

## **NILA Questions and Answers: Protecting Access to Medicare Act (PAMA) Section 216 Regulations**

On June 17, 2016, the Centers for Medicare and Medicaid Services (CMS) released a final regulation to implement Medicare laboratory payment reform under the *Protecting Access for Medicare Act of 2014* (PAMA, Section 216). The final regulation follows a proposed regulation released by the agency in October 2015 and months of Congressional weigh-in with the agency. A brief summary of the key provisions of the rule, followed by a fuller overview in the form of questions and answers by category appears below. NILA intends to continue to add to this Q&A document as questions are received and subregulatory guidance is provided by CMS.

### **Summary of Key Provisions**

#### *Date of New Reimbursement Rates*

- New reimbursement rates take effect on January 1, 2018, and are expected to first be made available for review and public comment in September 2017 before the agency finalizes the rates in November 2017.

#### *Reporting Requirements*

- All private payer data must be reported by “applicable laboratories” to CMS from January 1, 2017 – March 31, 2017.

#### *Data Reported*

- The data reporting period is retroactive. Private payer data reported is to reflect the final payment rate for tests paid from January 1, 2016 – June 30, 2016. The period for reporting data is expected to always remain at six months.

#### *Applicable Laboratory*

- CMS defines an applicable laboratory as an entity that receives more than 50 percent of its total Medicare revenue from either the Part B Clinical Laboratory Fee Schedule (CLFS) or Physician Fee Schedule (PFS) **AND** bills Medicare Part B under its own National Provider Identifier (NPI). An entity that otherwise qualifies under this definition but receives less than \$12,500 for Medicare Part B services performed under the CLFS during the six-month reporting period is not considered an applicable laboratory and does not have to report any payment data. The only exception to this low economic exclusion is if a laboratory is a single laboratory that is only offering and furnishing an “Advanced Diagnostic Laboratory Test” (ADLT) – the laboratory still must report its data even if its Medicare Part B revenues are less than \$12,500 during the six-month reporting period. If such a laboratory is performing Clinical Diagnostic Laboratory Tests (CDLTs) and ADLTs and meets the low economic exclusion of less than \$12,500, it does not have to report data for the CDLTs performed, but still must report payment data for the ADLTs.

- Clinical laboratories must re-evaluate their status as an applicable laboratory with each reporting period. The reporting period is every 3 years for CDLTs and every (1) year for ADLTs.
- A Taxpayer Identification Number (TIN)-level entity is responsible for reporting the data to CMS even though data is being collected by each entity at the NPI-level.

### *Applicable Information*

- The applicable information that a laboratory must report is the rate for each final private payor payment received during the data collection period and the associated volumes of tests performed at each rate for every test associated with a list of HCPCS codes to be provided by CMS at a later date through subregulatory guidance. The final rate shall reflect all discounts, coupons and concessions applied by a private payor. Patient copays/coinsurance and deductibles are also to be included in the rates reported. Tests paid under a capitated or bundled payment model are not to be reported. Tests that are HCPCS level II miscellaneous/“not otherwise classified” (NOC) and tests with unlisted CPT codes are also excluded from reporting. Tests paid at zero dollars or payments that are clustered as one payment by a payor are not to be reported. Capitated or bundled payment rates are also not included.

### *Advanced Diagnostic Laboratory Test (ADLT)*

- CMS defines an ADLT as a test performed by a laboratory that furnishes the test and may also design, offer and sell the test and includes entities that own the laboratory or that the laboratory owns. An ADLT may be offered by an entity that has more than one CLIA certificate. An ADLT is a test that provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests that is an analysis of multiple biomarkers of DNA, RNA, or proteins, combined with a unique algorithm or an FDA-cleared or approved test. A new ADLT is to be paid at the actual list charge for an initial period lasting 3 calendar quarters, which will begin when the test is covered by Medicare Part B and after CMS approves a test as having ADLT status.

### *ADLT Actual List Charge*

- The actual list charge is the rate that is publicly available on the first day the new ADLT is offered or marketed to the public as a test available for patients. The actual list charge may be known well in advance of the new ADLT initial period.

### *Private Payor*

- Private payors, as defined by statute, include health insurers, group health plans, Medicare Advantage plans under part C, and Medicaid managed care organizations. Therefore, some Medicare data will be reported as it pertains to Medicare Advantage plans.

## Subregulatory Guidance

- CMS plans to make available additional “subregulatory” guidance to laboratories on how to comply with and implement provisions of PAMA. According to CMS, this guidance could be expected as early as the end of July and it will be made available on the CMS CLFS website [here](#). Subregulatory guidance is not part of the formal rulemaking process and it is not subject to a period of public comment.

