NPI.

**Q3.11. If the laboratory does not have a distinct NPI from the hospital, does that indicate that the laboratory is not required to submit applicable information to CMS?**

A3.11. As discussed above, hospital outreach laboratories that bill Medicare Part B using the hospital's NPI instead of under its own unique NPI (separate from the hospital) must determine applicable laboratory status based on Medicare revenues from the Form CMS-1450 14x TOB. That is, the hospital must determine whether its hospital outreach laboratory meets the majority of Medicare revenues threshold and low expenditure threshold using Medicare revenues from the 14x TOB. If the outreach laboratory meets the definition of an applicable laboratory, then its reporting entity must report applicable information during the data reporting period.

**Q3.12. Do hospital outreach laboratories that bill Medicare Part B under the hospital's NPI need to meet the majority of Medicare revenues threshold? If so, should all of the hospital's revenue be factored into total Medicare revenues (the denominator of the majority of Medicare revenues threshold)?**

A3.12. A CLIA certified hospital outreach laboratory must meet the majority of Medicare revenues threshold and low expenditure threshold to be an applicable laboratory. Hospital outreach laboratories, that bill Medicare Part B using the hospital's NPI (and therefore, use the revenues attributed to the 14x TOB to determine applicable laboratory status) should only include the Medicare revenues attributed to the 14x TOB in the denominator of the majority of Medicare revenues threshold.

**Q3.13. For hospital outreach laboratories that bill Medicare Part B under the hospital's NPI and therefore, determine applicable laboratory status based on the 14x TOB, what revenues are included in the numerator of the majority of Medicare revenues threshold?**

A3.13. The numerator of the majority of Medicare revenues threshold equation includes Medicare revenues derived from the CLFS and/or PFS attributed to the 14x TOB during the data collection period. As noted above, the denominator includes total Medicare revenues received during the data collection period attributed to the 14x TOB.

**Q3.14. For hospital laboratories that bill Medicare Part B under their own unique NPI (separate from the hospital), what revenues are included in the numerator and denominator of the majority of Medicare revenues threshold equation?**

A3.14. For hospital outreach laboratories that bill Medicare Part B under their own unique NPI, separate from the hospital's NPI, the numerator includes all CLFS and PFS revenues received during the data collection period by the hospital outreach laboratory's own unique NPI (which is separate from the hospital's NPI). The denominator includes total Medicare revenues attributed to the hospital outreach laboratory's own unique billing NPI (separate from the hospital's NPI).

**Q3.15. Are hospital outreach laboratories likely to meet the majority of Medicare revenues threshold?**

A3.15. Hospital outreach laboratories 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, for a given CLIA certified hospital outreach laboratory, the revenues from the CLFS and or PFS services included in the numerator are essentially the same as its total Medicare revenues included in the denominator. Therefore, hospital outreach laboratories would likely meet the majority of Medicare revenues threshold. However, note that to be an applicable laboratory, the hospital outreach laboratory must also meet the low expenditure threshold, that is, receive at least \$12,500 in CLFS revenues during a data collection period.

**Q3.16. Given that most hospital NPI's receive the majority of their Medicare revenues from the hospital Inpatient Prospective Payment System, how would determining applicable laboratory status based on the 14x TOB increase the number of hospital laboratories reporting data?**

A3.16. Since using the 14x TOB for determining applicable laboratory status only applies to the hospital outreach laboratory component of a hospital's total business, only the revenues associated with the hospital outreach laboratory (non-hospital patient testing), as attributed to the 14x TOB, are included in the numerator and the denominator of the majority of Medicare revenues threshold equation. Therefore, as noted above, hospital outreach laboratories that bill Medicare part B for non-hospital patients using the hospital's NPI would likely meet the majority of Medicare revenues threshold hospital. If a CLIA certified hospital outreach laboratory also meets the low expenditure threshold, it would be an applicable laboratory and report applicable information which is used to calculate CLFS rates.

**Q3.17. Are hospital outreach laboratories already paid on the private payor rate-based CLFS for testing furnished to non-hospital patients?**

A3.17. The private payor rate-based CLFS applies to all laboratories regardless of whether the laboratory is an applicable laboratory or not. In other words, hospital outreach laboratories that were not considered applicable laboratories for CYs 2018 through 2020, are currently receiving payment under the private payor rate-based CLFS for testing furnished to Medicare beneficiaries that are non-hospital patients.

