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Centers for Medicare & Medicaid Services
Clinical Diagnostic Laboratory Test Payment System Final Rule Call
MLN Connects National Provider Call
Moderator: Diane Maupai
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Contents

Operator: At this time, I'd like to welcome everyone to today's MLN Connects® National Provider Call. All lines will remain in a listen-only mode until the question-and-answer session. This call is being recorded and transcribed. If anyone has any objections, you may disconnect at this time.

I'll now turn the call over to Diane Maupai. Thank you. Diane, you may begin.

Announcements and Introduction

Diane Maupai: Thank you. Hello everyone. I'm Diane Maupai from the Provider Communications Group here at CMS in Baltimore, and I'll be your moderator today. I'd like to welcome you to this MLN Connects National Provider Call on the Clinical Diagnostic Laboratory Test Payment System Final Rule. MLN Connects Calls are part of the Medicare Learning Network®.

During this call, CMS experts will provide a high-level overview of the final policies in the Clinical Diagnostic Laboratory Test Payment System Final Rule (CMS-1621F). This rule, issued by CMS on June 17th, significantly revises the Medicare payment system for clinical diagnostic laboratory tests and discusses a related data collection system. A question-and-answer session will follow the presentation.

Before we get started, I have a couple of announcements. You should have received a link to the slide presentation for today's call in previous registration emails. If you have not already done so, please view or download the presentation from the following URL: www.cms.gov —g-o-v— /npc. Again, that URL is www.cms.gov/npc. At the left side of the webpage, select National Provider Calls and Events, and select the July 6 call from the list.

Second, this call is being recorded and transcribed. An audio recording and written transcript will be posted to the MLN Connects Call website. An announcement will be placed in the MLN Connects Provider eNews when these are available.

We thank everyone who took the opportunity to submit questions when they registered for this call. We'll answer some of those questions before we open the lines for a live question-and-answer session after the presentations.

We have three presenters today from the Division of Ambulatory Services at CMS, and they are listed on the front of the slide deck. I'll now turn the call over to our first presenter, Rasheeda Johnson.

Presentation

New Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor-Based Payment Rates

Rasheeda Johnson: Thanks, Diane. New Medicare clinical laboratory fee schedule (CLFS) private payor-based payment rates: Medicare pays for clinical diagnostic laboratory tests under the clinical laboratory fee schedule, which throughout this presentation, we'll often refer to by its acronym, the CLFS, or as the fee schedule. The fee schedule was first adopted in 1984 when the payment rates were based on charges for Medicare programs. Slide 5 provides an overview of the Medicare fee schedule.

New CLFS Requirements: Section 216 of the Protecting Access to Medicare Act of 2014, also known as PAMA, added a new section, 1834A, of the Social Security Act and requires significant changes to the process for pricing clinical diagnostic laboratory tests, also called CDLTs, under the fee schedule. CMS's proposal for implementing the provisions of PAMA was displayed in the *Federal Register* on September 25th, 2015, and published on October 1st, 2015.

On June 17th, 2016, CMS announced its final rule implementing Section 216 of PAMA that requires private payor rates paid to applicable laboratories for CDLTs to report it to CMS and used to calculate Medicare payment rates. This final rule also announced CMS's decision to move the implementation date for the private payor rate-based fee schedule to January 1 of 2018.

Definition of Applicable Laboratory: PAMA requires applicable laboratories to report applicable information to CMS. PAMA defines an applicable laboratory as having the majority of its Medicare revenues paid under the CLFS or the physician fee schedule.

A laboratory is defined in CMS's Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations. Using its National Provider Identifier, or NPI, it's considered an applicable laboratory if the majority, or more than 50 percent, of its total Medicare revenues are received from payments under the CLFS and the physician fee schedule.

On slide 8, we describe how we revised the definition of an applicable laboratory in the final rule. In the proposed rule, we proposed to define the laboratory by its tax identification number, or TIN. In response to public comment, in the final rule, we revised the definition of applicable laboratory in terms of the NPI rather than the TIN. Therefore, the majority of Medicare revenues thresholds and the low-expenditure thresholds during a data collection period are applied by the NPI-level, rather than the TIN-level, entity.

In the proposed rule, we proposed to define the low-expenditure threshold as less than $50,000 per year. In the final rule, we revised the low-expenditure threshold amount

consistent with the revisions made to the definitions of applicable laboratory and data collection period. That is, the applicable laboratory is defined by NPI, and the data collection period will now be 6 months instead of 12 months. Under the final policy, CMS will exclude from the definition of applicable laboratory NPI-level entities that receive less than $12,500 from the CLFS during the data collection period.

The final rule also specifies that an entity that does not meet the definition of applicable laboratory will not be permitted to report applicable information to CMS. For a laboratory that provides ADLTs, we waive the requirement that they must meet the $12,500 threshold for the ADLTs they furnish. They must also, however, still meet the majority of Medicare revenue thresholds for the ADLTs.

Slide 9. Under the new fee schedule, reporting entities must report applicable information for each CDLT furnished by its component applicable laboratory. This slide provides details on what is considered applicable information.

In general, there are three major pieces of information that are required to submit to CMS as applicable information. This information includes (1) the specific HCPCS code associated with the test, (2) the private payor rate for each test for which the final payment has been made during the data collection period, and (3) the associated volume for each test corresponding to each private payor rate. PAMA defines the term private payor as (a) a health insurance insurer in the group health plan as defined in the Public Health Service Act, (b) a Medicare Advantage plan under Part C, and (c) a Medicaid managed care organization as defined in the Social Security Act.