## Questions and Answers

### Key Dates for New Payment Reform System

*When are laboratories required to begin collecting data on private payor rates for clinical diagnostic laboratory tests (CDLTs) performed?*

Laboratories are required to collect final (not under appeal or not yet finalized) payment data retroactively on tests performed and for which final payments are received beginning **January 1, 2016**, to **June 30, 2016**, and subsequently every three years following the initial data collection period.

*When are laboratories required to report payment information to CMS?*

Laboratories are required to submit collected payment information for CDLTs and existing ADLTs to CMS during the data reporting period beginning **January 1, 2017**, to **March 30, 2017**, and every 3 years subsequent to the initial data reporting period. (See requirements for new ADLTs below.)

*When will the new payment rates for CDLTs take effect?*

The new Medicare payment rates calculated by CMS and based on the laboratory reported private payor data are set to take effect on **January 1, 2018**. The agency will announce preliminary rates in **September 2017**, allowing laboratories to comment on the changes taking place before finalizing them in **November 2017**.

When new payment rates are announced, CMS will publish a list of test codes along with the associated new payment rates for those codes. No other information regarding the identity of specific payors or laboratories, or prices charged or paid to a specific laboratory will be included in the publication of the new rates.

<b>Data Collection Period</b>	<b>Six Month Window</b>	<b>Data Reporting Period</b>	<b>Used for CLFS Rate Years</b>
1/1/2016 – 6/30/2016	7/1/2016 – 12/31/2016	1/1/2017 – 3/31/2017	2018 – 2020
1/1/2019 – 6/30/2019	7/1/2019 – 12/31/2019	1/1/2020 – 3/31/2020	2021 – 2023
Continues every 3 <sup>rd</sup> subsequent calendar year	Continues every 3 <sup>rd</sup> subsequent calendar year	Continues every 3 <sup>rd</sup> subsequent calendar year	New CLFS rate every 3 <sup>rd</sup> year

*When are laboratories required to begin collecting data on private payor rates for new advanced diagnostic laboratory tests (ADLTs) performed?*

Laboratories furnishing a new ADLT shall begin collecting private payment data on the first day of the first full calendar quarter following the latter of either the date of receipt of a Medicare Part B coverage determination or the date when CMS grants ADLT status. During this initial period, lasting three calendar quarters, CMS will pay the actual list price for the new ADLT. Note: Medicare payment does not begin until a coverage determination has been made.

For every subsequent year following the new ADLT initial period, laboratories will collect final private payor data on ADLTs during the collection period beginning on **January 1** and ending **June 30**.

*When are laboratories required to report payment information for new ADLTs to CMS?*

Laboratories furnishing a new ADLT must submit private payor data to CMS by the last day of the second quarter of the initial period.

For every subsequent year following the initial period, laboratories must submit final private payor data to CMS during the reporting period beginning **January 1** and ending **March 31** of the year following the first six month data collection period for that ADLT.

*When will the new payment rates calculated by CMS take effect?*

The new weighted median payment rates calculated by CMS for a new ADLT will take effect on the first day of the first calendar quarter following the new ADLT initial period and on January 1 for every subsequent year following the annual collection and reporting requirements.

<b>Test is Covered by Medicare Part B</b>	<b>ADLT Status is Granted</b>	<b>New ADLT Initial Period (Actual List Charge)</b>	<b>Data Collection Period</b>	<b>Data Reporting Period</b>	<b>Data Used for CLFS (Weighted Median Private Payor Rate)</b>
4/6/2018	5/1/2018	7/1/2018 – 3/31/2019	7/1/2018 – 12/31/2018	By 12/31/2018	4/1/2019 – 12/31/2020

**Note:** Medicare payment from 5/1/2018 to 1/1/2018 will be determined by the Medicare Administrative Contractor (MAC) that has jurisdiction for the laboratory offering the ADLT.

<b>Data Collection Period</b>	<b>Six Month Window</b>	<b>Data Reporting Period</b>	<b>Used for CLFS Rate Year</b>
1/1/2019 – 6/30/2019	7/1/2019 – 12/31/2019	1/1/2020 - -3/31/2020	2021
1/1/2020 – 6/30/2020	7/1/2020 – 12/31/2020	1/1/2021 – 3/31/2021	2022
Continues every year	Continues every year	Continues every year	New CLFS rate every year

## Applicable Laboratories

*What laboratories are considered to be applicable laboratories for the purpose of reporting data to CMS?*

An “applicable laboratory” is a laboratory that receives more than 50 percent of its Medicare revenues from payments made under the Clinical Laboratory Fee Schedule (CLFS) or Physician Fee Schedule (PFS). Medicare laboratory revenues are to be assessed by looking at all Medicare revenues under a given laboratory’s National Provider Identifier (NPI). If a hospital laboratory does not have its own NPI, but bills through the hospital’s NPI, then the 50 percent threshold is determined across the hospital’s overall Medicare revenue.

