# Clinical Laboratory Fee Schedule: PAMA Reporting Frequently Asked Questions (FAQs)

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### Background:

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. A final rule entitled "Medicare Clinical Diagnostic Laboratory Tests Payment System" (CLFS final rule), which appeared in the Federal Register on June 23, 2016 (81 FR 41036), implemented section 1834A of the Act at 42 CFR part 414, subpart G.

Under the CLFS final rule, "reporting entities" must report to CMS during a "data reporting period" "applicable information" collected during a "data collection period" for their component "applicable laboratories." The first data collection period occurred from January 1, 2016, through June 30, 2016. The first data reporting period occurred from January 1, 2017, through March 31, 2017.

In the CY 2019 Physician Fee Schedule (PFS) final rule (83 FR 59667-59681), 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 future data reporting periods, 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.

Beginning in 2019, Congress passed a series of legislation to modify the statutory requirements for the data reporting period and phase-in of payment reductions under the CLFS for clinical diagnostic laboratory tests (CDLTs) that are not advanced diagnostic laboratory tests (ADLTs) under Section 1834A of the Act, including:

- Section 105 (a) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116-94, enacted December 19, 2019)
- Section 3718 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Pub. L. 116-136, enacted March 27, 2020)
- Section 4 of the Protecting Medicare and American Farmers from Sequester Cuts Act (PMAFSCA) (Pub. L. 117–71, enacted December 10, 2021)
- Section 4114 of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328, enacted December 29, 2022)
- Section 502 of the Further Continuing Appropriations and Other Extensions Act, 2024

(FCAOEA, 2024) (Pub. L. 118–22, enacted November 17, 2023)
- Section 6209 of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 (Pub. L. 119-37, enacted November 12, 2025)

Most recently, section 6226 of the Consolidated Appropriations Act, 2026 (CAA of 2026) (Public Law 119–75, enacted February 3, 2026) further delayed the reporting requirement, the application of the 15% phase-in reduction, and changed the data collection period. In summary, under these revisions:

- The next data reporting period for CDLTs that are not ADLTs will be May 1, 2026 through July 31, 2026 and will be based on a data collection period of January 1, 2025 through June 30, 2025.
- After this data reporting period, the three-year data reporting cycle for these tests will resume (that is 2029, 2032, etc.).
- The statutory phase-in of payment reductions resulting from private payor rate implementation is extended by an additional year, that is, through CY 2029. There is a 0.0 percent reduction for CY 2021 through 2026, and payment may not be reduced by more than 15 percent for CYs 2027 through 2029 as compared to the prior year. Section 1834A(b)(3) of the Act limits the reduction of the payment amount for an existing test as compared to the payment amount for the preceding year.

**For additional information:**

- Questions on the CLFS data collection and reporting requirements may be submitted to CMS' CLFS mailbox (clfs_inquiries@cms.hhs.gov).
- Questions on system access to the CLFS portal to report applicable information may be submitted to the CLFS Helpdesk (clfshelpdesk@dcca.com).
- For additional resources, please see CMS' CLFS website

## Section 1: Current Data Collection and Reporting Dates:

### Q1.1. What is the data reporting period and when does the next data reporting period occur for CDLTs that are not ADLTs?

A1.1. The data reporting period is from May 1, 2026-July 31, 2026. This reporting period is based on data collected from January 1, 2025-June 30, 2025.

### Q1.2. When is the next private payor rate-based CLFS update for most tests scheduled to occur?

A1.2. The upcoming reported data for CDLTs that are not ADLTs will be used to determine CLFS payment rates for CY 2027 through CY 2029.

## Section 2: General Information

### Q2.1. What are laboratories required to do?

A2.1. Under the CLFS, applicable laboratories or "reporting entities" collect and report to CMS "applicable information" consisting of private payor rates for each test and the volume of tests paid at each rate, and the specific Healthcare Common Procedure Coding System (HCPCS) codes associated with the test. CLFS payment amounts will be determined based on the weighted median private payor rate for a given laboratory test, with certain exceptions for new tests and a group of tests defined by statute as new ADLTs.

### Q2.2. How are laboratory tests paid under the private payor rate-based CLFS?

A2.2. 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 CDLTs for which CMS receives no applicable information.