**Q3.18. Many private payors don't pay for hospital outreach laboratory services per individual CPT/HCPCS code; rather they bundle payment and/or pay at the claims level. Would hospitals have to report private payor data that is not paid by private payors at the CPT/HCPCS code level? If so, how would that work?**

A3.18. Only HCPCS level applicable information is reported to CMS, bundled payment data is not reported. Bundled payment amounts or claims level payments are not private payor rates for purposes of determining applicable information and therefore not reported to CMS by the reporting entity during the data reporting period.



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

**Q3.19. How do hospital outreach laboratories report applicable information to CMS?**

A3.19. Applicable information will continue to be reported by the reporting entity (TIN-level entity) at the NPI-level. For hospital outreach laboratories that bill Medicare Part B using the hospital's NPI (and therefore, determine applicable laboratory status based on the revenues attributed to the 14x TOB) the reporting entity must **report** applicable information to CMS under the hospital's NPI.

For hospital outreach laboratories that bill Medicare Part B using a unique NPI (separate from the hospital's NPI), the reporting entity must report applicable information under the hospital outreach laboratory's own unique NPI. Additional instructions regarding the CMS data collection system and how reporting entities are to report applicable information is available on the CLFS website.

**Q3.20. How does data reporting work when a hospital has more than one hospital outreach laboratory that bills Medicare Part B under the hospital's NPI?**

A3.20. Presuming the applicable laboratory criteria are met, the reporting entity collectively reports applicable information for its hospital outreach laboratories that bill Medicare Part B under the hospital's NPI.

**Q3.21. How does data reporting work when a hospital has more than one hospital outreach laboratory that bills Medicare Part B using its own NPI (separate from the hospital's NPI)?**

A3.21. When a hospital includes more than one hospital outreach laboratory that bills Medicare Part B using its **own unique NPI** (separate from the hospital's NPI), the reporting entity reports applicable information associated with each individual NPI that is an applicable laboratory. In other words, the reporting entity separates the applicable information by each unique billing NPI (that is separate from the hospital's NPI) and submits applicable information during the data reporting period for each applicable laboratory.

**Q3.22 Do hospital outreach laboratories that are applicable laboratories based on the revenues attributed to the 14x TOB only need to collect and report the private payor data that is billed using a 14x TOB? Or, would hospital outreach laboratories need to collect and report private payor data that is billed in other ways as well?**

A3.22. Reporting applicable information is not discretionary. If the hospital outreach laboratory is an applicable laboratory, it would be responsible for collecting and reporting all applicable information attributed to its applicable laboratory. When a hospital outreach laboratory is an applicable laboratory as defined by the revenues attributed to the 14x TOB, applicable

information for all non-patient laboratory test services must be reported, regardless of the TOB required by the private payor for laboratory tests furnished to non-hospital patients.

**Q3.23. What if the private payor does not use the Form CMS-1450 14x TOB for laboratory tests furnished to non-hospital patients?**

A3.23. 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) for laboratory tests furnished to non-patients (the applicable laboratory) from private payor fee-for-service payments (and associated volume) for laboratory tests furnished to hospital patients. For example, if a private payor requires a hospital laboratory to use the Form CMS-1450 13x TOB for laboratory tests furnished for hospital outpatients and non-hospital patients (instead of the 13x TOB for hospital outpatients and the 14x TOB for non-hospital patients), the hospital must develop a mechanism to identify the private payor rates and corresponding volume furnished to non-hospital patients.

**Q3.24. If a hospital outreach laboratory bills Medicare Part B under the hospital's NPI and meets the definition of an applicable laboratory based on the revenues attributed to the 14x TOB, is the hospital required to collect and report applicable information for all of its CLIA certified laboratories under the hospital's NPI, or just specific to the hospital outreach laboratory?**

A3.24. For purposes of determining Medicare rates under the private payor rate-based CLFS, only applicable information attributed to the applicable laboratory is reported to CMS. In the scenario described, wherein a hospital outreach laboratory meets the definition of an applicable laboratory based on its revenues attributed to the 14x TOB, the applicable laboratory is defined by the 14x TOB (which is used by Medicare Part B for laboratory testing furnished to non-hospital patients). Therefore, only applicable information associated with the hospital's outreach laboratory business, that is testing furnished to non-hospital patients, must be collected and reported during the data reporting period.

