Frequently Asked Questions
CMS 1621 P
Medicare Program--Medicare Clinical Diagnostic Laboratory Test Payment System Proposed Rule

On September 25, 2015 CMS announced its proposal to implement section 216 of the Protecting Access (PAMA) to Medicare Act of 2014 that would require clinical laboratories to report on how much private insurers pay for lab tests. This data will be used to determine Medicare's payment for lab tests beginning January 1, 2017. CMS will solicit public comments on the proposed rule until November 24, 2015. A compilation of frequently asked questions (FAQs) about this proposal and the CMS response(s) are provided below.

Q1.Why is CMS changing the CLFS?

A1. Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), which established section 1834A of the Social Security Act (the Act), requires changes to the process for pricing Clinical Diagnostic Laboratory Tests (CDLTs) under the Medicare clinical laboratory fee schedule (CLFS). Section 1834A of the Act requires CMS to implement the new rates under the revised CFLS beginning January 1, 2017.

Q2.What type of input will be sought from clinicians and technical experts?

A2.CMS will consult with an external expert advisory panel, which may include molecular pathologists, clinical laboratory researchers, and individuals with expertise in clinical laboratory science or economics of clinical laboratory services. This advisory panel will provide input on the establishment of payment rates for new CDLTs and the factors used in determining coverage and payment processes for new CDLTs.

Q3.Will the annual public meeting continue to occur?

A3.The statute requires CMS to continue to convene the annual laboratory public meeting for purposes of receiving comments and recommendations, and data on which the recommendations are based. This meeting is typically held in July each year.

Q4.What are laboratories required to do?

A4.Under the new CLFS, applicable laboratories will be required to collect and report applicable information, which is private payor rates (and the volume of tests paid at each rate) to CMS. 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 advanced diagnostic laboratory tests (or ADLTs).

Q5.How will laboratories be defined for purposes of determining an applicable laboratory under the new CLFS?

A5.CMS is proposing to use the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulatory definition of a laboratory and incorporate that into the definition of applicable laboratory. An applicable laboratory would be an entity that is a laboratory (under the CLIA definition) or, if it is not itself a laboratory, has at least one component laboratory (under the CLIA definition). For example, for a laboratory network consisting of multiple facilities performing laboratory testing under a parent organization such as the Mayo Clinic, the Mayo Clinic would be considered the applicable laboratory.

Additionally, an applicable laboratory would also have to receive at least $50,000 in Medicare revenues from CLFS services and more than 50 percent of its Medicare revenues from physician fee schedule and CLFS services.

Q6.How is CMS proposing to determine whether the majority of revenues for a laboratory are from the CLFS and or PFS?

A6. Applying the standard definition of majority, which is more than 50 percent, an entity would be considered an applicable laboratory if more than 50 percent of the total Medicare revenues of its entire organization, which includes all of its component NPI entities, are from the CLFS and PFS.

Q7.Did CMS propose to apply a low volume or low expenditure threshold for determining the definition of applicable laboratory (for purposes of reporting private payor rate data to CMS)?

A7. Yes. CMS would exclude from the definition of applicable laboratory all entities that receive less than $50,000 per year from the CLFS. The proposed rule specifies that an entity that does not meet the definition of applicable laboratory would not be permitted to report applicable information (private payor rate and volume data) to CMS. Entities would look at their entire organization, including all component NPI entities, in determining whether they meet the $50,000 per year threshold.

Q8.Who is required to report data?

A8.Only “applicable laboratories” are required to report applicable information to CMS.

Q9.What type of private payor data must be reported?

A9.Applicable laboratories must report all private payor payment rates and the associated volume for each test to CMS. 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, it would report each such payment rate and the volume for the test at each such rate.

Q10. How frequently must private payor data be reported to CMS?

A10. Applicable laboratories would be required to report information every three years for CDLTs, and every year for ADLTs, except for an ADLT in its initial data collection period (in which case an applicable laboratory would report by the end of the second quarter of the new ADLT initial period).

Q11.What is the data collection period and time frame for reporting private payor data to CMS?

A11. Except for an ADLT in its initial data collection period, the data collection period would be a full calendar year. CMS is proposing that data would be reported for a data collection period, which would be the previous calendar year, by April 1 (January 1 through March 31 data reporting period). However, the first data collection period proposed is July 1, 2015 through December 31, 2015, with data to be reported between January 1, 2016 and March 31, 2016.

Q12. Would each CLIA certified laboratory be required to report private payor rate and volume data to CMS?

A12. No. Only applicable laboratories would report applicable information. Applicable laboratories would have at least $50,000 in Medicare revenues for laboratory services and receive more than 50 percent of their Medicare revenues from CLFS or PFS.

Q13. Is CMS concerned with the administrative burden the reporting requirement places on laboratories?