## Section 3: Applicable Laboratories and Reporting Entity

### Q3.1. What is an applicable laboratory?

A3.1. 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 National Provider Identifier (NPI) or for hospital outreach laboratories, bills Medicare Part B on the Form CMS-1450 under Type of Bill (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 Physician Fee Schedule (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.

### Q3.2. What entity is responsible for reporting applicable information to CMS?

A3.2. The Tax Identification Number (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 National Provider Identifier (NPI) or the 14x Type of Bill (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.

### Q3.3. How is CMS determining whether the "majority of Medicare revenues" for a laboratory are from the CLFS and/or the Physician Fee Schedule (PFS)?

A3.3. Applying the standard definition of majority, which is more than 50 percent, a National Provider Identifier (NPI) that is a laboratory (under the CLIA regulatory definition of laboratory) would meet the "majority of Medicare revenues" threshold if more than 50 percent of its total Medicare revenues are from the CLFS and/or the PFS during a data collection period.

### Q3.4. What modification did CMS make to the majority of Medicare revenues threshold?

A3.4. Effective January 1, 2019, Medicare Advantage (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. 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.

### Q3.5. Is voluntary reporting permitted for laboratories that do not meet the definition of applicable laboratory?

A3.5. Only applicable information of applicable laboratories may be reported. Applicable information may not be reported for an entity that does not meet the definition of applicable laboratory.

### Q3.6. Will each National Provider Identifier (NPI)-level entity that is a CLIA-certified laboratory be required to report private payor rate and volume data to CMS?

A3.6. No. As discussed above in A3.4, the TIN-level entity is the reporting entity. The reporting entity must report applicable information for all of its component NPI-level entities that meet the definition of an applicable laboratory. Applicable laboratories generally must receive at least $12,500 in Medicare CLFS revenues for laboratory services during a data collection period and receive more than 50 percent of their Medicare revenues from CLFS and Physician Fee Schedule (PFS) services during the data collection period.

### Q3.7. Why did CMS make changes in the CY 2019 Physician Fee Schedule final rule to the definition of applicable laboratory to include the Form CMS-1450 14x Type of Bill (TOB)?

A3.7. 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.

### Q3.8. Can a hospital laboratory that bills under the hospital's NPI ever be considered a potential applicable laboratory since it does not have its own NPI number?

A3.8. Yes. However, it is highly unlikely because the majority of Medicare revenues for the NPI will not be derived from the Medicare CLFS and or the Medicare PFS. Example 7 from the Medicare Learning Network article SE1619 is an example of this scenario.

This example is provided below.

Example: A CLIA-certified hospital laboratory that performs laboratory services primarily for its hospital inpatients and hospital outpatients has the same NPI as the hospital. Laboratory services performed for non-hospital patients are billed using the hospital's NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to the NPI of the entire hospital. In this circumstance, it is unlikely that the hospital laboratory qualifies as an applicable laboratory because the majority of Medicare revenues for the NPI are received from the Hospital Inpatient Prospective Payment System and/or Hospital Outpatient Prospective Payment System, not from the CLFS and/or PFS.

### Q3.9. Would a hospital outreach laboratory with its own billing NPI (separate from the hospital's NPI) qualify as an applicable laboratory?

A3.9. The majority of Medicare revenues threshold and low expenditure threshold would be applied to the NPI of the hospital outreach laboratory and not to the hospital's NPI. If the hospital outreach laboratory, by its own billing NPI, meets the majority of Medicare revenue threshold and low expenditure threshold, it would qualify as an applicable laboratory.

**Q3.10. Would a hospital outreach laboratory (with its own NPI) that bills for its laboratory services to Medicare Part A be considered Medicare Part B revenue, and therefore part of the numerator for calculating the majority of Medicare revenues threshold?**

A3.10. Yes, all revenues received from the CLFS and PFS are Medicare Part B revenues and would be included in the numerator for purposes of determining whether a laboratory meets the majority of Medicare revenues threshold. If the hospital outreach laboratory bills for services paid on the CLFS and PFS using the CMS 1450 to the A/B MAC (A), the revenues are paid from Part B.

### Q3.11. If a hospital laboratory has the same National Provider Identifier (NPI) as the hospital, is that considered the laboratory's own billing NPI?

A3.11. 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. 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 Type of Bill (TOB) (not the hospital's NPI).