A hospital outreach laboratory that bills Medicare Part B under the hospital's NPI that meets the definition of an applicable laboratory based on revenues attributed to the 14x TOB, may not report applicable information for other components of the hospital's laboratory business such as testing performed for hospital outpatients or hospital inpatients.

**Q3.25. What about a hospital outreach laboratory that bills Medicare Part B under its own unique NPI (separate from the hospital's NPI), does the reporting entity only report applicable information associated with the hospital's outreach laboratory business, that is, only the testing furnished to non-hospital patients?**

A3.25. As noted previously, all applicable information attributed to the applicable laboratory must be reported by the reporting entity during the data reporting period. If a hospital outreach laboratory bills Medicare Part B under its own unique NPI (separate from the hospital's NPI) the determination of applicable laboratory status is based on Medicare revenues attributed to its own billing NPI and therefore, the applicable laboratory is defined by its own NPI. In this scenario,

the reporting entity reports all applicable information (private payor data) attributed to the laboratory's own unique billing NPI, which may include testing furnished to non-hospital patients as well as testing furnished to hospital patients.

#### **Section 4: Condensed Data Reporting Option**

##### **Q4.1. What is the condensed data reporting option?**

A1. For the next data reporting period, that is January 1, 2020 through March 31, 2020, reporting entities have the option of condensing certain applicable information at the TIN-level instead of reporting individually for each component that is an applicable laboratory. Under the condensed data reporting option, 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 reporting entity may combine the volume paid at the same private payor rate for the same HCPCS code for its component applicable laboratories.

##### **Q4.2 What NPI is reported under the condensed data reporting option?**

A4.2. 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.

##### **Q4.3. Is condensed reporting a requirement?**

A4.3. No. 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.

#### **Section 5: Additional Information**

##### **Q5.1. Should a laboratory report applicable information if it only has applicable information for 1 test?**

A5.1. Yes. If a laboratory meets the definition of an applicable laboratory and the 1 test is subject to the data collection and reporting requirements, the reporting entity must report applicable information for the test.

##### **Q5.2. If a private payor paid an initial claim amount for a test before the data collection period, then during the data collection period the private payor denies payment for the initial claim would that claim be reportable?**

A5.2. No, because the final paid claim during the data collection period is \$0.00. 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, \$0.00 for a laboratory test code is not reported. Only the final paid claim amount and the associated volume of tests paid at the final paid claim amount are reported.

**Q5.3. If the private payor paid an amount for a test during the data collection period and closed it out with a different “final” payment after the data collection period was over, would this claim be reportable?**

A5.3. In this scenario, the final paid claim occurred after the data collection period ended. Only final paid claims received during the data collection period are applicable information. Therefore, this claim would not be considered applicable information and is not reported. Please note that applicable laboratories should use the “6-month window” (July 1, 2019 through December 31, 2019) to review, assess and validate the applicable information before reporting to CMS during the data reporting period.

**Q5.4. Does the data reporting requirement apply to critical access hospitals?**

A5.4. All applicable laboratories are subject to the data collection and data reporting requirements. To the extent that a critical access hospital has an outreach laboratory (that is, a CLIA certified laboratory that performs testing for non-hospital patients), and the outreach laboratory meets the majority of Medicare revenues threshold and low expenditure threshold, it would meet the definition of an applicable laboratory and be subject to the data reporting requirements.

**Q5.6. Is the data reporting period for the entire year or will reporting entities be required to report monthly starting in 2020?**

A5.6. The data reporting period is the 3-month period from January 1<sup>st</sup> through March 30<sup>th</sup> during which a reporting entity reports applicable information to CMS. The reporting entity reports applicable information collected during the data collection period. The current data collection period is January 1, 2019 through June 30, 2019. The next data reporting period is January 1, 2020 through March 31, 2020. The reporting entity reports applicable information for its component applicable laboratory(s) only during the data reporting period.