In the final rule, CMS provides examples of what would be considered applicable information. For example, 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. Additionally, if a laboratory filed an appeal for a test furnished prior to a data collection period and the appeal was resolved before the final payment for the test was received during the 6-month data collection period, the final rate paid would be considered applicable information. Laboratories should look to their claims data for guidance on which final payment was received during the data collection period.

Also in the final rule, we clarify that applicable information includes private payor rates for out-of-network laboratories as long as the final payment for the laboratory test was made by the private payor during the data collection period. We also note that non-contracted amounts paid to laboratories would include any patient cost-sharing amount, if applicable.

Slide 10 provides some clarification on what applicable information does not include. Applicable information does not include unresolved appeals. For example, where a

laboratory test is still under review by the private payor or is under appeal during the data collection period, the amount that has already been paid would not be considered a final payment rate and would, therefore, not be considered applicable information.

Applicable information does not include payments that do not reflect specific HCPCS code-level amounts. For example, for claims where the payment was made for a panel of tests and the panel consists of several HCPCS codes and the individual private payor rate of the individual tests within the panel cannot be distinguished, this would not be considered applicable information.

The final rule also specifies, for each CDLT, the associated volumes of tests performed corresponding to each private payor rate is a component of the definition of an applicable information. Where the associated volume of tests performed corresponding to each private payor rate cannot be discerned by a laboratory from the private payor's remittance, those payment amounts would not be considered applicable information and should not be reported to CMS.

Additionally, where a private payor groups test-level payments into a claim-level payment instead of an individual HCPCS code, those rates would not be applicable information. For example, if multiple tests were performed and payments were bundled or grouped during one encounter, and the laboratory is unable to ungroup tests performed during that encounter, this would not be considered applicable information. In general, if a laboratory cannot correlate a private payor payment amount to a specific HCPCS code, those amount – that amount is not a private payor rate for purposes of applicable information.

Applicable information also does not include denied payments. For example, if no payment amount was made for the test—if a test is performed during a data collection period but a final payment is not made until after the data collection period, that payment amount would not be a private payor rate for purposes of applicable information and, therefore, not be reported to CMS.

We also specify in the final rule that private payor rate does not include price concessions applied by a laboratory, for example, a laboratory's decision to waive payment deductibles and/or coinsurance.

Slides 11 and 12 provide more detail on the definition of private payor and private payor rates.

Slide 13 provides an overview of what applicable information must be reported. CMS finalized the definition of applicable laboratory at the NPI level rather than the TIN level. However, CMS is retaining the TIN-level entity as a reporting entity, now defined separately from the applicable laboratory. As such, the TIN-level entity is responsible for

reporting applicable information for all of its component NPI-level entities that meet the definition of applicable laboratory.

Additionally, when reporting applicable information, voluntary reporting is not permitted. That is, applicable information may not be reported for an entity that does not meet the definition of applicable laboratory.

Also, reporting applicable information is not discretionary. For example, all applicable information must be reported for each component NPI that is an applicable laboratory. That is, reporting entities cannot selectively report applicable information for their component applicable laboratories. For example, laboratories cannot report some applicable information but not other applicable information.

Slide 14 describes the frequency of data collection and reporting. We finalized, as proposed, that reporting entities are required to report applicable information every 3 years for CDLTs and every year for ADLTs, except for an ADLT in its initial data collection period. A more detailed discussion of ADLTs will occur later in this presentation.

Slide 15 provides an overview of the data collection and reporting periods. In the proposed rule, the data collection period was 12 months. In the final rule, CMS revised the data collection period from 12 months to 6 months. Therefore, the initial data collection period is January 1, 2016, through June 30th, 2016. The data collection period is followed by a 6-month window and then a data reporting period between January 1, 2017, through March 31st, 2017, with an implementation date of January 1, 2018.

Subsequent data collection reporting periods will correspond to the same schedule. For example, for update year calendar year 2021, the data collection period will begin January 1, 2019, and end June 30th, 2019. The reporting period will begin January 1, 2020, and end March 31st, 2020, and the implementation date will be January 1, 2021.

This ends my portion of the presentation. Before Craig Dobyski proceeds with the next section on the new clinical lab fee schedule payment methodology for CDLTs and ADLTs, I'll turn the presentation back briefly to Diane.

Keypad Polling

Diane Maupai: Thank you, Rasheeda. And at this time, we're going to pause for a few minutes to complete keypad polling so that CMS has an accurate count of the number of participants on the line with us today. Please note there will be a few moments of silence while we tabulate the results. Holley, we're ready to start polling.

Operator: CMS appreciates that you minimize the Government's teleconference expense by listening to these calls together using one phone line. At this time, please use your telephone keypad and enter the number of participants that are currently listening in. If you are the only person in the room enter 1; if there are between more and – between two and eight of you listening in, enter the corresponding number. If there are nine or more of you in the room, enter 9. Again, if you are the only person in the room, enter 1. If there are between two and eight of you listening in, enter the corresponding number. If there are nine or more of you in the room, enter 9. Please hold while we complete the polling.

Again, please hold while we complete the polling.

Again, please hold while we complete the polling.

Thank you for your participation. I'll turn the call back over to Diane Maupai to continue. Diane?

Presentation Continued

Diane Maupai: Well, thank you, Holley. I'll now turn the call over to Craig Dobyski.

New CLFS Payment Methodology for CDLTs and ADLTs

Craig Dobyski: Thank you, Diane. For this next segment, we're going to be providing a brief overview of the new clinical lab fee schedule payment methodology for CDLTs and ADLTs.