### Q3.12. What is the definition of a hospital outreach laboratory?

A3.12. For purposes of determining applicable laboratory status under the private payor rate-based CLFS, a hospital outreach laboratory means a hospital-based laboratory that furnishes laboratory tests to patients other than inpatients or registered outpatients of the hospital. A hospital outreach laboratory bills for Medicare Part B services furnished to non-hospital patients using the Form CMS-1450 14x Type of Bill (TOB).

### Q3.13. What is the definition of non-patient?

A3.13. 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.

### Q3.14. How does a hospital outreach laboratory that bills Medicare Part B using the hospital's National Provider Identifier (NPI) determine applicable laboratory status under the private payor rate-based CLFS?

A3.14. 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 Type of Bill (TOB).

### Q3.15. If a hospital has more than one outreach laboratory that bills Medicare Part B under the hospital's National Provider Identifier (NPI), how would applicable laboratory status be determined?

A3.15. 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 Type of Bill (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.

### Q3.16. How does a hospital outreach laboratory that bills Medicare Part B under its own unique National Provider Identifier (NPI) (separate from the hospital's NPI) determine applicable laboratory status under the private payor rate-based CLFS?

A3.16. 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.

### Q3.17. 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?

A3.17. 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 Type of Bill (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.

### Q3.18. 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?

A3.18. 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 Type of Bill (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.

### Q3.19. 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)?

A3.19. 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 Type of Bill (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.

### Q3.20. For hospital outreach laboratories that bill Medicare Part B under the hospital's National Provider Identifier (NPI) and therefore, determine applicable laboratory status based on the 14x Type of Bill (TOB), what revenues are included in the numerator of the majority of Medicare revenues threshold?

A3.20. The numerator of the majority of Medicare revenues threshold equation includes Medicare revenues derived from the CLFS and/or Physician Fee Schedule (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.

### Q3.21. For hospital laboratories that bill Medicare Part B under their own unique National Provider Identifier (NPI) (separate from the hospital), what revenues are included in the numerator and denominator of the majority of Medicare revenues threshold equation?

A3.21. 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 Physician Fee Schedule (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).

### Q3.22. Are hospital outreach laboratories likely to meet the majority of Medicare revenues threshold?

A3.22. 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 Physician Fee Schedule (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.

**Q3.23. Given that most hospital National Provider Identifier (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 Type of Bill (TOB) increase the number of hospital laboratories reporting data?**

A3.23. 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.

**Q3.24. Are hospital outreach laboratories already paid on the private payor rate-based CLFS for testing furnished to non-hospital patients?**

A3.24. The private payor rate-based CLFS applies to all laboratories regardless of whether the laboratory is an applicable laboratory or not. Hospital outreach laboratories are currently receiving payment under the private payor rate-based CLFS for testing furnished to Medicare beneficiaries that are non-hospital patients.

**Q3.25. Are payments received from Medicare Advantage (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?**

A3.25. 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.

**Q3.26. 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?**

A3.26. 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.

### Q3.27. Please clarify whether a physician's office laboratory may be an applicable laboratory regardless of whether they use a 14x bill type?

A3.27. Use of the 14x Type of Bill (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 National Provider Identifier (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.

### Q3.28. In order to qualify as an applicable laboratory, does a laboratory have to be assigned its own unique National Provider Identifier (NPI) number (that is, the NPI is assigned only to a given laboratory) which then bills for its laboratory services only under its unique laboratory NPI?

A3.28. No, a laboratory could share an NPI with another laboratory or other supplier such as a physician's office or group practice. That is, although a laboratory must have its own NPI, the group practice could also be assigned the same NPI as the laboratory. In other words, the laboratory's NPI doesn't have to be unique to the laboratory. If the laboratory and group practice are both assigned the same NPI and the group practice bills for its laboratory's services, then in essence, the laboratory's services are being billed under its own NPI. For example: An entity consists of five physician offices and one CLIA-certified laboratory. All five physician offices and the CLIA-certified laboratory are assigned 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, the entity is considered a single laboratory for purposes of applying the majority of Medicare revenues threshold and low expenditure threshold.

### Q3.29. Can a laboratory qualify as an applicable laboratory if the laboratory and group practice are assigned different National Provider Identifiers (NPIs)?

A3.29. If the group practice is assigned a different NPI (different from its laboratory) and the group practice bills for its laboratory's services under the group practice NPI, the laboratory's services are not being billed under the laboratory's own NPI. The laboratory does not qualify as an applicable laboratory if no services are billed to Medicare Part B under its own NPI because no revenues attributed to the NPI are assigned to the laboratory.