*Who is required to report?*

Laboratories that meet the definition of an “applicable laboratory” are required to collect and submit data to CMS unless they earn less than \$12,500 of their Medicare revenues from the Clinical Lab Fee Schedule (CLFS) during the 6 month data collection period. Laboratories earning less than the \$12,500 threshold are exempt from collecting or submitting data to CMS. However, these laboratories are still subject to the new rates beginning January 1, 2018, that will take effect based on this data collection process.

*Who is required to submit applicable information to CMS on behalf of the laboratory?*

The “reporting entity” is the entity, laboratory or otherwise, that reports tax-related information to the Internal Revenue Service (IRS) using its Tax Identification Number (TIN) for all of its component NPI-level entities that are applicable laboratories. This entity is required to report the collected data to CMS for all its NPI-level components meeting the definition of an “applicable laboratory.” For most community and regional laboratories, this entity will be the same for both the TIN and the NPI. This mainly pertains to hospitals and physician offices.

## Collection and Reporting of Applicable Information

*What information is required to be collected and reported to CMS?*

Laboratories must collect final private payor rates for each test paid for during the data collection period beginning **January 1, 2016**, to **June 30, 2016**, as well as the volume of tests for each payor at each individual payment rate. The rates must reflect all discounts, coupons, and concessions applied by a private payor. CMS has not yet published a list of all CPT codes that must be included in the information submitted and has stated such information will be forthcoming in subregulatory guidance.

*Are copays/coinsurance and deductibles to be included in the information reported by laboratories?*

Yes, all copays/coinsurance and deductibles must be included in the final private payor payment rate reported to CMS.

*Are laboratories required to report capitated or bundled payment rates?*

No, capitated and bundled payment rates are not to be included in the information reported by laboratories to CMS.

*Do laboratories need to report zero dollar payments?*

No, denied or zero dollar payments, and payments that are clustered by a payor as one payment for multiple tests, are not to be reported.

*How will collected data be submitted to CMS?*

Additional guidance on the methods of submitting data to CMS is forthcoming. Such information is expected to be provided through subregulatory guidance or as an addition to the Medicare Providers Manual.

*Do laboratories report payments under appeal?*

No. If a laboratory has filed an appeal on a payment, then the amount that has been paid is not considered final and therefore would not be reported as a final private payor rate. For appeals filed prior to the data collection period, only those for which final payment is made during the collection period should be reported. If an appeal is settled during the collection period, but the private payor does not make final payment until after the collection period, then no final rate is reported.

*What concessions must be included in the final payment rate?*

The statute lists discounts, rebates, coupons, volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates (except for Medicaid rebates) as examples of concessions that must be included in the final rate. CMS notes this list is not exhaustive. Additional price concessions not specified by statute that are applied to the amounts paid by private payors must be reflected in the private payor rate. However, concessions made by a laboratory to patients for hardship purposes or otherwise do not need to be included in the final rate. Example: A laboratory charges \$10 for a test, but offers a discount of \$2 per test if a payer exceeds a certain volume threshold for that test in a given time period. If the payer exceeds the volume threshold, the private payer rate for that payer for that test, taking into account the \$2 discount, is \$8.

*What if I have more than one payment rate from the same payor for the same test?*

Laboratories that have more than one payment rate from the same payor for the same test or those that have more than one payment rate from different payors for the same test, must report each payment rate along with the associated volume for the test at each rate.

*What are the penalties for omitting or reporting incorrect information to CMS?*

CMS has discretion to impose penalties on laboratories that the agency determines fail to report, misrepresent or omit information. CMS can impose penalties of up to \$10,000 per day for each failure, misrepresentation or omission. CMS notes that this is the maximum penalty that may be assessed and that in assessing penalties, the agency will work with Office of the HHS Inspector General (OIG) to determine whether a penalty should be applied and will rely on the facts and circumstances surrounding the violation to determine the appropriate amount of the penalty.

*Who in the laboratory is required to approve the data submitted to CMS?*

Data submitted to CMS must be certified by the President, CEO, or CFO of the reporting entity or by a proxy individual who has been delegated the authority and who reports directly to the President, CEO, or CFO. Additional information on the reporting and certification of applicable information is expected to be included in subregulatory guidance from CMS.

*May laboratories that do not meet the definition of an applicable laboratory voluntarily report information to CMS?*

No. Only applicable information from a laboratory meeting the definition of an applicable laboratory and exceeding the low expenditure threshold may be reported.