As noted on slide 17, we finalized the new payment methodology for CDLTs that are not ADLTs, as proposed. Using applicable information reported to us, CMS will calculate the weighted median private payor rate for each CDLT payable on the clinical lab fee schedule. That is, for each test code, we will list each private payor rate and the associated volume paid at that rate and determine the median. The weighted median becomes the new CLFS payment rate.

We also finalized our proposal to use crosswalking or gapfilling methodologies to establish a payment amount when no private payor rate data are received for an existing test or for new or substantial revised tests. For crosswalking, an existing test or a combination of tests with similar methodology and resources is used as a basis for the payment amount. Gapfilling is used when there is no other test with similar methodology and resources. In this case, Medicare Administrative Contractors develop a payment amount for the test. Once private payor rate data is received for a test during a data reporting period, we would establish a payment amount using the weighted median private payor rate methodology.

Slide 19 illustrates the statutory requirements for a special category of test designated as advanced diagnostic laboratory tests, or ADLTs. The statute defines ADLTs in two parts.

Part 1 is an overarching requirement that applies to all ADLTs. Under the first part, PAMA requires that the test be a clinical diagnostic lab test, which is covered under Medicare Part B, offered and furnished only by a single lab, and not sold for use by the original developing lab or successor owner.

For the second part, PAMA requires a test to meet one of the following criteria:

- Criterion 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, or

- Criterion B—the test is cleared or approved by the Food and Drug Administration, or

- Criterion C—the test meets other similar criteria established by the Secretary.

On the next slide, slide 20, we outline our final definition of single laboratory and successor owner. In response to public comments, we did not adopt our proposal to define a single lab as a single CLIA certificate. For purposes of an ADLT, we revised the definition of a single lab to mean a laboratory as defined under the CLIA regulatory definition of a laboratory that furnishes the test, which may also design, offer, or sell the test. The final definition of a single laboratory would also include the entities that own the laboratory and the entities that are owned by the laboratory. For example, a corporate entity that owns multiple laboratories could furnish a new ADLT at each laboratory site. Additionally, the definition of single laboratory would enable other parts of the single laboratory organization to be involved with aspects of the ADLT, such as research and development. However, only the laboratory parts of the single lab organization may actually perform the test.

A successor owner, for purposes of an ADLT, means a single lab that has assumed ownership of the laboratory that designs a test through a partnership, unincorporated sole proprietorship, or corporation. We also clarified in the final rule that there could be a successor to a successor owner. In other words, a single lab could assume ownership of the single lab that is a successor owner to the original laboratory that designed the test.

In response to public comments, we also revised our proposal – our proposed requirements under criterion A to include tests that are solely comprised of proteins. Under our final policy, tests solely comprised of proteins may qualify for ADLT status under criterion A. Additionally, we removed the proposed requirement that the test

must be a molecular pathology analysis. However, we finalized all other requirements under criterion A as proposed. To qualify for ADLT status under criterion A, the test must predict the development of a certain condition or response to a particular therapy and provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests.

As mentioned previously, criterion B is FDA clearance or approval. As an alternative to criterion A, the test could qualify as an ADLT if it receives FDA clearance or approval. We finalized the requirements under criterion B as proposed.

Under criterion C, PAMA provides CMS the authority to establish and apply other similar criteria by which to determine that a test is an ADLT. We did not establish any additional criteria to qualify a test as an ADLT. However, if we propose to do so in the future, it would be done through notice and comment rulemaking.

Slide 22 highlights new ADLTs versus existing ADLTs. In the final rule, we modify the definition of new ADLT to reflect the revised implementation date of the private payor rate-based CLFS. Therefore, a new ADLT is an ADLT for which payment has not been made under the clinical lab fee schedule prior to January 1st, 2018. While an existing ADLT would be any ADLT that has been paid for under the CLFS prior to January 1st, 2018. In other words, there would be no new ADLTs until January 1st, 2018.

Slide 23: new ADLT initial period. PAMA requires new ADLTs to be paid based on their actual list charge during a new ADLT initial period consisting of three calendar quarters. In response to public comments, we revised the proposed start date of the new ADLT initial period, which was previously based on the date the test was first performed.

Under our final policy, the new ADLT initial period will begin on the first day of the first full calendar quarter following the later of: the date a Medicare Part B coverage determination is made for the test or the date ADLT status is granted by CMS. For example, if the test is covered under Medicare Part B on February 15th and CMS grants ADLT status for the test on March 1st, the new ADLT initial period would begin on April 1st and end December 31st.

Slide 24 illustrates the chronology of payment methodologies for new ADLTs, which were also finalized as proposed. Before a new ADLT's initial period, the local Medicare Administrator Contractor would determine the payment amount for the test.

During the new ADLT initial period, PAMA requires that new ADLTs be paid based on the actual list charge for the test. We finalized the definition of actual list charge as proposed. The actual list charge is the publicly available rate on the day the test is available to the public, not necessarily the date it's first performed.

After the new ADLT initial period is over, the payment amount is based on the same weighted median private payor rate methodology that applies to CDLTs that are not ADLTs. However, the payment rate for ADLTs would be updated annually instead of every 3 years, as is the case for CDLTs that are not ADLTs.

Slide 25. We revised payment for existing ADLTs to reflect the revised implementation date of the new clinical lab fee schedule. Prior to January 1st, 2018, existing ADLTs would be paid based on either crosswalking or gapfilling methodologies.

Beginning January 1st, 2018, the payment amount for existing ADLTs will be based on the weighted median private payor rate methodology. In other words, beginning January 1st, 2018, payment for existing ADLTs would go immediately to the weighted median private payor rate. The initial period only applies to new ADLTs.