### Q3.30. For determining whether a laboratory meets the majority of Medicare revenue threshold and low expenditure threshold, with regard to the "billing NPI" does it mean the individual physician's National Provider Identifier (NPI) (Box 24J on the claim), or the group NPI (box 33 on the claim)?

A3.30. The majority of Medicare revenues threshold and low expenditure threshold is applied to the laboratory's own billing NPI. As noted in a previous response, if the laboratory in the group practice is assigned the same NPI as the ordering provider's NPI, and the ordering provider's NPI is used to bill for the laboratory's services, the majority of Medicare revenues threshold and low expenditure threshold would be applied to the billing NPI (Item 33a on the CMS-1500). However, if the laboratory has a different NPI from the billing NPI or if the laboratory has not been assigned an NPI, the laboratory does not qualify to be an applicable laboratory. In other words, in order to qualify to be an applicable laboratory, the CLIA certified laboratory must be assigned an NPI and have its services

billed to Medicare Part B under that NPI.

For example, if a group practice did not separately apply for an NPI for its Physician Office Laboratory (POL) and did not include the laboratory as part of the practice when applying for an NPI, the laboratory would not be assigned an NPI. In this instance, the POL cannot qualify as an applicable laboratory. Or, if an independent laboratory that has not been assigned an NPI uses another laboratory to bill for its laboratory services, the laboratory that does not have an NPI cannot qualify as an applicable laboratory.

### Q3.31. If a physician's office practice that is assigned its own National Provider Identifier (NPI) and bills both its physician services and its laboratory services under its own NPI and not under a unique laboratory NPI, can the physician's office laboratory be considered an applicable lab?

A3.31. If the physician office practice and physician office laboratory are assigned different NPIs, the answer is no. In other words, if the laboratory is not assigned the same NPI as the physician office practice, and the physician office practice bills for laboratory services using the NPI of the physician office practice, the laboratory does not qualify to be an applicable laboratory.

### Q3.32. Can a physician office laboratory qualify as an applicable laboratory if its laboratory services are billed using the National Provider Identifier (NPI) of the laboratory when the laboratory and physician's office practice are assigned different NPIs?

A3.32. Yes. If the laboratory's services are billed under the laboratory's NPI (and not the physician's office NPI), the laboratory could qualify as an applicable laboratory if the laboratory's NPI meets the majority of Medicare revenue threshold and low expenditure threshold.

### Q3.33. Are laboratories in Rural Health Clinics or Federally Qualified Health Centers subject to the data collection and reporting requirements under PAMA?

A3.33. Although RHCs and FQHCs may be required to furnish certain laboratory services, laboratory services are not within the scope of the RHC or FQHC benefit and are not billed under the RHC or FQHC payment methodologies. Therefore, if the laboratory is CLIA certified, has its own National Provider Identifier (NPI) and its laboratory services are billed under the laboratory's own NPI, the laboratory must determine whether it qualifies as an applicable laboratory for purposes of reporting applicable information to CMS.

### Q3.34. Should beneficiary deductible and coinsurance amounts be included in the numerator as well as the denominator of the majority of Medicare revenues threshold equation?

A3.34. With regard to determining whether a laboratory meets the majority of Medicare revenues threshold, we clarify that any applicable beneficiary cost sharing, for example, deductible and coinsurance, should be included in both the numerator (PFS revenues + CLFS revenues) and denominator (total Medicare revenues). Although laboratory services paid under the CLFS are generally not subject to a beneficiary deductible or coinsurance amount, many services paid under the Physician Fee Schedule (PFS) are subject to beneficiary deductible and coinsurance.

### Q3.35. With regard to the majority of Medicare revenues threshold, should anesthesia payments be included in the Physician Fee Schedule (PFS) revenues or are they to be excluded from the calculation?

A3.35. PAMA requires that the majority of the laboratory's Medicare revenues be derived from sections 1848, 1833(h) and 1843A of the Social Security Act. The statutory authority for the anesthesia services fee schedule is section 1848(b)(2)(B) of the Social Security Act. Therefore, with regard to the application of the majority of Medicare revenues threshold, we clarify that payments under the anesthesia fee schedule should be included in both the numerator (CLFS revenues + PFS revenues) and the denominator (total Medicare revenues).