A13. CMS is proposing a low expenditure threshold to reduce the reporting burden on small laboratories. 94 percent of physician office laboratories and 52 percent of independent laboratories would not be required to report applicable information under our proposed low expenditure criterion.

Additionally, we believe requiring applicable laboratories to report data at the TIN level would be less administratively burdensome for the laboratory industry as compared to requiring data to be reported at the NPI level. We believe defining an applicable laboratory by TIN, rather than by NPI, will result in the same applicable information being reported at a higher level, require less reporting, and therefore, be less burdensome to the laboratory industry.

Q14. Do you expect that precluding more than half of all independent laboratories and approximately 94 percent of all physician office laboratories will distort the data that CMS receives to set private payor rates?

A14. No. Even though we would be substantially reducing the number of physician offices and independent laboratories that would report applicable information, we estimate those physicians and laboratories that would be required to report account for 96 percent of CLFS spending on

physician office laboratories and more than 99 percent of CLFS spending on independent laboratories

Q15. Will the private payor rates collected (and reported to CMS) include discounts?

A15. The private payor rates reported to CMS are required by statue to reflect all discounts, rebates, coupons, and other price concessions. Therefore, applicable laboratories would need to report private payor rates net of discounts, rebates, coupons and other price concessions. For example, there may be a laboratory that typically charges $10 for a particular test, but offers a discount of $2 per test if a payor exceeds a certain volume threshold for that test in a given time period. If the payor exceeds the volume threshold, the private payor rate for that payor for that test, taking into account the $2 discount, is $8. We note that other price concessions that are not specified in the statute might be applied to the amounts paid by private payors, and we would expect those to be accounted for in the private payor rate. In other words, the amount paid by a private payor for a CDLT must be the amount after all price concessions were applied.

Q16. Does the law include any penalties for non-reporting?

A16. The statute authorizes CMS to impose civil monetary penalties of up to $10,000 per day for each failure to report or each misrepresentation or omission in reporting applicable information. Additional guidance on reporting will be issued after publication of the CLFS final rule.

Q17. What is an advanced diagnostic laboratory test (ADLT)?

A17. PAMA defines ADLTs as: "a clinical diagnostic laboratory test covered under this part that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and meets one of the following criteria:

(A) The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result.
(B)The test is cleared or approved by the Food and Drug Administration.
(C)The test meets other similar criteria established by the Secretary."

Q18. Did CMS propose any specific requirements for tests qualifying as an ADLT under criterion (A)?

A18. CMS is proposing that tests qualifying as an ADLT under criterion (A): (i) must be a molecular pathology analysis of multiple biomarkers of DNA or RNA; (ii) when combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy or therapies; (iii) provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and (iv) may include other assays.

CMS would require laboratories to submit documentation to support their application, including evidence of their empirically derived algorithms and how their test provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests.

Q19. How would payment for new ADLTs be determined under the new CLFS?

A19. New ADLTs will be paid using their actual list charge during the new ADLT initial period, which is a period of three full calendar quarters. CMS proposes that actual list charge would be defined as the publicly available rate on the first day the new ADLT is obtainable by a patient who is covered by private insurance, or marketed to the public as a test a patient can receive, even if the test has not yet been performed on that date.

Q20. When does the initial period begin?

A20. The new ADLT initial period would begin on the first day of the first full calendar quarter following the first day a new ADLT is performed. For example, if an ADLT is first performed on February 15, the new ADLT initial period would begin on April 1 and end December 31.

Q21. How would the payment amount be determined for ADLTs prior to the new ADLT initial period?

A21. The local Medicare Administrative Contractor (MAC) would determine the payment amount for a new ADLT prior to the initial period. Using the example from the preceding question, the local Part B MAC would determine the payment amount for the new ADLT from February 15 through March 31. Once the new ADLT initial period begins, payment for the new ADLT would be the actual list charge amount.

Q22. How would payment for ADLTs be determined after the new ADLT initial period is over?

A22. The applicable laboratory that performs a new ADLT would be required to report applicable information to CMS no later than the last day of the second quarter of the new ADLT initial period. The payment amount based on the weighted median methodology would apply after the new ADLT initial period and continue to apply until the year following the next data collection period. In other words, CMS would pay a new ADLTs actual list charge amount for the three full calendar quarters after the new ADLT is first performed. Once the new ADLT initial period is over, payment for a new ADLT would be based on the applicable information reported by the single applicable laboratory that performs the new ADLT.

Q23. What is a new ADLT?

A23. A new ADLT would be an ADLT for which payment has not been made under the CLFS prior to January 1, 2017.

Q24. What are existing ADLTs?

A24. Existing ADLTs would be ADLTs that have been furnished between April 1, 2014 (the enactment date of PAMA), and December 31, 2016. In other words, existing ADLTs are ADLTs that are paid for under the CLFS prior to January 1, 2017.

Q25. How will existing ADLTs be paid prior to January 1, 2017?