On slide 26, we discuss the final ADLT recoupment policy. PAMA requires a recoupment of payments made during the new ADLT initial period when the actual list charge substantially exceeds private payor rates. The recoupment provision is applied when the actual list charge is greater than 130 percent of the weighted median private payor rate, which was calculated during the new ADLT initial period.

In response to public comments, CMS revised its proposal to recoup the entire difference between the actual list charge and the weighted median private payor rate. Under our final policy, we will only recoup the difference between 130 percent of the ADLT's weighted median private payor rate and its actual list charge. In other words, we will pay for ADLTs during the new ADLT initial period up to 130 percent of the weighted median private payor rate determined from applicable information collected and reported during the new ADLT initial period. However, if the difference between actual list charge and the weighted median private payor rate is not greater than 130 percent, the recoupment provision would not apply and the test would be paid at the full actual list charge during the entire new ADLT initial period.

The final slide on ADLTs outlines ADLT data collection and reporting. For new ADLTs during the new ADLT initial period, we finalized the data collection reporting requirements as proposed. Consistent with PAMA requirements, private payor rates for new ADLTs must be collected and reported to CMS no later than the last day of the second quarter of the new ADLT initial period. For example, for a new ADLT initial period starting the second quarter of 2018, which would be April 1st, 2018, and ending the last day of the fourth quarter of 2018, which would be December 31st, 2018, the reporting entity would be required to report applicable information for the new ADLT by the end of the third quarter of 2018, which would be September 30th.

As mentioned previously, PAMA requires ADLTs to collect and report private payor rate data annually instead of every 3 years, as is required for lab tests that are not ADLTs. In the final rule, we revised the data collection and reporting requirements for existing

ADLTs and new ADLTs after the new ADLT initial period to reflect our finalized 6-month data collection period. The data collection period would be conducted annually from January 1st through June 30th, while the data reporting period would run from January 1st through March 31st.

At this point, I would like to turn the presentation over to my colleague Sarah Harding who will be discussing other provisions from the final rule and will also provide an overview of the data collection system.

Other Provisions

Sarah Harding: Thank you, Craig. The final provisions I'm going to speak about today are those that we wanted to touch on in this call, although nothing regarding these topics has actually changed from what we initially wrote in the proposed rule to what was ultimately finalized in the final rule.

Looking at slide 29, I wanted to talk a bit about the coding provisions under PAMA. As we have spoken about before, CMS adopts CPT codes that are established by the American Medical Association. These are known as Level I HCPCS codes. If there are products or supplies not included in these CPT codes, CMS has the ability to establish Level II HCPCS codes so that these services may be covered and paid for.

PAMA set the requirement that, for new and existing ADLTs as well as new and existing CDLTs that are either cleared or approved by the FDA, that these tests must be granted unique HCPCS codes.

For this final rule, we adopted what was proposed earlier to simply continue the use of the CPT codes that are assigned by the AMA for both new and existing ADLTs and new and existing CDLTs with FDA approval when they are available. If CMS does need to create a code for any of these types of tests, we will plan to use a G-code, which is a type of Level II HCPCS codes that we reserved for laboratory tests.

Looking at slide 30, this describes the limitation on payment reduction for existing laboratory tests. This refers to the limit on how much a test's payment rate can be reduced over the first 6 years after PAMA's implementation date of January 1, 2017.

****Post-Call Clarification: This refers to the limit on how much a test's payment rate can be reduced over the first 6 years after PAMA's implementation date of January 1, 2018.****

Once again, we finalized the policies that we had initially proposed, except to revise the dates for which the phased-in reduction applies. The 2017 National Limitation Amount, or NLA, will be used as each test's baseline. After we collect all applicable information, we will calculate the CLFS payment rates for each test and compare them to the 2017 NLA. For those tests whose calculated weighted medians fall below the 2017 NLA

for the first 3 years following the implementation of PAMA—so in this case, 2018, 2019, and 2020—CLFS payment rates cannot be reduced more than 10 percent of the prior year's rates. Subsequently, in years 2021, 2022, and 2023, the CLFS payment rates cannot be reduced more than 15 percent of the prior year's rates.

Moving on to slide 31, which speaks to the confidentiality provisions under PAMA, again, these policies were finalized as they were initially proposed. CMS cannot release any information that might identify your lab or a specific private payor for whom you report data. In addition, CMS and its contractors cannot release specific charges or payments made to your lab.

There are exceptions to this, however, as shown on this slide, including if certain agencies such as the Office of the Inspector General, MedPAC, or any other law enforcement agency may need to review this information. These decisions will be made, however, on a case-by-case basis, as needed.

Finally, on slide 32, we received several public comments requesting that CMS release a payment data file in advance of the final payment rates so that preliminary rates might be reviewed or checked for any errors. In the final rule, we described a timeline in which, in early September following the data reporting period, CMS will release a file of the preliminary CLFS payment rates after the weighted medians have been calculated, along with a summary file reporting volume information we received for each code, as well as other aggregate level data analyses. We are still exploring whether we can release an even more granular level of data without compromising the confidentiality requirements I spoke about on the previous slide.

In early November, following a data reporting period, CMS will release the final payment rate file set to be implemented the following January 1st.

Data Collection System

Sarah Harding: Now, we've spoken about this in previous presentations, but I did want to touch on the data collection system we are implementing that will assist in compiling all of the information labs will be submitting to CMS.

Slide 34 gives a very brief description of a web-based data collection system that will provide laboratories a secure method of either uploading or manually entering applicable information.