### Q3.36. Under what "NPI" circumstances can a Physician Office Laboratory (POL) potentially qualify as an applicable laboratory?

A3.36. To qualify as an applicable laboratory, the CLIA certified laboratory must be assigned an National Provider Identifier (NPI) and have its services billed to Medicare Part B under that NPI (item 33a of the CMS-1500). Therefore, a POL may qualify as an applicable laboratory if the laboratory has been assigned a unique NPI and the laboratory's unique NPI is used to bill for its in-office laboratory tests; or the laboratory shares the NPI of the group practice and the NPI of the group practice is used to bill for its in-office laboratory tests; or the laboratory shares the NPI of the physician in a solo physician practice and the physician's NPI is used to bill for its in-office laboratory tests.

### Q3.37. How does a physician's office laboratory determine whether it shares the National Provider Identifier (NPI) of the physician group practice?

A3.37. The determination as to whether the Physician Office Laboratory (POL) has been assigned the same NPI as the physician group practice is based on the NPI application process. If the physician group practice did not separately apply for an NPI for its CLIA certified laboratory but included the laboratory as part of the practice when they applied for an NPI, then the POL is assumed to share the NPI of the physician group practice. Therefore, the majority of Medicare revenues threshold and low expenditure threshold must be assessed for the NPI of the physician group practice which includes the POL.

In contrast, the POL would not be assigned the same NPI as the physician group practice if the physician group practice separately applied for an NPI for its CLIA certified laboratory. In this case, the laboratory would have a different NPI, not a shared NPI with the physician group practice. In circumstances where the laboratory has a different NPI from the physician group practice, and the physician group practice NPI is used to bill for its laboratory services (item 33a of the CMS-1500), the laboratory does not qualify to be an applicable laboratory because no Medicare revenues are attributed to the laboratory's NPI.

### Q3.38. If the Physician Office Laboratory (POL) (s) shares the National Provider Identifier (NPI) of the group practice, how would the majority of Medicare revenues threshold and low expenditure threshold be assessed?

A3.38. In determining whether the group practice NPI meets the majority of Medicare revenues threshold, the numerator would include CLFS revenues + PFS revenues for the entire group practice and the denominator would include total Medicare revenues for the entire group practice. The low expenditure threshold (at least $12,500 in CLFS revenues during the data collection period) would also be assessed for the entire group practice.

If the entire group practice NPI, which includes the POL(s), meets the majority of Medicare revenues threshold and low expenditure threshold, the group practice NPI would be an applicable laboratory. The reporting entity must report applicable information for the entire NPI, for all providers linked to the group practice NPI. In other words, for the Healthcare Common Procedure Coding System (HCPCS) codes subject to the data collection and data reporting requirements, the Tax Identification Number (TIN)level entity would report each private payor rate and the volume paid at each rate and the NPI of the group practice.

### Q3.39. What if a group practice bills for its in-office laboratory tests under the unique individual National Provider Identifier (NPI) of each of its physicians/practitioners (and not the group practice NPI), can the physician office laboratory qualify as an applicable laboratory?

A3.39. The Physician Office Laboratory (POL) cannot share multiple NPIs. In other words, if the POL has not been assigned its own unique NPI, the POL cannot share the NPI of each individual billing practitioner in the group practice. Therefore, if a group practice's in-office laboratory services are billed under each individual practitioner's NPI (item 33a of the CMS -1500), the POL cannot qualify as an applicable laboratory.

### Q3.40. What if a solo physician practice employs a physician assistant and both the physician and physician assistant have their own unique National Provider Identifier (NPI), can the in-office laboratory qualify as an applicable laboratory?

A3.40. If the physician practice did not separately apply for an NPI for its CLIA certified laboratory and all physician/practitioner services and all in-office laboratory services are billed using the physician's NPI, this scenario would be equivalent to a Physician Office Laboratory (POL) sharing the NPI of the physician in a solo physician practice. In this circumstance, the majority of Medicare revenues threshold and low expenditure threshold would be assessed for the solo physician practice, which includes the POL.

However, as noted above, a POL cannot share multiple NPIs. Therefore, if professional services and in-office laboratory services are billed under each individual practitioner's NPI, for example, the physician's NPI is used to bill for professional services performed and in-office laboratory tests ordered by the physician and the physician assistant's NPI is used to bill for professional services performed and in-office laboratory tests ordered by the physician assistant (item 33a of the CMS -1500) then the POL cannot qualify as an applicable laboratory.