## **New Rate Setting**

*How will CMS determine the new payment rates for Clinical Diagnostic Laboratory Tests (CDLTs)?*

CMS will use the private payor rates and associated test volume or number of tests to calculate a weighted median of private payor rates. The weighted median will then be used as a baseline to calculate the new reduced rates, which will be phased in over a six year period – not to exceed cuts of more than 10 percent in any one year for the first three years and not to exceed cuts of more than 15 percent for any one year for the following three years through 2023. If no applicable information is available for certain CDLTs, CMS will use crosswalking and gapfilling to determine the new rate.

*What is the actual list charge for a new ADLT?*

The actual list charge is the rate that is publicly available on the first day the new ADLT is offered or marketed to the public as a test available for patients.

*How will CMS determine the new payment rates for new ADLTs?*

For new ADLTs, initial payment will be based on the actual list charge of the test for 3 calendar quarters up to 130 percent of the weighted median private payor rate; thereafter, the payment rate will be determined using the weighted median of private payor rates and associated volume (number of tests) reported every year. Following the initial period, CMS will compare the weighted median private payor rate to the actual list charge paid during the initial period.

If the actual list charge paid was more than 130 percent of the new weighted median private payor rate, CMS will recoup the difference between the actual list charge and 130 percent of the weighted median rate.

Alternatively, if there is no private payor data available, CMS will use crosswalking and gapfilling methodologies to determine pricing for the new ADLT, which will take effect after the new ADLT initial period. This method will be used until private payor data is available to determine a rate under the weighted median methodology.

### **Advanced Diagnostic Laboratory Tests (ADLTs)**

*What are the requirements for a test to qualify for ADLT status?*

A qualifying ADLT may only be designed, offered and furnished by a single laboratory and may not be sold to other laboratories for use. A single laboratory may have multiple locations if all are owned by a single corporate entity or laboratory.

*How does a laboratory obtain ADLT status for a test?*

CMS plans to establish, through additional subregulatory guidance, an application process for laboratories to request ADLT status for a particular test. The application will require laboratories to provide information consistent with the definition of an ADLT, including a demonstration that the test is “offered and furnished” by a single laboratory and has not been sold to another laboratory for use outside of the laboratory that designed the test. Guidance will also include details on the timeline for agency review.

*Is the information submitted in a new ADLT application confidential?*

Information submitted by a laboratory to demonstrate a test’s ADLT status is not exclusively protected from release and public disclosure under a Freedom of Information Act (FOIA) request. However, FOIA does include an exemption for trade secrets and commercial and financial information and CMS encourages applicants to indicate on its application a proprietary or confidential marking and a statement claiming “substantial competitive harm” if the information is disclosed. These claims will be evaluated by CMS and **may** preclude disclosure of sensitive information.

*How will codes for new ADLTs and CDLTs be assigned?*

As required by statute, CMS will assign a temporary G code to a new ADLT or new CDLT that is cleared or approved by the FDA and does not already have an assigned CPT or HCPCS Level II code. The temporary G code will be effective for up to 2 years until a permanent HCPCS code is established and may be extended by CMS if no permanent code has been assigned by the AMA and the agency determines there is a continued need to pay for the test under Medicare.



*What is the process for establishing unique identifiers for certain existing ADLTs and new CDLTs?*

CMS will adopt unique codes for existing ADLTs and new CDLTs approved or cleared by the FDA, which are specific to an individual test. The new codes will be subject to the review and public comment process provided as part of CMS's annual public meeting for new and reconsidered tests under the Part B CLFS. In addition, CMS will require laboratories to inform the agency of tests that require a unique code. Details regarding this process will be provided through additional subregulatory guidance.

### **Miscellaneous**

*Will CMS consolidate the MACs responsible for making local coverage decisions and for processing claims?* The PAMA statute provides CMS the discretion to limit the number of Medicare Administrative Contractors (MACs) establishing Local Coverage Determinations (LCDs) and/or processing Medicare claims for CDLTs. This provision allows CMS to reduce the current 12 MACs responsible for issuing Local Coverage Determinations (LCDs) for CDLTs to 4 or less. However, CMS acknowledges a reduction in the number of MACs issuing policies for CDLTs requires a significant overhaul of Medicare policies, programs and computer systems. This, CMS believes, could take 5 to 6 years to implement and would involve significant costs. For this reason, CMS is continuing to review comments on consolidating the MACs for coverage and /or claims processing for CDLTs and CMS does not plan to propose consolidation of MACs at this time, but may revisit this issue at a later date.

*When can the CMS subregulatory guidance be expected?*

CMS says it may issue subregulatory guidance as early as the end of July 2016, but has not announced a specific date. The subregulatory guidance will be made available on the CMS CLFS website [here](#).