We will be making a lot more information and direction available on how to access the system, as well as the template file that you will be required to use if you seek to upload the data to the system. This is simply a CSV file—so, similar to Excel files—that will be available on the CLFS website that you can use ahead of time when either programming your own systems or else collecting your data. It will be required that you use our specific template to upload that data so that our system can recognize the correct fields. Once again, we will be having several future opportunities for system demonstration and how to register for the system.

Slide 35, again, just briefly speaks to the registration process. We are using a service that is offered by CMS known as the Enterprise Identification Management System. We,

again, will be making information available on how to access the system, but we certainly encourage labs to register as early as possible for this data collection system. We plan to have registration open as early as October 2016 so that all labs will be ready for data reporting starting January 1st, 2017.

Thank you very much.

Question-and-Answer Session

Diane Maupai: I think now we're going to turn it over to Craig, who's going to talk about – respond to some of the questions that were submitted during registration.

Craig Dobyski: Yes, thank you, Diane. The first question from the stakeholders pertains to ADLTs. The question is: How long can a test retain its ADLT status? For example, if CMS grants test X ADLT status in 2018, but in 2019 new tests are commercially available that are similar and provide similar information as test X, does test X retain or lose or risk losing its ADLT status?

CMS response is: Test X would lose its ADLT status if its algorithm no longer provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests. Once test X is no longer an ADLT, though, the reporting entity would only need to report applicable information for the test every 3 years instead of every year.

And the next question: How many hospital outreach laboratories have their own NPI, and what percentage of hospital outreach business does that represent?

CMS responds: We do not have information currently on the number of hospital outreach labs that have their own NPI or the percentage of business hospital outreach labs with unique NPIs represent of the total hospital outreach laboratory business. By defining applicable lab by NPI, it allows hospital labs to qualify as applicable labs.

Next question is: When do you plan to release the subregulatory guidance?

We anticipate posting subregulatory guidance on the CLFS website later this month.

The next question is: Please clarify reporting requirement per NPI. Is it more than 50 percent of total Medicare revenues received from payment under the CLFS and physician fee schedule, or just the CLFS?

The majority of Medicare revenues threshold is calculated by summing the revenues received under the CLFS and PFS and dividing by total Medicare revenues. If greater

than 50 percent of the revenues are attributed to CLFS and/or PFS, then the majority of Medicare revenue threshold is met.

The next question is: Will there be any consideration given for large academic practice plans who have hundreds of individual providers and, as such, hundreds of individual NPIs? Or will these practices still need to determine the revenue requirement based on individual NPIs?

An applicable lab is defined by the individual NPI. Each NPI will need to determine whether it meets the majority of Medicare revenue threshold and the low expenditure threshold. In other words, both the majority of Medicare revenue threshold and low expenditure threshold are applied at the individual NPI level.

Next question is: Provide more information on the specifics of what to report.

Additional information or additional guidance on the information to be reported by reporting entities will be provided via subregulatory guidance.

The next question is: When does the applicable information reporting requirement start—both what service dates or payment dates to start collecting data and first date that the report is due?

CMS response: As noted during the slide presentation, the first data collection period is January 1st, 2016, through June 30th, 2016, and the first data reporting period is January 1st, 2017, through March 31st, 2017.

The next question is: Where do we submit this list to? How are we to collect this data?

As Sarah mentioned, applicable information is submitted by entities – reporting entities through the data reporting system. Applicable laboratories should work with their reporting entity to determine the best way to collect the private payor rate data from their final paid claims data.

The next question is: Will clinical labs specializing in testing drugs of abuse, HCPCS codes G0480 through G0483, be subject to the initial collection and reporting periods outlined in the final PAMA rule?

The answer is: Yes. If the lab meets the definition of applicable laboratory, it would be subject to the reporting requirements. However, if no data is reported, we would use crosswalking or gapfilling methodologies to establish a price for the test.

And the final question is: Will this also impact reimbursement for hospitals, outpatient facilities, or physician offices that bill for lab services?

The new private payor rate-based CLFS impacts lab services paid on the CLFS. We will be posting a list of services for which applicable information must be reported as part of our subregulatory guidance.

This concludes our responses to questions received during the registration process.

Diane Maupai:Okay, thank you very much, Craig. So, our experts are now going to take your questions on the clinical laboratory fee schedule. But before we begin, I'd like to remind everyone that this call is being recorded and transcribed. Before asking your question, please state your name and the name of your organization. And in an effort to get to as many of your questions as possible, we ask that you limit your question to just one.

If you would like to ask a followup question or have more than one question, you may press star 1 to get back in the queue, and we'll address additional questions as time permits.

All right, Holley, we're ready to take our first question.

Operator: To ask a question, press star followed by the number 1 on your touchtone phone. To remove yourself from the queue, press the pound key. Please remember to pick up your handset before asking your question to assure clarity. And please note your line will remain open during the time you're asking your question, so anything you say or any background noise will be heard in the conference. Please hold while we compile the Q&A roster. Again, to come to the queue, press star 1, to withdraw a question, press the pound key.

And our first question comes from the line of Barry Allison.

Barry Allison: Hi. This is Barry Allison and Lou Imbragno with the Center for Primary Care in Augusta, Georgia. My question today is: Concerning the $50,000 in Medicare revenue from the CLFS condition and the 50 percent of the Medicare revenue from the physician fee schedule, is that going back to the federal tax ID if you have multiple physicians practicing under one TIN, or are those two conditions evaluated at the unique physician NPI level? Thank you.