### Q3.41. Do end-stage renal disease (ESRD) laboratories need to meet the majority of Medicare revenues threshold and low expenditure threshold to be considered an applicable laboratory?

A3.41. Yes, in order to be an applicable laboratory, ESRD laboratories must meet both the majority of Medicare revenues threshold (that is, greater than 50 percent of total Medicare revenues received from the CLFS and or Physician Fee Schedule (PFS)) and the low expenditure threshold (at least $12,500 in Medicare revenues received for CLFS services) during a data collection period. However, note that a laboratory that receives most of its Medicare revenues under the ESRD facility's bundled payment would not be an applicable laboratory, because the majority of its total Medicare revenues would not be derived from the CLFS and or PFS.

## Section 4: Applicable Information & Reporting Data

### Q4.1. What is a private payor?

A4.1. For purposes of the private payor rate-based CLFS, the term "private payor" is defined as: (1) A health insurance issuer as defined in Section 2791(b)(2) of the Public Health Service (PHS) Act); Or (2) A group health plan as defined in Section 2791(a)(1) of the PHS Act); Or (3) A Medicare Advantage Plan under Part C as defined in section 1859(b)(1) of the Social Security Act (the Act); Or (4) A Medicaid Managed Care Organization (MCO) (as defined in Section 1903(m) of the Act).

### Q4.2. What private payor data must be reported to CMS?

A4.2. 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 Healthcare Common Procedure Coding System (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.

### Q4.3. Does the entire claim (which may include multiple laboratory test codes) need to be paid in final in order for all tests on the claim to qualify as applicable information?

A4.3. The determination of final payment is made at the test code level, not the entire claim level. For example, if Test A and Test B are both included on the same claim and final payment was made during the data collection period for Test A, but not for Test B, the private payor data for Test A would be considered applicable information and would be reported to CMS. Private payor data for Test B would not be reported because final payment for Test B did not occur during the data collection period.

### Q4.4. Some private payors may initially withhold a percentage of the allowed payment amount for laboratory tests. At the end of each quarter (or annually), the private payor may issue a lump sum check to the laboratory for the withheld amount if the laboratory has met certain quality standards. How should those lump sum payments be accounted for in reporting private payor data to CMS?

A4.4. If the private payor makes a final payment for a laboratory test (identified by a specific HCPCS code) during the data collection period, the private payors rate for the test would be considered applicable information. Therefore, the reporting entity would report the HCPCS code for the test, that is, 100 percent of the private payors fee schedule amount (allowed amount) and the associated volume paid at that amount.

In circumstances where the private payor makes a preliminary payment for a specific HCPCS code (at less than the private payors full allowed amount), then subsequently makes a "final" lump sum payment (identified by the specific HCPCS code) during the data collection period, as noted above, the reporting entity would report the HCPCS code for the test, 100 percent of the private payors fee schedule amount (allowed amount) and the associated volume paid at that amount.

However, if (because of the private payors "lump sum" payment), the final private payor rate amount

paid by HCPCS code and the associated volume paid at that final rate cannot be determined, the payment amount is not a private payor rate for purposes of applicable information and therefore is not reported to CMS.

In general, if because of how the private payor makes payment for a test or group of tests, a laboratory cannot correlate a private payors final 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 and would not be reported to CMS.

### Q4.5. For purposes of reporting private payor data to CMS, should the reporting entity include data where the primary private payor has reimbursed the laboratory, but the secondary payor or the patient has not paid their portion? In other words, must laboratory test codes be in a "final state" (that is, completely paid by all parties) before they are included as applicable information?

A4.5. Applicable information includes three major components: (1) the specific Healthcare Common Procedure Coding System (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; and (3) the associated volume for each test.

For purposes of applicable information, the private payor rate for a test code should include any patient cost sharing responsibilities required by the private payor (for instance, patient deductible and/or coinsurance amounts) and payments due from a secondary insurer and or collection agency. In other words, the private payor rate is 100 percent of the private payors fee schedule amount for the test. For example, if the private payors fee schedule (e.g. allowable amount) is $150 and the private payors final claims paid amount of $130 was received during the data collection period, and the patient's responsibility of $20 was not received until after the data collection period, the reporting entity should report a private payor rate of $150 for the test(s).