**Q5.7. Will CMS be updating the instructions on the data collection system used for reporting applicable information? If so, where will the revised instructions be available?**

A5.7. We will be updating the instructions on how the reporting entity must report applicable information for its component applicable laboratories under the CMS data collection system. Updated instructions regarding the CMS data collection period for purposes of reporting applicable information during the data reporting period, that is, January 1, 2020 through March 31, 2020 will be made available on the CLFS website.

**Q5.8. When reporting applicable information, is the volume paid at each private payor rate for each laboratory test code applied at the individual claim level or does the volume apply to the entire data collection period?**

A5.8. Applicable information includes the specific HCPCS code associated with the test, each private payor rate for which final payment has been made during the data collection period and the associated volume of tests performed corresponding to each private payor rate. The volume reported reflects the total number of times a specific private payor rate was paid for a specific HCPCS code during the entire data collection period, January 1, 2019 through June 30, 2019.

**Q5.9. Are payments received from MA plans for laboratory test codes included on the CLFS considered as “CLFS revenues” for purposes of determining whether a laboratory meets the low expenditure threshold?**

A5.9. The low expenditure threshold component of the definition of an applicable laboratory requires a laboratory to receive at least \$12,500 of its Medicare revenues from the CLFS in a data collection period. MA plan payments are excluded for purposes of determining whether a laboratory meets the low expenditure threshold. MA plan payments under Part C are not considered Medicare revenues for purposes of determining applicable laboratory status. MA plan payments to laboratories can be considered to only be private payor payments under the CLFS. Therefore, an applicable laboratory that receives MA plan payments is to consider those MA plan payments in identifying its applicable information, which must be reported to CMS.

**Q5.10. Are Railroad Medicare payments for laboratory tests included on the CLFS considered as “CLFS revenues” for purposes of determining whether a laboratory meets the low expenditure threshold?**

A5.10. With regard to Railroad payor rates, Railroad Medicare is essentially the same as regular Medicare. The main difference is that retired railroad workers enroll in Medicare through the Railroad Retirement Board (RRB) rather than the Social Security Administration. Railroad Medicare beneficiaries have the same access to Medicare Parts A, B, C, and D as other Medicare beneficiaries. Therefore, revenues received from the Medicare Part B CLFS for testing furnished to a Medicare beneficiary enrolled through the RRB, are included for the purpose of determining whether a laboratory meets the low expenditure threshold.

**Q5.11. Please clarify whether a physician’s office laboratory may be an applicable laboratory regardless of whether they use a 14x bill type?**

A5.11. Use of the 14x TOB for determining whether a laboratory meets the majority of Medicare revenues threshold and low expenditure threshold only applies to hospital outreach laboratories that bill Medicare Part B under the hospital’s NPI. A physician’s office laboratory may be an applicable laboratory if its laboratory is CLIA certified and by its own billing NPI meets the majority of Medicare revenues threshold and low expenditure threshold.

**Q5.12. Where can I find the laboratory tests subject to the data collection and data reporting requirements?**

A5.12. A list of laboratory test codes that are subject to the data collection and data reporting requirements for purposes of calculating the CY 2021 through CY 2023 private payor rate-based CLFS is available from the CLFS website, PAMA regulations tab:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html>.

Select: [CLFS Applicable Information HCPCS Codes \[ZIP, 57KB\]](#) from the “Downloads” section.

**Q5.13. If a private payor is using a miscellaneous CPT code to pay for a laboratory test code that is subject to the data collection and data reporting requirements, should the miscellaneous CPT code be crosswalked back to the specific laboratory test code subject to the data collection and reporting requirements?**

A5.13. No. Because miscellaneous codes do not identify a specific laboratory test, they are not subject to the data collection and data reporting requirements. The reporting entity should not crosswalk private payor data from a miscellaneous CPT code to a laboratory test code subject to the data collection and reporting requirements.

**Q5.14. Are any additional FAQs relevant to the private payor rate-based CLFS available?**

A5.14. Yes. Additional FAQs regarding the private payor rate-based CLFS are available from the CLFS website, PAMA regulations tab: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html>.

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