Craig Dobyski: This is Craig. Yes, you're correct. The second part of your question is correct; the majority of Medicare revenue threshold and the low expenditure threshold are both applied at the unique NPI level.

Diane Maupai: Thank you, Craig.

Valerie Miller: This is Valerie Miller. I just want to add one clarification: that the low expenditure threshold is $12,500 of revenues under the clinical lab fee schedule. Our

original proposal was $50,000, but as Rasheeda mentioned in her presentation, it was changed to $12,500 in the final rule. Thank you.

Diane Maupai: Thank you, Valerie. We're ready for our next question.

Operator: And your next question will come from the line of Renee Pickrel.

Renee Pickrel: Yes, ma'am. I'm calling from Southside Neurology and Nephrology. Can you explain how this applies to an in-office laboratory in a physician's office with multiple physicians? We would still be required to report this data as well?

Craig Dobyski: A physician…

Diane Maupai: This is Craig, go ahead.

Craig Dobyski: Yes, this is Craig. If a physician office laboratory would meet the definition of an applicable laboratory, that is, if they meet the majority of Medicare revenues threshold and the low expenditure threshold, they would be required along with the reporting entity to collect applicable information and report that information to CMS during the data reporting period.

Renee Pickrel: Okay, thank you.

Craig Dobyski: Yes.

Diane Maupai: Thank you, Craig. Next question.

Operator: And your next question will come from the line of Esther Gerena.

Esther Gerena: Gerena. Could you just tell me, does this apply to hospital OPPS labs under one NPI, the hospital NPI?

Craig Dobyski: Go ahead.

Valerie Miller: If a hospital has an outreach laboratory, meaning that it provides – the hospital's laboratory provides services to non-inpatients and non-outpatients, it could meet the definition of an applicable lab if it also has its own NPI. The threshold for that lab alone would be $12,500 in expenditures under the clinical lab fee schedule and, in determining whether or not it meets the 50-percent threshold, if more than 50 percent of its revenues come from the CLFS or the PFS, the hospital would just look at the revenues, the Medicare revenues, for that lab alone.

Under our old definition that we have proposed in the proposed rule, the hospital would have had to consider its total revenues across all of its components. But in the final rule,

the 50-percent threshold and the low expenditure threshold of $12,500 would only apply to the laboratory that's identified by its specific NPI.

Esther Gerena: Thank you.

Diane Maupai: Thank you, Valerie.

Operator: And your next question will come from the line of Kimberly Castillo.

Mida Lesto: Hi. This is Mida Lesto from Sharp HealthCare. The question or the clarity we needed is for the data collection: is it based on data service January 1st through June 30th, or paid date – or payment date from January 1st through June 30th?

Valerie Miller: Hi, this is Valerie Miller. The latter part of your comment was the accurate source of data—claims paid from January 1st, 2016, through June 30th, 2016.

Mida Lesto: Thank you.

Diane Maupai: Thank you, Valerie.

Operator: And your next question will come from the line of Debra Downs.

Debra Downs: Hi. I wanted to know if you would be able to expand upon the information in the final rule that discusses the challenges associated with only having anywhere from one to four MACs that will be writing either LCDs associated with labs and/or possibly performing the claims management on those?

Valerie Miller: This is Valerie Miller. The staff that worked on that part of the rule are not here with us today, but if you have any questions—Diane, can you provide information for submitting specific questions?

Diane Maupai: Yes, we have a resource mailbox set up for questions, and the address for that is going to be – it's MLNConnectsCalls@cms.hhs.gov. Again, MLNConnects—Connects is plural—Calls—Calls is plural—@cms.hhs.gov. Now, this email address will be included in an email that's going to come out shortly after the call today asking you to evaluate the call. Thank you for that.

****Post-Call Clarification - After the call, a new mailbox was created for your questions about the Clinical Laboratory Fee Schedule. Please send your questions to CLFS_Inquiries@cms.hhs.gov. ****

We're ready for our next question.

Operator: All right. And our next question will come from the line of Kathleen Nadeau.

Christine Leibold: Hello. Can you hear me?

Diane Maupai: Yes, we can.

Christine Leibold: Thank you. My question – this is Christine Leibold from the University of Vermont Medical Center. And my question is whether or not a hospital-based outreach lab that does not have its own NPI and that submits claims under the hospital's NPI ever be an applicable lab? Thank you.

Valerie Miller: Hi. This is Valerie Miller. The hospital outreach lab would have to have its own NPI.

Christine Leibold: Okay, thank you.

Diane Maupai: Thank you.

Operator: And our next question will come from the line of Lorraine Brue.

Lorraine Brue: Hi. This is Lorraine Brue from UMass Memorial Medical Center. So if a hospital lab's total revenue is comprised of 20 percent related to Medicare with a very small percentage of volume related to outreach, is – they are not considered an applicable lab. Is that correct?

Valerie Miller: This is Valerie Miller. A majority of its Medicare revenues would have to be from services provided under the PFS, physician services, or the CLFS, clinical laboratory services. So, it is not a majority of its total revenues across payors; it is the majority of its Medicare revenues that it looks to.

Lorraine Brue: And so, is that for all services or the lab services?

Valerie Miller: The laboratory services - the services that are provided by that particular outreach lab that's identified by its specific National Provider Identifier.

Diane Maupai: Thank you, Valerie.

Operator: Okay. And our next question will come from the line of Mary Lu Barraza.

Mary Luisa Barraza: Hello. I'm calling from Arizona Community Physicians in Tucson, Arizona. My question has to do with whether or not a medical group practice made up of physicians is considered an applicable lab. Our lab services are billed under the physician's NPI and not the lab.