A25. Prior to January 1, 2017, existing ADLTs would be paid based on crosswalking or gapfilling methodologies.

Q26. How will existing ADLTs be paid after the effective date of PAMA?

A26. The applicable laboratory that performs an existing ADLT would be required to report applicable information annually during the reporting period to CMS. The payment amount based on the weighted median methodology would apply. In other words, CMS would pay for an existing ADLT based on the applicable information reported by the single applicable laboratory that performs the existing ADLT. The initial period only applies to new ADLTs as defined in a previous response.

Q27. How frequently must private payor rates be collected (and reported to CMS) for ADLTs?

A27. The single applicable laboratory that furnishes the ADLT must collect applicable information annually on a calendar year basis and report to CMS during the data reporting period, which is January 1 through March 31, following the data collection period.

Q28. How would the recoupment work for new ADLTs if actual list charge exceeds the market rate?

A28. If the recoupment threshold is reached for a new ADLT that is, when the actual list charge is greater than 130 percent of the weighted median private payor rate calculated using applicable information collected during the new ADLT initial period, CMS is proposing to recoup the entire amount of the difference between the actual list charge and the median private payor rate. In such cases, claims paid during the new ADLT initial period would be re-priced using the weighted media rate. If the actual list charge amount is less than the recoupment threshold (that is, not greater than 130 percent of the weighted median private payor rate amount), the recoupment provision would not apply.

Q29. What type of code will be used to identify new and existing ADLTs and new and existing CDLTs (that are not ADLTs) that are cleared or approved by the FDA?

A29.CMS is proposing to use G codes to identify new and existing ADLTs as well as new and existing CDLTs (that are not ADLTs) that are cleared or approved by the FDA.

Q30. How will the payment amounts for new tests be determined?

A30. For a CDLT that is assigned a new or substantially revised HCPCS code on or after the date of enactment of PAMA (that is, April 1, 2014), and which is not a new ADLT, the statute specifies that payment for the test will be determined on the basis of a crosswalking methodology or a gapfilling process.

Q31. How would CMS establish a payment rate when no private payor rate data is reported for a test?

A31. If CMS receives no applicable information for a given CDLT or ADLT; CMS would use crosswalking or gapfilling to price the test.

Q32. Does PAMA limit the amount of payment reduction for existing laboratory tests?

A32. 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 the first three years after implementation (CY 2017 through CY 2019), the statue limits the reduction to 10 percent, and to 15 percent for the following three years (CY 2020 through CY 2022). CMS is proposing to apply this phased-in payment amount limit per year for existing tests paid under the CLFS prior to 1/1/2017 using the 2016 national limitation amount (NLA) for the existing test as the baseline payment amount. To determine the application of the phased-in payment reduction limit for a test, the weighted median private payor rate calculated for CY 2017 would be compared to the CY 2016 NLA.

Q33. Would the maximum 10 percent (or 15 percent) reduction be applied to the prior year's payment rate?

A33. Yes, the maximum reduction would be applied to the prior year's payment rate until the reduction becomes less than 10 percent for CYs 2017 through 2019(or 15 percent for CYs 2020 through 2022). For example, if an existing test under the CLFS for CY 2016 has a payment rate of $20.00, but the weighted median private payor rate calculated during CY 2016 (using July 1, 2015, through December 31, 2015 applicable information) produces a payment rate of $15.00, then for CY 2017, the payment rate for the test becomes $18.00 ($20.00-$2.00), which is the maximum 10 percent reduction from the current payment amount. The following year, a 10 percent reduction would equal $1.80, lowering the total payment to $16.20. This process would continue until the CLFS payment goes to the weighted median of the private payor rates (in this example, $15.00).

Q34. Is the information provided by the laboratories to CMS considered confidential?

A34. 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 is necessary to implement section 1834A of the Act and to permit the Comptroller General, the Director of the CBO, the HHS OIG, the MedPAC, or other law enforcement entities such as the Department of Justice to review the information.

Q35. How would CMS establish a unique identifier for purposes of tracking and monitoring ADLTs or CDLTs that is cleared or approved by the FDA, if requested by a laboratory or manufacturer?

A35. If a laboratory or manufacturer specifically requests a unique identifier for tracking and monitoring an ADLT or an FDA-approved or cleared CDLT, CMS proposes to assign the test a unique HCPCS code if it does not already have one.

Q36. What impact will these changes have on beneficiary cost-sharing for laboratory services?

A36. The proposed changes to the CLFS will not have any impact on beneficiary cost-sharing for laboratory services. Coinsurance and deductibles do not apply to CDLTs paid under the CLFS.

Q37. Will implementation of this new system save or cost Medicare money? How much?

A37. The effect on the Medicare program is expected to be - $360 million less in program payments for CLFS tests furnished in FY 2017; and - $5.14 billion less over 10 years.