The important concept here is that if the primary private payors final paid claim for a laboratory test code is made during the data collection period, the reporting entity reports the HCPCS code, 100 percent of the private payors fee schedule amount for the test (the allowed amount) and the associated volume paid at that amount.

### Q4.6. Should a laboratory report applicable information if it only has applicable information for 1 test?

A4.6. 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.

### Q4.7. 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?

A4.7. 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.

### Q4.8. 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?

A4.8. 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 "reviewing window" to review, assess and validate the applicable information before reporting to CMS during the data reporting period.

### Q4.9. 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?

A4.9. 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. These guides are available on the CMS CLFS webpages.

### Q4.10. 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?

A4.10. Applicable information includes the specific Healthcare Common Procedure Coding System (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.

### Q4.11. Where can I find the laboratory tests subject to the data collection and data reporting requirements?

A4.11. A list of laboratory test codes that are subject to the data collection and data reporting requirements for purposes of calculating the private payor rate-based CLFS is available from the CLFS website.

### Q4.12. 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?

A4.12. 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.

### Q4.13. How does CMS establish a payment rate when no private payor rate data are reported for a test?

A4.13. If CMS receives no applicable information for a given CDLT or ADLT, CMS will use crosswalking or gapfilling to price the test. These tests will be discussed at a special public meeting

held in the fall of 2026.

**Q4.14. Is the applicable information provided to CMS considered confidential?**

A4.14. The statute requires that CMS and its contractors may not disclose reported applicable information in a form that would identify a specific payor or laboratory, or prices charged or payments made to a laboratory, except as CMS determines necessary to implement section 1834A of the Act and to permit the Comptroller General, the Director of the CBO, the HHS OIG, MedPAC, or other law enforcement entities such as the Department of Justice to review the information.

**Q4.15. Will the private payor rates collected (and reported to CMS) include discounts?**

A4.15. The private payor rates reported to CMS are required by statute to reflect all discounts, rebates, coupons, and other price concessions.

### Q4.16. Many private payors don't pay for hospital outreach laboratory services per individual Current Procedural Terminology (CPT)/ Healthcare Common Procedure Coding System (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?

A4.16. 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.

### Q4.17. How do hospital outreach laboratories report applicable information to CMS?

A4.17. Applicable information will continue to be reported by the reporting entity (TIN-level entity) at the National Provider Identifier (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 Type of Bill (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.

### Q4.18. How does data reporting work when a hospital has more than one hospital outreach laboratory that bills Medicare Part B under the hospital's National Provider Identifier (NPI)?

A4.18. 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.

### Q4.19. How does data reporting work when a hospital has more than one hospital outreach laboratory that bills Medicare Part B using its own National Provider Identifier (NPI) (separate from the hospital's NPI)?

A4.19. 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.

### Q4.20. If a hospital outreach laboratory bills Medicare Part B under the hospital's National Provider Identifier (NPI) and meets the definition of an applicable laboratory based on the revenues attributed to the 14x Type of Bill (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?

A4.20. 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.

### Q4.21What about a hospital outreach laboratory that bills Medicare Part B under its own unique National Provider Identifier (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?

A4.21. 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.

### Q4.22. Does the data reporting requirement apply to critical access hospitals?

A4.22. 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.

## Section 5: Condensed Reporting

### Q5.1. What is the condensed data reporting option?

A5.1. For the next data reporting period for CDLTs that are not ADLTs, 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 Healthcare Common Procedure Coding System (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.

### Q5.2 What National Provider Identifier (NPI) is reported under the condensed data reporting option?

A5.2. 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 Tax Identification Number (TIN)that meets the definition of an applicable laboratory and designate that NPI as the reporting NPI for reporting the condensed applicable information.

### Q5.3. Is condensed reporting a requirement?

A5.3. No. Reporting entities have the option of condensing the volume paid at the same private payor rate for a specific Healthcare Common Procedure Coding System (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 6: Penalties

### Q6.1. Does the law include any penalties for non-reporting?

A6.1. The statute authorizes CMS to impose civil monetary penalties of up to $10,000 per day, adjusted for inflation as required by the Inflation Adjustment Act Improvements Act of 2015, for each failure to report or each misrepresentation or omission in reporting applicable information.