Valerie Miller: This is Valerie Miller. Does the lab have a certified – I mean, does the physician's practice have a certified – a CLIA-certified laboratory?

Mary Luisa Barraza: Yes.

Valeri Miller: Okay. And it's all part of the practice?

Mary Luisa Barraza: Yes.

Valerie Miller: Does it bill for services under the clinical laboratory fee schedule?

Mary Luisa Barraza: Yes.

Valerie Miller: Okay. Then it could be an applicable lab if it meets the criteria that we discussed previously: the majority of Medicare revenues would have to come from the PFS (physician fee schedule) or the clinical lab fee schedule.

Mary Luisa Barraza: Okay.

Valerie Miller: And as far as its laboratory services, it has to receive more than $12,500 during the data collection period from services provided under the clinical laboratory fee schedule.

Mary Luisa Barraza: And those are measured by individual – by each individual NPI?

Valerie Miller: Yes.

Mary Luisa Barraza: Each physician's NPI, so we would need to look at each physician individually?

Valerie Miller: No, you're looking to see if the lab is an applicable lab. So are you saying that the laboratory and the physician's offices have separate NPIs?

Mary Luisa Barraza: They do have separate NPIs, but the billing is done by the individual physician NPI. We never bill under the lab NPI.

Valerie Miller: Okay. That scenario, we'll have to follow up with you on. If you…

Mary Luisa Barraza: Okay.

Valerie Miller: …could again submit your question to the mailbox that Diane had indicated.

Mary Luisa Barraza: Okay.

Valerie Miller: Thank you.

Mary Luisa Barraza: All right, I'll do that. Thank you.

Diane Maupai: Thank you, Valerie.

Operator: And your next question will come from the line of Cameron Cox.

Cameron Cox: Yes, thank you. This is Cameron Cox calling, MSOC Health in North Carolina. I guess I'm wondering by the – such kind of broad definitions, are there any laboratories that you guys can visualize as not being applicable?

Diane Maupai: Please give us one minute to consult.

Cameron Cox: I'm sorry? Hello?

Diane Maupai: Excuse me, this is Diane. I was just saying, please give me one minute to consult – give us one minute to consult about this question.

Cameron Cox: All right, thank you.

Diane Maupai: Okay, here we go.

Craig Dobyski: Yes, this is Craig. Yes, it's a small rural laboratory that would have a very, very small amount of revenue under the clinical lab fee schedule that would fall below the low expenditure threshold of $12,500 during a data collection period, which is 6 months. That type of laboratory would not meet the definition of applicable laboratory, and they would not need to report applicable information to us.

Valerie Miller: This is Valerie Miller. Also, for example, say, if it is specifically a physician office laboratory where the services of the physician mainly fall under the physician fee schedule and they only offer a small portion of laboratory tests during the data collection period, or they offer a significant volume of laboratory tests during the data collection period but the total expenditures for those tests do not meet our $12,500 threshold.

We – when we came up with the threshold, we based it on claims-level data, and we anticipate that the majority of physician offices would not meet the threshold required for reporting—that they would likely meet the 50-percent threshold for the majority of their revenues coming either from the physician fee schedule or the clinical lab fee schedule, however, that they would most likely – the majority of physician's office laboratories - would most likely not meet the $12,500 low expenditure threshold for the 6-month period. And again, that's based on claims – our analysis of claims data.

Diane Maupai: Thank you, Valerie.

Operator: All right. And your next question will come from the line of Sharon Bennett.

Sharon Benett: Hi, this is Sharon Bennett. I'm part of the Physician Network in Lincoln, Nebraska, and I have a question similar to the lady from Arizona. We have a situation where we have multiple NPIs all using the same laboratory, but the laboratory work is billed under the individual provider NPI number, not from a laboratory, but we are all included under one tax ID number. Will I need to check each provider NPI number to see whether they meet the criteria? And then if there are certain providers that don't meet the criteria, will I exclude their data and only send you the data from the provider's NPI numbers that do meet the criteria?

Valerie Miller: The criteria is applied at the NPI level. So…

Sharon Benett: Okay.

Valerie Miller: …if you are an organization that has multiple NPIs under one tax ID number, you'd have to assess each NPI individually to determine if that particular NPI met the requirements of – met the criteria for an applicable laboratory, and only report data for those NPIs that are applicable laboratories.

Sharon Bennett: Okay.

Diane Maupai: Thank you, Valerie.

Sharon Bennett: Thank you.

Operator: And your next question will come from the line of Bonnie DeMuth.

Bonnie DeMuth: Yes. We have a single doctor office and one NPI number. When you're discussing over 50 percent of revenue coming from the clinical lab fee schedule or the physician fee schedule, does the physician fee schedule include every CPT code on the physician fee schedule—as an example, even office visits?

Valerie Miller: Yes. All services paid under the physician fee schedule would be considered.

Diane Maupai: Thank you, Valerie.

Operator: And your next question will come from the line of Cully Chapman.

Cully Chapman: Hi, this is Cully from Community Health Systems. Rasheeda touched on it on slide 9, the cost-sharing portion, and I just need clarity. When we're looking at the paid claims data for the private payors, we include the cost-sharing portion, and if it hasn't been collected yet, do – what do we do with that? Thanks.

Diane Maupai: Yes, we're consulting for a minute; we'll be right back on.

Okay, here we go.

Craig Dobyski: This is Craig. Yes, it would include beneficiary deductible and coinsurance. In other words, it would be 100 percent of the private payor rate.

Diane Maupai: Thank you, Craig. We're ready for our next question.

Operator: Okay. And your next question will come from the line of Percy Clocuh.

Percy Clocuh: Hi. My name is Percy Clocuh calling from Bayhealth. My question is: The implementation date is January 1st, 2018, so from January 1st, 2016, through January 30th, 2016 – is this only data collection period?

Valerie Miller: That's correct. That is the period that you would be looking at your paid claims and extracting data, private payor data, to report to us.

Percy Clocuh: So that should be reported latest by June 30th?

Valerie Miller: No, – now, the reporting period is different; you are required to report data to CMS as early as January 1st, 2017, and as late as March 31st, 2016 - I'm sorry, 2017. So you have a January 1 through June 30th, 2016, data collection period. You have a 6-month period in between to develop that data, to get that data ready to report to us, and then you have to report it to us between January 1, 2017, and March 31st, 2017.

Percy Clocuh: Okay. But then my next question – okay, thank you.

Diane Maupai: Thank you. Star 1 to get back in the queue.

Percy Clocuh: Okay.

Diane Maupai: We'll have our next question.

Operator: All right. And your next question will come from the line of Lark Ivy.

Lark Ivy: Yes, hi. This is Lark Ivy in Miami, Florida. If they're an independent laboratory—their primary business is surgical pathology, so greater than 50 percent of their total Medicare revenue is a combination of the physician fee schedule for surgical pathology, but less than $12,500 comes from clinical lab fee schedule, then they would not need to report. Is that correct?

Sarah Harding: This is Sarah. That sounds like you have interpreted the policy correctly, yes.

Lark Ivy: Okay, great. Thank you.

Diane Maupai: Thank you. We're ready for our next question.

Operator: All right. Your next question will come from the line of Elizabeth Lopez.

Elizabeth Lopez: Hi, thank you. My name is Elizabeth Lopez. I am calling from Colorado Healthcare Policy on Financing. My question is simple: What is going to happen with the base rate until implementation of the new payment methodology? Thank you.

Valerie Miller: So until January 1, 2018, the clinical lab fee schedule methodology is still as it has been. So, the rates on the clinical lab fee schedule for existing tests will still be the same rates that you will receive through 2017. For any new tests that come on the clinical lab fee schedule—for example, this year our annual public meeting is in July, July 18, for new and reconsidered test codes—they will be determined under our current methodologies of either gapfilling or crosswalking. So everything's the status quo until January 1, 2018.

Diane Maupai: Thank you, Valerie.

Operator: Okay. And your next question will come from the line of Pam MacLeod.

Pam MacLeod: Hi. I'm Pam MacLeod. I'm from UW Health in Madison, Wisconsin. My question has to do with HMO capitated payments. We participate with a number of HMOs in Madison and Dane County and receive capitated payments. Are those to be included in the contracted private payor rates?

Craig Dobyski: Yes, hi, this is Craig. Applicable information does not include information about a test which is made on a capitated basis. For example, payments that do not reflect specific HCPCS code-level payment amounts would not be included as applicable information and would not be reported to CMS.

Pam MacLeod: Okay. Thank you.

Diane Maupai: Thanks, Craig.

Operator: Okay. And your next question will come from the line of James Goosie.

James Goosie: Yes. Originally, they had listed that there was going to be a fine imposed if you did not report and it was going to be a $10,000 fine. Is that still in the rule?

Valerie Miller: Yes, that's a statutory requirement; it is still in the rule.

Diane Maupai: Okay, Holley, we have time for one final question.

Operator: Okay. Our final question then will come from the line of Brian Kemp.

Brian Kemp: Hi, this is Brian Kemp from McKesson. I had a question about the template. I know you said the registry would be open sometime in October 2016. Is there a sneak peek to that template available prior to that time?

Sarah Harding: This is Sarah. Yes, we hope to make the template available as soon as possible following the final rule. We needed to make a couple little tweaks to it, just once those policies were absolutely finalized. So, it should – we plan to have it up online ideally within the next couple of weeks so that it can be used. We just – we definitely do not want to publish anything that then gets changed at a later date because that would kind of defeat the purpose. So, please look for that. And as I mentioned, it will be on the CLFS website, but we will also be making some significant efforts to get these – to get this type of information on the systems out among as many professional societies, as many groups as possible, to make sure everyone can access the information.

Diane Maupai: Thank you, Sarah.

Brian Kemp: Thank you.

Additional Information

Diane Maupai: Unfortunately, that's all the time we have for questions today. If we didn't get to your question, you can refer to the resources on slide 37 or you can email MLNConnectsCalls@cms.hhs.gov, which, again, will be in the email you get asking you to evaluate the call.

****Post-Call Clarification: After the call, a new mailbox was created for your questions about the Clinical Laboratory Fee Schedule. Please send your questions to CLFS_Inquiries@cms.hhs.gov.****

An audio recording and a written transcript of today's call will be posted on the MLN Connects Call website. We'll release an announcement in the MLN Connects Provider eNews when these are available.

On slide 38 of the presentation, you will find a list of acronyms used today, so feel free to refer to that. On slide 39 of the presentation, you'll find information and a URL to evaluate your experience with today's call. Evaluations are anonymous, confidential, and voluntary. We hope you'll take a few moments to evaluate your MLN Connects Call experiment – experience.

My name is Diane Maupai. I'd like to thank Rasheeda, Craig, and Sarah for presenting today, and thank you for participating in today's MLN Connects Call on the clinical lab fee schedule. Have a great day everyone.

Operator: This concludes today's call. Presenters, please hold.

-END-


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